PHA

Regional Meetings

2024

PHA PENNSYLVANIA HOMECARE ASSOCIATION

THANK YOU TO OUR

SPONSORS

HHA eXchange

Caribou REWARDS

Vitable

Community HealthChoices

UPMC Community HealthChoices

pa health & wellness

MB HEALTHCARE CONSULTANTS LLC

overclockedIT LLC

Fox Rothschild

PHA PENNSYLVANIA HOMECARE ASSOCIATION

Table of Contents

Fact Sheets Jun 26, 2024

Calendar Year (CY) 2025 Home Health Prospective Payment System Proposed Rule Fact Sheet (CMS-1803-P)

Billing & payments Policy Home health agencies

On June 26, 2024, the Centers for Medicare & Medicaid Services (CMS) issued the Calendar Year (CY) 2025 Home Health Prospective Payment System (HH PPS) proposed rule, which would update Medicare payment policies and rates for Home Health Agencies (HHAs). These changes can support timely admission to home health services, which has demonstrated improvements for patient outcomes and reducing risk of hospital readmissions.

As required by the Bipartisan Budget Act of 2018, which amended section 1895(b) of the Social Security Act, this rule proposes a permanent prospective adjustment to the CY 2025 home health payment rate of -4.067%, to account for the impact of implementing the Patient-Driven Groupings Model (PDGM). This adjustment accounts for differences between assumed behavior changes and actual behavior changes on estimated aggregate expenditures due to the CY 2020 implementation of the PDGM and the change to a 30-day unit of payment. For CY 2023 and CY 2024, CMS previously applied a 3.925% reduction and a 2.890% reduction, respectively, which were half of the estimated required permanent adjustment.

In addition, CMS is proposing to: recalibrate the PDGM case-mix weights; update the fixed dollar loss (FDL) for outlier payments; update the low utilization payment adjustment (LUPA) thresholds, functional impairment levels, and comorbidity adjustment subgroups for CY 2025; establish a home health occupational therapy (OT) LUPA add-on factor; and update other LUPA add-on factors. This rule also proposes to adopt the core-based statistical area (CBSA) delineations for the home health wage index using the 2020 Decennial Census. Additionally, this rule includes a proposed rate update for the CY 2025 intravenous immune globulin (IVIG) items and services' payment under the IVIG benefit. It discusses how the CY 2025 payment rate update for the negative pressure wound therapy disposable device (dNPWT) will be applied.

The actions CMS is taking in this proposed rule would help improve patient care and protect the Medicare program's sustainability for future generations.

CY 2025 Proposed Payment and Policy Updates for Home Health Agencies

This rule proposes routine, statutorily required updates to the home health payment rates for CY 2025. The CY 2025 updated rates include the proposed CY 2025 home health payment update of 2.5% ($415 million increase), which is offset by an estimated 3.6% decrease and required by statute, that reflects the proposed permanent behavior adjustment ($595 million decrease) and an estimated 0.6% decrease that reflects a proposed FDL ($100 million decrease). CMS estimates that Medicare payments to HHAs in CY 2025 would decrease in the aggregate by 1.7%, or $280 million, compared to CY 2024, based on the proposed policies.

PDGM and Behavior Assumptions

On January 1, 2020, CMS implemented the home health PDGM and a 30-day unit of payment, as required by section 1895(b) of the Social Security Act, as amended by the Bipartisan Budget Act of 2018. The PDGM better aligns payments with patient care needs, especially for clinically complex individuals. The law required CMS to make assumptions about

behavior changes that could occur because of the 30-day unit of payment and the PDGM. CMS finalized three behavior assumptions in the CY 2019 HH PPS final rule: clinical group coding, comorbidity coding, and LUPA threshold. The law also requires CMS to annually determine the impact of differences between assumed behavior changes and actual behavior changes on estimated aggregate expenditures, beginning with 2020 and ending with 2026, and to make temporary and permanent increases or decreases, as needed, to the 30-day payment amount to offset such increases or decreases. Additionally, in the CY 2019 HH PPS final rule (83 FR 56455), CMS stated that we interpret actual behavior change to encompass both behavior changes that were previously outlined, as assumed by CMS when determining the budget-neutral 30-day payment amount for CY 2020, and other behavior changes not identified at the time the 30-day payment amount for CY 2020 was determined.

In the CY 2023 HH PPS final rule (87 FR 66790), CMS finalized a methodology for analyzing the impact of the differences between assumed and actual behavior changes on estimated aggregate expenditures and calculated levels of actual and estimated aggregate expenditures. Based on analyses of CYs 2020 and 2021 claims data, CMS determined a permanent adjustment was needed and finalized implementing half (-3.925%) of the permanent adjustment estimated at the time (-7.85%).

In the CY 2024 HH PPS final rule (88 FR 77676), using CY 2022 claims and the finalized methodology, CMS determined that an additional permanent adjustment needed to be applied and finalized, implementing half (-2.890%) of the permanent adjustment estimated at the time (-5.779%). This estimated permanent adjustment necessary for CY 2024 included the remaining -3.925% (to account for CYs 2020 and 2021) that was not applied to the CY 2023 payment rate.

For the CY 2025 HH PPS proposed rule, using CY 2023 claims and the methodology finalized in the CY 2023 HH PPS final rule, CMS determined that Medicare still paid more under the new system than it would have under the old system. Therefore, we are proposing an additional permanent adjustment of -4.067% to be made to the 30-day base payment rate. This proposal would continue to satisfy the statutory requirements at section 1895(b)(3)(D) of the Act to offset any increases or decreases on the impact of differences, between assumed behavior and actual behavior changes, on estimated aggregate expenditures, reduce the need for any future large permanent adjustments, and help slow the accrual of the temporary payment adjustment amount. The proposed permanent adjustment is also anticipated to lessen any potential temporary adjustment(s) in future years. While we are not proposing to implement a temporary adjustment in CY 2025, the proposed rule does provide the calculated temporary adjustment based on analysis of CY 2023 claims. The law provides CMS the discretion to make any future permanent or temporary adjustments in a time and manner determined appropriate through analysis of estimated aggregate expenditures through CY 2026.

Crosswalk for Mapping OASIS-D Data Elements to The Equivalent OASIS-E Data Elements

The Outcome and Assessment Information Set (OASIS)-D was the home health assessment instrument used under the prior 153-group system and the first three years (CYs 2020-2022) of the current PDGM; however, the Office of Management and Budget (OMB) approved an updated version of the OASIS instrument, OASIS-E, on November 30, 2022, effective January 1, 2023 (OMB-control number 0938-1279). To accurately determine payments under the 153-group system, we use the October 2019 3M Home Health Grouper (v8219) to assign a Health Insurance Prospective Payment System (HIPPS) code to each simulated 60-day episode of care. This older version of the Home Health Grouper requires responses from OASIS-D. Therefore, to continue with the repricing methodology, CMS will need to impute responses for the three items from OASIS-D that have changed in the OASIS-E. Additionally, 13 items on the OASIS-E are no longer required to be asked at a follow-up visit. For these items, we can use the most recent SOC/ROC to determine a response, which would not require imputation. We are proposing a methodology to address this issue by mapping the OASIS-E items in this proposed rule.

Proposed OT LUPA Add-on Factor and LUPA Add-on Factor Updates

With sufficient recent claims data available and to establish equitable compensation for all home health services, CMS is now proposing to establish a definitive occupational therapy (OT) specific LUPA add-on factor and discontinue the temporary use of the physical therapy (PT) LUPA add-on factor as a proxy. We propose using the same methodology to establish the skilled nursing (SN), PT, and speech-language pathology (SLP) LUPA add-on factors, as described in the

CY 2014 HH PPS final rule. The proposed OT LUPA add-on factor (1.7266) will be updated based on more complete CY 2023 claims data in the final rule.

Additionally, we propose updating LUPA add-on factors to more accurately reflect current healthcare practices and costs, by proposing to use recent claims through CY 2023 to update the SN, PT, and SLP LUPA add-on factors.

Recalibration of PDGM Case-Mix Weights

Each of the 432 payment groups under the PDGM has an associated case-mix weight and LUPA threshold. CMS' policy is to annually recalibrate the case-mix weights and LUPA thresholds using the most complete utilization data available at the time of rulemaking. In this proposed rule, CMS is proposing to recalibrate the case-mix weights — including the functional levels and comorbidity adjustment subgroups — and LUPA thresholds using CY 2023 data, to more accurately pay for the types of patients HHAs are serving.

Wage Index Update

This rule proposes to update the home health wage index and adopt the new labor market delineations from the July 21, 2023, OMB Bulletin No. 23-01 based on data collected from the 2020 Decennial Census. The July 21, 2023, OMB Bulletin No. 23-01 contains several significant changes. It is standard practice to adopt the latest OMB update when available, as using the most recent OMB statistical area delineations results in a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions. For example, there are new CBSAs, urban counties that have become rural, rural counties that have become urban, and existing CBSAs that have been split. We note that existing home health PPS regulations limit one-year wage index decreases to 5%, which will help mitigate the impact of CBSA changes on payment.

Home Health (HH) Quality Reporting Program (QRP) Updates

CMS is proposing to collect four new items as standardized patient assessment data elements in the social determinants of health (SDOH) category, and to modify one item collected as a standardized patient assessment data element in the SDOH category, beginning with the CY 2027 HH QRP via the OASIS. The four assessment items proposed for collection are: one living situation item, two food items, and one utilities item. In addition, CMS is proposing to modify the current transportation item beginning with the CY 2027 HH QRP via the OASIS instrument.

CMS is also proposing an update to remove the suspension to change all-payer data collection to begin with the start of care OASIS data collection timepoint instead of the discharge timepoint.

Lastly, we are seeking input on future HH QRP measure concepts.

Expanded Home Health Value-Based Purchasing (HHVBP) Model

Request for Information (RFI) on Future Performance Measure Concepts for the Expanded HHVBP Model

CMS is including in the proposed rule an RFI that would build on input from the Expanded Home Health Value-Based Purchasing (HHVBP) Model's Implementation and Monitoring technical expert panel (TEP), which met in November 2023. Discussions included potential future measure concepts that could fill measurement gaps in the expanded HHVBP Model. These include function measures complementing the existing cross-setting Discharge (DC) Function measure. These measures would include care activities like bathing and dressing, which are important for home health patients and caregivers but are not included in the DC Function measures. Based on TEP feedback, CMS may also consider adding the existing Medicare Spending per Beneficiary measure in future rulemaking. Other potential areas for measure development activities discussed with the TEP include family caregiver status and claims-based falls with major injuries.

Health Equity Update

CMS is including an update on health equity to let stakeholders know that we are committed to developing approaches to meaningfully incorporate the advancement of health equity into the expanded HHVBP Model. As we move this

important work forward, we will continue to take input from home health stakeholders and monitor the application of proposed health equity policies across CMS initiatives, such as proposed payment adjustments in the Hospital and SNF Value-Based Purchasing Programs.

Home Health Conditions of Payment (CoPs) Updates

CMS is proposing changes to the HHA CoPs to reduce avoidable care delays by helping ensure that referring entities and prospective patients can select the most appropriate HHA based on their care needs.

CMS proposes adding a new standard that would require HHAs to develop, implement, and maintain through an annual review, a patient acceptance to service policy that is applied consistently to each prospective patient referred for home health care. We are proposing that the policy must address, at a minimum, the following criteria related to the HHA's capacity to provide patient care: the anticipated needs of the referred prospective patient, the HHA's caseload and case mix, the HHA's staffing levels, and the skills and competencies of the HHA staff. This proposed rule would not prevent HHAs from maintaining their existing acceptance to service policies; rather, it is intended to complement them. Additionally, CMS is proposing that HHAs make available to the public accurate information regarding the services offered by the HHA and any service limitations related to types of specialty services, service duration, or service frequency. HHAs would be required to review this information annually.

Request for Information on Rehabilitative Therapists and HHAs Scope of Services

Lastly, we are seeking public comments on two RFIs. First, we are seeking information regarding the feasibility of rehabilitative therapists conducting the comprehensive assessment for cases that have both therapy and nursing services ordered as part of the plan of care. Second, we are seeking information regarding the HHA scope of services and how these services interact with HHA operations. We are soliciting comment on the communications that occur between patients' physicians and allowed practitioners in establishing and reviewing the plan of care. We are also seeking information on how the physician and allowed practitioners ensure patients receive the right mix, duration, and frequency of services to meet measurable outcomes and goals identified by the HHA and the patient.

Long-Term Care (LTC) Facility Acute Respiratory Illness Data Reporting

CMS proposes replacing the current COVID-19 reporting standards for LTC facilities that sunset in December 2024 with a new standard that will address a broader range of acute respiratory illnesses. This new standard would require that, beginning on January 1, 2025, facilities electronically report information about COVID-19, influenza, and respiratory syncytial virus (RSV) to the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN). CMS proposes that the data elements for which reporting would be required include facility census; resident vaccination status for COVID-19, influenza, and RSV; confirmed resident cases of COVID-19, influenza, and RSV (overall and by vaccination status); and hospitalized residents with confirmed cases of COVID-19, influenza, and RSV (overall and by vaccination status). CMS continues to believe that sustained data collection and reporting of respiratory illnesses outside of emergencies will help LTC facilities gain important insights related to their evolving infection control needs.

CMS also recognizes that, while necessary, these data may not be sufficient during an actual emergency event. Accordingly, we are also proposing that in the event of a declared — or significantly likely — national public health emergency (PHE) for an acute respiratory illness, there may be additional categories or reporting required, such as: reporting data up to a daily frequency and additional or modified data elements relevant to the PHE — including but not limited to relevant confirmed infections, supply inventory shortages, and additional demographic factors.

CMS is seeking comment on ways the reporting burden can be minimized while still providing adequate data; whether we should expand the proposed requirements for what is collected and how often, both during and outside a declared — or significantly likely — PHE; the value of these data in protecting the health and safety of residents in LTC facilities both during and outside of a PHE; system readiness and capacity to collect and report these data; and whether race, ethnicity, or other demographic information, such as socioeconomic factors or disability status, should be included in the requirements for ongoing reporting beginning on January 1, 2025.

Medicare Provider Enrollment

CMS is proposing to add providers and suppliers that are reactivating their Medicare billing privileges to the categories of new providers and suppliers subject to additional oversight. CMS may impose a provisional period of enhanced oversight (PPEO) for 30 days to one year for new providers and suppliers. The goal of a PPEO is to reduce and prevent fraud, waste, and abuse. During a PPEO, CMS may, among other things, conduct prepayment medical review and cap payments. Currently, CMS can apply a PPEO to new providers or suppliers, which are defined as providers or suppliers that are: (1) newly enrolling; (2) undergoing a change of ownership under 42 CFR § 489.18; and/or (3) undergoing a 100% change of ownership via a change of information. This proposal would add reactivating providers and suppliers as another category of new providers and suppliers subject to a PPEO.

Resources

For additional information about the Home Health Prospective Payment System, visit: https://www.cms.gov/medicare/medicare-fee-for-service-payment/homehealthpps and https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.

For additional information about the Home Health Patient-Driven Groupings Model, visit https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/HH-PDGM.

For additional information about the expanded Home Health Value-Based Purchasing Model, visit: https://innovation.cms.gov/innovation-models/expanded-home-health-value-based-purchasing-model.

The proposed rule can be downloaded from the Federal Register at**:** https://www.federalregister.gov/public-inspection/current**.**

###

Previous Newsroom article

Next Newsroom article

Kenneth Albert, R.N., Esq.
Chairman of the Board

HOMECARE & HOSPICE
National Association for Home Care & Hospice
228 Seventh Street, SE, Washington, DC 20003 • Ph: 202/547-7424 • 202/547-3540 fax

William A. Dombi, Esq.
President

August 26, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1803-P
P.O Box 8013
Baltimore, MD 21244-8013

Re: **CMS-1803-P: Medicare Program; Calendar Year (CY) 2025 Home Health Prospective Payment System (HH PPS) Rate Update; HH Quality Reporting Program Requirements; HH Value-Based Purchasing Expanded Model Requirements; Home Intravenous Immune Globulin (IVIG) Items and Services Rate Update; and Other Medicare Policies**

Dear Administrator Brooks-LaSure,

The Centers for Medicare and Medicaid Services (CMS) and the U.S. Department of Health and Human Services have proposed several reforms affecting the Medicare home health benefit and the CY 2025 payment rates in the Notice of Proposed Rulemaking (NPRM). 89 Fed. Reg. 55312 (July 3, 2023).

The NAHC-NHPCO ALLIANCE (formerly the National Association for Home Care & Hospice), hereinafter "ALLIANCE," respectfully submits these comments regarding the proposals contained within the NPRM. The ALLIANCE is the largest trade association representing the interests of Medicare home health agencies (HHAs) and hospices nationwide including nonprofit, proprietary, urban, and rural based, hospital affiliated, public and private corporate entities, and government run providers of home care since 1982. ALLIANCE members provide most Medicare home care services throughout the U.S.

The ALLIANCE is also an original provider-member of the Leadership Council of Aging Organizations (LCAO) as it has put patients first in its health policy and advocacy positions since its inception. Each year, ALLIANCE members serve millions of patients of all ages, infirmities, and disabilities, providing an opportunity for individuals to be cared for in their own homes, the care setting preferred by most people.

Many members of our Forum of State Associations also support these comments. We are specifically joined on this letter by numerous state home care associations listed on the final page. Many others are filing their own comments too. State associations are an important voice in understanding the

impact of the proposed rules in their local settings. Their "on the ground" perspective deserves special attention.

We are aware that numerous other organization and representatives of the HHA community have submitted comments as well. We especially recommend that CMS provide thoughtful consideration to those comments submitted by the Partnership for Quality Home Health along with those submitted by several by our the EMR/IT business partner members that offer extensive "real-time" data analysis.

At the outset, we respectfully express that the existing and newly proposed payment rate cuts will continue to serve to significantly reduce access to essential home health services throughout the country and set the stage for further annual rate cuts that will dismantle this crucial benefit. That outcome stems from the application of a budget neutrality adjustment methodology that will perpetually rebase payment rates reflecting the natural and foreseeable reaction of home health agencies (hereinafter "HHAs") to reduced reimbursement. CMS understands HHAs, like all health services providers, will reduce costs in reaction to payment reductions. Cost reductions often can include service reductions involving the admission of patients, the scope of services offered, and the extent of services provided. Consequently, the CMS budget neutrality methodology will continue to trigger further payment rate reductions that will eventually destroy the value of the home health services benefit.

CMS has the authority and the responsibility to prevent such an outcome under 42 USC 1395fff to determine the "time and manner" of applying any rate adjustments under PDGM. CMS has the full discretionary power to go forward with the 2025 rate setting without the proposed 4.067% rate cut.

While we once again will not relitigate here our position that the budget neutrality methodology fails to conform with statutory mandates, CMS does have the clear authority to determine the time and manner of any permanent and temporary adjustments under the payment model and has used that power in past rulemakings. **We once again strongly recommend that CMS use that authority to withhold any such adjustments in 2025 to provide the opportunity for a full and deep review of the direction of the home health benefit, its impact on access to care, and options to preserve a longstanding benefit that has brought high quality of care and essential health care services to millions of Medicare beneficiaries since 1965, along with great value to the Medicare program through expenditure savings far in excess of any other Medicare benefit. Since the initiation of PDGNM in CY2020, CMS's own data shows the significant deterioration of the home health benefit and the increasing reduction in access across the country. As detailed below, fewer Medicare beneficiaries have access to the home health benefit and those that do face a significantly reduced scope and depth of care.**

Specific comments on all elements of the NPRM are below. We offer the following summary of our overall recommendations:

OVERALL RECOMMENDATIONS

A. Home Health Services Payment Rates

- CMS should postpone application of any further permanent adjustments related to PDGM budget neutrality to preserve current access to home health services and the scope of care available.

- CMS should maintain its position to withhold any part of the PDGM budget neutrality temporary adjustments in 2025.
- CMS should recognize the disruptive, continuing, and permanent financial impact of its forecasting error with respect to the annual Market Basket Index updates from 2021 and 2022 and implement a one-time adjustment to account for the 5.2% forecasting error.
- CMS should consider the negative and disruptive financial impacts of its proposed wage index changes and case mix weight recalibrations on care access as it finalizes the 2025 payment rates and any systemic reforms.

B. HH QRP

- CMS should limit revisions to the OASIS data set to intervals no less than 4 years from the last revision.
- CMS should consider imbedding the AHC-HRSN core question screening tool into the PAC assessments if feasible.
- CMS should monitor additions to the OASIS data set to ensure that the tool is manageable for HHAs.
- CMS should provide sufficient data on HHA quality measures and assessment items prior to implementing any changes in the OASIS data set.

C. HH QRP Measure Concepts

- CMS should not consider including in the HH QRP the "Adult Immunization Status" measure, or any similar measure related to vaccinations that requires extensive review of data sources.
- CMS must consider the limitations for HHAs to address a depression diagnosis when considering the measure concept for the HH QRP
- CMS should not move forward with a measure concept related to SUD for inclusion in the HH QRP

D. HHVBP Measure Concepts

- CMS must consider the complexity and potential burden for data collection when developing a measure to address the needs of the family caregivers for home health patients.
- CMS should not include the falls with injury measure into the HHVBP
- CMS should not include the MSPB measure in the HHVBP
- The ALLIANCE supports the inclusion of additional function measures in the HHVBP that complement the DC Function measure.

E. Home Health CoP Changes -Acceptance to Service Policy

- CMS should withdraw its proposal, at § 484.105(i)(1)(i) through (iv), for an acceptance to service policy and to require HHAs make publicly available information on services, and limitations on frequency and duration.
- CMS should continue to seek feedback from stakeholders to determine the root cause for the decreases in patient access to home health services.
- Withdraw the position that HHAs can only decline an admission to care based on a finding that it cannot safely and effectively meet the clinical needs of the patient**.**

SPECIFIC COMMENTS ON PROPOSED RULE AND POLICY CHANGES

The Proposed Payment Rate Cuts Further Exacerbate Significant Care Access Barriers for Patients and Will Bring the Home Health Benefit to a Point of Crisis

For several years, Medicare payment policies have seriously diminished the Medicare home health benefit. Concurrent with rate reductions, payment model changes, case mix weight recalibrations, and inaccurate cost inflation forecasts there continues to be a corresponding dilution of the home health benefit resulting in a significant, negative impact on care access. The ALLIANCE forecast this outcome in it CY2020 comments with added support for the contention each year thereafter. While CMS thankfully responded to those concerns by withholding any application of the growing temporary adjustments along with a reduced permanent adjustment in CY 2023 and CY 2024, the deterioration of the benefit and access to it continues. The outcome has been startling with several hundred thousand less Medicare beneficiaries annually using home health services, less care provided to patients, and fewer provider options. Such dramatic changes cannot be accounted for because of oversight activities, marketplace changes, or the increased enrollment in Medicare Advantage plans as an alternative to traditional Medicare enrollment. This deterioration is clearly displayed even in the limited data offered by MedPAC and data routinely available to CMS.

The 2023 MedPAC data analysis shows a decline of 400,000 home health users between 2017 and 2021. In-person visits per user declined by over 17% from 30.7 to 25.4. Active HHAs fell by 1,232 from 2016-2021. The active provider numbers continue to decline to date, except for California where program integrity issues have been raised. **This data does not depict a stable home health benefit in any form.**

As predicted by the ALLIANCE in its earlier PDGM comments, the data analysis shows a continuing decline in home health users, in-person visits per user, and active HHAs. **An ongoing pattern of loss of access to care cannot be ignored by CMS, particularly when the obvious cause is the flawed payment model established and introduced by CMS in 2020.** An alternative explanation does not lie in increased Medicare Advantage enrollment as the percentage of Medicare Fee-for-Service enrollees using home health services is declining, not just the gross number of users. Similarly, the explanation does not lie in a reduced inpatient population as the majority of HHA admissions is from the community and those enrollees that would have come from an inpatient stay to home health in the past still have health care needs even if they are no going to inpatient care. Finally, CMS cannot reasonably adopt the MedPAC view that there has been a reduction in use of home health along with a declining number of HHAs since 2013 as the explanation. The institution of PDGM re-triggered the benefit deterioration that began with the Affordable Care Act's rate rebasing mandate after just two years of a modicum of "stability."

All told, the PDGM era to date has shown a combination of:

- **Nearly 500,000 fewer Medicare beneficiaries accessing home health services**
- **A 22.4% decline in the proportion of Medicare fee-for-service beneficiaries accessing home health services.**
- **A 9% nationwide reduction in active HHAs accessible to beneficiaries**
- **A 15.6% reduction in the number of clinical visits in a 30-day period**

These data do not portray a budget neutral transition to PDGM. Instead, these data depict a crucial and essential benefit in the Medicare program, one that has demonstrated dynamic positive impact

through cost and care avoidance, which is on a continuing downward path to being effectively dismantled.

The chart that follows shows that fewer beneficiaries as a percentage of enrollees have accessed home health services in all 50 states since the initiation of PDGM in 2020. This should concern every Medicare enrollee, particularly as the US population ages overall while consumers increasingly express a very strong desire to age in place with health care services in their own homes. It should also concern CMS as Medicare heads towards significant financial challenges with its ongoing reliance on inpatient and institutional care. It is time for CMS to recognize, in its practices, what it has conveyed regarding the Home Health Value Based Purchasing demonstration program—home health services reduce overall Medicare expenditures—when used.

The following data from the CMS Market Saturation Report details the decline in home health utilization. CMS cannot ignore its own data and the obvious impact of PDGM during the period involved. Coincidences are not simply happenstance. Notably, both CMS and Congress recognized that Medicare payment changes lead to provider behavior changes. These data support that assumption. Reduced payment rates have led to reduced care access and usage. Correspondingly, the proposed further reductions in payment rates for CY2025 will lead to further reductions in care access and usage.

Home Health Utilization
FFS Beneficiaries as % of Total FFS Beneficiaries

	CY 2019	CY 2020	CY 2021	CY 2022	CY 2023
National	8.5%	7.8%	7.9%	7.4%	6.6%
Alabama	10.5%	10.0%	10.0%	9.3%	8.1%
Alaska	3.3%	3.4%	3.6%	3.4%	3.1%
Arizona	5.9%	5.5%	5.7%	5.4%	4.8%
Arkansas	7.8%	7.5%	7.7%	7.3%	6.4%
California	9.3%	8.8%	9.1%	8.9%	8.3%
Colorado	6.0%	5.5%	5.7%	5.2%	4.5%
Connecticut	10.9%	10.0%	10.0%	9.3%	8.3%
DC	5.9%	6.0%	6.1%	5.1%	4.9%
Delaware	8.5%	7.7%	7.8%	7.4%	6.9%
Florida	11.7%	10.8%	10.7%	10.0%	9.0%
Georgia	7.9%	7.4%	7.4%	6.9%	6.0%
Hawaii	2.7%	2.8%	2.9%	2.9%	2.4%
Idaho	6.8%	6.5%	6.6%	6.2%	5.4%
Illinois	9.1%	8.2%	8.3%	7.8%	6.8%
Indiana	6.8%	6.4%	6.4%	5.9%	5.1%
Iowa	4.6%	4.6%	4.6%	4.1%	3.5%
Kansas	6.6%	6.5%	6.9%	6.4%	5.6%
Kentucky	8.6%	7.9%	7.8%	7.3%	6.3%
Louisiana	10.7%	10.2%	9.7%	9.1%	7.9%
Maine	8.3%	7.3%	7.2%	6.5%	5.6%
Maryland	7.8%	7.2%	7.3%	6.9%	6.1%
Massachusetts	10.9%	9.8%	10.2%	9.7%	8.8%
Michigan	9.4%	8.2%	8.2%	7.6%	6.6%
Minnesota	5.6%	5.4%	5.5%	5.2%	4.6%
Mississippi	11.7%	11.5%	11.4%	10.8%	9.5%
Missouri	7.1%	6.8%	6.8%	6.2%	5.4%
Montana	3.7%	3.6%	3.4%	3.1%	2.7%
Nebraska	5.6%	5.5%	5.5%	5.2%	4.6%
Nevada	9.2%	8.5%	8.7%	8.3%	7.5%
New Hampshire	8.8%	8.0%	8.1%	7.5%	6.4%
New Jersey	7.5%	6.7%	7.0%	6.6%	5.8%
New Mexico	6.3%	5.8%	6.0%	5.6%	5.0%
New York	7.8%	6.9%	7.1%	6.7%	5.8%
North Carolina	8.2%	7.5%	7.4%	6.9%	6.1%
North Dakota	3.1%	3.5%	3.5%	3.2%	3.0%
Ohio	8.2%	7.4%	7.5%	6.7%	5.8%
Oklahoma	11.4%	10.8%	10.7%	10.1%	9.0%
Oregon	5.2%	5.0%	5.0%	4.8%	4.2%
Pennsylvania	8.4%	7.7%	7.9%	7.3%	6.4%
Rhode Island	9.5%	8.7%	9.0%	8.5%	7.3%
South Carolina	8.4%	8.1%	8.5%	8.2%	7.4%
South Dakota	3.7%	3.5%	3.7%	3.5%	3.0%
Tennessee	8.4%	8.1%	8.2%	7.6%	6.7%
Texas	10.5%	9.3%	9.1%	8.3%	7.2%
Utah	9.0%	8.6%	8.8%	8.3%	7.2%
Vermont	8.7%	8.0%	8.3%	7.6%	6.7%
Virginia	8.3%	7.7%	7.9%	7.4%	6.4%
Washington	5.2%	5.0%	5.1%	4.9%	4.3%
West Virginia	8.0%	7.4%	7.6%	7.2%	6.1%
Wisconsin	5.2%	5.0%	5.1%	4.9%	4.2%
Wyoming	4.1%	4.3%	4.5%	4.1%	3.5%

Source: CMS, Market Saturation Utilization State-County.

https://data.cms.gov/summary-statistics-on-use-and-payments/program-integrity-market-saturation-by-type-of-service/market-saturation-utilization-state-county

While the ALLIANCE does not consider the below MedPAC analyses to be wholly accurate in comparison to the CMS Market Saturation Reports, those analyses are categorically consistent with the downward trends displayed in the CMS data. Nearly 600,000 fewer users of home health services, a 6% decline in the proportion of FFS beneficiaries utilizing home health services between 2019 and 2022, reduced lengths of stay receiving home health services, and a significant decline in the number of in-person clinical visits to patients are all consistent with the Market Saturation Report data compiled by CMS.

MedPAC March 2023 Report to Congress

TABLE 8–2

In 2021, the share of FFS beneficiaries using home health care increased, while the number of in-person home health visits per user declined

	Prepandemic			Pandemic		Average annual percent change	
	2017	2018	2019	2020	2021	2017–2019	2020–2021
Medicare FFS home health users (in millions)	3.4	3.4	3.3	3.1	3.0	–1.7%	–1.1%
Share of FFS beneficiaries using home health care	8.8%	8.7%	8.5%	8.1%	8.3%	–1.3	2.5
Total visits (in millions)	104.8	103.9	99.7	81.1	76.8	–2.5	–5.3
In-person visits per user	30.7	30.8	30.2	26.6	25.4	–0.8	–4.2
30-day periods (in millions)				9.6	9.3		–2.9
30-day periods per 100 FFS Medicare beneficiaries				25	26		0.7

Note: FFS (fee-for-service). Percentage change was calculated on unrounded data.

Source: MedPAC analysis of home health standard analytic files from CMS and the 2022 annual report of the Boards of Trustees of the Medicare trust funds.

MedPAC March 2024 Report to Congress

TABLE 7-2

In 2022, the share of FFS Medicare beneficiaries receiving home health care declined

					Average annual percent change	
FFS Medicare volume	**2019**	**2020**	**2021**	**2022**	**2019–2022**	**2021–2022**
Home health users (in millions)	3.3	3.1	3.0	2.8	-5.0%	-6.3%
Share of beneficiaries using home health care	8.5%	8.1%	8.3%	8.0%	-1.8	-3.0
30-day periods (in millions)	N/A	9.6	9.3	8.6	N/A	-7.5
30-day periods per 100 FFS Medicare beneficiaries	N/A	25.3	25.5	24.4	N/A	-4.3
30-day periods per FFS Medicare beneficiary who received home health care	N/A	3.13	3.08	3.04	N/A	-1.3

Note: FFS (fee-for-service), N/A (not available). Percentage changes were calculated on unrounded data. CMS implemented a 30-day period as the unit of payment in the home health prospective payment system in 2020; data for prior years in this unit of payment are not available.

Source: MedPAC analysis of home health standard analytic files from CMS and the 2023 annual report of the Boards of Trustees of the Medicare trust funds.

MedPAC March 2023 Report to Congress

TABLE 8-4

In 2021, the number of in-person visits per 30-day period declined

	Prepandemic	Pandemic		2019–2021		2020–2021	
	2019	**2020**	**2021**	**Change in number of visits**	**Average annual percentage change**	**Change in number of visits**	**Average annual percentage change**
Skilled nursing	4.6	4.6	4.3	-0.3	-3.7%	-0.3	-8.0%
Physical therapy	3.5	2.9	3.0	-0.6	-10.0	0.1	1.1
Occupational therapy	1.1	0.9	0.8	-0.3	-18.3	-0.1	-1.5
Speech–language pathology	0.2	0.2	0.2	-0.1	-20.5	-0.1	-5.2
Medical social services	0.1	0.1	0.1	0.1	-20.8	-0.1	-8.4
Home health aide	0.7	0.6	0.5	-0.2	-18.5	-0.1	-14.5
Total	10.2	9.2	8.8	-1.4	-8.1	-0.4	-4.7

Note: Home health services initiated in 2019 were paid under 60-day episodes. For this table, home health care services initiated in 2019 were recalculated as 30-day periods to provide comparable units of service in the two years. Thirty-day periods are included in the year that the period ended. Components may not sum to totals due to rounding. Visit counts have been rounded. "Change in number of visits" and "average annual percentage change" columns were calculated on unrounded data.

Source: MedPAC analysis of 2019 home health Limited Data Set file and standard analytic files for 2020 and 2021.

MedPAC March 2024 Report to Congress

TABLE 7–5 **Since 2020, the average number of home health in-person visits per 30-day period has declined**

Volume measure	2019	2020	2021	2022	Total change in number of visits 2019–2020	Total change in number of visits 2020–2022	Percent change 2019–2022
Total visits per 30-day period	10.2	9.2	8.8	8.6	–1.0	–0.6	–15.6%
Visits per 30-day period by discipline:							
Physical therapy, occupational therapy, and speech-language pathology	4.9	3.9	3.9	4.0	–0.9	<0.1	–18.6
Skilled nursing	4.6	4.6	4.3	4.1	<0.1	–0.5	–10.5
Medical social services and home health aide	0.8	0.7	0.6	0.5	–0.1	–0.1	–32.3

Note: Home health services initiated in 2019 were paid under 60-day episodes. For this table, home health care services initiated in 2019 were recalculated as 30-day periods to provide comparable units of service in the later years. Thirty-day periods are included in the year that the period ended. Components may not sum to totals due to rounding. Visit counts have been rounded. "Total change in number of visits" column was calculated on unrounded data.

Source: MedPAC analysis of 2019 home health Limited Data Set file and standard analytic files from 2019 through 2022.

CMS also offers important data on the level of care provided under the home health benefit in the NPRM that shows the continuing decline is services provided as each year of PDGM advances.

TABLE 3: UTILIZATION OF VISITS PER 30-DAY PERIODS OF CARE BY HOME HEALTH DISCIPLINE, CYs 2018-2023

Discipline	CY 2018 (Simulated)	CY 2019 (Simulated)	CY 2020	CY 2021	CY 2022	CY 2023
Skilled Nursing	4.53	4.49	4.35	4.05	3.90	3.86
Physical Therapy	3.30	3.33	2.70	2.74	2.77	2.78
Occupational Therapy	1.02	1.07	0.79	0.78	0.77	0.76
Speech Therapy	0.21	0.21	0.16	0.15	0.14	0.14
Home Health Aide	0.72	0.67	0.54	0.48	0.43	0.41
Social Worker	0.08	0.08	0.06	0.05	0.05	0.05
Total (all disciplines)	**9.86**	**9.85**	**8.59**	**8.25**	**8.06**	**8.00**

89 Fed. Reg. 55312, 55318 (July 3, 2024).

The pattern is clear and unambiguous. Rate cuts under PDGM lead to care cuts.

The decline in the number of active, billing HHAs continues to plummet nationwide, with very frwe states excepted. Notably, California is the unicorn among the states with 534 active HHAs added between 2019 and 2023. Active is defined as billing for Medicare homne health services during that calenadr year. Active is contrasted with simply existing as a certified HHA as that status does not help define care access.

The data from the CMS Market Saturation Reports shows a 9% decline in the number of active HHAs since prior to PDGM. All but six states (AZ, CA, ME, NV, RI, and WA) show a sizeable decline in the number of HHAs that are active. California is suspected to have seen growth with a large number of new HHAs raising program integrity concerns. With California excepted, the decline in active HHAs during PDGM is in excess of 17%

STATE	2019	2020	2021	2022	2023	2019-2023	
Alabama	129	119	120	113	114	-15	-12%
Alaska	16	14	15	14	13	-3	-19%
Arizona	135	135	136	137	135	0	0%
Arkansas	101	98	94	96	93	-8	-8%
California	1,343	1,417	1,546	1,743	1,877	534	40%
Colorado	114	112	109	102	101	-13	-11%
Connecticut	84	80	68	67	65	-19	-23%
DC	26	26	26	25	22	-4	-15%
Delaware	25	21	24	21	21	-4	-16%
Florida	815	800	812	781	742	-73	-9%
Georgia	109	111	112	105	106	-3	-3%
Hawaii	14	12	13	12	10	-4	-29%
Idaho	53	53	51	47	49	-4	-8%
Illinois	597	532	527	498	482	-115	-19%
Indiana	171	160	152	140	133	-38	-22%
Iowa	128	123	117	113	110	-18	-14%
Kansas	112	106	104	98	96	-16	-14%
Kentucky	102	94	90	87	86	-16	-16%
Louisiana	175	173	171	170	165	-10	-6%
Maine	25	24	28	27	26	1	4%
Maryland	63	64	62	63	61	-2	-3%
Massachusetts	147	137	142	130	114	-33	-22%
Michigan	398	353	340	311	279	-119	-30%
Minnesota	111	111	107	94	86	-25	-23%
Mississippi	48	47	46	46	45	-3	-6%
Missouri	153	145	144	136	128	-25	-16%
Montana	26	25	24	23	23	-3	-12%
Nebraska	66	65	62	60	57	-9	-14%

Nevada	143	147	146	160	157	14	10%
New Hampshire	39	35	37	37	35	-4	-10%
New Jersey	52	49	52	49	46	-6	-12%
New Mexico	66	67	69	68	63	-3	-5%
New York	142	135	132	131	123	-19	-13%
North Carolina	173	166	166	160	157	-16	-9%
North Dakota	18	17	18	16	16	-2	-11%
Ohio	321	285	268	251	230	-91	-28%
Oklahoma	232	226	220	215	205	-27	-12%
Oregon	61	55	59	57	58	-3	-5%
Pennsylvania	274	246	244	226	209	-65	-24%
Rhode Island	22	24	24	22	22	0	0%
South Carolina	85	85	85	82	75	-10	-12%
South Dakota	28	24	26	25	24	-4	-14%
Tennessee	136	128	129	127	126	-10	-7%
Texas	1,490	1,346	1,242	1,138	1,056	-434	-29%
Utah	82	79	79	76	71	-11	-13%
Vermont	14	14	14	13	12	-2	-14%
Virginia	220	210	202	199	196	-24	-11%
Washington	63	64	68	67	68	5	8%
West Virginia	62	57	58	53	50	-12	-19%
Wisconsin	97	84	84	84	81	-16	-16%
Wyoming	30	29	32	28	26	-4	-13%
Total	**9,136**	**8,729**	**8,696**	**8,543**	**8,345**	**-791**	**-9%**
Total w/o CA	**7,793**	**7,312**	**7,150**	**6,800**	**6,468**	**-1,325**	**-17%**

Source: CMS Market Saturation Reports, https://data.cms.gov/summary-statistics-on-use-and-payments/program-integrity-market-saturation-by-type-of-service/market-saturation-utilization-state-county

The ALLIANCE also considers the CMS Market Saturation Reports a superior data source on access to HHAs to that displayed by MedPAC as it relies on robust claims data analyzed by CMS itself. Nevertheless, even the MedPAC analyses in 2023 and 2024 depict a continuiing decline in available HHAs. Such a finding supports the concerns voiced by the ALLIANCE over the past PDGM years that the access to care has been materially diminished and is facing an ongoing threat to a complete loss in some parts of the country due to the continuing PDGM rate cuts based on the flawed budget neutrality assessment methodology applied by CMS.

MedPAC March 2023 Report to Congress

TABLE 8–1 Rate of decline in home health agencies participating in Medicare has slowed

	Prepandemic			Pandemic		Average annual percent change	
	2013	2018	2019	2020	2021	2013–2019	2020–2021
Active HHAs	12,788	11,699	11,569	11,556	11,474	–1.7%	–0.8%
Number of HHAs per 10,000 Medicare beneficiaries	2.4	1.9	1.9	1.8	1.8	–4.2	–2.1

Note: HHA (home health agency). "Active HHAs" includes all agencies operating during a year, including agencies that closed or opened at some point during the year. Average annual changes were calculated on unrounded data.

Source: MedPAC analysis of CMS's Quality, Certification and Oversight file and 2021 annual report of the Boards of Trustees of the Medicare trust funds.

MedPAC March 2024 Report to Congress

TABLE 7–1 Annual rate of decline for home health agencies participating in Medicare has been approximately 1 percent per year

					Average annual percent change	
	2019	2020	2021	2022	2019–2022	2021–2022
Active home health agencies	11,569	11,565	11,474	11,353	–0.6%	–1.1%
Number of home health agencies per 10,000 Medicare beneficiaries	1.88	1.83	1.79	1.75	–2.3	–2.7

Note: "Active home health agencies" includes all agencies operating during a year, including agencies that closed or opened at some point during the year. Average annual changes were calculated on unrounded data.

Source: MedPAC analysis of CMS's Quality, Certification and Oversight file and the 2021 annual report of the Boards of Trustees of the Medicare trust funds.

Sources: March 2023 Report to the Congress: Medicare Payment Policy. Medicare Payment Advisory Commission, Chapter 8, Pages 242, 243, 245. https://www.medpac.gov/document/march-2023-report-to-the-congress-medicare-payment-policy/

March 2024 Report to Congress: Medicare Payment Policy. Medicare Payment Advisory Commission, Chapter 7, Pages 206-211. https://www.medpac.gov/document/march-2024-report-to-the-congress-medicare-payment-policy/

MedPAC's mischaracterization of the data trends as offering sufficient access to care should be given no weight as the numbers speak for themselves—care utilization is significantly down, less care is provided today than in prior years, and there are fewer HHA choices for beneficiaries. While full data is not yet available, there are clear indications that the reduction in patients using home health services and the volume of in-person visits continue to decline post-2022 along with the number of active HHAs.

Further indications of the fragility of the financial status of HHAs are found in cost report data from calendar year 2022. The ALLIANCE analyzed cost reports for all HHAs with a fiscal year end of

12/31/22 to evaluate the impact of CY2022 payment rates, cost inflation, service changes, and other factors related to 2022 influences and behavior in a consistent manner. The ALLIANCE methodology trimmed out reports with no data on revenue and/or costs along with an application of the common 90/10 natural log trim. The ALLIANCE evaluated both "Medicare margins" (the difference between reported fee-for-service Medicare revenue and reported fee-for-service Medicare costs) as well as "Overall Margins" (total home health revenue compared to total home health costs).

The ALLIANCE notes the following regarding the cost report data analysis:

1. Cost report data came from CMS at https://www.cms.gov/research-statistics-data-and-systems/downloadable-public-use-files/cost-reports/cost-reports-by-fiscal-year
2. Cost reports used were limited to those with 12/31/22 fiscal year ends. An estimated 30% of HHAs use alternative fiscal years.
3. Cost report inputs were used as reported.
4. CMS cost reporting standards do not consider certain usual and ordinary business costs, such as marketing, telehealth services and equipment, and certain taxes as "allowable" thereby depressing the amount of costs in the margin analysis.
5. The wide range in margins makes the nature of the cost report trimming affect the margin calculation.

Most notable from the cost report analysis is that HHAs experience a wide range of financial outcomes in both the "Medicare Margin" and the "Overall Margin." This outcome occurs regardless of HHA geographic location, urban or rural service area, tax status, or size. The wide range of financial outcomes of a payment model set out below itself demonstrates current fragility and uncertainty in the financial status of the organization along with the impact of any future rate changes. Most importantly, it demonstrates that relying upon averages is a high risk undertaking when setting or evaluating payment rates and any changes in payment rates, particularly as it relates to the impact on care access as averaging masks the impact that comes from losing those providers with margins below the average.

HHAs with FYE 12/31 data	**2022**	**2022**	**2023**	**2023**
Region	**Total Medicare FFS Reimbursement**	**Number of HHAs**	**Total Medicare FFS Reimbursement**	**Number of HHAs**
National	$11,625,894,736	5,639	$12,399,838,395	6.145
Medicare Margin	**Number of HHAs**	**Percentage of HHAs**	**Number of HHAs**	**Percentage of HHAs**
Greater than 20%	2,958	52.6%	3,326	54.2%
Between 0% and 20%	1,479	26.2%	1,546	25.1%
Less than 0%	2,681	21.2%	1,273	20.6%

It should be apparent that HHAs with current negative Medicare Margins would face significant financial difficulties in absorbing the proposed additional 4.067% rate cut for 2025 and 2.89% in 2024 based on FYE 2022 data alone. With those providers, serious negative impact on patients can be fully expected if the affected HHA is to continue operations.

For HHAs with Medicare Margins above zero percent, those difficulties are also serious and insurmountable without negative impacts on patients. As we have seen over the years, rate cuts have reduced access in several ways, including HHA closures, reduced service areas, reduced admissions, and reduced scope of services.

However, we advise CMS not to confine its access impact analysis to a silo built on Medicare Margins data. While payers may prefer to limit their rate impact evaluation to the relationship of its rate to provider cost, the economic model of HHAs necessitates a view consistent with the HHAs' evaluation of its overall financial condition. HHAs do not have the luxury of confining its evaluation to a payer-centered one. Instead, it must look at the overall combination of payers to determine the impact of any single payer change on its operations because HHAs' business is a variety of government or quasi-government-based payers where payment rates are assigned by the payer, not determined by the provider. For HHAs, most payments come from traditional Medicare, Medicare Advantage, Medicaid, the VA, and Tricare. Most HHAs have little or no commercial insurance or private pay home health services, unlike most other health care sectors.

HHAs serve patients and do not distinguish between traditional Medicare patients and those patients covered by Medicare Advantage, Medicaid, the VA, or other payers. HHA nurses, therapists, and home health aides provide patient care, not Medicare patient care, Medicare Advantage patient care. Medicaid patient care, or care that is different based on payer source. Professional standards of care make home health services payer-agnostic. The Medicare Conditions of Participation apply equally to all payers too.

It is notable that MedPAC evaluates the full financial outcome for inpatient hospital services and SNF services in its consideration of the impact of Medicare rates of payment on access to care. Such makes sense as health care providers do not operate in payer-related silos. As previously stated, the Medicare Conditions of Participation apply equally to all patients without regard to payer source. In home health services, all patients are subject to the OASIS patient assessment and quality of care measures along with public quality data reporting do not distinguish patients by payer source. The Medicare cost report does require delineation by Medicare, Medicaid, and "Other," but cost calculations blend all costs without regard to payer source.

The ALLIANCE recognizes that, based on cost report data and inputs from The ALLIANCE members, traditional Medicare payments may subsidize other payers such as Medicare Advantage or Medicaid. In some respects that is the reality that HHAs must deal with every year. In other respects, it may be a creature of cost reporting weaknesses. Either way, HHAs operate as an HHA, not a Medicare Fee-for-Service HHA. It is not unusual for one payer's revenue to be needed to subsize a shortfall from another payer.

While it may not be the best Medicare payment policy, currently it must be recognized as a central impacting feature of the financial status of HHAs. Changing payment rates in traditional Medicare has a ripple effect on the entire patient population of an HHA. That is particularly the case when the other payers are highly unlikely to step up and improve their payment rates as we have here in home health with Medicare Advantage and Medicaid, both having rate setting power that is sanctioned by CMS. Accordingly, CMS must recognize the need to apply its discretion on the application of PDGM permanent adjustments taking into consideration the overall impact of rate cuts on the ability of HHAs to

maintain full access to care. Here the proposed rate cuts are clearly highly disruptive in relation to continued care access. The "Overall Margins" of HHAs, as discussed below, demonstrates that the level of disruption is monumental.

The projected national Overall Margin for 2024 with the existing base rate cut shows that 52.7% of freestanding HHAs would be "underwater" with overall margins below 0% assuming no change in costs compared to 2022. The analysis is limited to freestanding HHAs due to the unavailability of such data from cost reports submitted by institution based HHAs. However, it can be safely assumed that the percentage would increase if those HHAs were capable of being included since the Medicare-related margins tend to be lower than freestanding HHAs as a starting point.

These data depict a substantial risk that a majority of HHAs would be in jeopardy of bankruptcy or closure with the proposed rate cut. Those HHAs' options to avoid that risk are highly limited, none of which would be good for the patient population and most have already been employed with the CY2023 rate cut. Those options include:

- Reducing the volume of visits in the episode of care. More than a full visit reduction on average would be needed to stay financially even.
- Reducing costs by narrowing the geographic scope of the service area to reduce travel time between visits or the need for a branch office. That action would effectively "close" the provider for a portion of previously served patients.
- Eliminate services to Medicare Advantage and Medicaid patients. This would require an HHA to address fixed and semi-variable costs that would remain through such a census reduction.
- Refocus Medicare home health services on certain patient populations that would not trigger financial losses in a manner consistent with nondiscrimination requirements.

Such changes in service are easy to predict since they are already ongoing due to the initial 4.36% rate cut at the start of PDGM, shortfalls triggered by inflation rate forecasting errors, and the 3.925% rate cut in 2023. Compounding the risk is the 5.2% forecast error in 2021 and 2022 as it relates to cost inflation and the resulting Market Basket Index (discussed further below). The proposed 4.067% rate reduction for 2025 will send the overall financial status of HHAs into the world of closures, bankruptcies, and patient service roadblocks and reductions. The data earlier presented and as further set out below shows that such a crisis has begun and will continue to grow nationwide. Exclusive of California, the number of active and somewhat accessible HHAs dropped by 332 between 2022 and 2023. With the cut imposed in 2024 and the proposed cut for 2025, that number can be reasonably expected to rise even further. Closure is that last action of financially troubled HHA would take. Prior to that, care access diminishes in a multitude of other ways including reduced coverage areas and limits on patient admissions.

State	HHAs	Overall Financial Projected Status	Percentage
Alabama	84	Percent of margins below 0%	47.6%
Alaska	6	Percent of margins below 0%	50.0%
Arizona	91	Percent of margins below 0%	65.9%
Arkansas	53	Percent of margins below 0%	47.2%
California	774	Percent of margins below 0%	58.3%
Colorado	65	Percent of margins below 0%	61.5%
Connecticut	28	Percent of margins below 0%	53.6%
Delaware	7	Percent of margins below 0%	42.9%
District of Columbia	4	Percent of margins below 0%	0.0%
Florida	484	Percent of margins below 0%	57.0%
Georgia	58	Percent of margins below 0%	48.3%
Guam	2	Percent of margins below 0%	50.0%
Hawaii	6	Percent of margins below 0%	16.7%
Idaho	34	Percent of margins below 0%	55.9%
Illinois	265	Percent of margins below 0%	53.2%
Indiana	87	Percent of margins below 0%	54.0%
Iowa	28	Percent of margins below 0%	39.3%
Kansas	38	Percent of margins below 0%	50.0%
Kentucky	37	Percent of margins below 0%	32.4%
Louisiana	98	Percent of margins below 0%	49.0%
Maine	11	Percent of margins below 0%	63.6%
Maryland	19	Percent of margins below 0%	21.1%
Massachusetts	56	Percent of margins below 0%	42.9%
Michigan	178	Percent of margins below 0%	55.1%
Minnesota	25	Percent of margins below 0%	48.0%
Mississippi	24	Percent of margins below 0%	16.7%
Missouri	57	Percent of margins below 0%	70.2%
Montana	7	Percent of margins below 0%	42.9%
Nebraska	19	Percent of margins below 0%	52.6%
Nevada	84	Percent of margins below 0%	50.0%
New Hamphire	5	Percent of margins below 0%	60.0%
New Jersey	26	Percent of margins below 0%	38.5%
New Mexico	22	Percent of margins below 0%	63.6%
New York	54	Percent of margins below 0%	51.9%
North Carolina	63	Percent of margins below 0%	30.2%
North Dakota		Insufficient Data	
Ohio	156	Percent of margins below 0%	56.4%
Oklahoma	134	Percent of margins below 0%	41.8%
Oregon	22	Percent of margins below 0%	45.5%
Pennsylvania	115	Percent of margins below 0%	41.7%
Puerto Rico	18	Percent of margins below 0%	50.0%
Rhode Island	14	Percent of margins below 0%	64.3%
South Carolina	35	Percent of margins below 0%	60.0%
South Dakota	4	Percent of margins below 0%	50.0%
Tennessee	65	Percent of margins below 0%	49.2%
Texas	703	Percent of margins below 0%	51.9%
Utah	51	Percent of margins below 0%	51.0%
Vermont	3	Percent of margins below 0%	66.7%
Virgin Islands	2	Percent of margins below 0%	100.0%
Virginia	116	Percent of margins below 0%	54.3%
Washington	47	Percent of margins below 0%	46.8%
West Virginia	29	Percent of margins below 0%	62.1%
Wisconsin	32	Percent of margins below 0%	37.5%
Wyoming	11	Percent of margins below 0%	45.5%
National		**Percent of margins below 0%**	**52.70%**

Source: FYE12/31/2022 Freestanding HHA cost reports, https://www.cms.gov/research-statistics-data-and-systems/downloadable-public-use-files/cost-reports/cost-reports-by-fiscal-year. The forecast is based on 2022 data trended forward with the 9.36% base rate cuts in 2023 and proposed for 2024 without regard to any cost changes that are greater than the 2023 MBI and proposed 2024 MBI. If cost to revenue changes were considered, it is expected that the number of HHAs with overall margins below zero would increase.

Most states are already in trouble with the existing 2024 rate cut. Extending a further cut of 4.067% in 2025 is bound to accelerate the decline in care access. Most geographic areas within each state are at risk of losing HHAs. In some areas, all HHAs are forecast to be faced with a negative net financial margin. The risk to access to care for Medicare beneficiaries and all others that need home health services is acute and undeniable. CMS cannot let that happen.

The Home Health Benefit Has Been Shrinking with Each Rate Cut: The Proposed 2025 Rate Cut Will Only Bring Further Shrinkage

In 1996, the number of visits per user of home health services was 74. By 2021 it had shrunk to 25.44. That shrinking occurred at various stages of payment model changes and payment rate reductions. The first generation of benefit shrinkage was in 1998, the first year of the ill-designed Interim Payment System (IPS), where average visits dropped to 51. With the onset of the Prospective Payment System in October 2000, the CY2001 average number of visits dropped to 31. With a few years of stability in the payment rates, visit volume per patient stabilized and rose slightly. However, within a six-year series of rate cuts, visits per patient dropped back down to an average of 31. With the additional rate cuts that began in 2014 and continued to 2017, per patient visit volume stayed steady, but by 2018 the number of patients served dropped by over 100,000 despite the growth in Medicare enrollment of more than 1.4 million.

With the onset of the PDGM system in CY2020, another drop in per patient visits occurred, reducing the average to 27.57. The second year of PDGM saw more of the same with the average reduced to 25.44 visits. While the level of services lost has been significant, the reduction in Medicare beneficiaries that use home health services has been even more dramatic, dropping from 3.6 million in 1996 to 3.02 million in 2021 despite a 2.7 million increase in traditional Medicare enrollees.

YEAR	Traditional Medicare Enrollees	USERS (1000s)	VISITS PER PERSON	VISITS PER EPISODE	MEDICARE HH PAYMENTS (1000s)	PAYMENTS PER PERSON	PAYMENTS PER EPISODE
1990	N/A	1967.1	36	N/A	$3,713,652	$1,892	N/A
1991	N/A	2242.9	45	N/A	5,369,051	2,397	N/A
1992	N/A	2506.2	53	N/A	7,396,822	2,955	N/A
1993	N/A	2874.1	57	N/A	9,726,444	3,389	N/A
1994	34,076	3179.2	66	N/A	12,660,526	3,987	N/A
1995	34,062	3469.4	72	N/A	15,391,094	4,441	N/A
1996	33,704	3599.7	74	N/A	16,756,767	4,660	N/A
1997	33,009	3557.5	73	N/A	16,718,263	4,704	N/A

1998	32,349	3061.6	51	31.6*	10,456,908	3,420	N/A
1999	32,179	2719.7	42	N/A	7,936,513	2,921	N/A
2000	32,740	2461.2	37	N/A	7,215,958	2.936	N/A
2001	33,860	2402.5	31	21.4*	8,513,702	3,545	N/A
2002	34,977	2544.4	31	20*	9,550,683	3,765	$2,329*
2003	35,815	2681.1	31	18.39**	10,069,628	3,770	N/A
2004	36,345	2835.6	31	18.0**	11,402,560	4,039	N/A
2005	36,685	2975.6	32	18.21**	12,779,158	4,314	$2,366*
2006	35,647	3026.2	34	18.45**	13,912,750	4,619	N/A
2007	35,490	3099.5	37	18.19**	15,565,441	5,046	$2,566*
2008	35,320	3171.6	38	19.1**	16,872,735	5,361	$2,705*
2009	35,360	3281.1	40	18.7**	18,733,108	5,747	N/A
2010	35,910	3434.4	37	18.0**	19,407,218	5,688	N/A
2011	36,458	3463.9	36	17.0**	18,362,264	5,357	$2,916*
2012	37,214	3459.6	34	17.0**	18,025,554	5,256	N/A
2013	37,613	3452.0	32	16.79	17,924,989	5,193	$2,687
2014	37,790	3417.2	32	16.66	17,736,862	5,190	2,703
2015	38,025	3454.4	32	16.60	18,203,863	5,280	2,762
2016	38,610	3451.5	31	16.63	18,117,018	5,249	2,780
2017	38,668	3392.9	31	16.60	17,830,844	5,255	2,823
2018	38,665	3365.9	31	16.67	17,934,054	5,328	2,876
2019	38,577	3281.4	31	16.57	17,850,864	5,440	2,952
2020***	37.776	3054.5	27.57	9.27	17,082,332	5,592	1881
2021***	36.356	3018.5	25.44	8.27	16.872,835	5.590	1.818

Sources: https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/cmsprogramstatistics ; https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Archives/MMSS

*Data from Medicare Payment Advisory Commission (MedPAC) various March Reports to Congress

** Data from CMS HHA cost reports

***The payment model shifted to a 30-day episode

Medicare Home Health Services Use Reductions Coincided with Payment Rate Reductions: The Proposed PDGM Cut Will Bring More

While payment rate and payment method are not the only contributing factors to service access and level of care changes in home health services, their impacts are natural and foreseeable. Since BBA 1997, home health services PPS episodic rates have been subject to numerous negative adjustments that began with the initial rate setting for FY2001. Due to the dramatic impact of the Interim Payment System in 1998-2000 and the BBA 1997 requirement that PPS be set in a budget neutral manner, the FY2001 payment rates were set at a level that was over $300 lower than provider costs $2115.50 versus $2416.01) due to a .88423 budget neutrality adjustment. https://www.govinfo.gov/content/pkg/FR-2000-07-03/pdf/00-16432.pdf. Thereafter, the episodic rates have been hit with multiple legislated and regulatory reductions. The table below sets out those reductions. The PDGM rate reductions have and will continue to have the same reduction in care access and level of services.

YEAR	MBI REDUCTION	PRODUCTIVITY ADJUSTMENT	BUDGET NEUTRALITY and CASE MIX WEIGHT ADJUSTMENT**	REBASING REDUCTION
FY2001			11.577%	
FY2002				
FY2003	1.1%		7%	
FY2004				
CY2005	0.8%			
CY2006	0.8%			
CY2007				
CY2008			2.75%	
CY2009			2.75%	
CY2010			2.75%	
CY2011	1.0%		3.79%	
CY2012	1.0%		3.79%	
CY2013	1.0%		1.32%	
CY2014				$80.65 (3.5%)
CY2015		0.5%		$80.65 (3.5%)
CY2016		0.4%	0.97%	$80.65 (3.5%)
CY2017		0.3%	0.97%	$80.65 (3.5%)
CY2018	2.0%		0.97%	
CY2019		0.8%	1.69%	
CY2020 PDGM begins			4.36%	
CY2021		0.3%		
CY2022		0.5%		
CY2023	5.2% forecast error	0.20%	3.925%	
CY2024		0.30%	2.89%	
CY2025 (proposed)		0.50%	4.067%	
TOTAL REDUCTIONS*	12.9%	3.8%	55.569%	$322.60 (14.0%)

Sources:

*This represents the sum of the cuts. However, the cumulative impact is much greater as each cut affects the base rate on a permanent basis.

** Reductions unrelated to adjustments made to achieve budget neutrality with case mix weight or wage index recalibrations

FY2001: https://www.govinfo.gov/content/pkg/FR-2000-07-03/pdf/00-16432.pdf

FY2002: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Downloads/CMS-1147-NC.pdf

FY2003: https://www.cms.gov/Regulations-and-Guidance/Regulations-and-Policies/QuarterlyProviderUpdates/Downloads/cms1198nc.pdf

FY2004: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Downloads/cms1473nc.pdf

CY 2005: https://www.cms.gov/Regulations-and-Guidance/Regulations-and-Policies/QuarterlyProviderUpdates/Downloads/cms1265f.pdf

CY2006: https://www.cms.gov/Regulations-and-Guidance/Regulations-and-Policies/QuarterlyProviderUpdates/Downloads/cms1301f.pdf

CY2007: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Downloads/cms1304f.pdf

CY2008: https://www.govinfo.gov/content/pkg/FR-2007-08-29/pdf/07-4184.pdf

CY2009: https://www.govinfo.gov/content/pkg/FR-2008-11-03/pdf/E8-26142.pdf

CY2010: https://www.govinfo.gov/content/pkg/FR-2009-11-10/pdf/E9-26503.pdf

CY2011: https://www.govinfo.gov/content/pkg/FR-2010-11-17/pdf/2010-27778.pdf

CY2012: https://www.govinfo.gov/content/pkg/FR-2011-11-04/pdf/2011-28416.pdf

CY2013: https://www.govinfo.gov/content/pkg/FR-2012-11-08/pdf/2012-26904.pdf

CY2014: https://www.govinfo.gov/content/pkg/FR-2013-12-02/pdf/2013-28457.pdf

CY2015: https://www.govinfo.gov/content/pkg/FR-2014-11-06/pdf/2014-26057.pdf

CY2016: https://www.govinfo.gov/content/pkg/FR-2015-11-05/pdf/2015-27931.pdf

CY2017: https://www.govinfo.gov/content/pkg/FR-2016-11-03/pdf/2016-26290.pdf

CY2018: https://www.govinfo.gov/content/pkg/FR-2017-11-07/pdf/2017-23935.pdf

CY2019: https://www.govinfo.gov/content/pkg/FR-2018-11-13/pdf/2018-24145.pdf

CY2020: https://www.govinfo.gov/content/pkg/FR-2019-11-08/pdf/2019-24026.pdf

CY2021: https://www.govinfo.gov/content/pkg/FR-2020-11-04/pdf/2020-24146.pdf

CY2022: https://www.govinfo.gov/content/pkg/FR-2021-11-09/pdf/2021-23993.pdf

CY2023: https://www.govinfo.gov/content/pkg/FR-2022-11-04/pdf/2022-23722.pdf

CY2024: https://www.govinfo.gov/content/pkg/FR-2023-07-10/pdf/2023-14044.pdf

CY2025: https://www.govinfo.gov/content/pkg/FR-2024-07-03/pdf/2024-14254.pdf

Current Care Access Problems Are Expected to Significantly Increase with the Proposed Rate Cut

In the CY 2024 rulemaking, the ALLIANCE and others presented stunning evidence about the growing barriers to care access faced by Medicare beneficiaries since the onset of PDGM. This evidence was dismissed by CMS in its rulemaking responses for a variety of reasons including that causation was not established, the data analysis may have relied on duplication of patients, and that the rejection of a patient by one HHA did not automatically translate to rejection by all HHAs.

Such a position begs for something more than a dismissal of concerns. Instead, CMS, with its ability to evaluate global data on home health care access, must take steps to answer the questions posed through the analyses presented by HHAs and their representatives. CMS is best positioned to undertake that analysis. Something more from CMS than a casual dismissal of relevant data analysis is a CMS responsibility.

One of the CY 2024 rulemaking commenters, Homecare Homebase, took added steps for its CY2025 rulemaking comments on the extraordinarily relevant question as to what becomes of patients that are rejected for admission by an HHA. In using its vast database of Medicare claims and other data, the recent comments submitted by Homecare Homebase confirm the concerns that have been previously voiced. Its data analysis shows that 35% of referrals to its clients are rejected and do not find access with any other of its clients. Given the significant market share for Homecare Homebase, at a minimum this outcome warrants a deeper dive by CMS. Even if one-half of those referrals find an alternative HHA, the impact on patients and Medicare of the remaining half finding no care is unacceptable. When combined with the continuing reduction in the number of home health users annually since PDGM, an investigation is the duty of CMS.

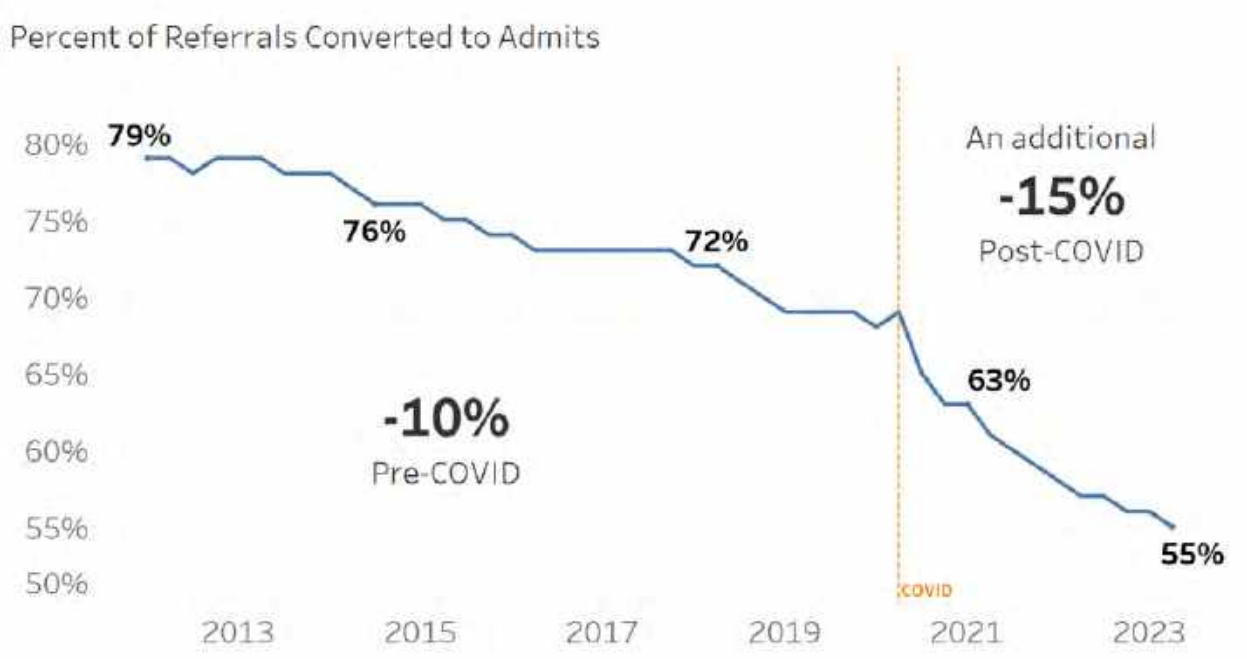
Here are several previously referenced signs of the existing difficulties in care access:

Hospital discharge data shows that hospitals are facing a growing level of patient referral rejections for prospective home health patients. This has led to delays in discharging patients to their homes, and extending costly inpatient stays as reported by the American Hospital Association. file:///C:/Users/wad/AppData/Local/Microsoft/Windows/INetCache/Content.Outlook/L69H8U3R/Issue-Brief-Patients-and-Providers-Faced-with-Increasing-Delays-in-Timely-Discharges.pdf

The delays in hospitals discharging patients to home health services is certain to create a significant cost to the hospitals, but also to Medicare.

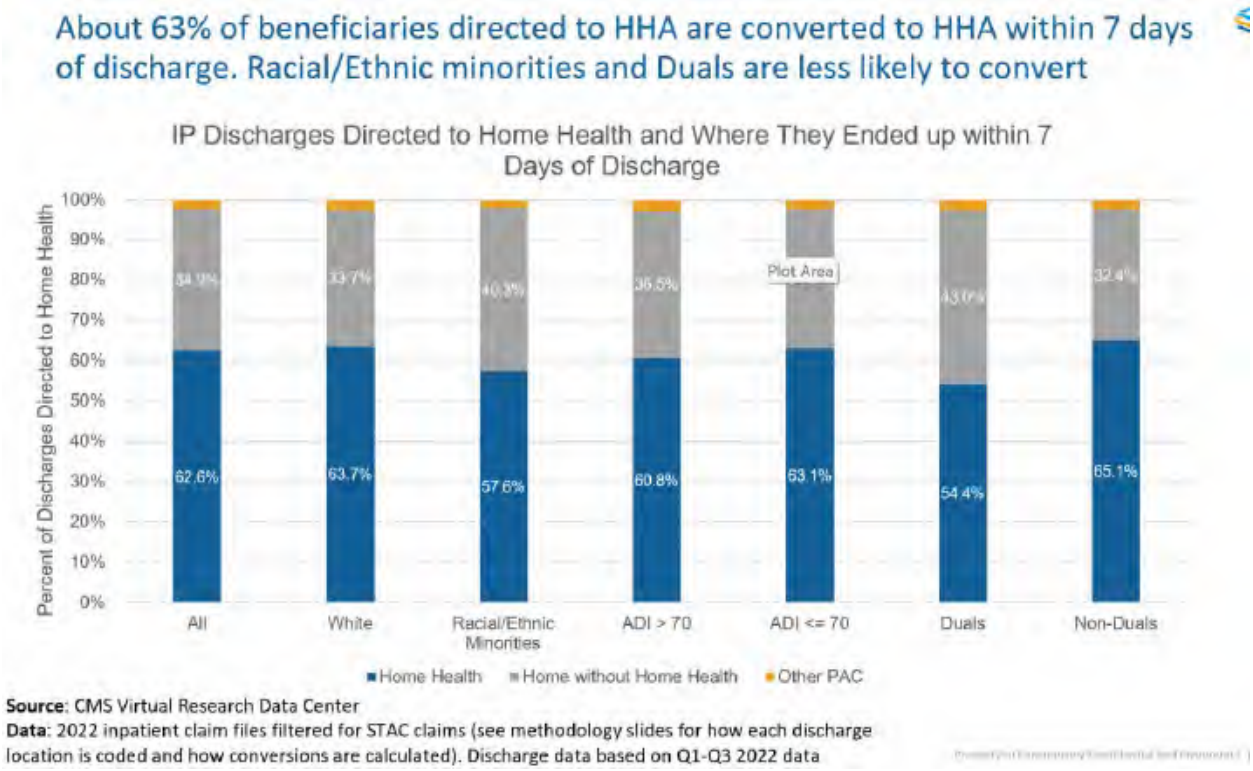
Source: July 25, 2023, WellSky Evolution of Care report, available at: https://careporthealth.com/about/results/the-evolution-of-care-2023/

Home Care Home Base, a large provider of EMR and billing services to HHAs further reports decreasing patient acceptance rates under the current PDGM payment rates.



Source: HCHB data, as presented in HCHB comments on this Proposed Rule.

Finally, data analytics company, Care Journey explains that only 63% of inpatient discharges are securing and initiating home health services within 7 days.



We characterized this data as "scary" in our CY 2024 comments. It has gotten worse and all trends point o the decline to continue. HHAs routinely express to the ALLIANCE that nurses are rejecting home health care employment every day due to compensation offers that fall short of what they can earn in other care sectors. Reducing payment rates at this time will certainly make care access even worse.

Additional Proposed Changes Affecting Medicare Payment Rate Will Greatly Increase the Disruptive Nature of the CY2024 Payment Rule Creating Further Risks to Care

The above analysis fully substantiates the ALLIANCE's concerns that the proposed rate cut in 2025 will be a disaster for home health services patients and HHAs. However, there are additional elements of the proposed rule that affect payment that can be fully expected to compound the negative impact of that rate cut. These other proposals include:

- The failure to correct the unprecedented error level in the forecast of HHA cost changes in 2021-2022.
- Significant shifts in the wage index values.
- Recalibration of the 432 case mix weights.
- Market Basket Index rebasing and revision of input weights.

The Financial Shortfall in the Market Basket Index Will Continue to Disrupt the Financial Stability of HHAs

CMS has confirmed that its modeling led to a Market Basket Index forecasting error for CY2021 through CY 2022. The ALLIANCE previously estimated that error to be 1.8 and 3.2 points in 2021 and 2022 respectively. In previous rulemaking, CMS declined to correct the error indicating it did not have such authority.As submitted in the ALLIANCE's CY 2024 NPRM comments, the estimated impact of that error cast is expected to result in an approximately $11 billion underpayment by Medicare over a ten-year period.

Projected Impact of 5.2 Forecast Market Basket Error in CY 2021 through CY 2030

Total Payments	Impact of CY 2021 and CY 2022 Forecast Error
2021	-$285,512,085
2022	-$867,452,091
2023	-$871,874,624
2024	-$1,115,186,361
2025	-$1,161,316,235
2026	-$1,225,352,343
2027	-$1,273,931,221
2028	-$1,342,554,653
2029	-$1,394,931,985
2030	-$1,449,139,655
Total	**-$10,987,251,254**

Source: Dobson | Davanzo

While CMS has not and is not likely to correct the error, the impact is nonetheless real for HHAs, creating another destabilizing force within the HHA community. When combined with the proposed rate reduction, the impact of significant swings in wage index values, and the recalibration of the 4432 case mix weights and resetting of the universe of LUPA thresholds, HHAs face multiple disruptions in operations that will affect patient access to care and the level of services available. The impact is not conjecture. Instead, it is a prognosis based on over a decade of experiences since 2011.

Significant Shifts in Wage Index Values Add to the Destabilization of the Home Health Benefit

Once again, the changes in wage index values significantly contribute to the instability on access to the home health benefit. As CMS well knows, HHAs are relegated to the pre-rural floor, pre-geographic reclassification inpatient hospital wage index while HHAs compete with hospitals that are subject to a different wage index for the same clinical and administrative staff. For 2024, CMS implemented a recalibration of the assigned wage index values, but also a resetting of the labor percentage of payment rates affected by the wage index. For 2025, in addition to the usual swings in the wage index for HHAs, CMS proposes to modify the county-level designations in CBSAs and rural areas. Since the home health NPRM was issued, CMS finalized these changes for other health care sectors operating on a federal fiscal year basis. As such, the disruptive effect of the proposed wage index changes

for home health can reasonably be presumed to be the reality for 2025 in home health services. These changes add to the complications wrought by the proposed rate reduction and other payment-affecting proposals.

The ALLIANCE compared the current 2024 wage index values with the proposed values post-5% cap for 2025, See, Appendix A attached).

Home Health Providers Significantly Impacted by Wage Index Change in CY 2025

Count	Number
Counties with wage index value change >/= -0.02	597
Counties with wage index value change >/= -0.03	370
Counties with wage index value change >/= -0.04	246
Counties with wage index value change >/= -0.05	71
Counties with wage index value change >/= -0.06	27
Counties with wage index value change >/= -0.07	9
Counties with wage index value change >/= -0.08	5
Counties with wage index value change >/= -0.09	2

The ALLIANCE recommends that CMS consider the impact of the wage index changes in determining whether to use its authority to postpone the proposed PDGM rate cuts to mitigate the expected overall access and care impacts already underway with home health services that will expand in 2025 with all these changes.

Medicare Stands to Lose Out in the HHVBP Demonstration as a Result of Expected Care Changes Triggered by the Proposed Rate Cuts

It was just two years ago that CMS moved to expand the successful Home Health Value Based Purchasing demonstration program from nine states to nationwide application. The ALLIANCE had been a supporter of the program since its initial design and fully supported the expansion. The program stood as one of the few value-based payment experiments to date with Medicare savings millions annually through reduced hospital admissions and more brought about through high quality home health services. CMS estimated that the nationwide expansion would reduce Medicare expenditures by nearly $3.4 billion over five years.

To get that savings takes dedication and innovation by HHAs. That effort also comes with a cost in resources. The proposed rule reducing payment rates by 4.067% and the combined effect of a 5.2% shortfall in the annual inflation update, a modified wage index, and the instabilities coming through case mix weight recalibrations are certain to diminish needed resources to succeed in HHVBP. There is only so much an HHA can do to produce the highest quality of care when the resources needed to deliver care are reduced. While we expect that HHAs will continue to provide an incredibly high quality of care as they have done following other rate reductions, we believe that they have reached a breaking point financially. As noted above, as rates of payment are decreased, access to care and the level of care available also decrease. These changes are bound to affect patient outcomes and the success of HHVBP.

The proposed rate reduction may be viewed by some as CMS's lack of respect for the value of home health services, which is at odds with the objective evidence in HHVBP that home health care

brings a dynamic value to Medicare and the patients its serves. The ALLIANCE believes that CMS maintains an understanding of the value of home health services and will recognize the need to preserve that value by postponing the proposed rate cut in 2025.

The ALLIANCE Maintains That the Methodology Applied by CMS to Determine Whether PDGM Is Budget Neutral Is Noncompliant with the Statutory Mandate

In the 2022 and 2023 HHPPS rulemaking, the ALLIANCE strenuously expressed its view that the budget neutrality assessment methodology used by CMS was fatally flawed both logically and under Medicare law. That view was supported by two independent legal analyses from highly respected law firms that included attorneys formerly with the CMS/HHS Office of General Counsel. The ALLIANCE will not repeat all the arguments presented to support that position.

While the U.S. District Court for the District of Columbia dismissed the case based on failure to exhaust the remedy of seeking expedited judicial review, the matter will be eventually refiled once that administrative step concludes. However, with the normal time involved in administrative appeals and the normal pace of litigation, it is unexpected that the matter will be resolved prior to January 1. 2025 effective date of the Final Rule that comes out of the pending proposed rule. For that reason, The ALLIANCE respectfully requests that CMS use its authority under 42 USC 1395fff to postpone the proposed 4.067% rate cut as the great harm outlined above must be avoided.

RECOMMENDATIONS:

1. **CMS should postpone application of any permanent adjustments related to PDGM budget neutrality to preserve current access to home health services and the scope of care available.**
2. **CMS should maintain its proposed position to withhold any part of the PDGM budget neutrality temporary adjustments in 2025.**
3. **CMS should recognize the disruptive and permanent financial impact of its forecasting error with respect to the annual Market Basket Index updates from 2021 and 2022 and implement a one-time adjustment to account for the 5.2% forecasting error.**
4. **CMS should consider the negative and disruptive financial impacts of its proposed wage index changes and case mix weight recalibrations on care access as it finalizes the 2025 payment rates and any systemic reforms.**

NON-PAYMENT PROVISIONS

III. Home Health Quality Reporting Program (HH QRP)

D. Proposal To Collect Four New Items as Standardized Patient Assessment Data Elements and Modify One Item Collected as a Standardized Patient Assessment Data Element Beginning With the CY 2027 HH QRP.

CMS proposes collecting one item that addresses living situation, two food items, and one for utilities, along with a proposal to modify the currently collected transportation assessment item using the Outcome and Assessment Information Set (OASIS) data set. The ALLIANCE supports collecting these additional social determinants of health (SDOH) data items. Although HHAs consider these SDOH for effective care planning, there is no standardized mechanism for collecting and reporting the data, which could provide valuable information for HH QRP and other federal programs. CMS might want to

consider including in future rulemaking the AHC HRSN core questions screening tool within the post-acute care (PAC) assessment instruments if there are plans to continue to propose and adopt items from the tool.

However, we have concerns with the frequency that CMS has modified the HH QRP necessitating updates to the OASIS data set over the last several years. The addition of the proposed new and modified items will require yet another revision of the OASIS data set to be issued sometime in 2026 to accommodate the January 1, 2027, proposed collection date. Since the implementation of the Improving Medicare Post - Acute Care Transformation (IMPACT) Act there have been multiple revisions to the OASIS data set to accommodate the development of standardized assessment items and cross setting measures as required by the Act. HHAs have had to adjust to a revised OASIS data set and instructions in 2019, 2020, and 2023[1]. The last revision related to the IMPACT Act requirements was implemented in 2023 (OASIS E). However, CMS continued to implement additional changes to the HH QRP requiring another revision to the OASIS data set, effective January 1, 2025. CMS, again, is proposing additional changes to be implemented in 2027.

Changes to the OASIS data set, even small changes, increase resource use for agencies in terms of staff training, coordination with vendors, and altered productivity associated with the learning curve required for collecting new material. The burden is magnified by increased rate cuts and a protracted workforce shortage. Also, the addition of assessment items without modifications to reduce the data set could result in a very lengthy assessment tool.

An additional concern with frequent changes to the HH QRP is the delay in data reporting for HHAs. HHAs have consistently been the last of the PAC settings subject to the IMPACT Act to have their data set modified for cross setting assessment items and quality measures. CMS has convened technical expert panels to address inclusion/exclusion of cross setting assessment items and measures based on data derived from the other PAC settings without the home health data being accessible to the participants or the home health agencies themselves.

Recommendations: CMS should:

1. **Limit revisions to the OASIS data set to intervals no less than 4 years from the last revision.**
2. **Considered imbedding the AHC-HRSN core question screening tool into the PAC assessments if feasible.**
3. **Monitor additions to the OASIS data set to ensure that the tool is manageable for HHAs.**
4. **Provide sufficient data on HHA quality measures and assessment items prior to implementing any changes in the OASIS data set.**

G. HH QRP Quality Measure Concepts Under Consideration for Future Years— Request for Information (RFI)

CMS is seeking feedback on four measure concepts that are part of the "Universal Foundation" of quality measures. The measures include immunizations (i.e. Adult Immunization Status measure); depression (i.e. Clinical Screening for Depression and Follow-up measure); pain management; and substance use disorder (i.e. Initiation and Engagement of Substance Use Disorder Treatment measure).

[1] Outcome and Assessment Information Set OASIS-E1 Manual, Centers for Medicare & Medicaid Services, effective 01/01/2025, https://www.cms.gov/files/document/draft-oasis-e1-manual-04-28-2024.pdf

Immunization - Adult Immunization Status measure:

The recommended measure for the immunization concept includes the following vaccine rates and reasons for not receiving the vaccine.

> Four individual vaccine rates: 1. Influenza rate: Beneficiaries who received an influenza vaccine on or between July 1 of the year prior to the Measurement Period and June 30 of the Measurement Period. 2. Td/Tdap rate: a. Beneficiaries who received at least one Td vaccine or one Tdap vaccine between nine years prior to the start of the Measurement Period and the end of the Measurement Period, or b. Members with a history of at least one of the following contraindications any time before or during the Measurement Period: i. Anaphylaxis due to the diphtheria, tetanus, or pertussis vaccine. ii. Encephalitis due to the diphtheria, tetanus, or pertussis vaccine. 3. Zoster rate: Beneficiaries who received at least one dose of the herpes zoster live vaccine or two doses of the herpes zoster recombinant vaccine at least 28 days apart, anytime on or after the beneficiary's 50th birthday and before or during the Measurement Period, or beneficiaries with anaphylaxis due to the herpes zoster vaccine any time before or during the measurement period. 4. Pneumococcal rate. Beneficiaries who were administered at least one dose of adult pneumococcal vaccine on or after their 19th birthday and before or during the measurement period, or beneficiaries with anaphylaxis due to the pneumococcal vaccine any time before or during the measurement period.

HHAs would not have access to information on the multiple vaccination status of patients without a tremendous amount of research across a patient's medical records and /or interviews with practitioners familiar with the patient. HHAs will likely have to rely on the patient's recall of their vaccination status, leading to inaccurate or misleading responses. The burden for HHAs to collect multiple vaccine rates far outweighs any benefit that could be derived from collecting the information. Additionally, many of the provider representatives on the Post-Acute Care (PAC) and Hospice Quality Reporting Program Cross-Setting Technical Expert Panel[2] did not support the measure for the reasons associated with the burden to collect the information. Therefore, we believe that the measure concept, as proposed, is not appropriate for the home health setting from a practicable standpoint.

Recommendation: CMS should not consider including in the HH QRP the "Adult Immunization Status" measure, or any similar measure related to vaccinations that requires extensive review of data sources.

Depression- (i.e. Clinical Screening for Depression and Follow-up measure)

The typical HHA is not set up to treat patients presenting with depression. Interventions to address a positive depression screen would not be within the HHAs control to facilitate without significant resources and an infrastructure to address a depression diagnosis. Additionally, home health patients are often discharged from services before any outcomes through community referrals can be realized.

If CMS were to include a measure for depression screening and follow-up, the follow-up would need to be limited to a referral to the patient's PCP for further interventions. The Clinical Screening for Depression and Follow-up measure or similar measure that CMS is considering is one that is used for

[2] Standing Technical Expert Panel for the Development, Evaluation, and Maintenance of Post-Acute Care (PAC) and Hospice Quality Reporting Program (QRP) Measurement Sets Summary Report. https://www.cms.gov/files/document/december-2023-pac-and-hospice-cross-setting-tep-summary-report.pdf-3

individual practitioners who have the expertise and authority to prescribe pharmacological interventions and have a relationship with the patient that supports the necessary follow-up for such interventions. As stated above, HHAs do not have a consistent relationship with most patients that would allow for the HHA to treat the patient. Unless an HHA specializes in the delivery of psychiatric nursing care it does not have staff with the training and expertise necessary to determine if a referral to a psychiatrist, psychologist, mental health counselor or primary care physician is most appropriate. Additionally, HHAs provide care to patients for an average of 3.1 episodes[3] which is conducive to the necessary monitoring and follow-up for pharmacological interventions. HHAs cannot be expected to provide intervention aimed directly at treating depression such as pharmacological interventions or other follow-up that involves long term planning.

Recommendation: CMS must consider the limitations for HHAs to address a depression diagnosis when considering the measure concept for the HH QRP

Substance use disorder (i.e. Initiation and Engagement of Substance Use Disorder Treatment measure).

Like the depression diagnosis, HHAs are not set up to address patients with a substance use disorder (SUD), either as a primary or secondary diagnosis. HHAs are even less likely to accept a patient onto service with an active SUD due to their inability to effectively provide interventions or ensure that community support is available for the treatment of the disorder. Patients with a SUD require interventions provided by specially trained clinicians to treat SUD, along with intensive therapies. There is a known shortage of these clinicians and programs within most communities, and the typical HHA does not have specialty trained clinicians on staff. HHAs would have limited control over the availability of such programs much less the interventions provided. Additionally, there is no data source currently available that captures SUD and interventions for home health patients, therefore, an added burden will be created for agencies to collect and report data needed for the measure concept.

As such, a measure concept for patients with SUD in the home health setting is not appropriate, particularly as described in the suggested measure for this concept.

Initiation and Engagement of Substance Use Disorder Treatment -measure description

1. Percentage of patients 13 years of age and older with a new substance use disorder (SUD) episode who received the following (Two rates are reported):
    a. Percentage of patients who initiated treatment, including either an intervention or medication for the treatment of SUD, within 14 days of the new SUD episode.
    b. Percentage of patients who engaged in ongoing treatment, including two additional interventions or short-term medications, or one long-term medication for the treatment of SUD, within 34 days of the initiation.

Recommendation: CMS should not move forward with a measure concept related to SUD for inclusion in the HH QRP.

Pain management

The ALLIANCE supports performance measures around pain management and has relevance for home health patients. However, CMS removed the improvement in pain management measure from the HH QRP in 2020 due to the opioid crisis. Therefore, it is unclear what CMS is seeking in terms of a pain management performance measure in the current environment.

[3] Home Care Chartbook, 2023. https://researchinstituteforhomecare.org/wp-content/uploads/Final-RIHC-Chartbook-2023-1.pdf

IV. The Expanded Home Health Value Based Purchasing (HHVBP) Model
B. Request for Information on Future Performance Measure Concepts for the Expanded HHVBP Model

CMS is seeking information on four measure concepts for inclusion in the HHVBP: family caregiver measure; falls with injury (claims-based) measure; Medicare Spending per Beneficiary measure; and function measures to complement existing cross-setting Discharge (DC) Function measure:

Family Caregiver Measure

The measure would address whether the needs of caregivers for home health patients have been met. CMS does not provide much information on exactly what is to be measured and how this measure would be constructed. Therefore, it is difficult to comment in support of the measure concept. The immediate concern is the additional burden around data collection for the measure. CMS would likely need to revise the standardized assessment tool or modify the HH CAHPs survey, which are already lengthy tools, for collecting and reporting of the data. Additionally, an HHA's focus is on the care of the patient and not the needs of the caregiver. Further, it is unknown if a measure can be developed that accurately reflects whether a caregiver's needs have been met. It is also questionable whether a measure can be developed that will allow for accurate comparisons among HHAs.

Recommendation: CMS must consider the complexity and potential burden for data collection when developing a measure to address the needs of the family caregivers for home health patients.

Fall with injury (Claims Based) measure

The ALLIANCE has the same concern with a potential claims-based measure for falls as it does with the OASIS based measure. The falls with injury measure (claims or OASIS based) does not take into consideration the nature of home health services. Care is provided on an intermittent basis with the focus on the home environment. The measure will capture a fall with injury anytime during the home health episode irrespective of whether the HHA had any control over the patient's movements. For example, the patient falls while outside the home, such as on the way to the physician's office. Fall prevention programs aimed at safety in the home for a particular patient might not be transferable to the general community setting.

Recommendation. CMS should not include the falls with injury measure into the HHVBP

Medicare Spending per Beneficiary (MSPB)

It is unclear how CMS intends to use the MSPB measure in the HHVBP. It is important to note that the MSPB measure is not a quality measure but a measure for Medicare spending. The measure is assumed to be a measure of efficiency if the HHA's MSPB is less than the Medicare spending of the national median home health agency's MSPB. However, the amount spent on care does not necessarily correlate with the efficient provision of services or the quality of care.

Recommendation: CMS should not include the MSPB measure in the HHVBP.

Function measures to complement existing cross-setting Discharge (DC) Function measure:

Recommendation: The ALLIANCE supports the inclusion of additional function measures in the HHVBP that complement the DC Function measure.

3. Requests for Information
a. RFI Regarding Rehabilitative Therapists Conducting the Initial and Comprehensive Assessment

How do HHAs currently assign staff to conduct the initial assessment and comprehensive assessment? Do HHAs implement specific skill and competency requirements?

HHAs provide all professional staff with additional training specific to the agency policies and procedures, completing the OASIS data set, and applying practice to the home health setting. Additionally, new hires to HHAs would go through some type of orientation and period of supervision to determine their readiness for providing home health services. The orientation and supervision would be tailored to the individual's clinical skills and needs. The clinical professionals (therapist and registered nurses) would be expected to have the skills necessary to conduct an initial and comprehensive assessment of a patient, and therefore when permitted by regulation, be able to conduct the assessments as needed.

What types of mentorships, preceptorship, or training do these disciplines have qualifying them to conduct the initial assessment and comprehensive assessment?

Do the education requirements for entry-level rehabilitative therapist provide them with the skills to perform both the initial assessment and comprehensive assessment? Is this consistent across all the therapy disciplines? How does this compare with entry-level education for nursing staff?

What, if any, potential education or skills gaps may exist for rehabilitative therapists in conducting the initial assessment and comprehensive assessment

This response is intended to address the above questions. In discussion with representatives from the professional associations for physical therapy, occupational therapy, and speech language pathology (American Physical Therapy Association (APTA), American Occupational Therapy Association, (AOTA) and the American Speech-Language Hearing Association (ASHA)) all concurred that the education and training for therapists is aimed to prepare the respective therapists to adequately conduct an initial and comprehensive assessments on home health patients. However, any new graduate (therapist or registered nurse) would not be expected to conduct an initial and comprehensive assessment without participating in a mentorship program and demonstrating that they have the necessary skills to conduct the initial and comprehensive assessments. It is important to note that HHA's typically do not hire new graduate therapists, the preference for new hires, for all disciplines, is to have several years of clinical experience.

Additionally, CMS notes in the proposed rule the specific training required by each discipline. PTs must hold a Doctor of Physical Therapy. Physical therapy entry-level education requires a Doctor of Physical Therapy degree. The Commission on Accreditation in Physical Therapy Education (CAPTE) of American Physical Therapy Association (APTA) accredits entry-level physical therapist education programs. Graduates of these programs are then eligible to take the National Physical Therapy Examination and apply for State licensure. The curriculum includes the general clinical skills required to conduct the initial and comprehensive assessments, both in the identification of immediate care and support needs, as well as the assessment of the patient's general health, psychosocial, functional, cognitive, and pharmacological status, and clinical experience.

.

SLPs must obtain a Certificate of Clinical Competence in Speech-Language Pathology as well as state licensure. SLP must obtain a master's, doctoral, or other recognized post-baccalaureate degree. Once students complete all academic coursework and a graduate student clinical practicum, they must also complete a clinical fellow.

This requires graduation from a program accredited by the Council on Academic Accreditation in Audiology and Speech-Language Pathology (CAA) of the American Speech-Language Hearing

Association (ASHA). Individuals applying for certification in speech-language pathology must have been awarded a master's, doctoral, or other recognized post-baccalaureate degree. Once students complete all academic coursework and a graduate student clinical practicum, they must also complete a clinical fellowship under the supervision of a SLP mentor. The clinical fellowship requires working at least 36 weeks and 1,260 hours and is intended to transition the fellow from a student enrolled in a communication sciences and disorders (CSD) program to an independent provider of speech-language pathology clinical services

OTs must hold either a Master's degree or Doctorate of Occupational Therapy. Education programs are accredited by the Accreditation Council for Occupational Therapy Education (ACOTE) of the AOTA. The ACOTE establishes, approves, and administers educational standards to evaluate occupational therapy educational programs. Graduates of ACOTE accredited programs are eligible to take the National Board for Certification in Occupational Therapy (NBCOT) certification exam and apply for State licensure

What challenges did HHAs and therapists that conducted these assessments under the PHE waiver experience that may have impacted the quality of these assessments?

Home health agencies did not report any challenges with exercising the waiver that expanded the role of therapists in conducting the initial and comprehensive assessments. Nor was there any evidence that quality of care for patients was impacted, suggesting that assessments conducted by therapist were completed accurately.

During the PHE, HHAs relied on therapists to conduct the initial and comprehensive assessments that were existing employees with the agency and had a proven record of clinical competence. New hires for HHAs were virtually nonexistent during the PHE.

For the HHAs and therapists that conducted the initial assessment and comprehensive assessment under the PHE waiver, what were the benefits and were there any unintended consequences of this on patient health and safety?

Because the regulations permit a therapist to conduct the initial and comprehensive assessments if therapy is the only discipline ordered, there has always been precedent for a therapist to conduct the assessments. Long before the PHE, we had advocated for a change in the regulations at §484.55 that provided a similar flexibility as the PHE waiver.

HHAs have overwhelmingly reported that this flexibility was most beneficial during the PHE in their ability to provide care to patients requiring home health services and allowed for the timely initiation of care during unprecedented workforce challenges. HHAs also reported that the waiver was the most widely used of all the PHE waivers.

The application of that waiver into HHA operations during the PHE had the same effect as a three-year demonstration project. During that time there were no adverse effects on the quality of care for home health patients. The waiver was particularly beneficial for patients in rural areas where workforce shortages were, and remain, the most profound.

What challenges, barriers, or other factors, such as workforce shortages, particularly in rural areas, impact rehabilitative therapists and nurses in meeting the needs of patients at the start of care and early in the plan of care?

The recent Medicare payment cuts to HHAs and the workforce shortages have significantly impacted HHAs in rural areas. Rural providers have unique challenges that include longer travel distances between visits and greater competition for qualified workers. Additionally, home health therapists and nurses often serve as the primary source for health evaluations and care delivery in underserved areas. Rural agencies are incurring significant unreimbursed costs to recruit and retain home care professionals and to integrate the use of technologies in agency operations. As a result, agencies have been forced to reduce service areas and refuse admission to patients whose care costs would place an agency at financial risk.

Reports from our rural provider members have sounded the alarm with closures and service area reductions. For example, one agency in rural Nebraska reported having to downsize from serving 13 counties (60-mile radius) to serving only one county (25- mile radius) with a drop in the average daily census (ADC) by 60% since 2020. An agency in rural Vermont has reduced its service area by a third with ADC down by nearly 50% over the past year. The state of Missouri alone has lost 56 home health agencies to closure since August 2017, and 14 of those just in the last 18 months. Sixty-six percent of these closures were in rural areas. It is reasonable to believe that this pattern of care delivery reductions and HHA closures is being repeated throughout rural America.

b. Plan of Care Development and Scope of Services Home Health Patients Receive

What factors influence an HHA's decision on what services to offer as part of its business model and how often do HHAs change the service mix?

Most HHAs do, or strive to, provide all services permitted under the home health benefit. Limitations to the services an agency provides is usually driven by available staff. Agencies report having difficulty recruiting and retaining nurses and home health aides, although we are also hearing of reports of difficulty in recruiting and retaining all discipline types, particularly in rural areas. Therefore, the change in services provided is often dictated by market forces and the availability of certain categories of staff.

What are the common reasons for an HHA to not accept a referral?

HHAs currently report that the most common reason for having to turn down referrals is because of workforce shortages particularly for nurses and home health aides, although HHAs also report difficulty in recruiting all disciplines to some degree. Some providers have reported a significant shortage of therapists in their region particularly in rural areas. Home health patients are being referred to home health with more complex conditions requiring multiple disciplines and the need for front loading of visits that the HHA may not be able to provide. Home health is experiencing a perfect storm of challenges whereby patients have greater needs, but the workforce is at a critical low.

Other reasons include incomplete referrals, particularly where the referral source is not able to identify a community provider to follow the patient or have the wrong provider listed. If the HHA cannot locate a practitioner to follow the patient timely, it places both the patient and agency at risk.

Discharge planners in acute/post-acute care facilities often routinely refer beneficiaries to home health care, irrespective of whether the beneficiary meets coverage criteria. It is not uncommon for inpatient referral sources to include a multitude of services on a referral irrespective of the needs of the patient. The HHA must explain to the beneficiary why they do not meet coverage criteria for some, or all, of the services ordered. Conversely, it is not unusual for HHAs to receive referrals for patients where the needs are too complex to be met in the home.

How do physicians and allowed practitioners use their role in establishing and reviewing the plan of care to ensure patients are receiving the right mix, duration, and frequency of services to meet the measurable outcomes and goals identified by the HHA and the patient?

Physicians and allowed practitioners use their role in establishing and reviewing the POC for adequacy of service delivery based on their professional judgement. HHAs may only provide care as ordered by a physician or allowed practitioner and therefore their role is critical in providing the appropriate mix of disciplines, and duration and frequency of services.

To what extent do physicians rely on HHA clinician evaluations and reports in establishing the mix of services, service frequency, and service duration included in the plan of care?

Community practitioners rely on the HHA's evaluation and reports to inform the plan of care. If a patient is being referred to home health from an acute/post-acute care facility the patient will have been followed by a hospitalist and/or a skilled nursing facility Medical Director who refers the patient to home health. The patient's primary care practitioner (PCP) resumes care only upon the patient's return home. The HHA is usually the first contact the patient has with a community healthcare provider. Therefore, the HHA's evaluation of the patient's condition and care needs relative to the home setting is necessary for effective care planning by the community practitioner. Even when a referral is received from the community PCP, the HHA provides a unique perspective for care planning in the individual's home.

What are the patient and caregiver experiences in receiving nursing, aide, and therapy services when under the care of a home health agency?

Sources for this information include the Home Health Consumer Assessment of Healthcare Providers and Systems (HHCAHPS) survey and the HHA complaint logs.

What additional evidence is available regarding negative outcomes or adverse events that may be attributable to the mix, duration, and service frequency provided by HHAs, including, but not limited to, avoidable hospitalizations?

CMS' discussion on negative outcomes for patients largely addressed those patients who were unable to access home health services timely. CMS cited several publications that addressed the workforce shortages related to the COVID-19 PHE. It is unclear what additional evidence CMS is seeking.

In what ways can referring providers and HHAs improve the referral process?

Improved communication between referral sources and HHAs is needed and should include consistent feedback regarding necessary information needed for a complete referral, coverage criteria for beneficiaries to receive Medicare covered home health services, and the HHAs capacity for acceptance with anticipated referrals.

CMS should support and encourage interoperability of health care information across providers. Interoperability will help facilitate the referral process by allowing HHAs to obtain the necessary information regarding the patient's current condition and care needs along with the past medical history and any social determinants of health that might impact care planning and delivery

What other factors may influence the provision of services that impact the timeliness of services and service initiation?

The increasing cost of providing care along with inadequate reimbursement from the primary sources of payment for home health services and the workforce shortage are not the only stressors on HHA resources. Federal policies that have impacted home health care operations include several recent initiatives that contribute to significant administrative burdens. For example, CMS' policy for the collection and reporting of the OASIS data set on all patients beginning in 2025. This policy alone has an unfunded $267 million price tag for HHAs, and for some HHAs, will have a significant impact on the availability for staff to meet the expanded collection requirement. Additionally, the nationwide Home Health Valiue Based Purchasing program and the Review Choice Demonstration requires HHAs to expend additional resources and disrupts agency operations. CMS must be mindful of the impact policies implemented by federal agencies have on HHA resources and operations.

What additional areas should CMS consider to address HHA patient health and safety concerns?

The problem of diminishing patient access to home health services is not a singular issue nor related solely to home health agency operations. As previously noted, there are multiple factors that are contributing to this systemic problem that need to be individually identified and addressed.

Therefore, CMS should develop a systematic approach to gathering additional information from all stakeholders with ideas for probable solutions. Although this RFI is a step in the right direction, CMS should not stop with this initiative to understand the root causes for patients' inability to access home health services.

VI. Home Health CoP Changes and Long Term (LTC) Requirements for Acute Respiratory Illness Reporting

A. Home Health CoP Changes

CMS claims they have received an increasing number of beneficiary complaints related to the difficulty finding a HHA to accept them for service. Beneficiaries complain that in some instances, HHA services are being altered or diminished from the original plan of care without an accompanying reduction in patient needs or achievement of the measurable outcomes and goals set forth in the plan of care.

In addition to the challenges of finding the right HHA and resultant potential delays in the timely initiation of home health care, CMS also expressed concern that HHAs are at higher risk of overextending their available resources when accepting new patients to HHA services. Delays in service initiation may indicate not only that referral sources have difficulty locating an appropriate HHA, but also that HHAs are accepting patients when and for whom they are not capable of delivering timely care.

To this end, CMS is proposing at § 484.105(i)(1)(i) through (iv), that HHAs would be required to include information regarding the HHA's case load and case mix (that is, the volume and complexity of the patients currently receiving care from the HHA), anticipated needs of the referred prospective patient, the HHA's current staffing levels, and the skills and competencies of the HHA staff. These proposed elements are designed to inform an HHA's assessment of its capacity and determine its suitability to meet the anticipated needs of the prospective patient that has been referred for HHA services.

CMS also proposes at § 484.105(i)(2) that HHAs make public accurate information regarding the services offered by the HHA and any limitations related to the types of specialty services, service duration, or service frequency, and that HHAs review that information annually or as necessary.

The ALLIANCE has concerns with CMS' proposal for the acceptance to service requirements, which include a prescribed acceptance to service policy and a requirement for HHAs to make publicly available information limitations on services, frequency and duration. The concerns CMS expresses around beneficiary access to home health services are not related to an agency's process for accepting admissions. HHAs are not able to accept patients onto service for multiple reasons. For example, available resources, an inability to identify a community practitioner, coverage criteria is not met, care needs are inappropriate for the home setting, to name a few.

However, in the current environment, the main reason beneficiaries are not able to access home health services is because HHAs do not have the capacity to accept all referrals. HHA capacity continues to shrink because of the increasing cost of providing services along with reduced reimbursement from the primary payer sources for home health services, compounded by an ongoing workforce shortage. HHAs are having an even greater time recruiting and retaining staff because of its precarious financial status that does not permit competitive compensation to clinicians in comparison to hospitals and other care settings. An additional challenge for staff recruitment and retention is the nature of delivering care in the home. Home care employees face a combination of occupational health and safety challenges that are not traditionally experienced by health care providers in other care settings.

Research studies have reported a range of 18% to 65% of home healthcare workers experiencing verbal abuse from patients. As many as 41% of home healthcare workers have reported sexual harassment. Between 2.5% and 44% of home healthcare workers have reported being physically assaulted. In one study, home healthcare registered nurses frequently reported demanding patients (34%), aggressive pets (27%), poor lighting in patient homes (21%), neighborhood violence/crime (19%), patients' challenging family members (18%), personal security fears (14%), drug use in patient homes (13%), firearms in the home (9%), and racial/ethnic discrimination (8%). Researchers have also reported that physical or verbal threats of violence were associated with providing home care services to patients with a history of violence or patients with mental illness or substance use disorders.[4] Although HHAs employ various strategies to protect workers these interventions also carry a cost and may not be enough to attract new hires.

In addition to staffing issues, we are hearing increasing reports of HHAs receiving incomplete referrals, particularly referrals for which there is not a community provider to follow the patient. The patient either has not identified a community practitioner or the referral source indicates an incorrect primary care practitioner. Referring patients to a HHA without identifying a community practitioner raises significant safety concerns for patients and liabilities for agencies. Because the HHA must conduct the initial evaluation visit within 48 hours of a patient's return home or referral, many HHAs will not accept these patients even if they believe a physician/practitioner can be identified readily.

CMS also expresses concern that "*delays in service initiation may indicate not only that referral sources have difficulty locating an appropriate HHA, but also that HHAs are accepting patients when and for whom they are not capable of delivering timely care.*" CMS seems to be setting policy on a presumed effect of delays in services, and does not provide any analysis on the scope of the problem or

[4] Felice, S.T., Goodwin, S.G., Oliveri, A., Socias-Morales, C., Castillo, D., & Olawoyin, R. (2021). Home Health care Workers: A Growing and Diverse Workforce at High Risk for Workplace Violence. Centers for Disease Control and Prevention. https://blogs.cdc.gov/niosh-science-blog/2021/09/02/hhc-violence

types of patients that have or may be impacted. CMS only states that they are "*..aware of anecdotal reports of home care agencies not providing care to meet patient needs."*

Although staffing changes can impact services provided and there will always be unforeseen circumstances, in any health care setting, that may alter capacity, HHAs do not routinely admit patients for which they cannot provide services. HHAs have admission policies in place that take into consideration the agency's capacity and clinical skills of staff when determining whether to accept a patient onto service. Additionally, there are standards at §484.60 to ensure HHAs only accept those patients for whom there is a reasonable expectation that the agency will be able to meet the patient's needs.

CMS' proposals for an acceptance to service policy and requiring HHAs make publicly available information on the HHA's service, duration and frequency, do not address the root causes around beneficiary access to home health services, and therefore, will not likely help to mitigate the problem. An acceptance to service policy as proposed will not increase an agency's capacity or help to address many of the other reasons for non-acceptance onto services. In terms of transparency and HHAs making publicly available information on services offered, many agencies list on their website the services they provide. This information is also available on the CMS Care Compare website. Perhaps referral sources are not consulting these resources. Also, there is confusion around what CMS expects regarding the HHA's listing limitations on frequency and duration of services that is to be made publicly available.

Furthermore, we have concerns with CMS' following stated position:

> "*…if an HHA accepts payment from both Medicare and another payment source, ''source X,'' the HHA's referral policy should be applied consistently to referrals for patients having Medicare or ''source X'' as a payment source. It is our position that HHAs should accept or decline patient referrals based solely on clinical considerations and the capacity of the HHA to safely and effectively deliver care to meet patient needs, rather than on financial factors related to the perceived adequacy of the payment rate that the HHA has already voluntarily agreed to accept upon establishment of relationships with its payment sources*."

CMS provides no statutory or regulatory references to support that position. While HHAs must comply with a variety of civil rights laws, there are none that prohibit an HHA from rejecting patients for admission based on a policy that limits admissions to patients with a payment source sufficient to cover the cost of care. Likewise, Medicare provider agreement requirements include no standard that obligates an HHA to admit all Medicare patients except those whose clinical needs cannot be met by that HHA. HHAs must accept Medicare payment as payment in full, but that requirement applies only for patients accepted into care by the HHA. Further, HHAS may not discriminate against Medicare patients in any respect where the restrictive admission standards do not apply equally to other patients.

With the standard referenced by CMS, an HHA could drive itself into bankruptcy where the referred Medicare patient census have a care plan and case mix adjustment categorization that provides reimbursement less than the cost of care. It is recognized that the PDGM prospective payment system will provide reimbursement that in some cases exceeds cost and other cases where the payment amount falls short of care costs. However, if an HHA is faced with a patient census that all or the majority fall into a financial loss outcome, that HHA will cease to exist and be inaccessible to all patients. A Medicare provider agreement is not the equivalent on indentured servitude.

If CMS believes that providers must act consistent with its above-referenced statement, the ALLIANCE respectfully asks that it provide a detailed rationale with full citations to any applicable statutory or regulatory authority or case law.

Recommendations: CMS should:

- **Withdraw its proposal at § 484.105(i)(1)(i) through (iv), for an acceptance to service policy and to require HHAs make publicly available information on services, and limitations on frequency and duration.**
- **Continue to seek feedback from stakeholders to determine the root cause for the decreases in patient access to home health services and develop policy and programs to help address these root causes.**
- **Withdraw the position that HHAs can only decline an admission to care based on a finding that it cannot safely and effectively meet the clinical needs of the patient.**

Conclusion

Thank you for the opportunity to submit these comments. As you will note from our comments, we take this process very seriously and we are confident that CMS will give our comments thoughtful consideration as well. The contents of the proposed rule will have a significant impact on the abilities of HHAs to serve individuals in need of essential home health services.

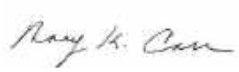
Very truly yours,

William A. Dombi

President and CEO-NAHC

President Emeritus and Of Counsel

NAHC-NHPCO ALLIANCE



Mary K. Carr, RN

Vice President for Regulatory Affairs-NAHC

NAHC-NHPCO ALLIANCE

2024 State Association Co-signers
Alaska Hospital & Healthcare Association
Arizona Association for Home Care
HomeCare Association of Arkansas
California Association for Health Services at Home
Home Care Association of Colorado
Connecticut Association for Healthcare at Home

Delaware Association for Home & Community Care
District of Columbia Home Health Association (DCHHA)
Home Care Association of Florida
The Georgia Association for Home Health Agencies, Inc.
Healthcare Association of Hawaii
Idaho Health Care Association
Illinois Homecare & Hospice Council
Indiana Association for Home and Hospice Care
Iowa Center for Home Care
Kansas Home Care & Hospice Association
Kentucky Home Care Association
Home Care & Hospice ALLIANCE of Maine
Maryland-National Capital Homecare Association.
Home Care ALLIANCE of Massachusetts
Michigan HomeCare and Hospice Association
Minnesota Home Care Association
Mississippi Association for Home Care
Missouri ALLIANCE for Home Care
Nebraska Association for Home Healthcare and Hospice
Home Care & Hospice Association of New Jersey
New Mexico Association for Home & Hospice Care
Home Care Association of New York State
Association for Home & Hospice Care of North Carolina
Granite State Home Health & Hospice Association (NH)
Ohio Health Care Association
Oregon Association for Home Care
Rhode Island Partnership for Home Care
South Carolina Home Care & Hospice Association
Tennessee Association for Home Care
Texas Association for Home Care and Hospice
Homecare and Hospice Association of Utah
West Virginia Council for Home Care and Hospice
VNAs of Vermont
Virginia Association for Home Care and Hospice
Home Care Association of Washington
Wisconsin Association for Home Health Care

118TH CONGRESS
1ST SESSION

S. 2137

To amend title XVIII of the Social Security Act to ensure stability in payments to home health agencies under the Medicare program.

IN THE SENATE OF THE UNITED STATES

JUNE 22, 2023

Ms. STABENOW (for herself and Ms. COLLINS) introduced the following bill; which was read twice and referred to the Committee on Finance

---

A BILL

To amend title XVIII of the Social Security Act to ensure stability in payments to home health agencies under the Medicare program.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Preserving Access to Home Health Act of 2023''.

SEC. 2. ENSURING STABILITY IN PAYMENTS TO HOME HEALTH AGENCIES.

(a) REPEAL OF PERMANENT AND TEMPORARY ADJUSTMENTS.—Section 1895(b)(3) of the Social Security

Act (42 U.S.C. 1395fff(b)(3)) is amended by striking subparagraph (D).

(b) EFFECTIVE DATE; IMPLEMENTATION.—

(1) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect as if included in the enactment of the Bipartisan Budget Act of 2018 (Public Law 115–123).

(2) IMPLEMENTATION.—The Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall implement such section 1895(b)(3) for 2024 and subsequent years as if the amendment made by section 51001(a)(2)(B) of division E of the Bipartisan Budget Act of 2018 (Public Law 115–123) (adding such subparagraph (D)) had not been made.

(c) CONSTRUCTION.—Nothing in this section shall be construed as signifying congressional approval or disapproval of the methodology promulgated by the Secretary to implement section 1895(b)(3)(D) of the Social Security Act in the final rule entitled, ''Medicare Program; Calendar Year (CY) 2023 Home Health Prospective Payment System Rate Update; Home Health Quality Reporting Program Requirements; Home Health Value-Based Purchasing Expanded Model Requirements; and Home Infusion Therapy Services Requirements'' published in the

Federal Register on November 4, 2022 (87 Fed. Reg. 66790).

SEC. 3. INTERACTION OF MEDICARE PAYMENT POLICIES WITH HEALTH CARE DELIVERY GENERALLY.

Section 1805(b)(2)(C) of the Social Security Act (42 U.S.C. 1395b–6(b)(2)(C)) is amended—

(1) by striking ''GENERALLY.—Specifically,'' and inserting ''GENERALLY.—

''(i) IN GENERAL.—Specifically,''; and

(2) by adding at the end the following new clause:

''(ii) SPECIAL RULE FOR HOME HEALTH AGENCIES.—

''(I) IN GENERAL.—When conducting the review of home health agency financial performance and its impact on access to care under the original fee-for-service system, the Commission shall—

''(aa) review and report on aggregate trends in spending, utilization, and financial performance under the Medicare Advantage program, the Medicaid program under title XIX (both fee-

for-service and managed care payment models), and other payers for home health agency services;

"(bb) evaluate and consider the impact of all payers on access to care for Medicare beneficiaries; and

"(cc) comprehensively disclose the methodologies used to evaluate and calculate home health agency margins under this title and all other payers, including the process for developing the data used.

Where appropriate, the Commission shall conduct such reviews in consultation with the Medicaid and CHIP Payment and Access Commission established under section 1900.

"(II) MEDICARE HOME HEALTH COST REPORT AMENDMENTS.—For cost reporting periods beginning in 2025 and subsequent years, the Secretary shall have in effect an amended

Medicare home health cost report that collects data on visit utilization and total payments by payer source, including original fee-for-service payments, Medicare Advantage, the Medicaid program under title XIX (both fee-for-service and managed care payment models), and other payers. The Secretary shall make such amended cost reports available to the Commission in the form and manner necessary to conduct the analysis described in subclause (I).

''(III) FINANCIAL DATA.—Prior to the availability of cost report data as described in subclause (II), the Commission shall utilize data on cost and revenues from sources it deems as reliable and valid for purposes of conducting the analysis described in subclause (I).''.

○

I

118TH CONGRESS
1ST SESSION

H. R. 5159

To amend title XVIII of the Social Security Act to ensure stability in payments to home health agencies under the Medicare program.

IN THE HOUSE OF REPRESENTATIVES

AUGUST 4, 2023

Ms. SEWELL (for herself and Mr. SMITH of Nebraska) introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

---

A BILL

To amend title XVIII of the Social Security Act to ensure stability in payments to home health agencies under the Medicare program.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Preserving Access to Home Health Act of 2023''.

SEC. 2. ENSURING STABILITY IN PAYMENTS TO HOME HEALTH AGENCIES.

(a) REPEAL OF PERMANENT AND TEMPORARY ADJUSTMENTS.—Section 1895(b)(3) of the Social Security Act (42 U.S.C. 1395fff(b)(3)) is amended by striking subparagraph (D).

(b) EFFECTIVE DATE; IMPLEMENTATION.—

(1) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect as if included in the enactment of the Bipartisan Budget Act of 2018 (Public Law 115–123).

(2) IMPLEMENTATION.—The Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall implement such section 1895(b)(3) for 2024 and subsequent years as if the amendment made by section 51001(a)(2)(B) of division E of the Bipartisan Budget Act of 2018 (Public Law 115–123) (adding such subparagraph (D)) had not been made.

(c) CONSTRUCTION.—Nothing in this section shall be construed as signifying congressional approval or disapproval of the methodology promulgated by the Secretary to implement section 1895(b)(3)(D) of the Social Security Act in the final rule entitled, ''Medicare Program; Calendar Year (CY) 2023 Home Health Prospective Payment System Rate Update; Home Health Quality Reporting

Program Requirements; Home Health Value-Based Purchasing Expanded Model Requirements; and Home Infusion Therapy Services Requirements'' published in the Federal Register on November 4, 2022 (87 Fed. Reg. 66790).

SEC. 3. INTERACTION OF MEDICARE PAYMENT POLICIES WITH HEALTH CARE DELIVERY GENERALLY.

Section 1805(b)(2)(C) of the Social Security Act (42 U.S.C. 1395b–6(b)(2)(C)) is amended—

(1) by striking ''GENERALLY.—Specifically,'' and inserting ''GENERALLY.—

''(i) IN GENERAL.—Specifically,''; and

(2) by adding at the end the following new clause:

''(ii) SPECIAL RULE FOR HOME HEALTH AGENCIES.—

''(I) IN GENERAL.—When conducting the review of home health agency financial performance and its impact on access to care under the original fee-for-service system, the Commission shall—

''(aa) review and report on aggregate trends in spending, utilization, and financial perform-

ance under the Medicare Advantage program, the Medicaid program under title XIX (both fee-for-service and managed care payment models), and other payers for home health agency services;

"(bb) evaluate and consider the impact of all payers on access to care for Medicare beneficiaries; and

"(cc) comprehensively disclose the methodologies used to evaluate and calculate home health agency margins under this title and all other payers, including the process for developing the data used.

Where appropriate, the Commission shall conduct such reviews in consultation with the Medicaid and CHIP Payment and Access Commission established under section 1900.

"(II) MEDICARE HOME HEALTH COST REPORT AMENDMENTS.—For

cost reporting periods beginning in 2025 and subsequent years, the Secretary shall have in effect an amended Medicare home health cost report that collects data on visit utilization and total payments by payer source, including original fee-for-service payments, Medicare Advantage, the Medicaid program under title XIX (both fee-for-service and managed care payment models), and other payers. The Secretary shall make such amended cost reports available to the Commission in the form and manner necessary to conduct the analysis described in subclause (I).

''(III) FINANCIAL DATA.—Prior to the availability of cost report data as described in subclause (II), the Commission shall utilize data on cost and revenues from sources it deems as reliable and valid for purposes of conducting the analysis described in subclause (I).''.

○

Home Health Certification/Recertification Requirements

To qualify for the Medicare home health benefit, under §§1814(a)(2)(C) and 1835(a)(2)(A) of the Act, a Medicare beneficiary must meet the following requirements:

- Be confined to the home
- Under the care of a physician or allowed practitioner
- Receiving services under a plan of care established and periodically reviewed by a physician or allowed practitioner
- Need skilled nursing care on an intermittent basis (fewer than 7 days each week or less than 8 hours of each day for periods of 21 days or less) or physical therapy or speech-language pathology
- Have a continuing need for occupational therapy

Confined to Home (Homebound)

An individual shall be considered "confined to the home" (homebound) if the following **two** criteria are met:

Criterion One:

The patient must either:

- Because of illness or injury, need the aid of supportive devices such as crutches, canes, wheelchairs, and walkers; the use of special transportation; or the assistance of another person in order to leave their place of residence.
- Have a condition such that leaving his or her home is medically contraindicated.

If the patient meets one of the criterion one conditions, then the patient **must ALSO** meet two additional requirements defined in criterion two below.

Criterion Two:

- There must exist a normal inability to leave home; AND,
- Leaving home must require a considerable and taxing effort.

Physician/Allowed Practitioner

Allowed practitioners in addition to physicians, can certify and recertify beneficiaries for eligibility, order home health services, and establish and review the care plan. Allowed practitioners are defined at § 484.2 as a physician assistant (PA), nurse practitioner (NP), or clinical nurse specialist (CNS) as defined at this part. NPs, CNSs, and PAs are required to practice in accordance with state law in the state in which the individual performs such services. Physician assistant means an individual as defined at § 410.74(a) and (c). Clinical nurse specialist means an individual as defined at § 410.76(a) and (b), and who is working in collaboration with the physician as defined at § 410.76(c)(3). Nurse practitioner means an individual as defined at § 410.75(a) and (b), and who is working in collaboration with the physician as defined at § 410.75(c)(3).

Content of the Plan of Care

The HHA must be acting upon a physician or allowed practitioner plan of care that meets the requirements of this section for HHA services to be covered. For HHA services to be covered, the individualized plan of care must specify the services necessary to meet the patient-specific needs identified in the comprehensive assessment. In addition, the plan of care must include the identification of the responsible discipline(s) and the frequency and duration of all visits as well as those items listed in 42 CFR 484.60(a) that establish the need for such services. All care provided must be in accordance with the plan of care.

Who Signs the Plan of Care

The physician or allowed practitioner who signs the plan of care must be qualified to sign the certification as described in 42 CFR 424.22.

Timeliness of Signature

The plan of care must be signed and dated by a physician or allowed practitioner as described who meets the certification and recertification requirements of 42 CFR 424.22 and before the claim for each 30-day period for services is submitted for the final percentage payment.

Frequency of Review of the Plan of Care

The plan of care must be reviewed and signed by the physician or allowed practitioner who established the plan of care, in consultation with HHA professional personnel, at least every 60 days. Each review of a patient's plan of care must contain the signature of the physician or allowed practitioner and the date of review.

Needs Skilled Nursing Care on an Intermittent Basis

The patient must need one of the following types of services:

- Skilled nursing care that is:
  - Reasonable and necessary as defined in §40.1
  - Needed on an "intermittent" basis as defined in §40.1.3; and
  - Not solely needed for venipuncture for the purposes of obtaining blood sample as defined in §40.1.2.13; or
- Physical therapy as defined in §40.2.2; or

- Speech-language pathology services as defined in §40.2.3; or
- Have a continuing need for occupational therapy as defined in §§40.2.4.

Physician Certification Including Face to Face (FTF)

The certifying physician must attest to the 5 required elements/certification statement and supply a face-to-face assessment (clinical) documentation which shows evidence of the beneficiary's homebound criteria, skilled need, and primary reason care was being initiated. This assessment must have occurred no more than 90 days prior to the SOC, or 30 days after.

Initial certification

Initial certification is considered to be anytime that a Start of Care (SOC) OASIS is completed to initiate care. In such instances, a physician must certify (5 elements) (attest) that:

- The home health services are or were needed because the patient is or was confined to the home as defined in the CMS Medicare Benefit Policy Manual (Pub. 100-02), chapter 7, §30.1.1.
- The patient needs or needed skilled nursing services on an intermittent basis or physical therapy, or speech-language pathology services.
- A plan of care has been established and is periodically reviewed by a physician or allowed practitioner.
- The services are or were furnished while the patient is or was under the care of a physician or allowed practitioner.
- A face-to-face encounter occurred no more than 90 days prior to or within 30 days after the start of the home health care, was related to the primary reason the patient requires home health services and was performed by a physician or non-physician practitioner. The certifying physician or allowed practitioner must also document the date of the encounter.

Note: If the patient is starting home health directly after discharge from an acute/post-acute care setting where the physician or allowed practitioner, with privileges, that cared for the patient in that setting is certifying the patient's eligibility for the home health benefit, but will not be following the patient after discharge, then the certifying physician or allowed practitioner must identify the community physician or allowed practitioner who will be following the patient after discharge.

Face-to-Face Encounter

As part of the certification of patient eligibility for the Medicare home health benefit, a face-to-face encounter with the patient must be performed by the certifying physician or allowed practitioner himself or herself, a physician or allowed practitioner that cared for the patient in the acute or post-acute care facility (with privileges who cared for the patient in an acute or post-acute care facility from which the patient was directly admitted to home health) or an allowed non-physician practitioner (NPP).

NPPs allowed to perform the encounter:

A nurse practitioner or a clinical nurse specialist working in accordance with State law and in collaboration with the certifying physician or in collaboration with an acute or post-acute care physician, with privileges, who cared for the patient in the acute or post-acute care facility from which the patient was directly admitted to home health.

A certified nurse midwife, as authorized by State law, under the supervision of the certifying physician or under the supervision of an acute or post-acute care physician with privileges who cared for the patient in the acute or post-acute care facility from which the patient was directly admitted to home health.

A physician assistant under the supervision of the certifying physician or under the supervision of an acute or post-acute care physician with privileges who cared for the patient in the acute or post-acute care facility from which the patient was directly admitted to home health.

The physician or allowed practitioner that performed the required face-to-face encounter must sign the certification of eligibility unless the patient is directly admitted to home health care from an acute or post-acute care facility and the encounter was performed by a physician or allowed practitioner in such setting.

Timeframe Requirements

The encounter must occur no more than 90 days prior to the home health start of care date or within 30 days after the start of care.

Physician Recertification

A physician's recertification is required at least every 60 days when there is a need for continuous home health care after an initial 60-day episode. Recertification should occur at the time the plan of care is reviewed and must be signed and dated by the physician who reviews the plan of care.

For recertification of home health services, the physician or allowed practitioner must certify (attest) that the home health services are or were needed because the patient is or was confined to the home as defined in §30.1. The patient needs or needed skilled nursing services on an intermittent basis (other than solely venipuncture for the purposes of obtaining a blood sample), or physical therapy, or speech-language pathology services; or continues to need occupational therapy, a plan of care has been established and is periodically reviewed by a physician or allowed practitioner; and the services are or were furnished while the patient is or was under the care of a physician or allowed practitioner.

Who May Sign the Certification or Recertification

The physician or allowed practitioner who signs the certification or recertification must be permitted to do so by 42 CFR 424.22. A physician or other allowed non-physician practitioner, other than the certifying physician or certifying allowed practitioner who established the home health plan of care, may sign the plan of care or the recertification statement in the absence of the certifying physician or certifying allowed practitioner. This is only permitted when such physician or allowed non-physician practitioner has been authorized to care for the certifying physician's or allowed practitioner's patients in his/her absence. The HHA is responsible for ensuring that the physician or allowed nonphysician practitioner who signs the plan of care and recertification statement was authorized by the physician or allowed practitioner who established the plan of care and completed the certification for his/her patient in his/her absence. The physician or allowed practitioner that performed the required face-to-face encounter must sign the certification of eligibility unless the patient is directly admitted to home health care from an acute or post-acute care facility and the encounter was performed by a physician or allowed practitioner in such setting.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality

Ref: QSO-24-07-HHA

DATE: March 15, 2024

TO: State Survey Agency Directors

FROM: Directors, Quality, Safety & Oversight Group (QSOG) and Survey & Operations Group (SOG)

SUBJECT: Revisions to Home Health Agencies (HHA) – Appendix B of the State Operations Manual

Memorandum Summary

- **Updates to the State Operations Manual (SOM) Appendix B - Guidance for Surveyors: Home Health Agencies –** The Centers for Medicare & Medicaid Services (CMS) is releasing interpretive guidelines and updates to Appendix B of the SOM because several final rules have amended the Home Health Agency (HHA) Conditions of Participation (CoPs). We made conforming revisions to the regulatory tags and interpretive guidelines. We are also combining the HHA survey protocol and interpretive guidelines into one document, updating Level 1 tags, and making clarifications and technical corrections to other guidance areas based on stakeholder feedback.

- **Several previously released S&C, QSO, and Admin Info memos that are now obsolete with the revision of Appendix B.** Memos: Admin Info 19-07, QSO-18-13, QSO-18-25, SC11-11, SC12-15, SC14-14, SC15-51, and SC15-52 are now expired. CMS will note the expiration date on these memos that are currently on the CMS website. This memo and the associated Appendix B update will supersede the expired memos.

Background:

CMS published several final rules which amended the HHA conditions of participation (CoPs):

- *Medicare and Medicaid Programs; Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies, and Hospital and Critical Access Hospital Changes to Promote Innovation, Flexibility, and Improvement in Patient Care* (84 FR 51836).
- *Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency* (85 FR 27550).
- *Medicare and Medicaid Programs; CY 2021 Home Health Prospective Payment System Rate Update* (85 FR 70298).

- *Medicare and Medicaid Programs; CY 2022 Home Health Prospective Payment System Rate Update* (86 FR 62240).

Discussion:
While the primary revisions to Appendix B are the result of the above referenced final rules which amended the CoPs, CMS has also updated the survey protocol, interpretive guidance, and tags. A general summary of the changes follows:

- Retires CMS memos that are no longer applicable or have been incorporated into Appendix B.
- Adds the survey protocol for HHAs to Part I of Appendix B. Appendix B replaces older CMS memos that we are retiring and describes the requirements and procedures for conducting an HHA survey.
- Revises the Level 1 standards that surveyors must assess during a standard survey. Added three Emergency Preparedness tags to Level 1 standards. A partial extended survey is conducted when noncompliance is identified in any Level 1 Standard.
- CMS no longer identifies specific Level 2 standards; instead, when noncompliance with a Level 1 standard is identified, all remaining standards within the relevant CoP are evaluated, and a determination must be made as to the compliance with the condition.
- Revises tags to reflect updated regulatory language based on final rules and adds interpretive guidance where appropriate.
- Consolidates tags to remove redundancy.
- Adds survey procedures to multiple tags to assist surveyors in assessing compliance with the regulatory requirements.
- Adds a cross-reference to Appendix Z for the HHA emergency preparedness tags.
- Makes multiple technical and formatting revisions to fix regulatory citations, acronyms, and tag titles.

The tags in the Internet Quality Improvement and Evaluation System (iQIES) for HHA surveys have been revised and renumbered. The Appendix B interpretive guideline revisions will be reflected in iQIES shortly following the release of this memo.

Surveyor Training:
The HHA regulations at §488.735 require that surveys must be conducted by individuals who meet minimum qualifications prescribed by CMS. In addition, before any State or Federal surveyor may serve on an HHA survey team (except as a trainee), they must have successfully completed the relevant CMS-sponsored Basic HHA Surveyor Training Course.

CMS is updating the existing "Home Health Agency Basic Training" surveyor course on the Quality, Safety & Education Portal (QSEP). We anticipate that the revised surveyor training course will be available in early 2024. Currently, the training is available free of charge through the QSEP website at https://qsep.cms.gov.

Contact:
For questions or concerns relating to this memorandum, please contact HHAsurveyprotocols@cms.hhs.gov.

Effective Date:
Immediately. Please communicate to all appropriate staff within 30 days.

/s/

Karen L. Tritz	David R. Wright
Director, Survey & Operations Group	Director, Quality, Safety & Oversight Group

Attachment(s) – Advance Copy of Appendix B

Resources to Improve Quality of Care:

Check out CMS's new Quality in Focus interactive video series. The series of 10–15 minute videos are tailored to specific provider types and intended to reduce the deficiencies most commonly cited during the CMS survey process, like infection control and accident prevention. Reducing these common deficiencies increases the quality of care for people with Medicare and Medicaid.

Learn to:

- *Understand surveyor evaluation criteria*
- *Recognize deficiencies*
- *Incorporate solutions into your facility's standards of care*

See the Quality, Safety, & Education Portal Training Catalog, and select Quality in Focus.

State Operations Manual
Appendix B – Guidance for Surveyors: Home Health Agencies (HHAs)

Table of Contents
(Rev. ADVANCED COPY)

Subpart C--Organizational Environment

§484.100 Condition of participation: Compliance with Federal, State, and local laws and regulations related to health and safety of patients.
§484.102 Condition of participation: Emergency preparedness.
§484.105 Condition of participation: Organization and administration of services.
§484.110 Condition of participation: Clinical records.
§484.115 Condition of participation: Personnel qualifications.

Survey Protocol for Home Health Agencies

Part I
(Rev.)

I. – Introduction

Home health agencies (HHAs) are required to meet the definition of an HHA as stated in section 1861(o) of the Social Security Act (the Act) and comply with the federal requirements set forth in the Medicare Conditions of Participation (CoPs) in order to be certified by the Medicare program. The HHA survey process evaluates compliance with the CoPs set forth at section 1891 of the Act and 42 CFR Part 484 to ensure that the HHA meets minimum health and safety standards.

The HHA survey process incorporates an approach that is patient-focused and outcome-oriented, making it effective and efficient in assessing, monitoring, and evaluating the quality of care delivered by an HHA.

The purpose of the survey protocols and interpretive guidelines (IGs) is to provide a standardized methodology for conducting the survey. Surveyors conduct the HHA survey in accordance with the appropriate protocols, which are intended to promote consistency in the survey process.

Compliance with the CoPs is evaluated from information gathered during observations of the HHA's performance and practices as well as clinical record reviews and interviews with the HHA's patients, patients' caregivers and HHA staff.

All mandatory requirements for HHAs are set forth in relevant provisions of the Social Security Act and in the Code of Federal Regulations (CFR). Although surveyors use the information contained in the IGs to help to make a determination about compliance with the requirements, the IGs are not binding and do not replace or supersede the law or regulations.

The IGs contain authoritative interpretations and clarification of statutory and regulatory requirements and are used to assist surveyors in making determinations about an HHA's compliance, however IGs may not be used alone as the sole basis for a citation.

A. Survey Team Size and Composition

Surveyor qualifications are specified at 42 CFR §488.735. Surveyors must successfully complete the Centers for Medicare & Medicaid Services (CMS)-sponsored Basic HHA Surveyor Training Course and any associated course prerequisites before they may serve on an HHA survey team (except as a trainee). Surveyor trainees may participate in an HHA survey under the supervision of an experienced surveyor. Each HHA survey team must include at least one Registered Nurse (RN).

The survey team size will vary depending on the size of the agency. Survey team size is determined by the State Survey Agency (SA) (or the CMS Location for federal teams) and influenced by the following factors:

- *The HHA patient census, number of unduplicated admissions, and number of branches at the time of the last survey;*
- *A pattern of past serious deficiencies or complaints.*

Home health agency surveys will also vary in duration, based on the patient census, the number of branches and their locations, number of home visits and travel time, as well as the number and complexity of concerns that are identified during the survey.

Prohibition of Conflicts of Interest

Prior to finalizing the survey team, SAs, federal teams, and Accreditation Organizations (AO) must ensure that no conflicts of interest are present between surveyors and the HHA being surveyed. Section 488.735(b) sets out the circumstances that would disqualify a surveyor from surveying a particular agency.

Any of the following circumstances disqualifies a surveyor from surveying an HHA.

- *The surveyor currently works for, or, within the past two years, has worked with the HHA to be surveyed as a direct employee, employment agency staff at the agency, or officer, consultant, or agent for the agency to be surveyed.*
- *The surveyor has a financial interest or an ownership interest in the HHA to be surveyed.*
- *The surveyor has a family member who has a relationship with the HHA to be surveyed.*
- *The surveyor has an immediate family member who is a patient of the HHA to be surveyed.*

B. Types of Home Health Agency Surveys

All agencies that seek to participate or are participating as HHAs in Medicare are subject to the following unannounced surveys:

1. Initial Certification Survey

Initial certification surveys are conducted when an agency seeks to participate in the Medicare program as an HHA. SAs or AOs with CMS deeming authority, may conduct the initial certification survey. The initial certification survey reviews all CoPs for compliance with the requirements.

Before the initial certification survey can be conducted, the prospective HHA must obtain Medicare Administrative Contractor (MAC) approval of the application for enrollment (CMS 855-A). The HHA must also meet the following criteria for an initial survey listed below:

- *Provide skilled nursing and at least one other therapeutic service (physical therapy, speech language pathology, occupational therapy, medical social services or home health aide) - See §484.105(f)(1); and*
- *Have provided care to a minimum of 10 skilled patients receiving care (not required to be Medicare beneficiaries) that is consistent with the CoPs. At least 7 of the 10 required patients should be receiving skilled care from the prospective HHA at the time of the initial certification survey. If the prospective HHA has not provided skilled care to at least 10 patients, the SA or the AO must contact the CMS Location to determine if the agency is in a medically underserved area (MUA). In making such a determination, the CMS locations may use the MUA Find search tool (https://data.hrsa.gov/tools/shortage-area/mua-find) developed by the Health Resources & Services Administration (HRSA). In this situation, the CMS Location may reduce the minimum number of skilled patients from 10 to 5. In such situations, at least 2 of the 5 required patients should be receiving skilled care from the prospective HHA at the time of the initial Medicare survey.*

Change of Ownership (CHOW)

HHAs that undergo a change in majority ownership by sale within three years of the effective date of its initial Medicare enrollment, or within three years of its most recent change in majority ownership, must enroll in the Medicare program as a new HHA provider (initial certification) under 42 CFR §424.550(b)(1) unless an exception under §424.550(b)(2) applies. Therefore, the HHA must undergo an initial certification survey by the SA or an AO with deeming authority. This is necessary to ensure that newly-sold HHAs are compliant with the CoPs.

2. Recertification Survey

Each HHA must be surveyed not later than 36 months after the last day of the previous standard survey as specified in 42 CFR §488.730. Recertification surveys begin as a standard survey, but may, as needed, be converted to a partial extended or an extended survey as outlined below in Part I, Section C. Survey Protocols: Standard, Partial Extended, and Extended Surveys.

3. Abbreviated Standard Survey

The abbreviated standard survey is a highly focused survey that evaluates an HHA's compliance with specific standards within a CoP or the CoP itself, as determined by the reason or purpose of the survey. An abbreviated standard survey may be based on complaints received, a change of ownership or management, or other indicators of specific concern such as reapplication for Medicare billing privileges following a deactivation.

Types of Abbreviated standard surveys include:

a. Complaint Survey (Investigation)

A complaint investigation is conducted to investigate specific allegations of noncompliance. Refer to the State Operations Manual (SOM), Chapter 5, for additional guidance regarding complaint surveys.

b. Post-Survey Revisit (Follow-up Survey)

When deficiencies have been cited during any type of survey, the surveyor may, as necessary, conduct a post-survey revisit to determine if the agency has made significant corrections to meet the requirements for participation for those cited deficiencies. However, the existence of condition-level deficiencies in any CoP requires an onsite post-survey revisit to determine if the HHA has corrected these deficiencies. See also, SOM, Chapter 2, for information on revisit surveys.

4. Validation Survey for Deemed HHAs

Section 1865(a)(1) of the Act permits providers and suppliers "accredited" by a CMS-approved program of a national AO to be exempt from routine surveys by SAs to determine compliance with CoPs if they apply for deemed status. These deemed status HHAs may be subject to validation surveys authorized by CMS, as a component of CMS's oversight of an AO's deeming program.

C. Survey Protocols: Standard, Partial Extended, and Extended Surveys

Section 1891(c)(2) of the Act establishes the requirements for surveying HHAs to determine whether they meet the Medicare conditions of participation. These requirements are reflected in the definitions at 42 CFR §488.705 for the standard survey, the partial extended survey, and extended survey as well as in the regulations at 42 CFR part 488, Subpart I.

1. Standard Survey

CMS has identified a select number of standards, called Level 1 standards, most closely related to the agency's ability to deliver quality patient care and services as required under the CoPs. Compliance with these Level 1 standards is associated with positive outcomes for patient care. ***See Table 1 for the Level 1 standards.***

The standard survey focuses on the Level 1 standards and utilizes information from clinical record reviews, observational home visits, and patient and staff interviews. Staff interviews are conducted as indicated to gain more information based on the findings from other information gathering tasks.

If no deficiencies are identified during home visits, clinical record reviews, and interviews with patients and staff, and no other concerns are identified, the HHA is considered to be compliant with the CoPs. Surveyors may conclude the survey and exit the HHA.

When noncompliance is identified with any Level 1 standard, the survey must be expanded to a partial extended survey to further investigate the noncompliance. If it is obvious during a survey

that noncompliance exists at the condition-level, the surveyor may immediately advance to an extended survey that examines all conditions of participation. The requirement to encode and transmit Outcome and Assessment Information Set (OASIS) data (§484.45(a)) is not designated as a Level 1 standard, however it is evaluated during the pre-survey preparation. A deficiency cited for this requirement does not trigger a partial extended or extended survey.

2. Partial Extended Survey

A partial extended survey is conducted when noncompliance is identified in any Level 1 standard. CMS no longer identifies specific Level 2 standards, instead, all remaining standards within the CoP that contains a Level 1 standard deficiency are evaluated and a determination must be made as to the compliance with the condition.

3. Extended Survey

Substandard care means noncompliance with one or more of the eight CoPs reviewed in the standard survey, including deficiencies which could result in actual or potential harm to patients of the HHA (see Table 1). When a standard or partial extended survey reveals substandard care, the surveyor must extend the survey to review all 15 CoPs. The extended survey may be conducted at any time at the discretion of the AO, SA or CMS Location, but must always be conducted when substandard care is identified.

The extended survey should be initiated immediately upon a finding of substandard care. Unless there are extenuating circumstances (for example, weather, scheduling, etc.), the extended survey should be completed without interruption. However, no longer than 14 calendar days can lapse before the extended survey is completed. For example, when a complaint investigation identifies condition-level noncompliance, the extended survey must be completed within 14 days.

Noncompliance with Requirements other than Level 1 Standards during the Standard or Partial Extended Survey

A surveyor may discover noncompliance unrelated to Level 1 standards during a standard or partially extended survey. In this case, the surveyor would determine any additional standards and conditions to examine based on findings of noncompliance. If noncompliance is identified in a non-Level 1 standard, the finding is documented on the Form CMS -2567 and the survey may continue as a standard survey.

Condition-level non-compliance in CoPs that do not contain Level 1 standards does not trigger an extended survey. However, at the discretion of the SA or CMS Location, the survey may be elevated to an extended survey at any time.

Table 1. Standard Survey Conditions of Participation and Tags that are Level 1 Standards

Condition of Participation	*Level 1 Tags*

§484.50 Patient Rights	*G412, G414, G416, G418, G422, G428, G430, G432, G434, G436, G438, G442, G444, G448, G454, G464, G478, G484, G486, G488, G490*
§484.55 Comprehensive Assessment of Patients	*G514, G516, G520, G528, G530, G532, G534, G536, G544, G546*
§484.60 Care planning, coordination of services, and quality of care.	*G572, G574, G576, G580, G582, G584, G588, G590, G592, G596, G598, G602, G604, G606, G608, G610, G612, G614, G616, G618, G620, G622*
§484.70 Infection prevention and control	*G682, G686*
§484.75 Skilled Professional Services	*G704, G706, G708, G710, G712, G714, G716, G718, G724, G726, G728, G730*
§484.80 Home Health Aide Services	*G768, G772, G798, G800, G802, G804, G808, G810, G812, G816, G818*
*§484.102 Emergency Preparedness *See Appendix Z for details*	*E-0004, E-0013, E-0036*
§484.105 Organization and Administration of Services	*G982, G984*
§484.110 Clinical Records	*G1012, G1014, G1016, G1018, G1022, G1024, G1028*

Part II – The Survey Tasks

The HHA survey process consists of seven standard tasks, listed below:

- *Task 1 Pre-Survey Preparation;*
- *Task 2 Entrance Conference;*
- *Task 3 Survey Sample Selection;*
- *Task 4 Information Gathering*
- *Task 5 Preliminary Decision Making and Analysis of Findings;*
- *Task 6 Exit Conference; and*
- *Task 7 Post-Survey Activities.*

Task 1 - Pre-Survey Preparation

The objectives of the pre-survey preparation are to review historical information about the HHA that may assist in identifying areas of potential concern during the survey and to establish the plan for the logistics of the survey. The primary pre-survey activities include:

A. Reviewing background information about the HHA;

B. Generating and printing OASIS Reports; and

C. Printing surveyor worksheets.

A. Reviewing Background Information

In preparation for the survey/resurvey, review documents of record including licensure records, previous survey reports including complaint investigations, media reports about the facility, and other publicly available information about the facility (e.g., the HHA's website; CMS Care Compare – HHAs). The background material that is reviewed in the SA and AO's files assists in determining the composition of the survey team and the time that may be required for the survey, as well as identifying potential concerns for a focused review. Review the following files:

- *The most recent form CMS-1572, Home Health Agency Survey Report; this provides information of the HHA from the last survey conducted as well as general information such as location, name of the administrator, staffing, services provided, and branches. This information can assist in the planning of the survey, for example, if branches need to be visited and determining the potential number of home visits.*
- *The most recent Form CMS-2567, Statement of Deficiencies and Plan of Correction; and*
- *All complaint investigations since the last recertification survey to evaluate for patterns of deficient practice.*

B. OASIS Reports

During the pre-survey preparation, four reports are downloaded from the CMS national data system for review:

1. *The Potentially Avoidable Event Report (12 months);*
2. *The Potentially Avoidable Event Report: Patient Listing (12 months);*
3. *The Agency Patient Related Characteristics Report (12 months); and*
4. *The HHA Error Summary by Agency (12 months).*

The reports are created from OASIS data elements. The requirements at §484.45, Reporting OASIS Information, specify that an HHA transmit OASIS elements to the CMS system. This data is utilized to populate the internet Quality Improvement & Evaluation System (iQIES) and generate reports.

The reports contain information that may assist the surveyor in identifying potential areas of concern that may need to be emphasized during the survey to help focus the survey, as well as identifying potential patients for the survey sample. OASIS coordinators can assist with providing available OASIS reports to surveyors.

1. The Potentially Avoidable Event Report

This report contains outcome measures that address potentially avoidable events, defined as outcomes that may or may not have been influenced by the care and services provided by the HHA. This report is used in conjunction with the Potentially Avoidable Event Patient Listing Report to select patients for closed record review.

2. The Potentially Avoidable Event Patient Listing Report
This report is a companion to the above Potentially Avoidable Event Report and provides the names of the patients who experienced the events noted in that report.

3. The Agency Patient-Related Characteristics (formerly Case Mix) Report
This report compiles several OASIS data elements into one report that provides a high-level overview of the HHA patient demographics, home care diagnoses, and agency statistics. The report displays the types of patients for whom the agency is providing care, their characteristics at the start of care, as well as outcome and discharge information. The agency's data is compared to a national reference sample, and to the HHA's own data from a prior reporting period. This data may inform the active sample selection. For example, the home visit sample may be influenced by high rates of recertification of care or clinically complex patient care services that might require increased coordination of care needs.

4. The HHA Error Summary by Agency Report
This report compiles OASIS submission errors to iQIES. While this report displays any warning or fatal errors encountered in OASIS records processed by iQIES for a user-specified time; the focus for this report should be on one specific error, -3330, "Record Submitted Late: The submission date is more than 30 days after M0090 (Date Assessment Completed) on this new record." The date criteria for this report is the prior calendar year. Any HHA with one or more assessments with error -3330 on this report will result in a citation at G372, Encoding and transmitting OASIS data (§484.45(a)).

C. Surveyor Forms

The forms for HHA surveys include:

- *Home Health Agency Survey Report, Form CMS-1572;*
- *Surveyor Notes Worksheet, Form CMS-807 (optional);*
- *Home Visit Consent Form CMS-36;*
- *HHA Survey Investigation Worksheet: Agency Summary (optional);*
- *HHA Survey Investigation Worksheet: Calendar (optional).*

Task 2 – Entrance Conference

The objectives of this task are to generally inform the HHA administrator or designee of the survey activities that will take place and request specific information that will be needed to

conduct the survey. Surveyors must be professional, organized, prepared, and courteous. The entrance conference should be informative, concise, and brief. If the HHA is not open when the surveyor arrives, the SA should be contacted for further guidance. See also State Operations Manual (SOM) Chapter 2 for additional details on entrance protocol.

Upon entrance, the survey team will:

- *Present identification;*
- *Introduce the survey team to the administrator or designee;*
- *Explain the purpose of the survey; and*
- *Provide the estimated survey duration.*

For all surveys, request assistance with the following from the administrator (or designee):

- *A private space for the survey team to work;*
- *Location of a copier and operation instructions;*
- *An assigned HHA staff person(s) who will be a resource to respond to the surveyor's questions and can obtain information for the surveyor;*
- *HHA staff who are most knowledgeable about clinical supervision, in-service training, and home health aide supervision;*
- *Orientation to the electronic and/or paper clinical records that includes:*
  - *The comprehensive assessment, the plan of care, physician's orders, progress notes and home visits, supervisory visits, case conferences, medication lists, medication administration records;*
  - *How to use electronic health records (EHR);*
  - *The designated individual who will respond to any questions or assist the surveyor as needed in accessing the EHR in a timely fashion; and*
  - *Computer terminals where the surveyors may access the electronic health records, if applicable.*

For a standard survey, request that the HHA provide the following documentation:

- *The number of unduplicated skilled care admissions from the 12 months prior to the survey, including all payer sources and all HHA locations, i.e. parent and all branch locations. The unduplicated skilled admission total is used to determine the survey sample size. Unduplicated means that patients are counted only once in 12 months for the number of skilled care admissions;*
- *A complete list of active skilled care patients (all payer sources) for the parent HHA and its branches containing, at a minimum, the following information for each patient:*
  - *Patient names;*
  - *Patient certification dates (start of care/resumption of care dates);*
  - *Admitting diagnosis;*
  - *Services provided by discipline (i.e. skilled nurse (SN), physical therapy (PT), occupational therapy (OT), speech-language pathology (SLP), or social worker*

(SW));

- *Clinically complex, specialized services or treatments, for example, infusion therapies, pediatrics, anticoagulant therapy management, mechanical ventilation, tracheostomy care, wound care, or pressure ulcer care.*

- *The schedule of home visits that will be performed during the survey for all locations including parent and branches; and*

- *A complete list of all discharged patients in the past six months with start of care and discharge dates, diagnoses, services provided, and the disposition of the patient.*

Request the agency provide the following additional information:

- *Current list of all direct and contracted employees including job title and date of hire;*
- *Whether outpatient therapy is provided at the parent or any of its branches; if so, contact the SA for guidance on including evaluation of the service during the survey;*
- *An updated Form CMS-1572, Home Health Agency Survey Report, by the end of the first day of the survey;*
- *Organizational chart for parent and branches;*
- *Admission packet;*
- *Complaint log; and*
- *Abuse tracking log, if available.*

When an extended survey is conducted, any additional information required may be requested at the time of the entrance (if it is a planned extended survey, e.g. initial), or when the survey is expanded to an extended survey.

- *Home health aide training records and/or competency evaluations and in-service training;*

- *The identity of, and governing body authorization for, the person who is authorized in writing to act on behalf of the administrator;*

- *The Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver for the agency and CLIA licenses for clinical laboratories where the agency sends specimens;*

- *The Quality Assessment and Program Improvement (QAPI) program activities and performance improvement projects including infection control; and*

- *The Emergency Preparedness Plan.*

Task 3 – Survey Sample Selection

The objective of this task is to select a case-mix stratified patient sample that represents the range of skilled services provided to a selection of home health patients from all operating locations (parent and branch). "Case-mix" means the sample contains a range of admitting

diagnoses, and "stratified" means the sample includes patients who receive a variety of skilled services including: nursing, physical therapy (PT), speech language pathology (SLP), occupational therapy (OT), medical social services, and home health aide services.

The sample consists of both closed (discharged) and active (current) patients for all payer sources. The active patient sample is comprised of two groups: record review only and record review with home visit.

Documents and Information Utilized for Sample Selection:

- *The list of unduplicated skilled care admissions in the 12 months prior to the survey from all payer sources and all HHA branches. The number of unduplicated skilled admissions determines the total patient sample size;*
- *The complete census of all active (current) skilled care patients (all payer sources) in the parent HHA and all branches;*
- *The list of patients receiving clinically complex services or treatments;*
- *The home visit schedule during the survey for all skilled services in all locations including parent and branches;*
- *The list of all discharged patients in the six months prior to the survey;*
- *iQIES Reports: Potentially Avoidable Event Report and Potentially Avoidable Event Patient Listing Report; and*
- *iQIES Report: Agency Patient-Related Characteristics (Case Mix) Report.*

A. Patient Sample Selection Protocol

Based on the number of unduplicated skilled service admissions, use Table 2, Survey Sample Table (below) to determine the minimum sample size for closed record review, active patient home visit with record review, and active patient record review only. The sample may be expanded per surveyor discretion at any point in the survey as needed to further investigate findings.

If the HHA has had a very low census of skilled admissions in the past 12 months and does not meet the minimum sample size (i.e. less than 7), the surveyor may use the skilled admissions since the last certification survey from which to pull the sample. For instance, if the HHA only has one skilled admission in the past 12 months, the surveyor should extend the period beyond 12 months to obtain additional skilled admissions for review. In these instances, the sample will be reduced to those skilled admissions that are available for review. The sample must, however, include patients receiving skilled services and the surveyor may not substitute non-skilled home health aide personal care observations to complete the home visit patient sample.

Table 2. Survey Sample Table

Number of Unduplicated Skilled Admissions for the Past 12 Months	***Closed Record Review (Discharged)***	***Active Sample: Home Visit with Record Review***	***Active Sample: Record Review Only***	***Total Patient Sample (Minimum)***
Less than 300	*2*	*3*	*2*	*7*
301 - 500	*3*	*4*	*3*	*10*
501 - 700	*4*	*5*	*4*	*13*
701 or more	*5*	*7*	*5*	*17*

For abbreviated surveys (complaint and revisit), surveyors should select at least 3 records for review to ensure the HHA is in compliance with the applicable CoP. Record review and the number of records is dependent upon the nature of the complaint and investigation or revisit follow up and may require more or less than 3 records based on observations, interviews, home visits, etc. Some abbreviated surveys may not require record review if the Medicare condition does not require medical record documentation. For complaint surveys, it is important to note that surveyors must assess the entire CoP related to the complaint allegation and therefore it is not enough to look only at the medical record for the complaint case when conducting a complaint investigation.

If surveyors find the HHA has no patients on the current patient roster (for any payment source) and has not provided care to any patients for twelve months or more, they should discuss with the appropriate CMS location whether continuing the survey is possible. The determination should be made whether to proceed with the survey and lead to possible enforcement actions or to allow the HHA to voluntary terminate based on cessation of business (see also 42 CFR 489.52(b)(3)). Please note that the twelve-month period is guidance to surveyors about when they should contact CMS locations about cessation of services. It does not limit CMS's ability to terminate a provider that has not provided services for a shorter period of time. Pursuant to section 1866(b)(2)(B) of the Act, CMS has the discretion to terminate a provider when it no longer meets the definition of an HHA at section 1861(o)(1). [42 CFR 489.53(a)(1).] CMS has the discretion to decide how long a cessation of services is too long, and may determine that a shorter period is appropriate in some cases.

B. Closed Record Sample Criteria

1. Potentially Avoidable Event Reports Review Procedure

The Potentially Avoidable Event Report and the Potentially Avoidable Event Patient Listing Report are used to select the closed record sample. Potentially avoidable events are outcomes that can be influenced, although not necessarily totally avoided, by following best practices in providing care. Utilize the reports as follows:

- *Review the Potentially Avoidable Event report for all outcomes greater than the national "observation" (language used in the OASIS Case Mix Report);*

- *In areas where the HHA exceeds the national observation, refer to the Potentially Avoidable Event Patient Listing Report to select the patients for the closed record sample; and*
- *Patients listed under one or more measures should be selected for the closed record review sample due to having more potentially avoidable events.*

Request the records for the patients selected from the report after the entrance conference to expedite the retrieval of these clinical records for review.

If there are no patients listed in the Potentially Avoidable Event, Patient Listing Report, or there is an insufficient number of patients to meet the required closed record sample size, complete the closed record sample using the discharged patient list, as well as the complaint log obtained during the entrance conference. When using the discharged patient list provided by the HHA, randomly select the patients from the list who had different discharge dispositions such as hospitalization, transfer to another provider, or routine discharge as planned.

Occasionally, the patients in the Potentially Avoidable Event reports have not yet been discharged from the HHA. When this occurs, consider adding that patient to the active sample, and replace with another patient to complete the closed record sample.

2. Agency Patient-Related Characteristics (Case Mix) Report Review Procedure

Review the Patient Diagnostic Information for:
- *Acute and Chronic Conditions;*
- *Home Care Diagnoses; and*
- *Active Diagnoses.*

Note the diagnoses where the HHA's observation exceeds the national average (as noted in the OASIS Case Mix Report data). For example, identify the type of patients the agency treats on a regular basis, such as orthopedic, neurological, musculoskeletal, wound care, and diabetes mellitus. Consider this information to assist in case mix stratification when selecting a sample that is representative of the HHA's patient population.

C. Active Patient Criteria

The active patient sample includes:
1) Active patient home visits with record review; and
2) Active patient record reviews only.

Use the following criteria for the active patient sample selection:
- *Include patients who receive more than one HHA service to assess for coordination of care across the disciplines;*
  - *The Agency Patient Characteristics Report can provide additional information on the type of patients where the HHA observation exceeds the national average to include in*

the sample.

- *Include patients from all branches of the HHA in addition to the parent location;*
- *Include patients who receive clinically complex services or treatments, for example:*
  - *Infusion therapies;*
  - *Wound and ulcer care, including negative pressure wound therapy;*
  - *Pediatric care;*
  - *Anticoagulant therapy management;*
  - *Diabetes management;*
  - *Congestive heart failure monitoring;*
  - *Enteral and parenteral nutrition;*
  - *Tracheostomy care;*
  - *Bi-level positive airway pressure (BiPap), and other respiratory therapy devices; and/or*
  - *Therapy modalities such as ultrasound and electrical muscle stimulation (e-stim).*

Active Patient Home Visit with Record Review Sample Selection

Surveyors may conduct home visits to any patients of the HHA who have given their permission for the surveyor to directly observe care and services. The surveyor selects the patients according to the sample criteria, rather than the HHA selecting the home visit sample. The home visit sample should represent the variety of services that the HHA provides. Home visits to patients being served by branch locations should be made whenever possible.

Use the Survey Sample Table (Table 2) to determine the number of active patients for home visits with record review. It is recommended to select a few more patients than the number of required home visits to accommodate possible refusals. Provide the HHA with the home visit sample as soon as possible so that the agency may begin to contact the patients to request their permission. Additional home visits may be made to address any concerns initially identified by survey findings.

For a small agency with a low skilled patient census, enough home visits may not be available during the survey to meet the home visit sample requirement. At least one home visit must be conducted to evaluate compliance with the CoPs. Additionally, the surveyor may substitute active record reviews as a first option, or closed records to review for a range of skilled services to meet the minimum sample size.

Record Review Only

Use the same criteria for record review only that is used for the home visit sample. If a home visit cannot be made to all branches, this is the opportunity to include patients from all branch location(s) in the record review sample and expand the sample as needed to ensure that at least one patient from each branch is included in the active sample record review. Select patients who are not receiving a home visit during the survey, but meet the active sample with home visit

criteria.

Task 4: Information Gathering

Information gathering is an organized, systematic, and consistent process designed to assist surveyors to make findings concerning the HHA's compliance with the CoPs during a survey. The information gathering activities in the home health agency survey consist of:

A. *Home Visit and Patient Interview Procedures*

B. *Clinical Record Review Procedures*

C. *Interviews with Agency Staff*

D. *Other HHA Documentation Review*

E. *Guidance for Evaluating Compliance with Level 1 Standards: Home Visit Observation and Interview, Clinical Record Review, and Other HHA Documentation Review*

F. *Home Visit Follow-Up Procedures*

Surveyors gather information by focusing on home visit observations, interviews, and clinical record reviews. Surveyors assess for compliance with the Level 1 standards to determine if patient outcomes were negatively influenced by non-compliance with the CoPs by the HHA. The findings determine whether the survey is elevated to a partial extended or extended survey as well as identifying possible areas for further investigation. Surveyors will validate any findings with additional document review and/or interviews.

The closed clinical record review is a review of agency services and patient care outcomes from admission through discharge. Closed record review differs from active record review in that surveyors will also evaluate whether the discharge and transfer summaries were completed as required per §484.110(a)(6), and evaluate the HHA's compliance with the 60-day recertification of care. The records are assessed for compliance with the CoPs to determine if the agency provided the necessary care and services to meet the patients' health needs.

A. Home Visit and Patient Interview Procedures

<u>Objective of Home Visits</u>

The purpose of the home visit is to evaluate whether the care being provided by the HHA meets the health and safety standards of the Medicare program (i.e., CoPs) and to confirm that the agency follows the patient's plan of care. The home visit is the only opportunity for the surveyor to observe direct care being provided by the HHA personnel and is thus the most important means of information gathering during the HHA survey. The surveyor uses observational and interview skills to assess the HHA's adherence to the requirements.

<u>Planning the Home Visit with the Agency</u>

After sample selection by the survey team, the HHA should contact the patient, family, or caregiver to request permission and make the arrangements for the home visit. If the patient refuses to allow the surveyor to visit, the surveyor should select an alternate patient.

Clinical records should be reviewed prior to and after the home visit. Prior to the home visit, obtain the information most relevant for the home visit, such as copies of the most current version of the plan of care, medication list, and aide instructions.

Conducting Home Visits and Patient Interviews

The surveyor must always be cognizant that as a guest in a patient's home or place of residence, courtesy, respect, and sensitivity to the patient's clinical status (physical and emotional) are necessary. Explain to the patient that the purpose of the visit is to ensure that the care being provided to them by the HHA meets the health and safety standards of the Medicare program and is provided in accordance with the plan of care ordered by the patient's physician or allowed practitioner. Prior to asking the patient to sign the home visit consent, confirm with the beneficiary that the HHA explained that the home visit and interview is voluntary and refusal would not affect their home health benefits.

Ask the patient or caregiver to sign a Consent for Home Visit (Form CMS-36) in a language and manner the individual(s) understands. Provide a copy of the signed consent form to the patient, a copy to the HHA for the patient's clinical record, and retain a copy for the survey file.

Observe, but do not interfere with, the delivery of care and the interactions between the HHA representative and the patient/family and/or caregiver. Home visit observations and the plan of care determine the focus and depth of questions asked of the patient and HHA staff by the surveyor. It may be appropriate to ask questions during patient care if it does not interfere with care or disturb the rapport of the HHA staff with the patient. The surveyor should ask the patient's permission to review the patient's information packet and written information that the HHA provided to the patient at the start of care and subsequent updates. The patient may not be able to locate the information readily, and if that is the case, do not press the issue with the patient and continue the visit.

The surveyor should end the interview or home visit if the patient expressly requests or indicates through body language a desire to conclude the interview or home visit. The surveyor should attempt to address any potential concerns of the patient by inquiring if the surveyor's presence is problematic and reassuring the patient of the role of the observational home visit. The surveyor should be alert to signals from the patient, such as displaying reluctance to speak in front of staff, appearing fatigued or distressed, that may be an indication of an unexpressed concern or unwillingness to participate. Surveyors should remain (if the opportunity presents) after the HHA staff leave to give the patient and family an opportunity to share information with them confidentially.

If conditions in the patient's home raise concerns for the surveyor's physical safety, the surveyor should discontinue the visit.

B. Clinical Record Review Procedures

The clinical record review is used to verify that HHA documentation thoroughly and accurately reflects the care and services provided by the HHA and confirms that services are provided in compliance with the plan of care and CoPs.

The surveyor should review the clinical record only in enough detail prior to the home visit to allow the surveyor to be prepared to observe the care and services that will be provided (e.g. the most current plan of care, medication list, and aide instructions). The surveyor should review the record in more detail after the home visit to address any concerns for non-compliance identified during the home visit and further evaluate the requirements of Level 1 standards included in the standard survey.

C. Interviews with Agency Staff

Interviews provide another method to collect information, and to verify and validate information obtained through observations, record reviews, and/or patient interviews. The depth of the interview and the number of interviewees is determined by the issues identified.

Informal interviews are conducted throughout the duration of the survey. The information obtained from interviews may be used to determine what additional observations, interviews, and record reviews are necessary to determine compliance or noncompliance with the CoPs.

Interviews should be focused on obtaining detailed information regarding a specific event, how a care task was completed or not completed, or action or inaction by the HHA. Ask open-ended questions whenever possible to elicit staff knowledge rather than questions that lead the staff member to certain responses. Interview agency staff, including the administrator, clinical managers, skilled professional staff, home health aides, and other HHA staff, only as necessary, to address concerns identified. For example, if concerns are identified with clinical record confidentiality during transport of records, the surveyor may ask the staff how they transport and secure protected health information while outside the HHA parent or branch office.

D *Other HHA Documentation Review*

When surveyors identify concerns that indicate actual or potential findings of noncompliance, surveyors should review additional documentation to assist the surveyor in making a compliance determination. Non-clinical record materials, such as personnel records, service contracts, policies and procedures, clinical practice guidelines, documentation of home health aide training and/or competency evaluation, documentation of complaint investigation and resolution, CLIA waiver, and/or other materials, are not routinely reviewed unless the surveyor identifies concerns during HHA staff interviews, patient/caregiver interviews, home visits, and clinical record reviews.

E. Home Visit Follow-Up Procedures

If the surveyor has any questions or concerns based on the home visit observation, the agency staff that was observed may also be interviewed following the home visit. Additionally, if the surveyor identifies concerns or potential noncompliance during the home visit, the surveyor may conduct additional record review and staff interviews as necessary to investigate findings.

If the patient or caregiver reports having lodged a complaint, review the complaint log to investigate how the HHA addressed the issue.

F. Additional Survey Considerations

Onsite Review of Approved Branches by the SA During Survey

The Form CMS-1572, the Home Health Agency Survey and Deficiencies Report, includes a field where the HHA indicates the total number of branches and the name and address of each branch location. The surveyor should enter this information regarding the HHA's branches into the national survey data system (iQIES as appropriate) after every survey as part of the survey kit.

As surveys are conducted, SAs, AOs and federal surveyors should verify that the information on branch locations is current and accurate. During a survey, if a surveyor finds that services are being provided from an unapproved location that is not listed on the CMS 1572, the surveyor must investigate this location to determine if it is a CMS-approved branch.

Application of Home Health Agency Conditions of Participation to Patients Who Do Not Receive Skilled Services

In addition to the home health services listed in §1861(m) of the Act, and Medicaid State Plan services identified in §1905(a) of the Act, some Medicare certified HHAs choose to offer non-skilled services through various Medicaid state programs including:

- *Personal care services, such as help with activities of daily living (ADLs) like bathing, dressing, eating, getting in or out of bed, moving around, and using the bathroom;*
- *Housekeeping services;*
- *General household chores; or*
- *Family and caregiver support services.*

The HHA may offer these services to individuals who choose to pay for them privately, and/or individuals who are provided these services from other state programs.

Two standards in the HHA CoP home health aide services, at 42 CFR §484.80, apply to beneficiaries who receive non-skilled services only:

- *42 CFR §484.80(h)(2) - see also G814*
- *42 CFR §484.80(i) - see also G828*

Review of these two requirements during survey is conducted through a separate sample than the sample used to evaluate compliance with skilled services requirements for HHA patients.

HHAs are required, as a part of the patient rights CoP, to advise the patient of the extent to which payment for HHA services may be expected from Medicare or other sources and the extent to which payment may be required from the patient. The HHA should explain to a beneficiary who is ending a Medicare episode and is considering to receive non-skilled services that Medicare does not pay for those services. For additional information, see the interpretive guidance and survey procedures at §484.50.

Agencies Serving Medicaid Waiver and State Plan Patients

*If a Medicare certified HHA provides **skilled** care services to non-Medicare beneficiaries under a Medicaid Waiver or State Plan, the HHA must meet all CoPs for these beneficiaries including the comprehensive assessment and OASIS data reporting requirements.*

Task 5 - Preliminary Decision Making and Analysis of Findings

A. General

The general objectives of this task are to integrate findings, review and analyze all information collected from observations, interviews, and record reviews, and to determine whether the HHA is in compliance with the CoPs. The information analysis process requires surveyors to review the information gathered during the survey and make judgments about the compliance of the HHA. An evaluation of whether a finding constitutes a standard-level deficiency or whether a condition-level deficiency exists should not be made until all necessary information has been collected. Survey activities and investigations including the record review, home visit observations and interviews substantiate and support any findings of non-compliance with the CoPs.

B. Analysis

Guidance for Citing Standard- versus Condition-Level Noncompliance

The regulations at 42 CFR §488.26(b) state in part, "The decision as to whether there is compliance with a particular requirement, condition of participation, or condition for coverage depends upon the manner and degree to which the provider or supplier satisfies the various standards within each condition."

When noncompliance with a particular standard within the CoP is noted, the determination of whether the lack of compliance is at the standard- or condition-level depends upon the nature of the noncompliance – i.e., how serious is the deficiency in terms of its potential or actual harm to patients – and the extent of noncompliance – e.g., how many different regulatory requirements within a CoP are being cited for noncompliance, or how widespread was a given noncompliant practice, etc. One instance of noncompliance with a standard that poses a serious threat to patient health and safety is enough to find condition-level noncompliance. Likewise, when an HHA has multiple standard-level deficiencies in a CoP, the extent of the non-compliance could be enough to find condition-level noncompliance.

When deficiencies are found during a survey, the surveyor should explain the noncompliance to the provider during the Exit Conference. It is not the surveyor's responsibility to provide

consultation on how to fix the deficiencies. Surveyors should maintain their role as representatives of a regulatory agency. Although non-consultative information may be provided to the HHA upon request, the surveyor is not a consultant and may not provide consulting services to the HHA. See also SOM Chapter 2 and 4 for additional information related to the regulatory role of surveyors.

Guidance for Level 1 Standards and Survey Type (Standard, Partial Extended, Extended)

During a standard survey, surveyors review Level 1 standards only. Because the Level 1 standards are identified as those most closely related to the delivery of high-quality patient care, a single finding may support a determination of noncompliance with the standard (i.e., standard level noncompliance), and warrant the move to a partial extended survey to investigate noncompliance at the condition level. However, if it is obvious that the noncompliance exists at the condition-level during a standard survey, the surveyor may immediately advance to an extended survey that examines all conditions of participation without expanding to a partial extended survey first.

The partial extended survey may be conducted at any time at the discretion of CMS, the SA, or AO, but must be conducted when a Level 1 finding indicates that a condition may be out of compliance. During a partial extended survey, all standards within the condition of participation that contains one or more Level 1 standards are evaluated. If a surveyor determines that noncompliance exists at the condition-level during a partial extended survey, the surveyor advances to an extended survey to review all conditions of participation. Advanced CMS Location approval is not required to extend the survey.

An extended survey may be conducted at any time at the discretion of CMS, the SA, or AO, but will always be conducted when substandard care is identified during a survey. Substandard care is defined in §488.705 as noncompliance with one or more conditions of participation identified on a standard survey, including deficiencies that could result in actual or potential harm to patients of an HHA. The HHA standard survey evaluates compliance with eight of the 15 HHA CoPs and noncompliance with any of these eight conditions would constitute substandard care. When substandard care is identified, the extended survey reviews and identifies the HHA's policies, procedures, and practices that produced the substandard care.

The extended survey should be initiated immediately upon finding substandard care. Unless there are extenuating circumstances, the extended survey should be completed without interruption. However, no longer than 14 calendar days may elapse before the extended survey is completed. For example, when a complaint investigation identifies condition-level noncompliance, the extended survey must be completed within 14 days.

If the surveyor identifies or suspects an immediate jeopardy (IJ) situation, they must immediately follow the guidelines in SOM Appendix Q, including use of the IJ template. Immediate jeopardy means a situation in which the provider's or supplier's non-compliance with one or more requirements, conditions of participation, conditions for coverage, or conditions for certification has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident or patient. [see 42 CFR 488.805 Definitions.] As noted in Appendix Q, if an IJ is identified,

surveyors must notify the administrator (or appropriate staff member who has full authority to act on behalf of the entity) that IJ has been identified and provide a copy of the completed IJ template to the entity

Non-Level 1 Deficiencies: *A surveyor may discover noncompliance unrelated to Level 1 standards during a standard or partially extended survey. In this case, the surveyor determines the additional standards and/or conditions to examine based on the finding of noncompliance. If noncompliance is identified in a non-Level 1 standard, the finding is documented on the Form CMS -2567 and the survey may continue as a standard survey. Condition-level noncompliance with CoPs that do not contain Level 1 standards does not trigger an extended survey. However, at the discretion of the SA/CMS location the survey may be elevated to an extended survey at any time.*

The requirement to encode and transmit OASIS data (§484.45(a)), while not a Level 1 standard, is evaluated during a standard survey. Deficiencies cited with this requirement do not trigger a partial or extended survey.

Task 6 - Exit Conference

The purpose of the exit conference is to inform the HHA staff of the observations and preliminary findings of the survey.

Because of ongoing dialogue between the surveyor(s) and HHA staff during the survey, there should be few instances where the HHA is not generally aware of the surveyor concerns prior to the exit conference. If the HHA asks for the specific regulatory basis for a finding of noncompliance, surveyors may provide the preliminary regulatory citation.

Additionally, surveyors will:

- *Conduct the exit conference with the HHA administrator, clinical managers, and other staff invited by the HHA. Clarify and note the names and positions of all HHA personnel or other individuals attending the meeting;*
- *Describe the regulatory requirements that the HHA does not meet and the preliminary findings that substantiate these deficiencies. Do not refer to any specific iQIES software data tag numbers when describing deficiency findings. In the process of writing up the findings the SA or AO will finalize just which tags/regulatory text to cite for each finding, so it would be premature to make such statements during the exit conference;*
- *Present findings regarding citations of deficient practice(s) in a straight forward, understandable way, and in a clear logical sequence. Offer examples to support the findings as appropriate;*
- *Answer questions regarding the findings and accept further pertinent information from the HHA for the surveyors to consider offsite prior to the completion of the Form CMS-2567;*

- *Respond to any HHA procedural questions with accurate survey process information (e.g., the timeframe for receiving Form CMS-2567 and submitting a plan of correction to the SA in response to the written citations); and*
- *Inform the HHA that the Form CMS-2567 will be provided in accordance with the State agency's policy, but generally no later than 10 working days after the exit conference.*

Discontinuation of an Exit Conference

CMS' general policy is to conduct an exit conference at the conclusion of all types of surveys as a courtesy to the provider/supplier and to promote timely remediation of quality of care for safety problems. However, there are some rare situations that justify refusal to conduct or continue an exit conference. For example, as noted in SOM Chapter 2:

> *• Surveyors may refuse to conduct or may discontinue the exit conference if the HHA is represented by an attorney who is present at the conference and the attorney attempts to turn it into an evidentiary hearing; or*
> *• If HHA staff /administration create an environment that is hostile, intimidating, or inconsistent with the informal and preliminary nature of an exit conference.*

Under such circumstances, it is suggested that the surveyor stop the exit conference and call the SA or AO for further direction. If a survey team is on-site, the Team Coordinator should take the above actions.

Recording the Exit Conference

If the facility wishes to audio tape the conference, it must provide two tapes and tape recorders, recording the meeting simultaneously. The surveyor or Team Coordinator should select one of the tapes at the conclusion of the exit conference to take back to the SA/AO. If the recording is electronic, a copy must be submitted to the surveyor immediately upon ending the conference. Videotaping is also permitted, if: 1) the surveyor/team agrees to this, and 2) a copy is provided the surveyor/team at the conclusion of the conference. The surveyor or survey team is under no obligation to consent to videotaping and is not required to offer a reason if it refuses to permit videotaping.

Task 7 – Post-Survey Activities

The general objective of this task is to complete the survey and certification requirements, in accordance with the regulations found at 42 CFR Part 488.

General Procedures

Each SA and CMS location must follow the instructions in the SOM including:

• Timelines for completing each step of the process;
• Responsibilities for completing the Form CMS 2567, "Statement of Deficiencies and Plan of Correction;"
• Notification to the HHA regarding survey results;
• Additional survey activities based on the survey results (e.g., revisit, forwarding documents to the CMS location for further action/direction, such as concurrence with findings for deemed HHAs); and
• Compilation of documents for the HHA's file.

Statement of Deficiencies Report & Plan of Correction

The Statement of Deficiencies Report and Plan of Correction (Form CMS-2567) is the official document that communicates the determination of compliance or noncompliance with federal requirements. Also, it is the form that the HHA will use to submit a plan to achieve compliance. Form CMS-2567 is an official record and is available to the public upon request. See SOM, Chapter 2 for information related to preparation of the Statement of Deficiencies and Plan of Correction. Refer to the document "Principles of Documentation" in SOM Chapter 9, Exhibit 7A, for detailed instructions on completing the Form CMS-2567.

Regulations and Interpretive Guidelines for Home Health Agencies

Subpart A--General Provisions

(Rev.)

G325

(New)

§484.1 Basis and Scope

(a) Basis. This part is based on:

(1) Sections 1861(o) and 1891 of the Act, which establish the conditions that an HHA must meet in order to participate in the Medicare program and which, along with the additional requirements set forth in this part, are considered necessary to ensure the health and safety of patients; and

(2) Section 1861(z) of the Act, which specifies the institutional planning standards that HHAs must meet.

(b) Scope. The provisions of this part serve as the basis for survey activities for the purpose of determining whether an agency meets the requirements for participation in the Medicare program.

Interpretive Guidelines §484.1

To qualify for a provider agreement as a home health agency under Medicare and Medicaid, an entity must meet and continue to meet all the statutory provisions of §1861(o), 1891 and 1861(z) of the Act, including the Condition of Participation (CoP) requirements.

This, in part, means the HHA:

- *is primarily engaged in providing skilled nursing services and other therapeutic services [§1861(o)(1) of the Act; 42 CFR 484.105, Organization and administration of services];*

- *has policies, established by a group of professional personnel (associated with the agency or organization), including one or more physicians and one or more registered professional nurses, to govern the services which it provides, and provides for supervision of such services by a physician or registered professional nurse [§1861(o)(2) of the Act; 42 CFR 484.75, Skilled professional services];*

- *maintains clinical records on all patients [§1861(o)(3) of the Act; 42 CFR 484.110, Clinical records];*

- *for any HHA in a state or local jurisdiction with a law that requires agencies or organizations like HHAs to be licensed, is licensed pursuant to such law, or is approved, by the State or local agency responsible for licensing agencies or organizations of this nature, as meeting the standards established for such licensing [§1861(o)(4) of the Act; 42 CFR 484.100, Compliance with Federal, State and local laws and regulations related to health and safety of patients];*

- *has in effect an overall plan and budget [§1861(o)(5) of the Act; 42 CFR 484.105, Organization and administration of services];*

- *meets the conditions of participation specified in section 1891(a) and such other conditions of participation as the Secretary may find necessary in the interest of the health and safety of individuals who are furnished services by such agency or organization [§1861(o)(6) of the Act; 42 CFR 484.1, Basis and Scope, et seq.];*

- *provides the Secretary with a surety bond [§1861(o)(7) of the Act; 42 CFR Part 489, Subpart F];*

- *meets such additional requirements (including conditions relating to bonding or establishing of escrow accounts as the Secretary finds necessary for the financial security of the program) as the Secretary finds necessary for the effective and efficient operation of the program [§1861(o)(8) of the Act; 42 CFR 484.1, Basis and Scope, et seq.];*

- *except that for purposes of part A "home health agency" shall not include any agency or organization which is primarily for the care and treatment of mental diseases. The Secretary may waive the requirement of a surety bond under paragraph (7) in the case of an agency or organization that provides a comparable surety bond under State law [§1861(o) of the Act; 42 CFR 484.1, Basis and Scope, et seq.].*

CMS is required to determine whether an HHA is complying substantially with the Medicare participation requirements established by the Act and regulations. Section 1866(b)(2)(B) of the Act states in part that a provider's participation agreement may be terminated if CMS determines that "the provider fails substantially to meet the applicable provisions of section 1861." To remain a Medicare participating HHA, the HHA must remain in substantial compliance with all conditions of participation.

No Tag

(Rev.)

§484.2 Definitions.

As used in subparts A, B, and C, of this part--

Allowed practitioner *means a physician assistant, nurse practitioner, or clinical nurse specialist as defined at this part.*

Branch office *means an approved location or site from which a home health agency provides services within a portion of the total geographic area served by the parent agency. The parent home health agency must provide supervision and administrative control of any branch office. It is unnecessary for the branch office to independently meet the conditions of participation as a home health agency.*

Clinical note *means a notation of a contact with a patient that is written, timed, and dated, and which describes signs and symptoms, treatment, drugs administered and the patient's reaction or response, and any changes in physical or emotional condition during a given period of time.*

Clinical nurse specialist *means an individual as defined at §410.76(a) and (b) of this chapter, and who is working in collaboration with the physician as defined at §410.76(c)(3) of this chapter.*

In advance *means that HHA staff must complete the task prior to performing any hands-on care or any patient education.*

Nurse practitioner *means an individual as defined at §410.75(a) and (b) of this chapter, and who is working in collaboration with the physician as defined at §410.75(c)(3) of this chapter.*

Parent home health agency *means the agency that provides direct support and administrative control of a branch.*

Physician *is a doctor of medicine, osteopathy, or podiatric medicine, and who is not precluded from performing this function under paragraph (d) of this section. (A doctor of podiatric medicine may perform only plan of treatment functions that are consistent with the functions he or she is authorized to perform under State law.)*

Physician assistant *means an individual as defined at §410.74(a) and (c) of this chapter.*

Primary home health agency *means the HHA which accepts the initial referral of a patient, and which provides services directly to the patient or via another health care provider under arrangements (as applicable).*

Proprietary agency *means a private, for-profit agency.*

Pseudo patient means a person trained to participate in a role-play situation, or a computer-based mannequin device. A pseudo-patient must be capable of responding to and interacting with the home health aide trainee, and must demonstrate the general characteristics of the primary patient population served by the HHA in key areas such as age, frailty, functional status, and cognitive status.

Public agency *means an agency operated by a state or local government.*

Quality indicator *means a specific, valid, and reliable measure of access, care outcomes, or satisfaction, or a measure of a process of care.*

Representative *means the patient's legal representative, such as a guardian, who makes health-care decisions on the patient's behalf, or a patient-selected representative who participates in making decisions related to the patient's care or well-being, including but not limited to, a family member or an advocate for the patient. The patient determines the role of the representative, to the extent possible.*

Simulation means a training and assessment technique that mimics the reality of the homecare environment, including environmental distractions and constraints that evoke or replicate substantial aspects of the real world in a fully interactive fashion, in order to teach and assess proficiency in performing skills, and to promote decision making and critical thinking.

Subdivision *means a component of a multi-function health agency, such as the home care department of a hospital or the nursing division of a health department, which independently meets the conditions of participation for HHAs. A subdivision that has branch offices is considered a parent agency.*

Summary report *means the compilation of the pertinent factors of a patient's clinical notes that is submitted to the patient's physician, physician assistant, nurse practitioner, or clinical nurse specialist.*

Supervised practical training *means training in a practicum laboratory or other setting in which the trainee demonstrates knowledge while providing covered services to an individual under the direct supervision of either a registered nurse or a licensed practical nurse who is under the supervision of a registered nurse.*

Verbal order *means a physician, physician assistant, nurse practitioner, or clinical nurse specialist order that is spoken to appropriate personnel and later put in writing for the purposes of documenting as well as establishing or revising the patient's plan of care.*

Subpart B--Patient Care

G350
(Rev.)

§484.40 Condition of participation: Release of patient identifiable OASIS information.

The HHA and agent acting on behalf of the HHA in accordance with a written contract must ensure the confidentiality of all patient identifiable information contained in the clinical record, including OASIS data, and may not release patient identifiable OASIS information to the public.

Interpretive Guidelines §484.40

An agent acting on behalf of the HHA is a person or organization, other than an employee of the agency that performs certain functions on behalf of, or provides certain services under contract or arrangement. HHAs often contract with specialized software vendors to submit OASIS data and are commonly referred to by the HHA as the Third-Party vendor.

HHAs and their agents must develop and implement policies and procedures to protect the security of all patient identifiable information contained in electronic format that they create, receive, maintain, and transmit. The agreements between the HHA and OASIS vendors must address policies and procedures to protect the security of such electronic records in order to:

- Ensure the confidentiality, integrity, and availability of all electronic records they create, receive, maintain, or transmit;
- Identify and protect against reasonably anticipated threats to the security or integrity of the electronic records;
- Protect against reasonably anticipated, impermissible uses or disclosures; and,
- Ensure compliance by their workforce

The HHA is ultimately responsible for compliance with these confidentiality requirements and is the responsible party if the agent does not meet the requirements. (See also §484.50(c)(6) Patient Rights)

G370
(Rev.)

§484.45 Condition of participation: Reporting OASIS information.

HHAs must electronically report all OASIS data collected in accordance with §484.55.

Interpretive Guidelines §484.45

The home health regulations at §484.55 require that each patient receive from the HHA a patient-specific, comprehensive assessment. As part of the comprehensive assessment of adult skilled patients, HHAs are required to use a standard core assessment data set, the OASIS. The OASIS data collection set must include the data elements listed in §484.55(c)(8) and be collected and updated per the requirements under §484.55(d).

G372
(Rev.)

§484.45(a) Standard: Encoding and transmitting OASIS data. **An HHA must encode and electronically transmit each completed OASIS assessment to the CMS system, regarding each beneficiary with respect to which information is required to be transmitted (as determined by the Secretary), within 30 days of completing the assessment of the**

beneficiary.

Interpretive Guidelines §484.45(a)

"CMS system" means the national *internet* Quality Improvement Evaluation System (*i*QIES).

"Encode" means to enter OASIS information into a computer.

"Transmit" means electronically send OASIS information, from the HHA directly to the CMS system.

An HHA must transmit a completed OASIS to the CMS system for all Medicare patients, Medicaid patients, and patients utilizing any federally funded health plan options that are part of the Medicare program (e.g., Medicare Advantage (MA) plans). An HHA must also transmit an OASIS assessment for all Medicaid patients receiving services under a waiver program receiving services subject to the Medicare Conditions of Participation as determined by the State.

Exceptions to the transmittal requirements are patients:

- Under age 18;
- Receiving maternity services;
- Receiving housekeeping or chore services only;
- Receiving only personal care services; and
- Patients for whom Medicare or Medicaid insurance is not billed.

The comprehensive assessment and reporting regulations are not applicable to patients receiving personal care only services, regardless of payor source.

As long as the submission time frame is met, HHAs are free to develop schedules for transmission of the OASIS assessments that best suit their needs.

G374
(Rev.)

§484.45(b) Standard: Accuracy of encoded OASIS data. **The encoded OASIS data must accurately reflect the patient's status at the time of assessment.**

Interpretive Guidelines §484.45(b)

"Accurate" means that the OASIS data transmitted to CMS is consistent with the status of the patient at the time the OASIS was completed.

G378
(Rev.)

§484.45(c) *Standard: Transmittal of OASIS data. An HHA must—*

(1) For all completed assessments, transmit OASIS data in a format that meets the requirements of paragraph (d) of this section.

Interpretive Guidelines §484.45(c)(1)

Successful transmission of OASIS data is verified through validation and feedback reports from *i*QIES. *Although not required by the regulation, it is recommended that the HHA keep copies of the electronic validation records, that indicate transmission was successful, for twelve months, or until the next set of reports are available. The validation reports may be needed as evidence if the HHA receives a denial from the Medicare Administrative Contractor (MAC) for missing OASIS assessments.*

G382
(Rev.)

§484.45(c) *Standard: Transmittal of OASIS data. An HHA must—*

(*2*) Transmit data using electronic communications software that complies with the Federal Information Processing Standard (FIPS 140-2, issued May 25, 2001) from the HHA or the HHA contractor to the CMS collection site.

Interpretive Guidelines §484.45(c)(*2*)

HHAs may directly transmit OASIS data (to the national data repository) via *iQIES* or other software that conforms to the FIPS 140-2.

G384
(Rev.)

§484.45(c) *Standard: Transmittal of OASIS data. An HHA must—*

(*3*) Transmit data that includes the CMS-assigned branch identification number, as applicable.

G386
(Rev.)

§484.45(d) Standard: Data Format.

The HHA must encode and transmit data using the software available from CMS or software that conforms to CMS standard electronic record layout, edit specifications, and data dictionary, and that includes the required OASIS data set.

G406
(Rev.)

§484.50 Condition of participation: Patient rights.

The patient and representative (if any), have the right to be informed of the patient's rights in a language and manner the individual understands. The HHA must protect and promote the exercise of these rights.

Interpretive Guidelines §484.50

Ensuring that patients (and representative, if any) are aware of their rights and how to exercise them is vital to quality of care and patient satisfaction. HHAs must inform patients of their rights and protect and promote the exercise of these rights, e.g., by informing the patient how to exercise those rights.

The manner and degree of noncompliance identified in relation to the standard level tags for §484.50 may result in substantial noncompliance with this CoP, requiring citation at the condition level.

Survey Procedures: §484.50

When there is a team surveying the HHA, survey of the Patient rights Condition should be coordinated by one surveyor. However, each surveyor, as they conduct their survey assignments, should assess the HHA's compliance with the Patient rights regulatory requirements. It is particularly important for the surveyor who will be conducting home visits to observe how the HHA's actions protect and promote those patients' exercise of their rights.

• Determine whether the HHA provides patients (or their representatives, if any), with notice of their rights, consistent with the standards under this condition. Review documents in the home provided by the HHA to the patient if the patient (or authorized representative) can provide them.

• Determine whether the HHA promotes the patients' exercise of their rights (or their representatives, as applicable), consistent with the standards under this condition. Interview the patient (or authorized representative) to assess whether they were informed that they are entitled to certain rights.

G410
(Rev.)

§484.50(a) Standard: Notice of rights. The HHA must—

(1) Provide the patient and the patient's legal representative (if any), the following information during the initial evaluation visit, in advance of furnishing care to the patient:

Interpretive Guidelines §484.50(a)(1)

The term “in advance” is defined at §484.2. “In advance” means that HHA staff must complete the task prior to performing any hands-on care or any patient education.

A “legal representative” is an individual who has been legally designated or appointed as the patient’s health care decision maker. When there is no evidence that a patient has a legal representative, such as a guardianship, a power of attorney for health care decision-making, or a designated health care agent, the HHA must provide the information directly to the patient.

The initial evaluation visit is the initial assessment visit that is conducted to determine the immediate care and support needs of the patient.

G412

(Rev.)

[§484.50(a) Standard: Notice of rights. The HHA must—(1) Provide the patient and the patient's legal representative (if any), the following information during the initial evaluation visit, in advance of furnishing care to the patient:]

(i) Written notice of the patient’s rights and responsibilities under this rule, and the HHA’s transfer and discharge policies as set forth in paragraph (d) of this section. Written notice must be understandable to persons who have limited English proficiency and accessible to individuals with disabilities;

Interpretive Guidelines §484.50(a)(1)(i)

We expect HHA patients to be able to confirm, upon interview, that their rights and responsibilities, as well as the transfer and discharge policies of the HHA, were understandable and accessible.

To ensure patients receive appropriate notification:

- Written notice to the patient or their representative of their rights and responsibilities under this rule should be provided via hard copy unless the patient requests that the document be provided electronically.

- If a patient or his/her representative’s understanding of English is inadequate for the patient’s comprehension of his/her rights and responsibilities, the information must be provided in a language or format familiar to the patient or his/her representative.

- Language assistance should be provided *using* competent bilingual staff, staff interpreters, contracts or formal arrangements with local organizations providing interpretation, translation services, or technology and telephonic interpretation services.

- All agency staff should be trained to identify patients with any language barriers which may prevent effective communication of the rights and responsibilities. Staff that have

on-going contact with patients who have language barriers, should be trained in effective communication techniques, including the effective use of an interpreter.

See §484.50(f) for discussion on communication of rights and responsibilities with patients who have disabilities that may hinder communication with the HHA.

G414
(Rev.)

§484.50(a) *Standard: Notice of rights. The HHA must—*

[(1) Provide the patient and the patient's legal representative (if any), the following information during the initial evaluation visit, in advance of furnishing care to the patient:]

(ii) Contact information for the HHA administrator, including the administrator's name, business address, and business phone number in order to receive complaints.

G416
(Rev.)

§484.50(a) *Standard: Notice of rights. The HHA must—*

[(1) Provide the patient and the patient's legal representative (if any), the following information during the initial evaluation visit, in advance of furnishing care to the patient:]

(iii) An OASIS privacy notice to all patients for whom the OASIS data is collected.

Interpretive Guidelines §484.50(a)(1)(iii)

Use of the OASIS Privacy Notice is required under the Federal Privacy Act of 1974 and must be used in addition to other notices that may be required by other privacy laws and regulations. The OASIS privacy notice is available in English and Spanish on the CMS website. The OASIS Privacy Notice must be provided at the time of the initial evaluation visit.

Survey Procedures: §484.50(a)(1)(iii)

Patient interview and clinical record review should confirm that the required privacy notice was provided.

G418
(Rev.)

§484.50(a) *Standard: Notice of rights. The HHA must—*

(2) Obtain the patient's or legal representative's signature confirming that he or she has received a copy of the notice of rights and responsibilities.

Survey Procedures: §484.50(a)(2)

Clinical record review should confirm that the required written notice of patient rights and responsibilities was provided to the patient. Note if the patient/legal representative's signature was obtained as required.

G420
(Rev.)

§484.50(a)(3)
[Reserved]

G422
(Rev.)

§484.50(a) ***Standard: Notice of rights. The HHA must—***

(4) Provide written notice of the patient's rights and responsibilities under this rule and the HHA's transfer and discharge policies as set forth in paragraph (d) of this section to a patient-selected representative within 4 business days of the initial evaluation visit.

G424
(Rev.)

§484.50(b) Standard: Exercise of rights.

(1) If a patient has been adjudged to lack legal capacity to make health care decisions as established by state law by a court of proper jurisdiction, the rights of the patient may be exercised by the person appointed by the state court to act on the patient's behalf.

(2) If a state court has not adjudged a patient to lack legal capacity to make health care decisions as defined by state law, the patient's representative may exercise the patient's rights.

(3) If a patient has been adjudged to lack legal capacity to make health care decisions under state law by a court of proper jurisdiction, the patient may exercise his or her rights to the extent allowed by court order.

Interpretive ***Guidelines §484.50(b)***

The HHA should obtain official documentation of: (1) any adjudication by a court that indicates that a patient lacks the legal capacity to make his or her own health care decisions; and (2) the name of any person identified by the court who may exercise the patient's rights.

G428
(Rev.)

§484.50(c) *Standard: Rights of the patient. The patient has the right to—*

(1) Have his or her property and person treated with respect;

Interpretive Guidelines §484.50(c)(1)

Respect for Property: The patient has the right to expect the HHA staff will respect his or her property and person while in the patient's home. The HHA must ensure that during home visits the patient's property, both inside and outside the home, is not stolen, damaged, or misplaced by HHA staff.

Respect for Person: The HHA must consider and accommodate any patient requests within the parameters of the assessment and plan of care, and the patient must be treated by the HHA as an active partner in the delivery of care. The HHA should make all reasonable attempts to respect the preferences of the patient regarding the services that will be delivered, such as the HHA visit schedule, which should be made at the convenience of the patient rather than of the agency personnel. The HHA must keep the patient informed of the visit schedule and timely and promptly notify the patient when scheduled services are changed.

G430
(Rev.)

§484.50(c) *Standard: Rights of the patient. The patient has the right to—*

(2) Be free from verbal, mental, sexual, and physical abuse, including injuries of unknown source, neglect and misappropriation of property;

Interpretive Guidelines §484.50(c)(2)

The patient has a right to be free from abuse from the HHA staff and others in his or her home environment. The HHA should address any allegations or evidence of patient abuse to determine if immediate care is needed, a change in the plan of care is indicated, or if a referral to an appropriate agency is warranted. (State laws vary in the reporting requirements of abuse. HHAs should be knowledgeable of these laws and comply with the reporting requirements.) In addition, the HHA should intervene immediately if, as indicated by the circumstances, any injury is the result of an HHA staff member's actions. The HHA should also immediately remove staff from patient care if there are allegations of misconduct related to abuse or misappropriation of property.

"Abuse" means the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish. Abuse may be verbal, mental, sexual, or physical and includes abuse facilitated or enabled through the use of technology.

"Verbal abuse" refers to abuse perpetrated through any use of insulting, demeaning, disrespectful, oral, written or gestured language directed toward and in the presence of the client.

"Mental abuse" is a type of abuse that includes, but is not limited to, humiliation, harassment, and threats of punishment or deprivation, sexual coercion and intimidation (e.g. living in fear in one's own home).

"Sexual abuse" is a type of abuse that includes any incident where a beneficiary is coerced, manipulated, or forced to participate in any form of sexual activity for which the beneficiary did not give affirmative permission (or gave affirmative permission without the mental capacity required to give permission), or sexual assault against a beneficiary who is unable to defend him/herself.

"Physical abuse" refers to abuse perpetrated through any action intended to cause physical harm or pain, trauma or bodily harm (e.g., hitting, slapping, punching, kicking, pinching, etc.). It includes the use of corporal punishment as well as the use of any restrictive, intrusive procedure to control inappropriate behavior for purposes of punishment.

"Injury of unknown" source is an injury that was not witnessed by any person and the source of the injury cannot be explained by the patient.

"Misappropriation of property" is theft or stealing of items from a patient's home. The HHA staff must investigate and take immediate action on any allegations of misappropriation of patient property by HHA staff and refer to authorities when appropriate.

Neglect means a failure to provide goods and/or services necessary to avoid physical harm, mental anguish or mental illness.

Survey Procedures: §484.50(c)(2)

Examine the extent to which the HHA has a system in place to protect patients from abuse, neglect, and misappropriation of property of all forms, whether from staff or from other persons. Determine the extent to which the HHA addresses the following issues:

- *How does the HHA staff conduct themselves in the patient's home in regards to demonstrating respect for persons and property?*
- *Does the HHA have policies and procedures for investigating allegations of abuse, neglect and misappropriation of property?*
- *Interview staff to determine if staff members know what to do if they witness abuse, neglect or misappropriation of property.*

- *Ask the HHA if it has had any allegations of patient abuse or neglect from any source during the past year. If it has, ask the HHA to provide the files and to describe how the matter was handled. Review the HHA records to see if the appropriate agencies were notified in accordance with State and federal laws regarding incidents of substantiated abuse and neglect.*

G432
(Rev.)

§484.50(c) *Standard: Rights of the patient. The patient has the right to—*

(3) Make complaints to the HHA regarding treatment or care that is (or fails to be) furnished, and the lack of respect for property and/or person by anyone who is furnishing services on behalf of the HHA;

Interpretive Guidelines §484.50(c)(3)

The HHA should have written policies and procedures that address the acceptance, processing, review, and resolution of patient complaints, including complaint intake procedures, timeframes for investigations, documentation, and potential outcomes and actions that the HHA may take to resolve patient complaints. See also §484.50(e) Investigation of complaints.

The HHA should record, in both the clinical record and the patient's home folder, that the patient was provided with information regarding his or her right to lodge a complaint to the HHA.

G434
(Rev.)

§484.50(c) *Standard: Rights of the patient. The patient has the right to—*

(4) Participate in, be informed about, and consent or refuse care in advance of and during treatment, where appropriate, with respect to –

(i) Completion of all assessments;
(ii) The care to be furnished, based on the comprehensive assessment;
(iii) Establishing and revising the plan of care;
(iv) The disciplines that will furnish the care;
(v) The frequency of visits;
(vi) Expected outcomes of care, including patient-identified goals, and anticipated risks and benefits;
(vii) Any factors that could impact treatment effectiveness; and
(viii) Any changes in the care to be furnished.

Interpretive Guidelines §484.50(c)(4)

The patient's informed consent on the items (i)-(viii) is not intended to be recorded on a single signed form. Informed consent and patient participation take place on an ongoing basis as the patient's care changes and evolves during his or her episodes of care. There must be evidence in the patient's medical record that, both initially and as changes occur in the patient's care, the patient was consulted and consented to planned services and care.

"Participation" means that the patient is given options regarding care choices and preferences. For example, patient preferences should be respected in encouraging the patient to choose between a bath and a shower, unless there are physical restrictions or medical contraindications that limit patient choice.

"Informed" means that all aspects of the planned care and services, and the *way* the care and services will be delivered, are reviewed by HHA staff with the patient and that, during such review, HHA staff solicits the patient's agreement or disagreement. When there is a change to the plan of care, whether initiated by the HHA/physician or at the request of the patient, documentation in the clinical record should indicate whether the patient was informed of and agreed to the changes.

G436
(Rev.)

§484.50(c) *Standard: Rights of the patient. The patient has the right to—*

(5) Receive all services outlined in the plan of care.

Survey Procedures: §484.50(c)(5)

Clinical record review and patient interview should confirm that the HHA is providing the services identified in the patient's individualized plan of care (see also §484.60(a)).

G438
(Rev.)

§484.50(c) *Standard: Rights of the patient. The patient has the right to—*

(6) Have a confidential clinical record. Access to or release of patient information and clinical records is permitted in accordance with 45 CFR parts 160 and 164.

Interpretive Guidelines §484.50(c)(6)

45 CFR Part 160 and 164 pertain to requirements of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). The HIPAA Privacy Rule (45 CFR Part 160 and Subparts A and E of Part 164), Security Rule (45 CFR Part 160 and Subparts A and C of Part 164), and Breach Notification Rule (45 CFR §§ 164.400–414) protect the privacy and security of health information and provide individuals with certain rights regarding their health information as follows:

• The Privacy Rule sets national standards for covered entities (health plans, health care clearinghouses, and health care providers that conduct certain health care transactions electronically) and their business associates, including appropriate safeguards to protect the privacy of protected health information (PHI) and the limits and conditions under which PHI is permitted or required to be used or disclosed;

• The Security Rule specifies safeguards that covered entities and their business associates must implement to protect the confidentiality, integrity, and availability of electronic protected health information (ePHI)

• The Breach Notification Rule requires covered entities and their business associates to notify affected individuals, U.S. Department of Health & Human Services (HHS), and in some cases, the media of a breach of unsecured PHI.

The HIPAA Privacy Rule also gives certain patients' rights over their health information, including rights to examine and obtain a copy of their health records, and to request corrections.

HHAs have unique concerns and risks regarding staff and contractors who transport documents and/or electronic devices containing PHI, such as during their visits to patient's homes. Compliance with §484.50(c)(6) is evidenced by documentation of HIPAA training for all staff and monitoring HIPAA compliance to manage the risk of inappropriate PHI disclosure or unsecured ePHI. Each covered entity and business associate is responsible for ensuring its compliance with the HIPAA Privacy, Security, and Breach Notification Rules, as applicable, including consulting appropriate counsel as necessary.

Survey procedures §484.50(c)(6)

Verify that the agency staff maintain the confidentiality of protected health information that they transport and use.

G440
(Rev.)

§484.50(c) *Standard: Rights of the patient. The patient has the right to—*

(7) Be advised, orally and in writing, of—

(i) The extent to which payment for HHA services may be expected from Medicare, Medicaid, or any other federally-funded or federal aid program known to the HHA,
(ii) The charges for services that may not be covered by Medicare, Medicaid, or any other federally-funded or federal aid program known to the HHA,
(iii) The charges the individual may have to pay before care is initiated; and
(iv) Any changes in the information provided in accordance with paragraph (c)(7) of this section when they occur. The HHA must advise the patient and

representative (if any), of these changes as soon as possible, in advance of the next home health visit. The HHA must comply with the patient notice requirements at 42 CFR 411.408(d)(2) and 42 CFR 411.408(f).

***Survey Procedures* §484.50(c)(7)**

Ask the patient or legal representative (if any) about whether the HHA informed them if there were any services that may not be covered by Medicare and, if so, how that would be addressed. If a notice of Medicare non-coverage was provided to the patient, confirm that it was received prior to the care being provided. Surveyors are not to advise the patient about finances, or coverage, or payment issues, but rather confirm if the HHA provided this information.

G442
(Rev.)

§484.50(c) *Standard: Rights of the patient. The patient has the right to—*

(8) Receive proper written notice, in advance of a specific service being furnished, if the HHA believes that the service may be non-covered care; or in advance of the HHA reducing or terminating on-going care. The HHA must also comply with the requirements of 42 CFR 405.1200 through 405.1204.

Interpretive Guidelines §484.50(c)(8)

§405.1200 through §405.1204 describe the expedited determination process, which is a right that Medicare beneficiaries may exercise to dispute the termination of Medicare-covered services in certain settings including home health.

Survey Procedures §484.50(c)(8)

Surveyors are not to advise the patient about finances, or coverage, or payment issues, but rather confirm if the HHA provided this information.

G444
(Rev.)

§484.50(c) *Standard: Rights of the patient. The patient has the right to—*

(9) Be advised of the state toll free home health telephone hot line, its contact information, its hours of operation, and that its purpose is to receive complaints or questions about local HHAs.

Survey Procedures §484.50(c)(9)

Determine if the patient is aware of the state home health hotline to lodge a complaint if dissatisfied with the care provided by the HHA. Inquire if the patient filed any complaints directly with the HHA and if the care and services were negatively affected by this action (see also §484.50(c)(11)).

G446
(Rev.)

§484.50(c) *Standard: Rights of the patient. The patient has the right to—*

(10) Be advised of the names, addresses, and telephone numbers of the following Federally-funded and state-funded entities that serve the area where the patient resides:

(i) Agency on Aging
(ii) Center for Independent Living
(iii) Protection and Advocacy Agency,
(iv) Aging and Disability Resource Center; and
(v) Quality Improvement Organization.

G448
(Rev.)

§484.50(c) *Standard: Rights of the patient. The patient has the right to—*

(11) Be free from any discrimination or reprisal for exercising his or her rights or for voicing grievances to the HHA or an outside entity.

Interpretive Guidelines §484.50(c)(11)

"Discrimination or reprisal against a patient for exercising his or her rights or for voicing grievances" is defined as treating a patient differently from other patients *after* receipt by the HHA of a patient complaint, without a medical justification for such different treatment.

Examples of discrimination or reprisal include, but are not limited to, a reduction of current services, a complete discontinuation of services, or discharge from the HHA *after* receipt by the HHA of a patient complaint, without a medical justification for the change of services or discharge.

Survey Procedures §484.50(c)(11)

Inquire if the patient filed any complaints directly with the HHA and if the care and services were negatively affected by this action. Determine if the patient is aware of the state HHA hotline to lodge a complaint if dissatisfied with the care provided by the HHA (§484.50(c)(9)).

G450
(Rev.)

§484.50(c) *Standard: Rights of the patient. The patient has the right to—*

(12) Be informed of the right to access auxiliary aids and language services as described in paragraph (f) of this section, and how to access these services.

G452
(Rev.)

§484.50(d) Standard: Transfer and discharge.

The patient and representative (if any), have a right to be informed of the HHA's policies for transfer and discharge. The HHA may only transfer or discharge the patient from the HHA if:

G454
(Rev.)

§484.50(d) *Standard: Transfer and discharge.*

[…The HHA may only transfer or discharge the patient from the HHA if:]

(1) The transfer or discharge is necessary for the patient's welfare because the HHA and the physician *or allowed practitioner* who is responsible for the home health plan of care agree that the HHA can no longer meet the patient's needs, based on the patient's acuity. The HHA must arrange a safe and appropriate transfer to other care entities when the needs of the patient exceed the HHA's capabilities;

Interpretive Guidelines §484.50(d)(1)

When a patient's care needs change to require more than intermittent services or require specialized services not provided by the agency, the HHA must inform the patient, patient representative (if any), and the physician *or allowed practitioner* who is responsible for the patient's home health plan of care that the HHA cannot meet the patient's needs without potentially adverse outcomes. *(As noted in §484.2, "allowed practitioner" means a physician assistant, nurse practitioner, or clinical nurse specialist as defined at this part.)* The HHA should assist the patient and his or her representative (if any) in choosing an alternative entity by identifying those entities in the patient's geographic area that may be able to meet the patient's needs based on the patient's acuity. Once the patient chooses an alternate entity, the HHA must contact that entity to facilitate a safe transfer. The HHA must ensure timely transfer of patient information to the alternate entity to facilitate continuity of care, i.e., the HHA must ensure that patient information is provided to the alternate entity prior to or simultaneously with the initiation of patient services at the new entity.

Also see *the discharge planning requirements at §484.58 and the requirements at* §484.110(a)(6)(ii) regarding time frame for the transfer summary.

G456
(Rev.)

§484.50(d) *Standard: Transfer and discharge.*

[…The HHA may only transfer or discharge the patient from the HHA if:]

(2) The patient or payer will no longer pay for the services provided by the HHA;

G458
(Rev.)

§484.50(d) *Standard: Transfer and discharge.*

[…The HHA may only transfer or discharge the patient from the HHA if:]

(3) The transfer or discharge is appropriate because the physician *or allowed practitioner* who is responsible for the home health plan of care and the HHA agree that the measurable outcomes and goals set forth in the plan of care in accordance with §484.60(a)(2)(xiv) have been achieved, and the HHA and the physician *or allowed practitioner* who is responsible for the home health plan of care agree that the patient no longer needs the HHA's services;

G460
(Rev.)

§484.50(d) *Standard: Transfer and discharge.*

[…The HHA may only transfer or discharge the patient from the HHA if:]

(4) The patient refuses services, or elects to be transferred or discharged;

Interpretive Guidelines §484.50(d)(4)

A patient who occasionally declines a service is distinguished from a patient who refuses services altogether, or who habitually declines skilled care visits. It is the patient's right to refuse services. It is the agency's responsibility to educate the patient on the risks and potential adverse outcomes that can result from refusing services. In the case of patient refusals of skilled care, the HHA must document its communication with the physician *or allowed practitioner* who is

responsible for the patient's home health plan of care, as well as the measures the HHA took to investigate the patient's refusal and the interventions the HHA attempted in order to obtain patient participation with the plan of care.

The HHA may consider discharge if the patient's decision to decline services compromises the agency's ability to safely and effectively deliver care to the extent that the agency can no longer meet the patient's needs.

G462
(Rev.)

§484.50(d) *Standard: Transfer and discharge.*

[…The HHA may only transfer or discharge the patient from the HHA if:]

(5) The HHA determines, under a policy set by the HHA for the purpose of addressing discharge for cause that meets the requirements of paragraphs (d)(5)(i) through (d)(5)(iii) of this section, that the patient's (or other persons in the patient's home) behavior is disruptive, abusive, or uncooperative to the extent that delivery of care to the patient or the ability of the HHA to operate effectively is seriously impaired. The HHA must do the following before it discharges a patient for cause:

Interpretive Guidelines §484.50(d)(5)

"Disruptive, abusive behavior" includes verbal, non-verbal or physical threats, sexual harassment, or any incident in which agency staff feel threatened or unsafe, resulting in a serious impediment to the agency's ability to operate safely and effectively in the delivery of care.

"Uncooperative" is defined as the patient's repeated declination of services or persistent obstructive, hostile or contrary attitudes to agency caregivers that are counterproductive to the plan of care.

The HHA must document in the patient's clinical record the behaviors and circumstances that warranted patient discharge for cause as well as the HHA's efforts to resolve the problems.

G464
(Rev.)

§484.50(d) *Standard: Transfer and discharge.*

[…The HHA must do the following before it discharges a patient for cause:]

(5)(i) Advise the patient, *the* representative (if any), the physician*(s) or allowed practitioners(s)* issuing orders for the home health plan of care, and the patient's primary care practitioner or other health care professional who will be responsible for providing

care and services to the patient after discharge from the HHA (if any) that a discharge for cause is being considered;

Interpretive Guidelines §484.50(d)(5)(i)

The HHA must notify the patient, his or her representative (if any), the physician*(s) or allowed practitioners(s)* issuing orders for the home health care and the patient's primary care practitioner that the HHA is considering a discharge for cause. If the HHA *can* identify other health care professionals who may be involved in the patient's care after the discharge occurs, then the HHA should notify those individuals of the discharge when discharge becomes imminent.

G466
(Rev.)

§484.50(d) *Standard: Transfer and discharge.*

[…The HHA must do the following before it discharges a patient for cause:]

(5)(ii) Make efforts to resolve the problem(s) presented by the patient's behavior, the behavior of other persons in the patient's home, or situation;

G468
(Rev.)

§484.50(d) *Standard: Transfer and discharge.*

[…The HHA must do the following before it discharges a patient for cause:]

(5)(iii) Provide the patient and representative (if any), with contact information for other agencies or providers who may be able to provide care; and

Interpretive Guidelines §484.50(d)(5)(ii) and (iii)

The clinical record should reflect:

- Identification of the problems encountered;
- Assessment of the situation;
- Communication among HHA management, patient caregiver, legal representative and the physician responsible for the plan of care;
- A plan to resolve the issues; and
- Results of the plan implementation.

Only in extreme situations when there is a serious imminent threat of physical harm to

HHA staff, the HHA may take immediate action to discharge or transfer the patient without first making efforts to resolve the underlying issue.

Evidence in the record should document that the HHA provided the patient and his or her representative (if any) with information including contact numbers for other community resources and names of other agencies or providers that may be able to provide services to the patient.

G470
(Rev.)

§484.50(d) ***Standard: Transfer and discharge.***

[…The HHA must do the following before it discharges a patient for cause:]

(5)(iv) Document the problem(s) and efforts made to resolve the problem(s), and enter this documentation into its clinical records;

G472
(Rev.)

§484.50(d) ***Standard: Transfer and discharge.***

[…The HHA may only transfer or discharge the patient from the HHA if:]

(6) The patient dies; or

G474
(Rev.)

§484.50(d) ***Standard: Transfer and discharge.***

[…The HHA may only transfer or discharge the patient from the HHA if:]

(7) The HHA ceases to operate.

Interpretive Guidelines §484.50(d)(7)

The agency must provide sufficient notice of its planned cessation of business to enable patients to select an alternative service provider and to enable the HHA to facilitate the safe transfer of its patients to other agencies.

G478
(Rev.)

§484.50(e) Standard: Investigation of complaints.

§484.50(e)(1) The HHA must—

(i) Investigate complaints made by a patient, the patient's representative (if any), and the patient's caregivers and family, including, but not limited to, the following topics:

(A) Treatment or care that is (or fails to be) furnished, is furnished inconsistently, or is furnished inappropriately;

(B) ***Mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and/or misappropriation of patient property by anyone furnishing services on behalf of the HHA.***

G484
(Rev.)

§484.50(e)(1) The HHA must—

(ii) Document both the existence of the complaint and the resolution of the complaint; and

Survey Procedures §484.50(e)(1)(ii)

Obtain the complaint log (or other format used for documenting complaints) to verify that the HHA is tracking complaints received from receipt of complaint through resolution.

G486
(Rev.)

§484.50(e)(1) The HHA must—

(iii) Take action to prevent further potential violations, including retaliation, while the complaint is being investigated.

Interpretive Guidelines §484.50(e)(1)

The HHA should have systems in place to record, track and investigate all complaints. Written policies and procedures on the acceptance, processing, review, and resolution of patient complaints should be developed and communicated to staff. These policies should include intake procedures, timeframes for investigations, documentation, and outcomes and actions that the

HHA may take to resolve patient complaints. Complaint investigations should be incorporated into the agency's Quality Assurance Performance Improvement program.

The HHA should be able to produce documentation for each complaint received that confirms that an investigation was conducted and records the investigation findings as well as the ultimate resolution of the complaint. The documentation should also describe any actions taken by the HHA to remove any risks to the patient while the complaint was being investigated.

G488
(Rev.)

§484.50(e)(2) Any HHA staff (whether employed directly or under arrangements) in the normal course of providing services to patients, who identifies, notices, or recognizes incidences or circumstances of mistreatment, neglect, verbal, mental, sexual, and/or physical abuse, including injuries of unknown source, or misappropriation of patient property, must report these findings immediately to the HHA and other appropriate authorities in accordance with state law.

Interpretive Guidelines §484.50(e)(2)

Immediately means reporting without delay, as soon as possible following the discovery. *States commonly have mandatory reporting requirements for providers, suppliers, and individuals making them legally responsible to report suspicions of abuse and neglect to appropriate State authorities. These entities and individuals should follow existing mandatory reporting requirements in their State in addition to any applicable Federal requirements. Action or inaction on the part of a provider or supplier to follow mandatory reporting requirements does not preclude an employee from fulfilling their reporting obligations.*

G490
(Rev.)

§484.50(f) *Standard: Accessibility.* Information must be provided to patients in plain language and in a manner that is accessible and timely to—

(1) Persons with disabilities, including accessible web sites and the provision of auxiliary aids and services at no cost to the individual in accordance with the Americans with Disabilities Act and Section 504 of the Rehabilitation Act.

(2) Persons with limited English proficiency through the provision of language services at no cost to the individual, including oral interpretation and written translations.

Interpretive Guidelines §484.50(f)

"Plain language" (also referred to as "Plain English") is communication the patient and/or his or her representative (if any) can understand the first time they read or hear it. Language that is

plain to one set of readers may not be plain to others. Written material is in plain language if the audience can:

- Find what they need;
- Understand what they find; and
- Use what they find to meet their needs.

Section 504 of the Rehabilitation Act and the Americans with Disabilities Act protect qualified individuals with disabilities from discrimination on the basis of disability in the provision of benefits and services. Concerns related to potential discrimination issues under 504 should be referred to the Office of Civil Rights for further review.

"Auxiliary aids and services" for individuals who are deaf or hard of hearing include services and devices such as, but not limited to: qualified interpreter services (on-site or through video remote interpreting (VRI)); note takers; real-time computer-aided transcription services; written materials; exchange of written notes; telephone handset amplifiers; assistive listening devices; assistive listening systems; telephones compatible with hearing aids; closed caption decoders; open and closed captioning, including real-time captioning; voice, text, and video-based telecommunications products and systems, including text telephones (TTYs), videophones, and captioned telephones, or equally effective telecommunications devices; videotext displays; and accessible electronic and information technology. Auxiliary aids and services for individuals who are blind or have low vision include services and devices such as: qualified readers; taped texts; audio recordings; Braille materials and displays; screen reader software; magnification software; optical readers; secondary auditory programs (SAP); large print materials; and accessible electronic and information technology.

The patient's clinical record should include evidence that the HHA facilitated the availability of needed auxiliary aids and language services.

G510
(Rev.)

§484.55 Condition of participation: Comprehensive assessment of patients.

Each patient must receive, and an HHA must provide, a patient-specific, comprehensive assessment. For Medicare beneficiaries, the HHA must verify the patient's eligibility for the Medicare home health benefit including homebound status, both at the time of the initial assessment visit and at the time of the comprehensive assessment.

Interpretive Guidelines §484.55

A comprehensive assessment of the patient, in which patient needs are identified, is a crucial step in the establishment of a plan of care. In addition, a comprehensive assessment identifies patient progress toward desired outcomes or goals of the care plan.

The manner and degree of noncompliance identified in relation to the standard level tags for §484.55 may result in substantial noncompliance with this CoP, requiring citation at the condition level.

G514
(Rev.)

§484.55(a) *Standard: Initial assessment visit.*

(1) A registered nurse must conduct an initial assessment visit to determine the immediate care and support needs of the patient; and, for Medicare patients, to determine eligibility for the Medicare home health benefit, including homebound status. The initial assessment visit must be held either within 48 hours of referral, or within 48 hours of the patient's return home, or on the physician*- or allowed practitioner*-ordered start of care date.

Interpretive Guidelines §484.55(a)(1)

For patients receiving only nursing services or both nursing and rehabilitation therapy services, a registered nurse must conduct the initial assessment visit. For patients receiving rehabilitation therapy services only, the initial assessment may be made by the applicable rehabilitation skilled professional rather than the registered nurse. See §484.55(a)(2).

The initial assessment bridges the gap between when the first patient encounter occurs and when a plan of care can be implemented. "Immediate care and support needs" are those items and services that will maintain the patient's health and safety through this interim period, i.e., until the HHA can complete the comprehensive assessment and implement the plan of care. "Immediate care and support needs" may include medication, mobility aids for safety, skilled nursing treatments, and items to address fall risks and nutritional needs.

The clinical record must demonstrate that homebound status/eligibility for the Medicare home health benefit was determined and documented during the initial visit.

An HHA that is unable to complete the initial assessment within 48 hours of referral or the patient's return home, shall not request a different start of care date from the ordering physician to ensure compliance with the regulation or to accommodate the convenience of the agency. *(**NOTE:** CMS OASIS coding guidance[1] for M0104 defines the referral date as the most recent date that verbal, written, or electronic authorization to begin or resume home care was received by the HHA.)*

In instances where the patient requests a delay in the start of care date, the HHA would need to contact the physician to request a change in the start of care date and such change would need to be documented in the medical record.

---

[1] *CMS, January 2020 CMS Quarterly OASIS Q&As, 2, Answer 3 (Jan. 2020) https://qtso.cms.gov/system/files/qtso/CMS_OAI_4th%20Qtr_2019_QAs_Jan_2020_final_c.pdf.*

G516
(Rev.)

§ 484.55(a)(2) When rehabilitation therapy service (speech language pathology, physical therapy, or occupational therapy) is the only service ordered by the physician *or allowed practitioner* who is responsible for the home health plan of care, *the initial assessment visit may be made by the appropriate rehabilitation skilled professional. For Medicare patients, an occupational therapist may complete the initial assessment when occupational therapy is ordered with another qualifying rehabilitation therapy service (speech-language pathology or physical therapy) that* establishes program eligibility.

G520
(Rev.)

§484.55(b) Standard: Completion of the comprehensive assessment.

(1) The comprehensive assessment must be completed in a timely manner, consistent with the patient's immediate needs, but no later than 5 calendar days after the start of care.

Interpretive Guidelines §484.55(b)(1)

The start of care date *is* the first visit where the HHA provides hands on, direct care services or treatments to the patient. If an initial assessment is completed without any direct care services being provided by the HHA during the assessment visit, the date of that initial assessment visit would not be the start of care date. The comprehensive assessment must be completed within 5 calendar days of the first visit where the HHA provides hands on, direct care services/treatments to the patient.

G522
(Rev.)

§484.55(b)(2) Except as provided in paragraph (b)(3) of this section, a registered nurse must complete the comprehensive assessment and for Medicare patients, determine eligibility for the Medicare home health benefit, including homebound status.

Interpretive Guidelines §484.55(b)(2)

The requirements for conducting the initial assessment visit and the comprehensive assessment for home health services are based on sections 1814(a)(2)(c) and 1835(a)(2)(A) of the Act regarding eligibility and payment for home health services. The requirements for these assessments are based on the professional disciplines that will be involved in, and coordinating, care for the patient. When nursing is assigned to the case, it is likely the patient will have a

greater need for nursing services than other services and therefore skilled nurses should conduct the initial assessment visit and initiate the comprehensive assessment (86 FR 62240, 62351 (Nov. 9, 2021)).

Survey Procedures §484.55(b)(2)

- *Through clinical record review, verify the initial assessment was conducted by a registered nurse unless the patient is receiving therapy services only.*

- *Through home visit observation, verify if the current comprehensive assessment and plan of care were completed and accurately reflect the patient's status.*

G524
(Rev.)

§484.55(b)(3) When physical therapy, speech-language pathology, or occupational therapy is the only service ordered by the physician *or allowed practitioner*, a physical therapist, speech-language pathologist or occupational therapist may complete the comprehensive assessment, and for Medicare patients, determine eligibility for the Medicare home health benefit, including homebound status. *For Medicare patients, the occupational therapist may complete the comprehensive assessment when occupational therapy is ordered with another qualifying rehabilitation therapy service (speech-language pathology or physical therapy) that establishes program eligibility.*

Interpretive Guidelines §484.55(b)(3)

In therapy-only cases, a qualified therapist (registered and/or licensed by the State in which they practice) *may conduct* the comprehensive assessment for therapy services ordered.

G528
(Rev.)

§484.55(c) Standard: Content of the comprehensive assessment. The comprehensive assessment must accurately reflect the patient's status, and must include, at a minimum, the following information:

(1) The patient's current health, psychosocial, functional, and cognitive status;

Interpretive Guidelines §484.55(c)(1)

Completion of the comprehensive assessment should provide the HHA with a complete picture of the patient's status to assist the HHA in developing the patient's plan of care.

Assessment of the patient's current health status includes relevant past medical history as well as all active health and medical problems.

Assessment of a patient's psychosocial status and his/her functional capacity within the community is intended to be a screening of the patient's relationships, living environment, impact on the delivery of services and ability to participate in his/her own care. Assessment of a patient's functional status includes the patient's level of ability to function independently in the home such as activities of daily living.

Assessment of a patient's cognitive status refers to an evaluation of the degree of his or her ability to understand, remember, and participate in developing and implementing the plan of care.

G530
(Rev.)

[*§484.55(c) *… The comprehensive assessment must accurately reflect the patient's status, and must include, at a minimum, the following information:]

(2) The patient's strengths, goals, and care preferences, including information that may be used to demonstrate the patient's progress toward achievement of the goals identified by the patient and the measurable outcomes identified by the HHA;

Interpretive Guidelines §484.55(c)(2)

Consistent with the principles of patient-centered care, the intent in identifying patient strengths is to empower the patient to take an active role in his or her care. The HHA must ask the patient to identify her or his own strengths and must also independently identify the patient's strengths to inform the plan of care and to set patient goals and measurable outcomes. Examples of patient strengths identified by HHAs through observation and by patient self-identification may include: awareness of disease status, knowledge of medications, motivation and readiness for change, motivation/ability to perform self-care and/or implement a therapeutic exercise program, understanding of a dietary regimen for disease management, vocational interests/hobbies, interpersonal relationships and supports, and financial stability.

The intent of assessing patient care preferences is to engage the patient to the greatest degree possible to take an active role in their home care rather than placing the patient in a passive recipient role by informing the patient what will be done for them and when.

"Patient goal" is defined as a patient-specific objective, adapted to each patient based on the medical diagnosis, physician's *or allowed practitioner's* orders, comprehensive assessment, patient input, and the specific treatments provided by the agency.

"Measurable outcome" is a change in health status, functional status, or knowledge, which occurs over time in response to a health care intervention. Measurable outcomes may include end-result functional and physical health improvement/stabilization, health care utilization measures (hospitalization and emergency department use), and potentially avoidable events. Because the nature of the change can be positive, negative, or neutral, the actual change in patient health status can vary from patient to patient, ranging from decline, no change, to improvement in patient condition or functioning.

G532
(Rev.)

[§484.55(c) … The comprehensive assessment must accurately reflect the patient's status, and must include, at a minimum, the following information:]

(3) The patient's continuing need for home care;

Interpretive Guidelines §484.55(c)(3)

Medicare does not limit the number of continuous 60-day episode recertifications for beneficiaries who continue to be eligible for the home health benefit. Therefore, the comprehensive assessment must clearly demonstrate the continuing need, i.e., eligibility, for the home health benefit.

G534
(Rev.)

[§484.55(c) … The comprehensive assessment must accurately reflect the patient's status, and must include, at a minimum, the following information:]

(4) The patient's medical, nursing, rehabilitative, social, and discharge planning needs;

Survey Procedures §484.55(c)(4)

Verify if the current comprehensive assessment accurately reflects the patient's current status.

G536
(Rev.)

[§484.55(c) … The comprehensive assessment must accurately reflect the patient's status, and must include, at a minimum, the following information:]

(5) A review of all medications the patient is currently using in order to identify any potential adverse effects and drug reactions, including ineffective drug therapy, significant side effects, significant drug interactions, duplicate drug therapy, and noncompliance with drug therapy.

Interpretive Guidelines §484.55(c)(5)

The patient's clinical record should identify all medications that the patient is taking, both prescription and non-prescription *(e.g., over-the-counter drugs, herbal remedies, and other alternative treatments that could affect drug therapy),* as well as *the dose, route, frequency, or time of administration when indicated on the prescription or order. T*he skilled professional *performing the comprehensive assessment* should consider, and the clinical record should document, that the skilled professional considered each medication the patient is currently taking for possible side effects and the list of medications in its entirety for possible drug interactions. *Each agency must determine the capabilities of current staff members to perform comprehensive assessments, considering professional standards or practice acts specific to the State. No specific discipline is identified as exclusively able to perform the medication review. However, only Registered Nurses (RNs), Physical Therapists (PTs), Occupational Therapists (OTs) and Speech-Language Pathologists (SLPs) are qualified to perform comprehensive assessments (see also §484.55(b)). While only the assessing clinician is responsible for accurately completing and signing a comprehensive assessment, the agency may develop a policy where clinicians may collaborate to collect data for all OASIS items. For example, to assess potential side effects and drug interactions, the agency may wish to have RNs or practical (vocational) nurses, as defined in §484.115, review the mediation lists.*

HHA should have policies that guide staff in the event there is a concern identified with a patient's medication that should be reported to the physician *or allowed practitioner*.

Survey Procedures §484.55(c)(5)

Through home visit observation and record review, confirm the medications the patient identifies they are taking against the medical record documentation to verify that the HHA identified all medications, both prescription and non-prescription.

G538
(Rev.)

[§484.55(c) … The comprehensive assessment must accurately reflect the patient's status, and must include, at a minimum, the following information:]

§484.55(c)(6) The patient's primary caregiver(s), if any, and other available supports, including their:

(i) Willingness and ability to provide care, and

(ii) Availability and schedules;

G540
(Rev.)

[§484.55(c) … The comprehensive assessment must accurately reflect the patient's status, and must include, at a minimum, the following information:]

(7) The patient's representative (if any);

G542
(Rev.)

[§484.55(c) … The comprehensive assessment must accurately reflect the patient's status, and must include, at a minimum, the following information:]

(8) Incorporation of the current version of the Outcome and Assessment Information Set (OASIS) items, using the language and groupings of the OASIS items, as specified by the Secretary. The OASIS data items determined by the Secretary must include: clinical record items, demographics and patient history, living arrangements, supportive assistance, sensory status, integumentary status, respiratory status, elimination status, neuro/emotional/behavioral status, activities of daily living, medications, equipment management, emergent care, and data items collected at inpatient facility admission or discharge only.

G544
(Rev.)

§484.55(d) Standard: Update of the comprehensive assessment.

The comprehensive assessment must be updated and revised (including the administration of the OASIS) as frequently as the patient's condition warrants due to a major decline or improvement in the patient's health status, but not less frequently than-

Interpretive Guidelines §484.55(d)

A marked improvement or worsening of a patient's condition, which changes, and was not anticipated in, the patient's plan of care would be considered a "major decline or improvement in the patient's health status" that would warrant update and revision of the comprehensive assessment.

G546
(Rev.)

[§484.55(d) Standard: Update of the comprehensive assessment…not less frequently than-]

(1) The last 5 days of every 60 days beginning with the start-of-care date, unless there is a-

(i) Beneficiary elected transfer;

(ii) Significant change in condition; or

(iii) Discharge and return to the same HHA during the 60-day episode.

G548
(Rev.)

[§484.55(d) Standard: Update of the comprehensive assessment…not less frequently than-]

(2) Within 48 hours of the patient's return to the home from a hospital admission of 24 hours or more for any reason other than diagnostic tests, or on physician *or allowed practitioner* -ordered resumption date;

G550
(Rev.)

[§484.55(d) Standard: Update of the comprehensive assessment…not less frequently than-]

(3) At discharge.

Interpretive Guidelines § 484.55(d)(3)

The update of the comprehensive assessment at discharge would include a summary of the patient's progress in meeting the care plan goals.

***(NOTE:** CMS OASIS coding guidance[2] notes that a discharge comprehensive assessment including OASIS is required within two days of the patient's discharge date.)*

G560
(Rev.)

§ 484.58 Condition of participation: Discharge planning.

Interpretive Guidelines § 484.58

The manner and degree of noncompliance identified in relation to the standard level tags for §484.58 may result in substantial noncompliance with this CoP, requiring citation at the condition level.

G562
(Rev.)

[2] *CMS, May 2022 CMS OASIS Q&As Category 2 – Comprehensive Assessment, Answer 15.3.7.* https://qtso.cms.gov/system/files/qtso/508_OASIS_CAT_2_Static_QA_FINAL_05_2022.pdf

§484.58(a) Standard: Discharge planning.

A home health agency must develop and implement an effective discharge planning process. For patients who are transferred to another HHA or who are discharged to a SNF, IRF or LTCH, the HHA must assist patients and their caregivers in selecting a post-acute care provider by using and sharing data that includes, but is not limited to HHA, SNF, IRF, or LTCH data on quality measures and data on resource use measures. The HHA must ensure that the post-acute care data on quality measures and data on resource use measures is relevant and applicable to the patient's goals of care and treatment preferences.

Interpretive Guidelines §484.58(a)

The goal of discharge planning is to prepare patients and caregivers to be active partners in post-discharge care, to effectively transition the patient from HHA to post-HHA care, and to reduce the factors that often lead to preventable readmissions.

Data on quality and resource use measures are available on the CMS.gov web site to assist consumers in making informed decisions about the performance of HHA and other providers including skilled nursing facilities (SNFs), inpatient rehabilitation facilities (IRFs), long term care hospitals (LTCHs) and hospices.

G564
(Rev.)

§484.58(b) Standard: Discharge or transfer summary content.

(1) The HHA must send all necessary medical information pertaining to the patient's current course of illness and treatment, post-discharge goals of care, and treatment preferences, to the receiving facility or health care practitioner to ensure the safe and effective transition of care.

Interpretive Guidelines §484.58(b)(1)

See also §484.110(a)(6) for discharge and transfer summary requirements.

G566
(New)

§484.58(b) Standard: Discharge or transfer summary content.

(2) The HHA must comply with requests for additional clinical information as may be necessary for treatment of the patient made by the receiving facility or health care practitioner.

G570
(Rev.)

§484.60 Condition of participation: Care planning, coordination of services, and quality of care.

Patients are accepted for treatment on the reasonable expectation that an HHA can meet the patient's medical, nursing, rehabilitative, and social needs in his or her place of residence. Each patient must receive an individualized written plan of care, including any revisions or additions. The individualized plan of care must specify the care and services necessary to meet the patient-specific needs as identified in the comprehensive assessment, including identification of the responsible discipline(s), and the measurable outcomes that the HHA anticipates will occur as a result of implementing and coordinating the plan of care. The individualized plan of care must also specify the patient and caregiver education and training. Services must be furnished in accordance with accepted standards of practice.

Interpretive Guidelines §484.60

"Reasonable expectation that an HHA can meet the patient's medical, nursing, rehabilitative, and social needs in his or her place of residence" means that, in consideration of the patient's level of acuity, the HHA can effectively and safely provide the patient with the skilled services that the patient needs within the patient's home.

"Accepted standards of practice" include guidelines and recommendations issued by nationally recognized organizations with expertise in the relevant field. The Agency for Healthcare Research and Quality (AHRQ) maintains a National Guideline Clearinghouse as a public resource for summaries of evidence-based clinical practice guidelines.

See *§*484.60(e) for written information that must be provided to the patient.

G572
(Rev.)

§484.60(a) Standard: Plan of care.

(1) Each patient must receive the home health services that are written in an individualized plan of care that identifies patient-specific measurable outcomes and goals, and which is established, periodically reviewed, and signed by a doctor of medicine, osteopathy, or podiatry acting within the scope of his or her state license, certification, or registration. If a physician *or allowed practitioner* refers a patient under a plan of care that cannot be completed until after an evaluation visit, the physician *or allowed practitioner* is consulted to approve additions or modifications to the original plan.

Interpretive Guidelines §484.60(a)(1)

"Patient-specific measurable outcome" is a change in health status, functional status, or knowledge, which occurs over time in response to a health care intervention that provides end-result functional and physical health improvement/stabilization.

Patient-specific goals must be individualized to the patient based on the patient's medical diagnosis, physician *or allowed practitioner* orders, comprehensive assessment and patient input. Progress/non-progress toward achieving the goals is evaluated through measurable outcomes. The HHA must include goals for the patient, as well as patient preferences and service schedules, as a part of the plan of care (See §484.60(a)(2) below).

"Periodically reviewed" means every 60 days or more frequently when indicated by changes in the patient's condition (see §484.60(c)(1)).

The patient's physician *or allowed practitioner* orders for treatments and services are the foundation of the plan of care. If the HHA misses a visit or a treatment or service as required by the plan of care*, the HHA should make every attempt to reschedule the missed visit. If the visit cannot be rescheduled, the responsible physician or allowed practitioner should be notified, and the HHA should document the potential clinical impact of missed treatments or services. The HHA should advise and educate the patient on the potential impacts of missed visits.*

If the patient or the patient's representative refuses care that could impact the patient's clinical wellbeing (such as dressing changes or essential medication) on more than one occasion, then the HHA must attempt to identify the reason for the refusal. If the HHA is unable to identify and address the reason for the refusal, then the HHA must communicate with the patient's responsible physician *or allowed practitioner* to discuss how to proceed with patient care.

The physician *or allowed practitioner* should not be approached to reduce the frequency of services based solely on the availability of HHA staff.

In instances where the HHA receives a general referral from a physician *or allowed practitioner* that requests HHA services but does not provide the actual plan of care components (i.e., treatments and observations) for the patient, the HHA will not be able to create a comprehensive plan of care to include goals and services until a home visit is done and sufficient information is obtained to communicate with and receive approval from the physician *or allowed practitioner*.

G574
(Rev.)

§484.60(a)(2) The individualized plan of care must include the following:

(i) All pertinent diagnoses;

(ii) The patient's mental, psychosocial, and cognitive status;

(iii) The types of services, supplies, and equipment required;

(iv) The frequency and duration of visits to be made;

(v) Prognosis;

(vi) Rehabilitation potential;

(vii) Functional limitations;

(viii) Activities permitted;

(ix) Nutritional requirements;

(x) All medications and treatments;

(xi) Safety measures to protect against injury;

(xii) A description of the patient's risk for emergency department visits and hospital re-admission, and all necessary interventions to address the underlying risk factors.

(xiii) Patient and caregiver education and training to facilitate timely discharge;

(xiv) Patient-specific interventions and education; measurable outcomes and goals identified by the HHA and the patient;

(xv) Information related to any advanced directives; and

(xvi) Any additional items the HHA or physician *or allowed practitioner* may choose to include.

Interpretive Guidelines §484.60(a)(2)

A detailed, individualized plan of care is critical to both the quality and safety of patient care and therefore each of the required elements must be included.

- *In general, pertinent diagnoses include, but are not limited to, the chief reason the patient is receiving home care and the diagnosis most related to the current home health plan of care. Additionally, comorbid conditions that exist at the time of the assessment, that are actively addressed in the patient's Plan of Care, or that have the potential to affect the patient's responsiveness to treatment and rehabilitative prognosis should be considered and documented.*

- Mental status is generally screened by asking the patient questions on orientation to time, place and person.

- Psychosocial status, as relevant to the patient's plan of care, may include but is not limited to, interpersonal relationships in the immediate family, financial status,

homemaker/household needs, vocational rehabilitation needs, family social problems and transportation needs.

- *In general, the plan of care should list the required supplies and equipment which are non-routine and medically necessary for the patient's care. Examples include, but are not limited to, shower chairs, catheters, tube feeding supplies, and ostomy bags.*

G576
(Rev.)

§484.60(a)(3) All patient care orders, including verbal orders, must be recorded in the plan of care.

Interpretive Guidelines §484.60(a)(3)

All patient care orders, including verbal orders are part of the plan of care. *The plan of care may include orders for treatment or services received from physicians other than the responsible physician.* The plan should be revised to reflect any verbal order received during the 60-day certification period so that all HHA staff are working from a current plan. It is not necessary for the physician *or allowed practitioner* to sign an updated plan of care until the patient is recertified to continue care and the plan of care is updated to reflect all current ongoing orders including any verbal orders received during the 60-day period.

NOTE: Pulse oximetry is a ubiquitous assessment tool, often used as a part of routine vital signs across health care providers. Routine monitoring of vital signs, including pulse oximetry, do not require a physician order.

G580
(Rev.)

§484.60(b) *Standard: Conformance with the physician or allowed practitioner orders.*

(1) Drugs, services, and treatments are administered only as ordered by a physician *or allowed practitioner*.

Interpretive Guidelines §484.60(b)(1)

Drugs, services and treatments *must be administered in accordance with the orders of a* physician *or allowed practitioner* that establishes and periodically reviews the plan of care. See *also* §484.60(a)(1).

G582
(Rev.)

§484.60(b)(2) Influenza and pneumococcal vaccines may be administered per agency policy developed in consultation with a physician, *physician assistant, nurse practitioner, or clinical nurse specialist,* and after an assessment of the patient to determine for contraindications.

Interpretive Guidelines §484.60(b)(2)

The HHA, in consultation with a physician, *physician assistant, nurse practitioner, or clinical nurse specialist* must develop a written policy that addresses vaccination screening for safety exclusions and assessing contraindications prior to administration of a vaccine, as well as written policies and procedures that address vaccine administration, including managing adverse reactions. No individual physician *or allowed practitioner* order is required for a vaccine. The administration of these vaccines is an exception to §484.60(b)(1).

G584
(Rev.)

§484.60(b)(3) Verbal orders must be accepted only by personnel authorized to do so by applicable state laws and regulations and by the HHA's internal policies.

§484.60(b)(4) When services are provided on the basis of a physician *or allowed practitioner's* verbal orders, a nurse acting in accordance with state licensure requirements, or other qualified practitioner responsible for furnishing or supervising the ordered services, in accordance with state law and the HHA's policies, must document the orders in the patient's clinical record, and sign, date, and time the orders. Verbal orders must be authenticated and dated by the physician *or allowed practitioner* in accordance with applicable state laws and regulations, as well as the HHA's internal policies.

Interpretive Guidelines §484.60(b)(4)

When services are furnished based on a physician *or allowed practitioner*'s verbal order, the order must be put into writing by personnel authorized to do so by applicable state laws as well as by the HHA's internal policies. The orders must be signed and dated with the date of receipt by the nurse or qualified therapist (i.e., physical therapist, speech-language pathologist, occupational therapist, or medical social worker) responsible for furnishing or supervising the ordered services.

In the absence of a state requirement, the HHA should establish a timeframe for physician *or allowed practitioner* authentication, i.e. for obtaining a physician *or allowed practitioner* signature for verbal/telephone orders received. The signature may be written or in electronic form following the requirements of the particular system. A method must be established to identify the signer.

When verbal orders are added to the plan of care, it is not necessary for the physician or allowed practitioner to sign an updated plan of care until the patient is recertified. However, all

verbal orders must be authenticated and dated by the physician or allowed practitioner in accordance with applicable state laws and regulations, as well as the HHA's internal policies.

G588
(Rev.)

§484.60(c) Standard: Review and revision of the plan of care.

(1) The individualized plan of care must be reviewed and revised by the physician *or allowed practitioner* who is responsible for the home health plan of care and the HHA as frequently as the patient's condition or needs require, but no less frequently than once every 60 days, beginning with the start of care date. . . .

Interpretive Guidelines §484.60(c)(1)

See Tag G590 for Interpretive Guidelines for §484.60(c)(1).

G590
(Rev.)

§484.60(c)(1)
. . . The HHA must promptly alert the relevant physician(s) *or allowed practitioner(s)* to any changes in the patient's condition or needs that suggest that outcomes are not being achieved and/or that the plan of care should be altered.

Interpretive Guidelines §484.60(c)(1) *(Tags G588 and G590)*

For "responsible physician" see §484.60(a)(1).

The signature and date of the review by the responsible physician *or allowed practitioner* verifies the interval between plan of care reviews.

In the event of a change in patient condition or needs that suggest outcomes are not being achieved and/or that the patient's plan of care should be altered, the HHA should notify both the responsible physician *or allowed practitioner* and the physician(s) *or allowed practitioner(s)* associated with the relevant aspect of care.

Changes in physician *or allowed practitioner* orders during the plan of care certification period do not automatically restart the timeframe for physician *or allowed practitioner* review of the plan of care.

G592
(Rev.)

§484.60(c)(2) A revised plan of care must reflect current information from the patient's updated comprehensive assessment, and contain information concerning the patient's progress toward the measurable outcomes and goals identified by the HHA and patient in the plan of care.

Survey Procedures §484.60(c)(2)

The clinical record should demonstrate that patients are assessed throughout the episode of care to assure that HHA services meet the needs of the patient; changes in a patient's status are consistently communicated; and the plan of care is updated as needed.

G594
(Rev.)

§484.60(c)(3) Revisions to the plan of care must be communicated as follows:

Survey Procedures §484.60(c)(3)

Ask the HHA to explain how changes to the plan of care are consistently communicated and verify through record review that communications occur.

G596
(Rev.)

§484.60(c)(3)(i) Any revision to the plan of care due to a change in patient health status must be communicated to the patient, representative (if any), caregiver, and all physicians *or allowed practitioners* issuing orders for the HHA plan of care.

Interpretive Guidelines §484.60(c)(3)(i)

There must be evidence in the clinical record that the HHA explained to the patient that a change to the plan of care has occurred and how the change will impact the care delivered by the HHA. The clinical record must also document that the revised plan of care was shared with all relevant physicians *or allowed practitioners* providing care to the patient.

G598
(Rev.)

§484.60(c)(3)(ii) Any revisions related to plans for the patient's discharge must be communicated to the patient, representative, caregiver, all physicians *or allowed practitioners* issuing orders for the HHA plan of care, and the patient's primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA (if any).

Interpretive Guidelines §484.60(c)(3)(ii)

Discharge planning begins early in the provision of care and must be revised as the patient's condition or life circumstances change. There must be evidence in the clinical record that the HHA discussed any such changes with the patient, his or her representative (if any) and the responsible physician *or allowed practitioner*. Other physicians *or allowed practitioner(s)* who contributed orders to the patient's plan of care must also be notified of changes to the patient's discharge plan

G602
(Rev.)

§484.60(d) Standard: Coordination of Care. The HHA must:

(1) Assure communication with all physicians *or allowed practitioners* involved in the plan of care.

Interpretive Guidelines §484.60(d)(1)

The physician *or allowed practitioner* who initiated home health care is responsible for the ongoing plan of care; however, to assure the development and implementation of a coordinated plan of care, HHA communication with all physicians *or allowed practitioner* involved in the patient's care is often necessary. While a patient may see several physicians *or allowed practitioner(s)* for various medical problems, not all the physicians *or allowed practitioner(s)* would necessarily be involved in the skilled services defined in the patient's home health plan of care. *Regarding* this requirement, "physicians *or allowed practitioners* involved in the plan of care" means those physicians *or allowed practitioners* who give orders that are directly related to home health skilled services.

G604
(Rev.)

§484.60(d)(2) Integrate orders from all physicians *or allowed practitioners* involved in the plan of care to assure the coordination of all services and interventions provided to the patient.

Interpretive Guidelines §484.60(d)(2)

The clinical manager or other staff designated by the HHA is responsible for integrating orders from all relevant physicians *or allowed practitioners* involved into the HHA plan of care and ensuring the orders are approved by the responsible physician *or allowed practitioner*.

G606
(Rev.)

§484.60(d)(3) Integrate services, whether services are provided directly or under arrangement, to assure the identification of patient needs and factors that could affect patient safety and treatment effectiveness and the coordination of care provided by all disciplines.

Interpretive Guidelines §484.60(d)(3)

The HHA must integrate services provided by various disciplines by:

- Managing the scheduling of patients, taking into consideration the type of services that are being provided on a given day. For example, a patient may become fatigued after a HH aide visit assisting with a bath, thus making a physical therapy session scheduled for directly after the HH aide visit less effective.
- Managing pain during physical therapy or physical care (i.e. dressing changes or wound care) to minimize patient discomfort while maximizing the effectiveness of the therapy session.
- Working with the patient to recommend and make safety modifications in the home.
- Assuring that staff who provide care are communicating any patient concerns and patient progress toward the goals identified in the plan of care with others involved in the patient's care.

G608
(Rev.)

§484.60(d)(4) Coordinate care delivery to meet the patient's needs, and involve the patient, representative (if any), and caregiver(s), as appropriate, in the coordination of care activities.

Survey Procedures §484.60(d)(4)

Determine through interview if the patient, representative, and caregiver, as applicable and appropriate, are involved in care coordination. For example, were individual schedules considered and accommodated as able?

G610
(Rev.)

§484.60(d)(5) Ensure that each patient, and his or her caregiver(s) where applicable, receive ongoing education and training provided by the HHA, as appropriate, regarding the care and services identified in the plan of care. The HHA must provide training, as necessary, to ensure a timely discharge.

Interpretive Guidelines §484.60(d)(5)

The comprehensive assessment, patient-centered plan of care and the goals identified therein inform the training and education objectives for each patient. The goals of the HHA episode are established at admission and revised as indicated by the patient's condition. With the discharge plan clearly identified, patient education and documentation of the patient response to the education begins upon admission and continues throughout the provision of HHA services. The HHA must monitor patient and caregiver responses to and comprehension of any training provided.

Survey Procedures §484.60(d)(5)

If education was conducted, did the HHA staff provide education and training to the patient and any caregivers, when appropriate, and according to the plan of care? Look for evidence that the education was conducted by reviewing the written information in the patient's home and/or interviewing the patient and HHA staff.

G612
(Rev.)

§484.60(e) Standard: Written information to the patient.

The HHA must provide the patient and caregiver with a copy of written instructions outlining:

Interpretive Guidelines §484.60(e)

The documents listed in (e)(1)-(5) must be provided to the patient and/or their his/her caregiver and representative (if any) no later than the next visit after the plan of care has been approved by the physician *or allowed practitioner*. The written information should be updated as the plan of care changes. Clear written communication between the HHA and the patient and the patient's caregiver and representative (if any) helps ensure that patients and families understand what services to expect from the HHA, the purpose of each service and when to expect the services.

G614
(Rev.)

[The HHA must provide the patient and caregiver with a copy of written instructions outlining…]

§484.60(e)(1) Visit schedule, including frequency of visits by HHA personnel and personnel acting on behalf of the HHA.

Interpretive Guidelines §484.60(e)(1)

The HHA must ensure that the written visit schedule provided to the patient is consistent with the patient's most current plan of care.

G616
(Rev.)

[The HHA must provide the patient and caregiver with a copy of written instructions outlining…]

§484.60(e)(2) Patient medication schedule/instructions, including: medication name, dosage and frequency and which medications will be administered by HHA personnel and personnel acting on behalf of the HHA.

Interpretive Guidelines §484.60(e)(2)

The HHA must prepare, and provide to the patient and his or her caregiver (if any) written information regarding the patient's medication regimen as based on the results of the medication review conducted at §484.55(c)(5). The medication administration instructions must be written in plain language that does not use medical abbreviations.

The HHA must provide this information to the patient regardless of whether the patient is receiving only rehabilitation therapy services. See §484.55(c)(5) for communication between the therapist and the HHA nurse regarding medications.

Survey Procedures §484.60(e)(2)

Review the most current medication list that the HHA personnel provided to the patient. Determine if the medications match those listed in the comprehensive assessment, the plan of care, and the written information to the patient. Investigate any discrepancies for additions or deletions to the medications since the information was last updated by the HHA.

G618
(Rev.)

[The HHA must provide the patient and caregiver with a copy of written instructions outlining…]

§484.60(e)(3) Any treatments to be administered by HHA personnel and personnel acting on behalf of the HHA, including therapy services.

G620
(Rev.)

[The HHA must provide the patient and caregiver with a copy of written instructions outlining…]

§484.60(e)(4) Any other pertinent instruction related to the patient's care and treatments that the HHA will provide, specific to the patient's care needs.

G622
(Rev.)

[The HHA must provide the patient and caregiver with a copy of written instructions outlining…]

§484.60(e)(5) Name and contact information of the HHA clinical manager.

Interpretive Guidelines §484.60(e)(5)

The name and contact information of the HHA's clinical manager, including the clinical manager's telephone number and, if the patient prefers electronic communication, e-mail, must be provided to the patient. The HHA explains to the patient when the clinical manager should be contacted for discussion about their services.

G640
(Rev.)

§484.65 Condition of participation: Quality assessment and performance improvement (QAPI).

The HHA must develop, implement, evaluate, and maintain an effective, ongoing, HHA-wide, data-driven QAPI program. The HHA's governing body must ensure that the program reflects the complexity of its organization and services; involves all HHA services (including those services provided under contract or arrangement); focuses on indicators related to improved outcomes, including the use of emergent care services, hospital admissions and re-admissions; and takes actions that address the HHA's performance across the spectrum of care, including the prevention and reduction of medical errors. The HHA must maintain documentary evidence of its QAPI program and be able to demonstrate its operation to CMS.

Interpretive Guidelines § 484.65

The manner and degree of noncompliance identified in relation to the standard level tags for §484.65 may result in substantial noncompliance with this CoP, requiring citation at the condition level.

G642
(Rev.)

§484.65(a) Standard: Program scope.

(1) The program must at least be capable of showing measurable improvement in indicators for which there is evidence that improvement in those indicators will improve health outcomes, patient safety, and quality of care.

(2) The HHA must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that enable the HHA to assess processes of care, HHA services, and operations.

Interpretive Guidelines §484.65(a)

The HHA selects the indicators that it will utilize in its QAPI program based upon identified adverse or negative patient outcomes or agency processes that the HHA wishes to monitor and measure. Each indicator must be measurable through data to evaluate any HHA change in procedure, policy or intervention.

The HHA QAPI program must include procedures for measurement and analysis of indicators and address the frequency with which such measurement and analysis will occur.

Per §484.70(b) the HHA must maintain a coordinated agency-wide program for the surveillance, investigation, identification, prevention, control and investigation of infectious and communicable diseases as an integral part of the QAPI program.

G644

(Rev.)

§484.65(b) Standard: Program data.

(1) The program must utilize quality indicator data, including measures derived from OASIS, where applicable, and other relevant data, in the design of its program.

(2) The HHA must use the data collected to-

(i) Monitor the effectiveness and safety of services and quality of care; and

(ii) Identify opportunities for improvement.

(3) The frequency and detail of the data collection must be approved by the HHA's governing body.

Interpretive Guidelines §484.65(b)(1)-(3)

HHAs seeking initial enrollment in the Medicare program are unlikely to have collected extensive data for their QAPI program indicators, since they likely have been in operation for a relatively brief time. Nevertheless, these initial applicants must have a QAPI program in place, and must be able to describe how the program functions, including which indicators/measures are being tracked, at what intervals, and how the information will be used by the HHA to improve quality and safety.

G646

(Rev.)

§484.65(c) Standard: Program activities.

(1) The HHA's performance improvement activities must—

(i) Focus on high risk, high volume, or problem-prone areas;
(ii) Consider incidence, prevalence, and severity of problems in those areas; and
(iii) Lead to an immediate correction of any identified problem that directly or potentially threaten the health and safety of patients.

Interpretive Guidelines §484.65(c)(1)

"High risk" areas may include global concerns such as a type of service (e.g., pediatrics), geographic concerns (e.g., safety of a neighborhood served); or specific patient care services (e.g., administration of intravenous medications or tracheostomy care). All factors would be associated with significant risk to the health or safety of patients.

"High volume" areas refers to care or service areas that are frequently provided by the HHA to a large patient population, thus possibly increasing the scope of the problem (e.g. laboratory testing, physical therapy, infusion therapy, diabetes management).

"Problem-prone" areas refer to care or service areas that have the potential for negative outcomes and that are associated with a diagnosis or condition for a particular patient group or a particular component of the HHA operation or historical problem areas.

G654

(Rev.)

§484.65(c)(2) Performance improvement activities must track adverse patient events, analyze their causes, and implement preventive actions.

Interpretive Guidelines §484.65(c)(2)

"Adverse patient events" are those patient events that are negative and unexpected, impact a patient's HHA plan of care, and have the potential to cause a decline in a patient's condition.

HHAs must track all adverse patient events, to determine through subsequent analysis whether they were the result of errors that should have been preventable, to reduce the likelihood of such events in the future. HHAs should also consider a way to identify errors that result in near misses, since such errors have the potential to cause future adverse events.

G656

(Rev.)

§484.65(c)(3) The HHA must take actions aimed at performance improvement, and, after implementing those actions, the HHA must measure its success and track performance to ensure that improvements are sustained.

G658
(Rev.)

§484.65(d) Standard: Performance improvement projects.

Beginning January 13, 2018 HHAs must conduct performance improvement projects.

> **(1) The number and scope of distinct improvement projects conducted annually must reflect the scope, complexity, and past performance of the HHA's services and operations.**
>
> **(2) The HHA must document the quality improvement projects undertaken, the reasons for conducting these projects, and the measurable progress achieved on these projects.**

Interpretive Guidelines §484.65(d)

The HHA should have at least one performance improvement project either in development, on-going or completed each calendar year.

The HHA decides, based on the QAPI program activities and data, what projects are indicated and the priority of the projects.

Survey Procedures §484.65(d)

• Ask the HHA to show you documentation for performance improvement projects currently underway, as well as those completed in the prior year.

• Does the HHA's documentation indicate the rationale for undertaking each project? Does the HHA have data indicating it had a problem in the area targeted for improvement, or could the HHA point to recommendations from a nationally recognized expert organization suggesting the activities?

• Does the documentation for the completed project(s) include the project's results? If a project was unsuccessful, ask the HHA what actions it took because of that information. If the project was successful, ask the HHA how it is sustaining the improvement.

G660
(Rev.)

§484.65(e) Standard: Executive responsibilities.

The HHA's governing body is responsible for ensuring the following:

(1) That an ongoing program for quality improvement and patient safety is defined, implemented, and maintained;

(2) That the HHA-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety, and that all improvement actions are evaluated for effectiveness;

(3) That clear expectations for patient safety are established, implemented, and maintained; and

(4) That any findings of fraud or waste are appropriately addressed.

Interpretive Guidelines §484.65(e)(1)-(4)

The governing body must assume overall responsibility for ensuring that the QAPI program reflects the complexity of the HHA and its services, involves all services (including those provided under contract or arrangement), focuses on indicators related to improved outcomes, and takes actions that address the HHA's performance across the spectrum of care. Additionally, the HHA's governing body must appropriately address any findings of fraud or waste in order to assure that resources are appropriately used for patient care activities and that patients are receiving the right care to meet their needs (82 FR 4504, 4510, 4561 (Jan. 13, 2017)). If the HHA identifies or otherwise learns of an action by an HHA employee, contractor or responsible or relevant physician *or allowed practitioner* that may be illegal, the HHA *should* report the action to the appropriate authorities in accordance with applicable law.

Survey Procedures §484.65(e)(1)-(4)

- *Ask the HHA for information about its governing body. If there are questions about who constitutes the HHA's governing body, it may help to review the information the HHA reported on its CMS Form 855A application, identifying those individuals with ownership interest or managing control of the HHA.*

- *Ask to see meeting minutes or other evidence of how the governing body exercises ongoing oversight of and accountability for the HHA's QAPI program.*

G680
(Rev.)

§484.70 Condition of participation: Infection prevention and control.

The HHA must maintain and document an infection control program which has as its goal the prevention and control of infections and communicable diseases.

Interpretive Guidelines § 484.70

The home health setting presents unique challenges for infection control, because: care is delivered in the home environment, not a structured facility; sterile supplies are transported by staff and may need to be stored and protected in the home; and patients may not have access to basic hygiene necessities in their home. It is essential that HHAs have a comprehensive and effective infection control program, because the consequences of poor infection prevention and control can be very serious.

The manner and degree of noncompliance identified in relation to the standard level tags for §484.70 may result in substantial noncompliance with this CoP, requiring citation at the condition level.

Survey Procedures § 484.70

- *Surveyors will focus their observation of infection control practices by the HHA during home visits.*
- *Determine whether the policies and procedures of the HHA's infection control program are implemented correctly based on observations of care.*
- *Determine that there is an ongoing, documented program for the prevention and control of infections and communicable diseases among patients and HHA personnel.*

G682
(Rev.)

§484.70(a) Standard: Prevention

The HHA must follow accepted standards of practice, including the use of standard precautions, to prevent the transmission of infections and communicable diseases.

Interpretive Guidelines §484.70(a)

Federal and state agencies such as the Centers for Disease Control and Prevention (CDC) and state departments of health, national professional organizations, have all developed infection prevention and control standards of practice. Examples of national organizations that promulgate nationally recognized infection and communicable disease control guidelines, and/or recommendations include: the CDC, the Association for Professionals in Infection Control and Epidemiology (APIC), and the Society for Healthcare Epidemiology of America (SHEA). An HHA should identify the source of the standards it selects and be capable of explaining why those standards were chosen for incorporation into the HHA's infection prevention and control program (82 FR 4543).

Standard precautions must be used to prevent transmission of infectious agents. "Standard precautions" are a group of infection practices that apply to all patients regardless of suspected or confirmed infection status at the time health care is delivered. *These practices protect*

healthcare personnel and prevent healthcare personnel or the environment from transmitting infections to patients.

*For example, t*he following are six (6) *core practices*, identified by the *CDC are based on the CDC's "Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings –Recommendations of The Healthcare Infection Control Practices Advisory Committee (HICPAC),*[3] *which is periodically updated. These are a core set of infection prevention and control practices that are recommended in all healthcare settings, regardless of the type of healthcare provided. Also, refer to "Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care" published by the National Center for Emerging and Zoonotic Infectious Diseases Division of Healthcare Quality Promotion, Version 2.3.*

1. Hand Hygiene

HHAs and surveyors are advised to review the most current CDC's hand hygiene recommendations for correct procedures. Hand Hygiene should be performed:

• Before *and after* contact with a patient;
• Before performing an aseptic task (e.g., insertion of IV, preparing an injection, performing wound care);
• After contact with blood, body fluids or contaminated surfaces;
• *After contact with the patient's immediate environment;*
• *When* moving from a contaminated body site to a clean body site during patient care; and
• After removal of personal protective equipment *(e.g., gloves, gown, facemask).*

The term "hand hygiene" includes both handwashing with either plain or antiseptic- containing soap and water, and use of alcohol-based products (gels, rinses, foams) that do not require the use of water. In the absence of visible soiling of hands, approved alcohol-based products for hand disinfection are preferred over antimicrobial or plain soap and water because of their superior microbiocidal activity, reduced drying of the skin, and convenience. The HHA must ensure that supplies necessary for adherence to hand hygiene are provided.

2. Environmental cleaning and disinfection

Environmental cleaning and disinfection presents a unique challenge for HHA personnel. The HHA staff have little control over the home environment but must *protect their equipment and supplies during the home visit. Examples of how this might be accomplished include but are not limited to: Cleaning and disinfecting or placing a clean barrier on the surface in the home where clean equipment will be placed and/or preparation of injectable medications will be performed. Additionally, items that are taken from one home to another should be cleaned and disinfected in accordance with accepted standards of practice, which include manufacturer's instructions for use.*

[3] *https://www.cdc.gov/hicpac/pdf/core-practices.pdf.*

3. Injection and Medication Safety

Safe injection practices include but are not limited to:

• Use of aseptic technique when preparing and administering medications;
• Not reusing needles, lancets, *lancet holding devices,* or syringes for more than one use on one patient; using single-dose vials for parenteral medications whenever possible;
• Not administering medications from a single-dose vial or ampule to multiple patients;
• Use of fluid infusion and administration sets (i.e., intravenous bags, tubing and connectors) for one patient only and disposal appropriately after use;
• Considering a syringe or needle/cannula contaminated once it has been used to enter or connect to patient's intravenous infusion bag or administration set;
• Entering medication containers with a new needle and a new syringe even when obtaining additional doses for the same patient;
• Insulin pens *are* dedicated for a single patient and never shared even if the needle is changed; and,
• Sharps disposal *complies with* applicable state and local laws and regulations.

4. Appropriate Use of Personal Protective Equipment

Appropriate Use of Personal Protective Equipment (PPE) is the use of specialized clothing or equipment worn for protection and as a barrier against infectious materials or any potential infectious exposure. PPE protects the caregiver's skin, hands, face, respiratory tract, and/or clothing from exposure. Examples of PPE include: gloves, gowns, face *protection (facemask and goggles or face shields).* The selection *and use* of PPE *is determined by the nature of patient interaction and potential for exposure to blood, body fluids and/or* infectious materials.

5. Minimizing Potential Exposures

Minimizing Potential Exposures in the home health setting *focuses* on prevention of *reducing the* exposure *and transmission of respiratory infections.* HHA staff *should also be careful to minimize potential exposures to infectious agents* while transporting medical specimens and medical waste, such as sharps.

6. Reprocessing, Storage, Transport, and Usage/Operation of Equipment or Devices Used for Patient Care

Cleaning and disinfecting of medical equipment is essential. *Staff should follow the manufacturer's instructions for reprocessing (i.e., cleaning and disinfection or cleaning and sterilization) and use and current standards of practice for transport and storage of patient care equipment. Single-use equipment is discarded after use according to the manufacturer's instructions for proper disposal.* Reusable medical equipment (e.g., blood glucose meters and *other point-of-care meters*, blood pressure cuffs, oximeter probes) *are reprocessed* prior to use on another patient and when soiled. The HHA must ensure that HHA staff are trained to maintain separation between clean and soiled equipment to prevent cross contamination *in the patient care environment and during transport*.

G684
(Rev.)

§484.70(b) Standard: Control.

The HHA must maintain a coordinated agency-wide program for the surveillance, identification, prevention, control, and investigation of infectious and communicable diseases that is an integral part of the HHA's quality assessment and performance improvement (QAPI) program. The infection control program must include:

Interpretive Guidelines §484.70(b)

The HHA should have a program for the surveillance, identification, prevention, control and investigation of infectious and communicable diseases specific to care and services provided in the home setting. The CDC defines surveillance as "the ongoing, systematic collection, analysis, interpretation and evaluation of health data closely integrated with the timely dissemination of this data to those who need it."

As part of its infection control program the HHA should: (1) observe and evaluate services from all disciplines to identify sources or causative factors of infection, track patterns and trends of infections; and (2) establish a corrective plan for infection control (if appropriate) and monitor the effectiveness of the corrective plan. Cross Reference to §484.65(a), QAPI Program Scope.

§484.70(b)(1) A method for identifying infectious and communicable disease problems; and

Interpretive Guidelines §484.70(b)(1)

The HHA must develop a procedure for the identification of infections or risk of infections among patients. It is the prerogative of the HHA to determine the methodology to be used for such identification. Example methodologies include, but are not limited to:

- Clinical record review;
- Staff reporting procedures;
- Review of laboratory results;
- Data analysis of physician *or allowed practitioner* and emergency room visits for symptoms of infection; and
- Identification of root cause of infection through evaluation of HHA personnel technique and self-care technique by patients or caregivers.

Analysis of surveillance data should be used to improve care practices and control infections and transmission of communicable diseases.

While not required by the regulation, CMS suggests HHAs have a way to receive alerts from the CDC Health Alert Network or local public health network as a means of staying up to date with

alerts and information related to public health incidents (as seen with the 2019 Novel Coronavirus public health emergency).

§484.70(b)(2) A plan for the appropriate actions that are expected to result in improvement and disease prevention.

Interpretive Guidelines §484.70(b)(2)

The HHA must develop a*n* action plan to address or prevent infections or transmission of communicable diseases. Such plan should be based on surveillance findings, any identified root cause of infection or disease transmission, tracking data and analysis of data findings.

Actions to facilitate improvements and disease prevention may include the following:
• Policy, procedure or practice changes to improve care;
• Education for patients, caregivers, and HHA personnel to prevent infections and transmission of communicable diseases; and
• The development of process or outcome measures which could be used to monitor and address identified issues (e.g., infection prevention and control observations for technique).

The HHA must evaluate and revise the plan as needed.

G686
(Rev.)

§484.70(c) Standard: Education.

The HHA must provide infection control education to staff, patients, and caregiver(s).

Interpretive Guidelines §484.70(c)

The regulation does not specify the form or content of education regarding infection prevention and control. However, in accordance with requirements under §484.60, patients and caregivers must be provided with education and training specific to the individualized plan of care. HHAs should also take into consideration the patient's and caregiver(s)' health conditions and individual learning needs. The HHA should review training information with the patient and his or her representative (if any), including information on how to clean and care for equipment (e.g., blood glucose meters or reusable catheters), at sufficient intervals to reinforce comprehension of the training.

Additionally, HHAs must provide infection control education to staff.

HHA staff infection control education should include the following:

• Information on appropriate use, transport, storage, and cleaning methods of patient care equipment according to manufacturer guidelines*/instructions for use*;

• Job-specific, infection prevention education and training to all health care personnel for all of their respective tasks;
• Processes to ensure that all health care personnel understand and are competent to adhere to infection prevention requirements as they perform their roles and responsibilities;
• Written infection prevention policies and procedures that are widely available, current, and based on current standards of practice;
• Training before individuals are allowed to perform their duties and periodic refresher training as designated by HHA policy;
• Additional training in response to recognized lapses in adherence and to address newly recognized infection transmission threats (e.g., introduction of new equipment or procedures);
• Infection control education provided to staff at periodic intervals consistent with accepted standards of practice. Such education must be provided at orientation, annually, and as needed to meet the staff's learning needs to provide adequate care; identify infection signs and symptoms; identify routes of infection transmission; appropriately disinfect/sanitize/transport equipment and devices used for patient care; and use proper medical waste disposal techniques. Such education must include instructions on how to implement current infection prevention/treatment practices in the home setting.

Survey Procedures §484.70(c)

- *Review the clinical record for evidence of patient/caregiver infection control education pertinent to the patient's condition and per the plan of care (see also §484.60).*

- *Ask the staff what training they received in infection control. Based on interview responses, follow up through HHA policy review and training records to ensure evidence of compliance.*

G700
(Rev.)

§484.75 Condition of participation: Skilled professional services.

Skilled professional services include skilled nursing services, physical therapy, speech-language pathology services, and occupational therapy, as specified in §409.44 of this chapter, and physician *or allowed practitioner* and medical social work services as specified in §409.45 of this chapter. Skilled professionals who provide services to HHA patients directly or under arrangement must participate in the coordination of care.

Interpretive Guidelines § 484.75

The manner and degree of noncompliance identified in relation to the standard level tags for §484.75 may result in substantial noncompliance with this CoP, requiring citation at the condition level.

G702
(Rev.)

§484.75(a) Standard: Provision of services by skilled professionals.

Skilled professional services are authorized, delivered, and supervised only by health care professionals who meet the appropriate qualifications specified under §484.115 and who practice according to the HHA's policies and procedures.

G704
(Rev.)

§484.75(b) Standard: Responsibilities of skilled professionals.

Skilled professionals must assume responsibility for, but not be restricted to, the following:

G706
(Rev.)

[§484.75(b) Standard: Responsibilities of skilled professionals. Skilled professionals must assume responsibility for, but not be restricted to, the following:]

(1) Ongoing interdisciplinary assessment of the patient;

Interpretive Guidelines §484.75(b)(1)

The term "interdisciplinary" refers to an approach to healthcare that includes a range of health service workers.

"Ongoing interdisciplinary assessment" is the continual involvement of all skilled professional staff involved in a patient's plan of care from the initial assessment through discharge, which should include periodic discussions among the team regarding the patient's health status and recommendations for the plan of care.

An interdisciplinary approach recognizes the contributions of various health care disciplines (MDs, RNs, *Licensed Practical/Vocational Nurses (*LPN/LVN*),* PT, OT, SLP, *Master of Social Work (*MSW*)*, HH aides) and their interactions with each other to meet the patient's needs.

G708
(Rev.)

[§484.75(b) Standard: Responsibilities of skilled professionals. Skilled professionals must assume responsibility for, but not be restricted to, the following:]

(2) Development and evaluation of the plan of care in partnership with the patient, representative (if any), and caregiver(s);

G710
(Rev.)

[§484.75(b) Standard: Responsibilities of skilled professionals. Skilled professionals must assume responsibility for, but not be restricted to, the following:]

(3) Providing services that are ordered by the physician *or allowed practitioner* as indicated in the plan of care;

G712
(Rev.)

[§484.75(b) Standard: Responsibilities of skilled professionals. Skilled professionals must assume responsibility for, but not be restricted to, the following:]

(4) Patient, caregiver, and family counseling;

Survey Procedures §484.75(b)(4)

Home visit observations with direct care observation and patient interview should assist in determining compliance with this requirement. The clinical record should reflect the education and counseling provided by skilled professionals to the patient, caregiver, and family (see also §484.75(b)(5)).

G714
(Rev.)

[§484.75(b) Standard: Responsibilities of skilled professionals. Skilled professionals must assume responsibility for, but not be restricted to, the following:]

(5) Patient and caregiver education;

Survey Procedures §484.75(b)(5)

Home visit observations with direct care observation and patient interview should assist in determining compliance with this requirement. The clinical record should reflect the education and counseling provided by skilled professionals to the patient, caregiver, and family (see also §484.75(b)(4)).

G716
(Rev.)

[§484.75(b) Standard: Responsibilities of skilled professionals. Skilled professionals must assume responsibility for, but not be restricted to, the following:]

(6) Preparing clinical notes;

G718
(Rev.)

[§484.75(b) Standard: Responsibilities of skilled professionals. Skilled professionals must assume responsibility for, but not be restricted to, the following:]

(7) Communication with all physicians involved in the plan of care and other health care practitioners (as appropriate) related to the current plan of care;

G720
(Rev.)

[§484.75(b) Standard: Responsibilities of skilled professionals. Skilled professionals must assume responsibility for, but not be restricted to, the following:]

(8) Participation in the HHA's QAPI program; and

Interpretive Guidelines §484.75(b)(8)

All skilled professional staff must provide input into and participate in the implementation of the HHA's QAPI program for the QAPI program to be effective. Every HHA skilled professional, regardless of whether the skilled professional is a direct employee or contractor of the HHA, is expected to contribute to all phases of the QAPI program. These contributions may include: identification of problem areas; recommendations to address problem areas; data collection; attendance at periodic QAPI meetings; and participation in performance improvement projects.

G722
(Rev.)

[§484.75(b) Standard: Responsibilities of skilled professionals. Skilled professionals must assume responsibility for, but not be restricted to, the following:]

(9) Participation in HHA-sponsored in-service training.

G724
(Rev.)

§484.75(c) Standard: Supervision of skilled professional assistants.

Interpretive Guidelines §484.75(c)

Documentation in the clinical record should show how communication and oversight exist between the skilled professional and assistant regarding the patient's status, the patient's response to services furnished by the assistant, and the effectiveness of any written instructions provided by the skilled professional to the assistant.

Any specific written instructions by skilled professionals to assistants are based on treatments prescribed in the patient's plan of care, patient assessments by the skilled professional, and accepted standards of professional practice. The skilled professional must periodically evaluate the effectiveness of the services furnished by the assistant to ensure the patient's needs are met.

Survey Procedures §484.75(c)

Documentation in the clinical record should demonstrate evidence that the skilled professionals supervise professional assistants as per HHA policy. Supervision of the skilled assistants must be conducted by the same discipline as the skilled professional that developed the assistant's instructions. Look for evidence in the clinical record that the skilled professional remains active in the ongoing plan of care through periodic supervisory follow-up. Review clinical notes to verify that professional assistants adhere to the instructions established by the skilled professional and that they document the treatment and patient response to the treatment.

G726
(Rev.)

§484.75(c)(1) Nursing services are provided under the supervision of a registered nurse that meets the requirements of §484.115(k).

Interpretive Guidelines §484.75(c)(1)

The HHA should identify a registered nurse (RN) to supervise the care provided by licensed practical/vocational nurses (LPN/LVNs). *§484.115(k) requires the RN be a graduate of an approved school of professional nursing who is licensed in the state where practicing.*

The identified RN must in turn monitor and evaluate LPN/LVN performance in the provision of services, provision of treatments, patient education, communication with the RN, and data collection regarding the patient's status and health needs (as delegated by the RN). Only a registered nurse may perform comprehensive assessment, evaluations, care planning and discharge planning.

G728
(Rev.)

§484.75(c)(2) Rehabilitative therapy services are provided under the supervision of an occupational therapist or physical therapist that meets the requirements of §484.115(f) or (h), respectively.

Interpretive Guidelines §484.75(c)(2)

An assistant must be supervised by a skilled therapy professional for the assistant's respective therapy type. For example, only a physical therapist may supervise a physical therapist assistant and only an occupational therapist may supervise an occupational therapy assistant. The

applicable therapist should monitor and evaluate the therapy assistant's performance *regarding* provision of treatments, patient education, communication with the therapist, and data collection regarding the patient's status and health needs (as delegated by the therapist). Only the skilled therapist may perform comprehensive assessments, patient evaluations, care planning and discharge planning.

G730
(Rev.)

§484.75(c)(3) Medical social services are provided under the supervision of a social worker that meets the requirements of §484.115(m).

Interpretive Guidelines §484.75(c)(3)

Any social service provided by a social work assistant must be supervised by a social worker who has a master's degree or doctoral degree from a school of social work accredited by the Council on Social Work Education *and has 1 year of social work experience in a health care setting.*

G750
(Rev.)

§484.80 Condition of participation: Home health aide services.

All home health aide services must be provided by individuals who meet the personnel requirements specified in paragraph (a) of this section.

Interpretive Guidelines §484.80

The manner and degree of noncompliance identified in relation to the standard level tags for §484.80 may result in substantial noncompliance with this CoP, requiring citation at the condition level.

G754
(Rev.)

§484.80(a) Standard: Home health aide qualifications.

(1) A qualified home health aide is a person who has successfully completed:

> **(i) A training and competency evaluation program as specified in paragraphs (b) and (c) respectively of this section; or**
>
> **(ii) A competency evaluation program that meets the requirements of paragraph (c) of this section; or**

(iii)A nurse aide training and competency evaluation program approved by the state as meeting the requirements of §483.151 through §483.154 of this chapter, and is currently listed in good standing on the state nurse aide registry; or

(iv) The requirements of a state licensure program that meets the provisions of paragraphs (b) and (c) of this section.

Interpretive Guidelines §484.80(a)(1)

The regulation describes four methods by which a home health aide may become qualified:

- The candidate may successfully complete a training and competency evaluation program offered by an HHA (except by an HHA specified in §484.80(f)).

- The candidate may successfully complete a competency evaluation program only. The competency evaluation program must address all requirements in §484.80(c).

- A nurse aide who successfully completes a nurse aide training and competency evaluation program, and is found to be in good standing in the state nurse aide registry, is considered to have met the training and competency requirements for an HHA aide. See also 42 CFR Part 483, Subpart D for requirements for states and state agencies on Nurse Aide Training and Competency Evaluation.

- The candidate may successfully complete a State administered program that licenses or certifies HHA aides and that meets or exceeds the requirements under paragraphs (b) and (c) of this section.

The HHA is responsible for ensuring that any HHA aide (whether employed directly or under arrangement) who provides home health aide services for the HHA meets the provisions of this regulation.

Any state requirement regarding aide education, training, competency evaluations, or certification and supervision that is more stringent that the corresponding federal requirement takes precedence over the federal requirement. Likewise, any federal requirement that is more stringent than a corresponding state requirement takes precedence over the more lenient state requirement

G756
(Rev.)

§484.80(a)(2) A home health aide or nurse aide is not considered to have completed a program, as specified in paragraph (a)(1) of this section, if, since the individual's most recent completion of the program(s), there has been a continuous period of 24 consecutive months during which none of the services furnished by the individual as described in §409.40 of this chapter were for compensation. If there has been a 24 month lapse in

furnishing services for compensation, the individual must complete another program, as specified in paragraph (a)(1) of this section, before providing services.

Interpretive Guidelines §484.80(a)(2)

If an individual has a 24 consecutive month lapse in furnishing aide services for compensation, regardless of the circumstances surrounding the lapse, the aide will be required to complete a new training and competency evaluation program, or a competency evaluation program, prior to providing aide services on behalf of the HHA. Compensation as it relates to home health aide means monetary compensation, as set forth in section 1891(a)(3)(A) of the Act (as noted in 82 FR 4545 preamble discussion).

G760
(Rev.)

§484.80(b) Standard: Content and duration of home health aide classroom and supervised practical training.

(1) Home health aide training must include classroom and supervised practical training in a practicum laboratory or other setting in which the trainee demonstrates knowledge while providing services to an individual under the direct supervision of a registered nurse, or a licensed practical nurse who is under the supervision of a registered nurse. Classroom and supervised practical training must total at least 75 hours.

Interpretive Guidelines §484.80(b)(1)

Home health aide training must include classroom and supervised practical training in a practicum laboratory or other setting in which the trainee demonstrates knowledge while providing services to an individual under the direct supervision of a registered nurse, or a licensed practical nurse who is under the supervision of a registered nurse. Alternative formats for classroom training, such as online course material or internet based interactive formats are acceptable delivery methods for the classroom training. These alternative formats should also provide an interactive component that permits students to ask questions and receive responses related to the training.

G762
(Rev.)

[§484.80(b) Standard: Content and duration of home health aide classroom and supervised practical training.]

(2) A minimum of 16 hours of classroom training must precede a minimum of l6 hours of supervised practical training as part of the 75 hours.

G764
(Rev.)

[§484.80(b) Standard: Content and duration of home health aide classroom and supervised practical training.]

(3) A home health aide training program must address each of the following subject areas:

(i) Communication skills, including the ability to read, write, and verbally report clinical information to patients, representatives, and caregivers, as well as to other HHA staff.

(ii) Observation, reporting, and documentation of patient status and the care or service furnished.

(iii) Reading and recording temperature, pulse, and respiration.

(iv) Basic infection prevention and control procedures.

(v) Basic elements of body functioning and changes in body function that must be reported to an aide's supervisor.

(vi) Maintenance of a clean, safe, and healthy environment

(vii) Recognizing emergencies and the knowledge of instituting emergency procedures and their application.

(viii) The physical, emotional, and developmental needs of and ways to work with the populations served by the HHA, including the need for respect for the patient, his or her privacy, and his or her property.

(ix) Appropriate and safe techniques in performing personal hygiene and grooming tasks that include—

- **(A) Bed bath;**
- **(B) Sponge, tub, and shower bath;**
- **(C) Hair shampooing in sink, tub, and bed;**
- **(D) Nail and skin care;**
- **(E) Oral hygiene;**
- **(F) Toileting and elimination;**

(x) Safe transfer techniques and ambulation;

(xi) Normal range of motion and positioning;

(xii) Adequate nutrition and fluid intake;

(xiii) Recognizing and reporting changes in skin condition; and

(xiv) Any other task that the HHA may choose to have an aide perform as permitted under state law.

(xv) The HHA is responsible for training home health aides, as needed, for skills not covered in the basic checklist, as described in paragraph (b)(3)(ix) of this section.

Interpretive Guidelines §484.80(b)(3)

Two requirements were added to 484.80(b)(3) in 2017 (82 FR 4504) that must be included in HHA training beginning on January 13, 2018:

1. Communication skills in regard to the aide's ability to read, write, and verbally report clinical information to patients, representatives, and caregivers, as well as to other HHA staff; and
2. Recognizing and reporting changes in skin condition.

For individuals who met the qualification requirements for HHA aides prior to January 13, 2018, new training content in these requirements may be completed via in-service training.

G766
(Rev.)

[§484.80(b) Standard: Content and duration of home health aide classroom and supervised practical training.]

(b)(4) The HHA must maintain documentation that demonstrates that the requirements of this standard have been met.

Survey Procedures §484.80(b)(4)

When aide services are observed during the surveyor home visit, or are included in the patient sample, review documentation of the HHA aide competency testing for those home health aides to confirm that it was completed. The competency evaluation consists of those subject areas specified in §484.80(b)(3).

G768
(Rev.)

§484.80(c) Standard: Competency evaluation.

An individual may furnish home health services on behalf of an HHA only after that individual has successfully completed a competency evaluation program as described in this section.

Interpretive Guidelines §484.80(c)

The HHA may not allow an aide to provide services to patients independently until they have successfully completed competency testing either at that HHA or at another training facility and successful completion is verified through documentation provided by the applicant or the training facility.

§484.80(c)(1) The competency evaluation must address each of the subjects listed in paragraph (b)(3) of this section. Subject areas specified under paragraphs (b)(3)(i), (iii), (ix), (x), and (xi) of this section must be evaluated by observing an aide's performance of the task with a patient or pseudo-patient. The remaining subject areas may be evaluated through written examination, oral examination, or after observation of a home health aide with a patient, or with a pseudo-patient as part of a simulation.

Interpretive Guidelines §484.80(c)(1)

The following skills must be evaluated by observing the aide's performance while carrying out the task with a patient *or pseudo-patient*.

(i) Communication skills, including the ability to read, write, and verbally report clinical information to patients, representatives, and caregivers, as well as to other HHA staff;
(iii) Reading and recording temperature, pulse, and respiration;
(ix) Appropriate and safe techniques in performing personal hygiene and grooming tasks that include—
  (A) Bed bath;
  (B) Sponge, tub, and shower bath;
  (C) Hair shampooing in sink, tub, and bed;
  (D) Nail and skin care;
  (E) Oral hygiene;
  (F) Toileting and elimination;
(x) Safe transfer techniques and ambulation;
(xi) Normal range of motion and positioning.

In accordance with §484.80(c)(3), a registered nurse, in consultation with other skilled professionals (as appropriate), must observe the HHA aide candidate perform each of the tasks above in its entirety to confirm the competence of the candidate.

HHA aides who successfully completed a competency evaluation prior to January 13, 2018, do not need to repeat the portions of the competency evaluation required to be done while providing services to a patient under §§484.80 (b) (i), (iii), (ix), (x), and (xi). For all HHA aides who receive a competency evaluation after January 13, 2018, however, these skills must be tested while the aide is providing care to a patient *or pseudo-patient.* A p*seudo-patient is a person who*

is trained to participate in a role-play situation, or a computer-based mannequin device. A pseudo-patient must be capable of responding to and interacting with the home health aide trainee, and must be similar in characteristics to the primary patient population served by the HHA in key areas such as age, frailty, functional status, and cognitive status.

When pseudo-patients are used to test home health aide competency, the simulated environment must mimic the reality of the homecare environment, including environmental distractions and constraints that evoke or replicate substantial aspects of the real world in a fully interactive fashion, to assess proficiency in performing skills.

G770
(Rev.)

§484.80(c)(4) A home health aide is not considered competent in any task for which he or she is evaluated as unsatisfactory. An aide must not perform that task without direct supervision by a registered nurse until after he or she has received training in the task for which he or she was evaluated as "unsatisfactory," and has successfully completed a subsequent evaluation. A home health aide is not considered to have successfully passed a competency evaluation if the aide has an "unsatisfactory" rating in more than one of the required areas.

G772
(Rev.)

§484.80(c)(5) The HHA must maintain documentation which demonstrates that the requirements of this standard have been met.

Interpretive Guidelines §484.80(c)(5)

Documentation of competency must:

- Include a description of the competency evaluation program, including the qualifications of the instructors;
- Confirm that competency was determined by direct observation and the results of those observations;
- Distinguish between skills evaluated during patient care and those taught in a laboratory, e.g., skills evaluated through use of a volunteer or direct observation of patient care versus a skill lab demonstration; and
- Describe how additional skills beyond the basic skills listed at §484.80(b)(3) were taught and tested.

An HHA aide that is unable to provide the above documentation will be required to successfully complete a competency evaluation before providing care to patients *(§484.80(c)(4))*.

G774
(Rev.)

§484.80(d) Standard: In-service training.

A home health aide must receive at least l2 hours of in-service training during each 12-month period. In-service training may occur while an aide is furnishing care to a patient.

Interpretive Guidelines §484.80(d)

The annual 12 hours of in-service training is met for the 12 months following successful completion of an HHA aide training and competency evaluation, unless the HHA introduces a new procedure that would indicate the need for further HHA aide in-service training.

When conducting in-service training during patient care, the patient must first be informed of and consent to the training and be informed of how the training will be conducted; patient rights, respect for the patient's preferences, and potential for care disruption must always guide such training.

G776
(Rev.)

§484.80(d)(1) In-service training may be offered by any organization and must be supervised by a registered nurse.

Interpretive Guidelines §484.80(d)(1)

RN supervision means that the RN approves the content of and attends the in-service training to ensure the content is consistent with the HHA's policies and procedures. *It would be permissible for HHAs to use in-service education through another organization, if it is under the supervision of an RN (82 FR 4545).*

G778
(Rev.)

§484.80(d)(2) The HHA must maintain documentation that demonstrates the requirements of this standard have been met.

Survey Procedures §484.80(d)(2)

Review a sample of HHA personnel and training records to verify compliance.

G780
(Rev.)

§484.80(e) Standard: Qualifications for instructors conducting classroom and supervised practical training.

Classroom and supervised practical training must be performed by a registered nurse who possesses a minimum of 2 years nursing experience, at least 1 year of which must be in home health care, or by other individuals under the general supervision of the registered nurse.

Interpretive Guidelines §484.80(e)

The required 2 years of nursing experience for the RN instructor should be "hands on" clinical experience such as providing care and/or supervising nursing services or teaching nursing skills in an organized curriculum or in-service program. At least 1 year of experience must be in home health care.

"Other individuals" *who may help with home health aide training would include health care professionals such as*:

- *Physicians;*
- Physical therapists;
- Occupational therapists;
- Speech-language pathologists;
- Medical social workers,
- LPN/LVNs; and
- Nutritionists.

G782
(Rev.)

§484.80(f) Standard: Eligible training and competency evaluation organizations.

A home health aide training program and competency evaluation program may be offered by any organization except by an HHA that, within the previous 2 years:

(1) Was out of compliance with the requirements of paragraphs (b), (c), (d), or (e) of this section; or

(2) Permitted an individual who does not meet the definition of a "qualified home health aide" as specified in paragraph (a) of this section to furnish home health aide services (with the exception of licensed health professionals and volunteers); or

(3) Was subjected to an extended (or partially extended) survey as a result of having been found to have furnished substandard care (or for other reasons as determined by CMS or the state); or

(4) Was assessed a civil monetary penalty of $5,000 or more as an intermediate sanction; or

(5) Was found to have compliance deficiencies that endangered the health and safety of the HHA's patients, and had temporary management appointed to oversee the management of the HHA; or

(6) Had all or part of its Medicare payments suspended; or

(7) Was found under any federal or state law to have:

(i) Had its participation in the Medicare program terminated; or

(ii) Been assessed a penalty of $5,000 or more for deficiencies in federal or state standards for HHAs; or

(iii) Been subjected to a suspension of Medicare payments to which it otherwise would have been entitled; or

(iv) Operated under temporary management that was appointed to oversee the operation of the HHA and to ensure the health and safety of the HHA's patients; or

(v) Been closed, or had its patients transferred by the state; or

(vi) Been excluded from participating in federal health care programs or debarred from participating in any government program.

Interpretive Guidelines §484.80(f)

The home health aide training and competency evaluation program may be offered by any HHA, except an HHA that falls under one of the exceptions specified in the regulation. These exceptions include, but are not limited to, agencies that have been found out of compliance with the home health aide requirements any time in the last 2 years, agencies that permitted an unqualified individual to function as a home health aide, and agencies that have been found to have compliance deficiencies that endangered patient health and safety. The full list of exceptions is included in the regulatory text.

"Substandard care" is defined as care that is noncompliant with federal HHA regulations at a condition-level.

If an HHA chooses to use volunteers to provide patient care services, the volunteer must either: (1) be licensed by the State to provide the service (RN/LPN/LVN/physical therapist, occupational therapist or speech therapist); or (2) have successfully completed any training and competency requirements applicable to the service performed.

The most reliable source of information to assure that an HHA has not been excluded from participating in federal health care programs is the List of Excluded Individuals and Entities on the HHS Office of Inspector General (OIG) website: https://oig.hhs.gov/exclusions/. In addition, a reliable source to confirm whether an HHA has been debarred (in accordance with the

debarment regulations at 2 CFR 180.300) is the System for Award Management (SAM), an official website of the U.S. government: https://www.sam.gov/portal/SAM/##11#1.

Prohibition/Loss of Home Health Aide Training and Competency Evaluation Program

If a partially extended survey is conducted, but no condition-level deficiency is found, then the HHA would not be precluded from offering its own aide training and/or competency evaluation program. If a condition-level deficiency is found during a partially extended or extended survey, then the HHA may complete any training course and competency evaluation program that is in progress; however, the HHA may not: (1) accept new candidates into the program; or (2) begin a new program for two years after receipt of written notice from the CMS Regional Office of such condition-level deficiency. Correction of the condition-level deficiency does not lift the two-year restriction identified in this standard.

If an HHA loses the authority to operate a home health aide training and competency evaluation program, that does not preclude the HHA from using a contractor to acquire training (see 54 FR 33354, 33358 (Aug. 14, 1989)). If the HHA has its own training and competency lab onsite, it may be permissible for a contractor to conduct the training on the HHA premises. However, the HHA must have no influence or role in the conduct of the training and competency evaluation. The program must be independent of the HHA in all other regards.

G798
(Rev.)

§484.80(g) Standard: Home health aide assignments and duties.

(1) **Home health aides are assigned to a specific patient by a registered nurse or other appropriate skilled professional, with written patient care instructions for a home health aide prepared by that registered nurse or other appropriate skilled professional (that is, physical therapist, speech-language pathologist, or occupational therapist).**

Interpretive Guidelines §484.80(g)*(1)*

The act of assigning a "specific patient" to a HH aide should be an intentional and deliberate decision that takes into consideration the skills of the aide, the availability of the aide for patient care continuity, patient preference (when possible), and other considerations as determined by the patient's care needs.

Most generally, HH aide services are provided in conjunction with, and as an adjunct to, a skilled nursing service. When both nursing and therapy services are involved, *either skilled professional may assign home health aides and develop written patient care instructions.*

G800
(Rev.)

§484.80(g)(2) A home health aide provides services that are:

(i) Ordered by the physician *or allowed practitioner*;
(ii) Included in the plan of care;
(iii) Permitted to be performed under state law; and
(iv) Consistent with the home health aide training

G802
(Rev.)

§484.80(g)(3) The duties of a home health aide include:

(i) The provision of hands on personal care;
(ii) The performance of simple procedures as an extension of therapy or nursing services;
(iii) Assistance in ambulation or exercises; and
(vi) Assistance in administering medications ordinarily self-administered.

Interpretive Guidelines §484.80(g)(3)

"Self-administration of medications" means that the patient (or the patient's caregiver, if applicable) *can* manage all aspects of taking her or his medication, including safe medication storage, removing the correct dose of medication from the container, taking the medication at the correct time, and knowing how to contact the pharmacy for refills or other questions.

"Assistance in administering medications," as referenced in this requirement, means that the HH aide may take only a passive role in this activity. Assistance may include items such as:

- Bringing a medication to the patient either in a pill organizer or a medication container as requested by the patient or caregiver;
- Providing fluids to take with the medication;
- Reminding the patient to take a medication;
- Applying a topical product, such as a non-prescription cream, to intact skin per home health aide instructions in how to apply it.

G804
(Rev.)

§484.80(g)(4) Home health aides must be members of the interdisciplinary team, must report changes in the patient's condition to a registered nurse or other appropriate skilled professional, and must complete appropriate records in compliance with the HHA's policies and procedures.

Interpretive Guidelines §484.80(g)(4)

As noted in 82 FR 4532, interdisciplinary teams work together, each member contributing their knowledge and skills, interacting with and building upon each other, to enhance patient care.

The interdisciplinary team model is the foundation of care in other health care providers, such as hospices and complex chronic care management practices. HHAs may choose to develop interdisciplinary team models based on the experiences and knowledge developed by these similar care providers, or may develop their own strategies and structures to create effective interdisciplinary teams. The term "interdisciplinary" refers to an approach to healthcare that includes a range of health service workers, *which may include but is not limited to,* MDs, RNs, LPN/LVN, PT & *Physical Therapy Assistant* (PTA), OT & *Occupational Therapy Assistant* (OTA), SLP, MSW, and HH aides.

During interdisciplinary team meetings, all HHA staff involved in the patient's care must be present for, and, where appropriate, should contribute to, any discussion regarding the patient's care. *Since home health aides play an integral role in the delivery of HHA services and have frequent and/or prolonged encounters with patients, their input as members of the interdisciplinary team is important for information sharing and their participation in the team should be reflected in the visit notes of the clinical record.* The HHA aide may participate in person, electronically or via telephone.

G808
(Rev.)

§484.80(h) Standard: Supervision of home health aides.

(1)(i) If home health aide services are provided to a patient who is receiving skilled nursing, physical or occupational therapy, or speech language pathology services—

> ***(A) A registered nurse or other appropriate skilled professional who is familiar with the patient, the patient's plan of care, and the written patient care instructions described in paragraph (g) of this section, must complete a supervisory assessment of the aide services being provided no less frequently than every 14 days; and***
>
> ***(B) The home health aide does not need to be present during the supervisory assessment described in paragraph (h)(1)(i)(A) of this section.***

Interpretive Guidelines §484.80(h)(1)(i)

An occupational therapist may conduct a home health initial assessment visit and complete a comprehensive assessment under the Medicare program, but only when occupational therapy is on the home health plan of care, with either physical therapy or speech therapy, and when skilled nursing services are not initially in the plan of care (86 FR 62242).

G810
(Rev.)

§484.80(h)(1)(ii) ***The supervisory assessment must be completed onsite (that is, an in person visit), or on the rare occasion by using two-way audio-video telecommunications technology***

that allows for real-time interaction between the registered nurse (or other appropriate skilled professional) and the patient, not to exceed 1 virtual supervisory assessment per patient in a 60-day episode.

G812
(Rev.)

§484.80(h)(1)(iii) ***If an area of concern in aide services is noted by the supervising registered nurse or other appropriate skilled professional, then the supervising individual must make an on-site visit to the location where the patient is receiving care in order to observe and assess the aide while he or she is performing care.***

G813
(New)

§484.80(h)(1)(iv) A registered nurse or other appropriate skilled professional must make an annual on-site visit to the location where a patient is receiving care in order to observe and assess each aide while he or she is performing care.

Interpretive Guidelines §484.80(h)(1)(iv)

In addition to the regularly-scheduled 14-day supervisory assessment and as-needed observation visits for aides providing care to patients receiving skilled services, HHAs are required to make an annual on-site, in person, visit to a patient's home to directly observe and assess each home health aide while he or she is performing patient care activities. The HHA is required to observe each home health aide annually with at least one patient (86 FR 62347). The skilled professional who supervises aide services should be familiar with the patient, the patient's plan of care, and the written patient care instructions.

If, during a supervisory visit described in §484.80(h)(1)(i*ii*), a concern is identified at a patient's home, but the aide is not present, then the skilled professional must go on-site with the aide at the next scheduled visit to observe and assess the aide while he or she is performing care.

G814
(Rev.)

§484.80(h)(2)*(i)* If home health aide services are provided to a patient who is not receiving skilled nursing care, physical or occupational therapy, or speech-language pathology services, —

> ***(A) The registered nurse must make an onsite, in person visit every 60 days to assess the quality of care and services provided by the home health aide and to ensure that services meet the patient's needs; and***
>
> ***(B) The home health aide does not need to be present during this visit.***

(ii) Semi-annually the registered nurse must make an on-site visit to the location where each patient is receiving care in order to observe and assess each home health aide while he or she is performing non-skilled care.

G816
(Rev.)

§484.80(h)(3) If a deficiency in aide services is verified by the registered nurse or other appropriate skilled professional during an on-site visit, then the agency must conduct, and the home health aide must complete, *retraining* and a competency *evaluation for the deficient and all related skills.*

G818
(Rev.)

§484.80(h)(4) Home health aide supervision must ensure that aides furnish care in a safe and effective manner, including, but not limited to, the following elements:

(i) Following the patient's plan of care for completion of tasks assigned to a home health aide by the registered nurse or other appropriate skilled professional;
(ii) Maintaining an open communication process with the patient, representative (if any), caregivers, and family;
(iii) Demonstrating competency with assigned tasks;
(iv) Complying with infection prevention and control policies and procedures;
(v) Reporting changes in the patient's condition; and
(vi) Honoring patient rights.

Interpretive Guidelines §484.80(h)(4)

During each supervisory visit the supervising registered nurse, or other appropriate skilled professional, should document his or her evaluation of the HH aide *regarding* each of the elements of this standard.

§484.80(h)(4)(ii) "Maintaining an open communication process" means that the aide *can* explain what *they are* going to do with the patient, ask the patient open-ended questions, seek feedback from the patient, and respond to the needs and requests of the patient, representative (if any), caregivers, and family.

G820
(Rev.)

§484.80(h)(5) If the home health agency chooses to provide home health aide services under arrangements, as defined in section 1861(w)(1) of the Act, the HHA's responsibilities also include, but are not limited to:

(i) Ensuring the overall quality of care provided by an aide;
(ii) Supervising aide services as described in paragraphs (h)(l) and (2) of this section; and
(iii) Ensuring that home health aides who provide services under arrangement have met the training or competency evaluation requirements, or both, of this part.

G828
(Rev.)

§484.80(i) Standard: Individuals furnishing Medicaid personal care aide-only services under a Medicaid personal care benefit.

An individual may furnish personal care services, as defined in §440.167 of this chapter, on behalf of an HHA. Before the individual may furnish personal care services, the individual must meet all qualification standards established by the state. The individual only needs to demonstrate competency in the services the individual is required to furnish.

Subpart C--Organizational Environment

G848
(Rev.)

§484.100 Condition of participation: Compliance with Federal, State, and local laws and regulations related to the health and safety of patients.

The HHA and its staff must operate and furnish services in compliance with all applicable federal, state, and local laws and regulations related to the health and safety of patients. If state or local law provides licensing of HHAs, the HHA must be licensed.

Interpretive Guidelines §484.100

Non-compliance with this condition includes: 1) the agency is not currently licensed per State requirements; or 2) the HHA has been cited by a Federal program (other than CMS), or a State or local authority for a non-compliance with licensing requirements. The Federal, State or local authority has made a final determination after all administrative procedures have been completed; all appeals have been finalized; and the findings of the noncompliance with the laws/regulations were upheld and enforced.

G850
(Rev.)

§484.100(a) Standard: Disclosure of ownership and management information.

The HHA must comply with the requirements of part 420 subpart C, of this chapter. The HHA also must disclose the following information to the state survey agency at the time of the HHA's initial request for certification, for each survey, and at the time of any change in ownership or management:

(1) The names and addresses of all persons with an ownership or controlling interest in the HHA as defined in §420.201, §420.202, and §420.206 of this chapter.

(2) The name and address of each person who is an officer, a director, an agent, or a managing employee of the HHA as defined in §420.20l, §420.202, and §420.206 of this chapter.

(3) The name and business address of the corporation, association, or other company that is responsible for the management of the HHA, and the names and addresses of the chief executive officer and the chairperson of the board of directors of that corporation, association, or other company responsible for the management of the HHA.

G860
(Rev.)

§484.100(b) Standard: Licensing.

The HHA, its branches, and all persons furnishing services to patients must be licensed, certified, or registered, as applicable, in accordance with the state licensing authority as meeting those requirements.

G862
(Rev.)

§484.100(c) Standard: Laboratory services.

(1) If the HHA engages in laboratory testing outside of the context of assisting an individual in self-administering a test with an appliance that has been cleared for that purpose by the Food and Drug Administration, the testing must be in compliance with all applicable requirements of part 493 of this chapter. The HHA may not substitute its equipment for a patient's equipment when assisting with self-administered tests.

Interpretive Guidelines §484.100(c)(1)

If an HHA nurse or other HHA employee only *assists* a patient who has her or his own glucose meter, then a Clinical Laboratory Improvement Amendment (CLIA) certificate is not required. If the HHA nurse or HHA employee conducts the test, regardless of whether the patient's

equipment or the HHA's equipment is used, then a CLIA certificate (specifically a Certificate of Waiver) is required.

The HHA may not substitute its equipment for a patient's equipment when assisting with self-administered tests, except that an HHA may allow a patient to use HHA testing equipment for a short, defined period of time until the patient has obtained his or her own testing equipment. As a part of the care planning process, HHAs are expected to help patients identify and obtain resources to secure the equipment needed for self-testing.

G864
(Rev.)

§484.100(c)(2) If the HHA refers specimens for laboratory testing, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the applicable requirements of part 493 of this chapter.

Interpretive Guidelines §484.100(c)(2)

HHAs may refer to Appendix C of the CMS State Operations Manual for regulations and interpretive guidelines for Part 493 (Laboratory Requirements).

REFER TO E-TAGS (Appendix Z)
(Rev.)

§484.102 Condition of participation: Emergency preparedness.

Interpretive Guidelines: § 484.102

HHAs must comply with the applicable emergency preparedness requirements referenced in Appendix Z of the State Operations Manual. For all applicable requirements and guidance for Emergency Preparedness, please refer to Appendix Z. We note that compliance with the emergency preparedness requirements is assessed in accordance with the survey protocol outlined within Appendix Z.

G940
(Rev.)

§484.105 Condition of participation: Organization and administration of services.

The HHA must organize, manage, and administer its resources to attain and maintain the highest practicable functional capacity, including providing optimal care to achieve the goals and outcomes identified in the patient's plan of care, for each patient's medical, nursing, and rehabilitative needs. The HHA must assure

that administrative and supervisory functions are not delegated to another agency or organization, and all services not furnished directly are monitored and controlled. The HHA must set forth, in writing, its organizational structure, including lines of authority, and services furnished.

Interpretive Guidelines §484.105

The roles of the governing body, administrator and clinical manager may not be delegated. In other words, an HHA must ensure that the responsibilities of the governing body, administrator and clinical manager (for the day-to-day operation of the HHA) are not relinquished to another person or organization on an on-going basis. This does not apply to periodic "acting" employees in the absence of the administrator or clinical manger. In addition, the use of payroll services, OASIS transmission contractors, and personnel training programs are not considered to be delegation of administrative and supervisory functions; these are service contracts that the agency may use to optimize administrative and supervisory efficiencies.

G942
(Rev.)

§484.105(a) Standard: Governing body.

A governing body (or designated persons so functioning) must assume full legal authority and responsibility for the agency's overall management and operation, the provision of all home health services, fiscal operations, review of the agency's budget and its operational plans, and its quality assessment and performance improvement program.

Interpretive Guidelines §484.105(a)

An HHA may establish a governing body composed of individuals of its choosing. The individuals that comprise the governing body are those who have the legal authority to assume responsibility for assuring that management and operation of the HHA is effective and operating within all legal bounds (as noted in 82 FR 4548).

G946
(Rev.)

§484.105(b)(1) Standard: Administrator. The administrator must:

(i) Be appointed by and report to the governing body;

Interpretive Guidelines §484.105(b)(1)(i)

The administrator is actively involved in the daily responsibilities of running the HHA. The administrator must be appointed by and accountable to the governing body; acting as a liaison between the daily functions of the HHA and the governing body (as noted in 82 FR 4548).

G948
(Rev.)

[§484.105(b)(1) The administrator must:]

(ii) Be responsible for all day-to-day operations of the HHA;

Interpretive Guidelines §484.105(b)(1)(ii)

The HHA administrator is required, among other things, to be responsible for all day-to-day operations of the HHA and to be available to patients, representatives, and caregivers to receive complaints (§ 484.50(a)(1)(ii) and (c)(3)). The administrator should be actively involved in the daily responsibilities of running the HHA, and each HHA should be able to demonstrate such involvement upon survey (as noted in 82 FR 4548).

G950
(Rev.)

[§484.105(b)(1) The administrator must:]

(iii) Ensure that a clinical manager as described in paragraph (c) of this section is available during all operating hours;

Interpretive Guidelines §484.105(b)(1)(iii)

"Operating hours" include all hours which the HHA is open and providing care to patients.

G952
(Rev.)

[§484.105(b)(1) The administrator must:]

(iv) Ensure that the HHA employs qualified personnel, including assuring the development of personnel qualifications and policies.

G954
(Rev.)

§484.105(b)(2) When the administrator is not available, a qualified, pre-designated person, who is authorized in writing by the administrator and the governing body, assumes the same responsibilities and obligations as the administrator. The pre-designated person may be the clinical manager as described in paragraph (c) of this section.

Interpretive Guidelines §484.105(b)(2)

"Pre-designation" means that the individual who is responsible for fulfilling the role of the administrator in his/her absence is established in advance and approved by the governing body.

Pre-designation needs to be by both the administrator and the governing body. The goal of this requirement is to provide management continuity within the HHA to the greatest degree possible. HHA staff should know and be able to verbalize upon interview who the pre-designated individual(s) is/are for this role (82 FR 4549).

G956
(Rev.)

§484.105(b)(3) The administrator or a pre-designated person is available during all operating hours.

Interpretive Guidelines §484.105(b)(3)

"Available" means physically present at the agency or able to be contacted via telephone or other electronic means.

G958
(Rev.)

§484.105(c) Standard: Clinical manager.

One or more qualified individuals must provide oversight of all patient care services and personnel. Oversight must include the following-

Interpretive Guidelines §484.105(c)

§484.115(c) provides that a clinical manager must be a licensed physician, physical therapist, speech-language pathologist, occupational therapist, audiologist, social worker, or a registered nurse.

G960
(Rev.)

[§484.105(c) Standard: Clinical manager…Oversight must include the following-]

(1) Making patient and personnel assignments,

G962
(Rev.)

[§484.105(c) Standard: Clinical manager…Oversight must include the following-]

(2) Coordinating patient care,

G964
(Rev.)

[§484.105(c) Standard: Clinical manager…Oversight must include the following-]

(3) Coordinating referrals,

G966
(Rev.)

[§484.105(c) Standard: Clinical manager…Oversight must include the following-]

(4) Assuring that patient needs are continually assessed, and

G968
(Rev.)

[§484.105(c) Standard: Clinical manager…Oversight must include the following-]

(5) Assuring the development, implementation, and updates of the individualized plan of care.

G972
(Rev.)

§484.105(d) Standard: Parent-branch relationship.

(1) The parent HHA is responsible for reporting all branch locations of the HHA to the state survey agency at the time of the HHA's request for initial certification, at each survey, and at the time the parent proposes to add or delete a branch.

Interpretive Guidelines §484.105(d)(1)

A "branch" is an approved location or site (physically separate from its parent's location) from which an HHA provides services within a portion of the total geographic area served by the

parent agency. A branch provides services under the same CMS certification number (CCN) as its parent agency. *See Chapter 2 of the State Operations Manual for additional information on HHA Branch CMS Certification Numbers.*

G974
(Rev.)

(2) The parent HHA provides direct support and administrative control of its branches.

Interpretive Guidelines §484.105(d)*(2)*

The parent location must provide supervision and administrative control of its branches daily to the extent that the branches depend upon the parent's supervision and administrative functions to meet the CoPs, and could not do so as independent entities. The parent agency must be available to meet the needs of any situation and respond to issues that could arise with respect to patient care or administration of a branch. A violation of a CoP in a branch would apply to the entire HHA. Therefore, it is essential for the parent to exercise adequate control, supervision, and guidance for all branches under its leadership.

"Direct support and administrative control" of a branch *includes that the* parent agency maintains responsibility for:

- The governing body oversight of the branch;
- Any branch contracts for services;
- The branch's quality assurance and performance improvement plan;
- Policies and procedures implemented in the branch;
- How and when management and direct care staff are shared between the parent and branch, particularly in the event of staffing shortfalls or leave coverage;
- Human resource management at the branch;
- Assuring the appropriate disposition of closed clinical records at the branch; and
- Ensuring branch personnel training requirements are met.

Survey Procedures §484.105(d)(2)

HHAs must demonstrate compliance through evidence of established policies and procedures to ensure adequate control, supervision, and guidance for all branches under an HHA's leadership.

G976
(Rev.)

§484.105(e) Standard: Services under arrangement.

(1) The HHA must ensure that all services furnished under arrangement provided by other entities or individuals meet the requirements of this part and the requirements of section 1861(w) of the Act (42 U.S.C. 1395x(w)).

G978
(Rev.)

§484.105(e)(2) An HHA must have a written agreement with another agency, with an organization, or with an individual when that entity or individual furnishes services under arrangement to the HHA's patients. The HHA must maintain overall responsibility for the services provided under arrangement, as well as the manner in which they are furnished. The agency, organization, or individual providing services under arrangement may not have been:

(i) Denied Medicare or Medicaid enrollment;

(ii) Been excluded or terminated from any federal health care program or Medicaid;

(iii) Had its Medicare or Medicaid billing privileges revoked; or

(iv) Been debarred from participating in any government program.

G980
(Rev.)

§484.105(e)(3) The primary HHA is responsible for patient care, and must conduct and provide, either directly or under arrangements, all services rendered to patients.

Interpretive Guidelines §484.105(e)

The HHA retains overall responsibility for all services provided, whether provided directly by the HHA or through arrangements (i.e., under contract). For example, in contracting for a service such as physical therapy, an HHA may require the contracted party to do the day-*to*-day professional evaluation component of the therapy service. The HHA may not, however, delegate its overall administrative and supervisory responsibilities *(see also §484.105(d))*. All HHA contracts for services should specify how HHA supervision will occur.

G982
(Rev.)

§484.105(f) Standard: Services furnished.

(1) Skilled nursing services and at least one other therapeutic service (physical therapy, speech-language pathology, or occupational therapy; medical social services; or home health aide services) are made available on a visiting basis, in a place of residence used as a patient's home. An HHA must provide at least one of the services described in this subsection directly, but may provide the second service and additional services under arrangement with another agency or organization.

Interpretive Guidelines §484.105(f)

The HHA must provide skilled nursing services and at least one other therapeutic service. However, only one service *must* be provided directly by the HHA.

An HHA is considered to provide a service "directly" when the persons providing the service for the HHA are HHA employees. An individual who works for the HHA on an hourly or per-visit basis may be considered an HHA employee if the HHA is required to issue a form W-2 on the individual's behalf with no intermediaries. An HHA is considered to provide a service "under arrangements" when the HHA provides the service through contractual or affiliation arrangements with other agencies or organizations, or with an individual(s) who is not an HHA employee.

Contracted staffing may supplement, but may not be used in lieu of, HHA staffing for services provided directly by the HHA. In addition, the use of contracted staff in a service provided directly by the HHA may occur only on a temporary basis to provide coverage for unexpected HHA staffing shortages, or to provide a specialized service that HHA employees cannot provide.

G984

(Rev.)

§484.105(f)(2) All HHA services must be provided in accordance with current clinical practice guidelines and accepted professional standards of practice.

Interpretive Guidelines §484.105(f)*(2)*

Accepted standards of practice include guidelines or recommendations issued by nationally recognized organizations with expertise in the field. Clinical practice guidelines and accepted professional standards of practice may be found in, but are not limited to:

- *State practice acts;*
- *Standards established by national organizations, boards, and councils (e.g., the American Nurses' Association standards); and*
- *The HHA's own policies and procedures.*

HHAs should consider identifying the clinical practice guideline or standard of practice used when developing and updating care policies and procedures.

G986

(Rev.)

§484.105(g) Standard: Outpatient physical therapy or speech-language pathology services.

An HHA that furnishes outpatient physical therapy or speech-language pathology services must meet all of the applicable conditions of this part and the additional health and safety

requirements set forth in §485.711, §485.713, §485.715, §485.719, §485.723, and §485.727 of this chapter to implement section 1861(p) of the Act.

Interpretive Guidelines §484.105(g)

In general, this guidance is for situations where a patient would be coming to the premises of the HHA for outpatient therapy services. The patient would not be receiving HHA services and OPT services at the same time and therefore not all the HHA CoPs would apply. For example, the patient could have a total joint operation and be discharged home to get HHA services inclusive of therapy. Then when the patient is doing better, they could transition to outpatient services provided by the HHA on the premises of the HHA where the HHA has a therapy gym.

If an HHA provides outpatient physical therapy services or speech-language pathology services it must also meet the conditions of the regulations summarized below*, among others*, as applicable:

§485.711 Condition of participation: Plan of care and physician involvement: For each patient in need of outpatient physical therapy or speech pathology services, there is a written plan of care established and periodically reviewed by a physician, or by a physical therapist or speech pathologist respectively.

§485.713 Condition of participation: Physical therapy services: If the HHA offers physical therapy services, it provides an adequate program of physical therapy and has an adequate number of qualified personnel and the equipment necessary to carry out its program and to fulfill its objectives.

§485.715 Condition of participation: Speech pathology services: If speech pathology services are offered, the HHA provides an adequate program of speech pathology and has an adequate number of qualified personnel and the equipment necessary to carry out its program and to fulfill its objectives.

§485.719 Condition of participation: Arrangements for physical therapy and speech pathology services to be performed by other than salaried organization personnel

The following two CoPs, §485.723 and §485.727, are applicable when specialized rehabilitation space and equipment is owned, leased, operated, contracted for, or arranged for at sites under the HHA's control and when the HHA bills the Medicare/Medicaid programs for services rendered at these sites.]

§485.723 Condition of participation: Physical environment. The building housing the HHA is constructed, equipped, and maintained to protect the health and safety of patients, personnel, and the public and provides a functional, sanitary, and comfortable environment.

§485.727 Condition of participation: Emergency preparedness. The HHA must establish and maintain an emergency preparedness program.

G988
(Rev.)

§484.105(h) Standard: Institutional planning.

The HHA, under the direction of the governing body, prepares an overall plan and a budget that includes an annual operating budget and capital expenditure plan.

(1) *Annual operating budget.* There is an annual operating budget that includes all anticipated income and expenses related to items that would, under generally accepted accounting principles, be considered income and expense items. However, it is not required that there be prepared, in connection with any budget, an item by item identification of the components of each type of anticipated income or expense.

(2) *Capital expenditure plan.* (i) There is a capital expenditure plan for at least a 3-year period, including the operating budget year. The plan includes and identifies in detail the anticipated sources of financing for, and the objectives of, each anticipated expenditure of more than $600,000 for items that would under generally accepted accounting principles, be considered capital items. In determining if a single capital expenditure exceeds $600,000, the cost of studies, surveys, designs, plans, working drawings, specifications, and other activities essential to the acquisition, improvement, modernization, expansion, or replacement of land, plant, building, and equipment are included. Expenditures directly or indirectly related to capital expenditures, such as grading, paving, broker commissions, taxes assessed during the construction period, and costs involved in demolishing or razing structures on land are also included. Transactions that are separated in time, but are components of an overall plan or patient care objective, are viewed in their entirety without regard to their timing. Other costs related to capital expenditures include title fees, permit and license fees, broker commissions, architect, legal, accounting, and appraisal fees; interest, finance, or carrying charges on bonds, notes and other costs incurred for borrowing funds.

(ii) If the anticipated source of financing is, in any part, the anticipated payment from title V (Maternal and Child Health Services Block Grant) or title XVIII (Medicare) or title XIX (Medicaid) of the Social Security Act, the plan specifies the following:

> **(A) Whether the proposed capital expenditure is required to conform, or is likely to be required to conform, to current standards, criteria, or plans developed in accordance with the Public Health Service Act or the Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963.**
>
> **(B) Whether a capital expenditure proposal has been submitted to the designated planning agency for approval in accordance with section 1122 of the Act (42 U.S.C. 1320a-1) and implementing regulations.**

(C) Whether the designated planning agency has approved or disapproved the proposed capital expenditure if it was presented to that agency.

(3) *Preparation of plan and budget.* The overall plan and budget is prepared under the direction of the governing body of the HHA by a committee consisting of representatives of the governing body, the administrative staff, and the medical staff (if any) of the HHA.

(4) *Annual review of plan and budget.* The overall plan and budget is reviewed and updated at least annually by the committee referred to in paragraph (i)(3) of this section under the direction of the governing body of the HHA.

G1008
(Rev.)

§484.110 Condition of participation: Clinical records.

The HHA must maintain a clinical record containing past and current information for every patient accepted by the HHA and receiving home health services. Information contained in the clinical record must be accurate, adhere to current clinical record documentation standards of practice, and be available to the physician(s) *or allowed practitioner(s)* issuing orders for the home health plan of care, and appropriate HHA staff. This information may be maintained electronically.

Interpretive Guidelines §484.110

The HHA must use the information contained in each medical record to assure that safe care is delivered to each HHA patient. In accordance with the provisions of the Patient rights Condition at §484.50(c)(6), the HHA must ensure the confidentiality of each patient's clinical record.

The manner and degree of noncompliance identified in relation to the standard level tags for §484.110 may result in substantial noncompliance with this CoP, requiring citation at the condition level.

G1012
(Rev.)

§484.110(a) Standard: Contents of clinical record. The record must include:

(1) The patient's current comprehensive assessment, including all of the assessments from the most recent home health admission, clinical notes, plans of care, and physician *or allowed practitioner* orders;

G1014
(Rev.)

[§484.110(a) Standard: Contents of clinical record. The record must include:]

(2) All interventions, including medication administration, treatments, and services, and responses to those interventions;

Interpretive Guidelines §484.110(a)(2)

"All interventions" refers to those interventions performed by the HHA.

G1016
(Rev.)

[§484.110(a) Standard: Contents of clinical record. The record must include:]

(3) Goals in the patient's plans of care and the patient's progress toward achieving them;

G1018
(Rev.)

[§484.110(a) Standard: Contents of clinical record. The record must include:]

(4) Contact information for the patient, the patient's representative (if any), and the patient's primary caregiver(s);

G1020
(Rev.)

[§484.110(a) Standard: Contents of clinical record. The record must include:]

(5) Contact information for the primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA; and

Interpretive Guidelines §484.110(a)(5)

If the patient identifies an attending physician (whether it is the responsible HHA physician or another physician) who will resume their care after the HHA episode, the contact information of the physician should be included in the clinical record.

G1022
(Rev.)

[§484.110(a) Standard: Contents of clinical record. The record must include:]

(6)(i) A completed discharge summary that is sent to the primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA (if any) within 5 business days of the patient's discharge; or

(ii) A completed transfer summary that is sent within 2 business days of a planned transfer, if the patient's care will be immediately continued in a health care facility; or

(iii) A completed transfer summary that is sent within 2 business days of becoming aware of an unplanned transfer, if the patient is still receiving care in a health care facility at the time when the HHA becomes aware of the transfer.

Interpretive Guidelines §484.110(a)(6)

Discharge summaries typically contain the following items:

- Admission and discharge dates;
- Physician responsible for the home health plan of care;
- Reason for admission to home health;
- Type of services provided and frequency of services;
- Laboratory data;
- Medications the patient is on at the time of discharge;
- Patient's discharge condition;
- Patient outcomes in meeting the goals in the plan of care; and
- Patient and family post-discharge instructions.

A discharge summary must be sent to the primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA (if any) within five (5) business days of the date of the order for discharge from the responsible physician.

The contents of a transfer summary typically contain the same components as a discharge summary.

G1024
(Rev.)

§484.110(b) Standard: Authentication.

All entries must be legible, clear, complete, and appropriately authenticated, dated, and timed. Authentication must include a signature and a title (occupation), or a secured computer entry by a unique identifier, of a primary author who has reviewed and approved the entry.

G1026
(Rev.)

§484.110(c) Standard: Retention of records.

(1) Clinical records must be retained for 5 years after the discharge of the patient, unless state law stipulates a longer period of time.

(2) The HHA's policies must provide for retention of clinical records even if it discontinues operation. When an HHA discontinues operation, it must inform the state agency where clinical records will be maintained.

G1028
(Rev.)

§484.110(d) Standard: Protection of records.

The clinical record, its contents, and the information contained therein must be safeguarded against loss or unauthorized use. The HHA must be in compliance with the rules regarding personal health information set out at 45 CFR parts 160 and 164.

Interpretive Guidelines §484.110(d)

HHA staff (whether employed directly or under arrangement) who carry documents and/or electronic devices containing Protected Health Information from patient's homes to the HHA office, or to and from the HHA staff member's home, create additional confidentiality/protection concerns with patient records.

Section 45 CFR Parts 160 and 164, generally known as the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security rules, establish standards for health care providers and suppliers that conduct covered electronic transactions, such as HHAs, among others, for the privacy of protected health information (PHI), as well as for the security of electronic phi (ePHI).

*In accordance with 45 CFR 164.530, a*ll HHA staff must receive comprehensive and periodic training on the protection of patient clinical records. HHAs must *also* establish policies and procedures to ensure the security of clinical records and the privacy of information contained within such records to prevent loss or unauthorized use in the patient's home, in transit*, in* the office setting*, or any other location.*

Survey Procedures §484.110(d)

During the home visit, observe how agency staff maintain the confidentiality of protected health information that they transport and use for patient care encounters as well as safeguard it against loss or unauthorized use.

CMS does not interpret or enforce the HIPAA Privacy and Security Rules, which fall under the jurisdiction of the Office for Civil Rights (OCR). Because there are a number of scenarios that

allow for using or disclosing PHI in full compliance with the HIPAA Privacy and Security Rules, surveyors must defer to OCR on whether the manner in which the HHA uses, discloses, maintains or destroys PHI is consistent with these requirements. Information on how to file a HIPAA Privacy or Security complaint with OCR may be found at http://www.hhs.gov/ocr/privacy/hipaa/complaints/index.html.

G1030
(Rev.)

§484.110(e) Standard: Retrieval of clinical records.

A patient's clinical record (whether hard copy or electronic form) must be made available to a patient, free of charge, upon request at the next home visit, or within 4 business days (whichever comes first).

G1050
(Rev.)

§484.115 Condition of participation: Personnel qualifications.

HHA staff are required to meet the following standards:

Interpretive Guidelines §484.115

The manner and degree of noncompliance identified in relation to the standard level tags for §484.115 may result in substantial noncompliance with this CoP, requiring citation at the condition level.

G1052
(Rev.)

§484.115 (a) Standard: Administrator, home health agency.

(1) For individuals that began employment with the HHA prior to January 13, 2018, a person who:

(i) Is a licensed physician;

(ii) Is a registered nurse; or

(iii) Has training and experience in health service administration and at least 1 year of supervisory administrative experience in home health care or a related health care program.

(2) For individuals that begin employment with an HHA on or after January 13, 2018, a person who:

(i) Is a licensed physician, a registered nurse, or holds an undergraduate degree; and

(ii) Has experience in health service administration, with at least 1 year of supervisory or administrative experience in home health care or a related health care program.

Interpretive Guidelines §484.115(a)

An "undergraduate degree" means a bachelor's or associate's degree.

G1054
(Rev.)

§484.115(b) Standard: Audiologist. A person who:

(1) Meets the education and experience requirements for a Certificate of Clinical Competence in audiology granted by the American Speech-Language-Hearing Association; or

(2) Meets the educational requirements for certification and is in the process of accumulating the supervised experience required for certification.

G1056
(Rev.)

§484.115(c) Standard: Clinical manager.

A person who is a licensed physician, physical therapist, speech-language pathologist, occupational therapist, audiologist, social worker, or a registered nurse.

G1058
(Rev.)

§484.115(d) Standard: Home health aide.

A person who meets the qualifications for home health aides specified in section 1891(a)(3) of the Act and implemented at §484.80.

G1060
(Rev.)

§484.115(e) Standard: Licensed practical (vocational) nurse.

A person who has completed a practical (vocational) nursing program, is licensed in the state where practicing, and who furnishes services under the supervision of a qualified registered nurse.

G1062
(Rev.)

§484.115(f) Standard: Occupational therapist. A person who—

(1)(i) Is licensed or otherwise regulated, if applicable, as an occupational therapist by the state in which practicing, unless licensure does not apply; or
(ii) Graduated after successful completion of an occupational therapist education program accredited by the Accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA), or successor organizations of ACOTE; and
(iii) Is eligible to take, or has successfully completed the entry-level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(2) On or before December 31, 2009—
(i) Is licensed or otherwise regulated, if applicable, as an occupational therapist by the state in which practicing; or
(ii) When licensure or other regulation does not apply—
(A) Graduated after successful completion of an occupational therapist education program accredited by the accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA) or successor organizations of ACOTE; and
(B) Is eligible to take, or has successfully completed the entry-level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc., (NBCOT).

(3) On or before January 1, 2008—
(i) Graduated after successful completion of an occupational therapy program accredited jointly by the Committee on Allied Health Education and Accreditation of the American Medical Association and the American Occupational Therapy Association; or
(ii) Is eligible for the National Registration Examination of the American Occupational Therapy Association or the National Board for Certification in Occupational Therapy.

(4) On or before December 31, 1977—
(i) Had 2 years of appropriate experience as an occupational therapist; and
(ii) Had achieved a satisfactory grade on an occupational therapist proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(5) If educated outside the United States, must meet both of the following:

(i) Graduated after successful completion of an occupational therapist education program accredited as substantially equivalent to occupational therapist entry level education in the United States by one of the following:

(A) The Accreditation Council for Occupational Therapy Education (ACOTE).

(B) Successor organizations of ACOTE.

(C) The World Federation of Occupational Therapists.

(D) A credentialing body approved by the American Occupational Therapy Association.

(E) Successfully completed the entry level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(ii) On or before December 31, 2009, is licensed or otherwise regulated, if applicable, as an occupational therapist by the state in which practicing.

G1064

(Rev.)

§484.115(g) Standard: Occupational therapy assistant. A person who—

(1) Meets all of the following:

(i) Is licensed or otherwise regulated, if applicable, as an occupational therapy assistant, by the state in which practicing, unless licensure does apply; or

(ii) Graduated after successful completion of an occupational therapy assistant education program accredited by the Accreditation Council for Occupational Therapy Education, (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA) or its successor organizations.

(iii) Is eligible to take or successfully completed the entry-level certification examination for occupational therapy assistants developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(2) On or before December 31, 2009—

(i) Is licensed or otherwise regulated as an occupational therapy assistant, if applicable, by the state in which practicing; or any qualifications defined by the state in which practicing, unless licensure does not apply; or

(ii) Must meet both of the following:

(A) Completed certification requirements to practice as an occupational therapy assistant established by a credentialing organization approved by the American Occupational Therapy Association.

(B) After January 1, 2010, meets the requirements in paragraph (f)(1) of this section.

G1066
(Rev.)

§484.115(h) Standard: Physical therapist.

A person who is licensed, if applicable, by the state in which practicing, unless licensure does not apply and meets one of the following requirements:

(1)(i) Graduated after successful completion of a physical therapist education program approved by one of the following:

(A) The Commission on Accreditation in Physical Therapy Education (CAPTE).

(B) Successor organizations of CAPTE.

(C) An education program outside the United States determined to be substantially equivalent to physical therapist entry level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or an organization identified in 8 CFR 212.15(e) as it relates to physical therapists.

(ii) Passed an examination for physical therapists approved by the state in which physical therapy services are provided.

(2) On or before December 31, 2009—

(i) Graduated after successful completion of a physical therapy curriculum approved by the Commission on Accreditation in Physical Therapy Education (CAPTE); or

(ii) Meets both of the following:

(A) Graduated after successful completion of an education program determined to be substantially equivalent to physical therapist entry level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or identified in 8 CFR 212.15(e) as it relates to physical therapists.

(B) Passed an examination for physical therapists approved by the state in which physical therapy services are provided.

(3) Before January 1, 2008 graduated from a physical therapy curriculum approved by one of the following:

(i) The American Physical Therapy Association.

(ii) The Committee on Allied Health Education and Accreditation of the American Medical Association.

(iii) The Council on Medical Education of the American Medical Association and the American Physical Therapy Association.

(4) On or before December 31, 1977 was licensed or qualified as a physical therapist and meets both of the following:

(i) Has 2 years of appropriate experience as a physical therapist.
(ii) Has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(5) Before January 1, 1966—

(i) Was admitted to membership by the American Physical Therapy Association;

(ii) Was admitted to registration by the American Registry of Physical Therapists; or
(iii) Graduated from a physical therapy curriculum in a 4-year college or university approved by a state department of education.

(6) Before January 1, 1966 was licensed or registered, and before January 1, 1970, had 15 years of fulltime experience in the treatment of illness or injury through the practice of physical therapy in which services were rendered under the order and direction of attending and referring doctors of medicine or osteopathy.

(7) If trained outside the United States before January 1, 2008, meets the following requirements:

(i) Was graduated since 1928 from a physical therapy curriculum approved in the country in which the curriculum was located and in which there is a member organization of the World Confederation for Physical Therapy.

(ii) Meets the requirements for membership in a member organization of the World Confederation for Physical Therapy.

G1068
(Rev.)

§484.115(i) Standard: Physical therapist assistant.

A person who is licensed, registered or certified as a physical therapist assistant, if applicable, by the state in which practicing, unless licensure does not apply and meets one of the following requirements:

(1)(i) Graduated from a physical therapist assistant curriculum approved by the Commission on Accreditation in Physical Therapy Education of the American Physical Therapy Association; or if educated outside the United States or trained in the United

States military, graduated from an education program determined to be substantially equivalent to physical therapist assistant entry level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or identified at 8 CFR 212.15(e); and

(ii) Passed a national examination for physical therapist assistants.

(2) On or before December 31, 2009, meets one of the following:

> **(i) Is licensed, or otherwise regulated in the state in which practicing.**
>
> **(ii) In states where licensure or other regulations do not apply, graduated before December 31, 2009, from a 2-year college-level program approved by the American Physical Therapy Association and after January 1, 2010, meets the requirements of paragraph (h)(1) of this section.**

(3) Before January 1, 2008, where licensure or other regulation does not apply, graduated from a 2-year college level program approved by the American Physical Therapy Association.

(4) On or before December 31, 1977, was licensed or qualified as a physical therapist assistant and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

G1070
(Rev.)

§484.115(j) Standard: Physician.

A person who meets the qualifications and conditions specified in section 1861(r) of the Act and implemented at §410.20(b) of this chapter.

G1072
(Rev.)

§484.115(k) Standard: Registered nurse.

A graduate of an approved school of professional nursing who is licensed in the state where practicing.

G1074
(Rev.)

§484.115(l) Standard: Social Work Assistant.

A person who provides services under the supervision of a qualified social worker and:

(1) Has a baccalaureate degree in social work, psychology, sociology, or other field related to social work, and has had at least 1 year of social work experience in a health care setting; or

(2) Has 2 years of appropriate experience as a social work assistant, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that the determinations of proficiency do not apply with respect to persons initially licensed by a state or seeking initial qualification as a social work assistant after December 31, 1977.

G1076
(Rev.)

§484.115(m) Standard: Social worker.

A person who has a master's or doctoral degree from a school of social work accredited by the Council on Social Work Education, and has 1 year of social work experience in a health care setting.

G1078
(Rev.)

§484.115(n) Standard: Speech-language pathologist.

A person who has a master's or doctoral degree in speech-language pathology, and who meets either of the following requirements:

(1) Is licensed as a speech-language pathologist by the state in which the individual furnishes such services; or

(2) In the case of an individual who furnishes services in a state which does not license speech-language pathologists:

(i) Has successfully completed 350 clock hours of supervised clinical practicum (or is in the process of accumulating supervised clinical experience);

(ii) Performed not less than 9 months of supervised full-time speech-language pathology services after obtaining a master's or doctoral degree in speech-language pathology or a related field; and

(iii) Successfully completed a national examination in speech-language pathology approved by the Secretary.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality

Ref: QSO-24-11-HHA & Hospice

DATE: May 3, 2024

TO: State Survey Agency Directors

FROM: Directors, Quality, Safety & Oversight Group (QSOG) and Survey & Operations Group (SOG)

SUBJECT: Revisions to the State Operations Manual (SOM) Chapter 10 –Informal Dispute Resolution (IDR) and Enforcement Procedures for Home Health Agencies and Hospice Programs

Memorandum Summary

- The Centers for Medicare & Medicaid Services (CMS) has revised the State Operations Manual (SOM) chapter 10 to provide procedures regarding the informal dispute resolution (IDR) process for both Home Health Agencies (HHAs) and hospice programs.
- Revisions also include guidance for State Agencies (SAs) and CMS Survey & Operations Group (SOG) Locations on recommending and imposing HHA alternative sanctions and hospice enforcement remedies.

Background:

On November 8, 2012, we published the Calendar Year (CY) 2013 Home Health Prospective Payment System (HH PPS) final rule (77 FR 67068) that set forth an IDR process for HHAs and alternative sanctions that can be imposed instead of, or in addition to, termination of an HHA's participation. On November 9, 2021, we published the CY 2022 HH PPS final rule (86 FR 62240) that set forth enforcement remedies that can be imposed instead of, or in addition to, termination of a hospice program's participation. Under these rules, CMS has the authority to impose the alternative sanctions or enforcement remedies of civil money penalties, directed in-service training, directed plans of correction, suspension of payment for new admissions, and temporary management on HHAs or hospice programs found to have condition-level deficiencies. A new hospice IDR process was also published in the CY 2024 HH PPS final rule (88 FR 77676) that offers hospice providers an informal opportunity to dispute any condition-level findings.

Discussion:

The survey and certification process provides a method for CMS to evaluate HHA and hospice programs' compliance with the Conditions of Participation (CoPs), ensuring that patient services

provided meet the minimum health and safety standards. This process is explained in Appendix B of the SOM for HHAs and Appendix M of the SOM for hospice programs. Chapter 10 provides guidance for the HHA and hospice program enforcement regulations and IDR processes at 42 CFR Part 488.

The regulations for IDR offer HHAs and hospice programs the option to request an informal opportunity to dispute condition-level survey findings warranting an alternative sanction or enforcement remedy following a facility's receipt of the Statement of Deficiencies (Form CMS-2567). Effective January 1, 2024, the IDR processes for hospices follow the same existing processes for HHAs, and Chapter 10 was updated to include hospices in the guidance.

We have also revised the SOM Chapter 10 guidance for the HHA and hospice program enforcement regulations at 42 CFR Part 488. The guidance will assist SAs in recommending, and Locations in imposing, an alternative sanction(s) or enforcement remedy(ies). CMS may terminate the provider agreement and should consider the imposition of one or more of the following sanctions/remedies. This guidance is outlined in the chapter revisions.

- Civil money penalties;
- Suspension of payment for all new admissions;
- Temporary management;
- Directed plan of correction; and
- Directed in-service training.

CMS training for Location enforcement staff on imposing the HHA alternative sanctions and the hospice program enforcement remedies is available on the CMS Quality, Safety, and Education Portal (QSEP) website. The training is titled *Enforcement Process for Home Health Agency and Hospice Programs.*

Contact:

For questions or concerns regarding HHAs, please contact hhasurveyprotocols@cms.hhs.gov.
For questions or concerns regarding hospices, please contact QSOG_Hospice@cms.hhs.gov.

Effective Date:

Immediately. Please communicate to all appropriate staff within 30 days.

/s/

Karen L. Tritz
Director, Survey & Operations Group

David R. Wright
Director, Quality, Safety & Oversight Group

Attachment- Advanced Copy of SOM Chapter 10 – Informal Dispute Resolution and Enforcement Procedures for Home Health Agencies and Hospice Programs

Resources to Improve Quality of Care:

Check out CMS's new Quality in Focus interactive video series. The series of 10–15-minute videos are tailored to provider types and intend to reduce the deficiencies most commonly cited during the CMS survey process, like infection control and accident prevention. Reducing these common deficiencies increases the quality of care for people with Medicare and Medicaid. Learn to:

- *Understand surveyor evaluation criteria*
- *Recognize deficiencies*
- *Incorporate solutions into your facility's standards of care*

See the Quality, Safety, & Education Portal Training Catalog, and select Quality in Focus

State Operations Manual

Chapter 10 – *Informal Dispute Resolution and* Enforcement Procedures for Home Health Agencies *and Hospice Programs*

Table of Contents

(Rev.)

Advanced Copy

Transmittals for Chapter 10

10000 - Introduction
(Rev.)

The Secretary has the responsibility to promote quality of care and the health and safety of patients receiving services through Medicare certified home health agencies (HHA) and hospice programs by ensuring that providers maintain compliance with the Conditions of Participation (CoP). The survey and certification process provides a method for CMS to evaluate HHA and hospice programs' compliance with the CoPs, ensuring that patient services provided meet the minimum health and safety standards and a basic level of quality. This process is explained in Appendix B of this manual for HHAs and Appendix M of this manual for hospice programs.

Chapter 10 provides guidance for the HHA and hospice program enforcement regulations at 42 CFR Part 488. No provisions contained in this chapter are intended to create any rights or sanctions not otherwise provided in law or regulation.

In accordance with 42 CFR §488.800 – §488.865 for HHAs and §488.1200-§488.1265 for hospice programs, in addition to termination of the HHA's or hospice program's provider agreement, sanctions such as civil money penalties (CMP), suspension of payment for all new admissions, temporary management, directed plans of correction, and directed in-service training can be imposed when an HHA or hospice program are out of compliance with Federal requirements.

Alternative sanctions in HHAs and enforcement remedies in hospice programs are recommended by the State survey agency (SA), and the CMS Location reviews the SA recommendation to ensure that it is supported by the SA findings. However, the CMS Location does not have the authority to delegate the imposition of sanctions to the State.

It should be noted that failure of CMS or the State to act timely does not invalidate otherwise legitimate survey and enforcement determinations.

10001 - Definitions and Acronyms
(Rev.)

Abbreviated standard *survey means a focused survey other than a standard survey that gathers information on an HHA's or hospice program's compliance with fewer specific standards or CoPs. An abbreviated standard survey may be based on complaints received or other indicators of specific concern such as reapplication for Medicare billing privileges following a deactivation. (HHA: 42 CFR §488.705; Hospice: SOM Appendix M, Task I)*

An abbreviated standard survey is a focused survey that examines any standard(s) related to the reason for the survey.

AO *– National Accreditation Organization whose program is approved by CMS. (42 CFR §488.1)*

Certification of compliance *means that the HHA or hospice program is in compliance with the CoPs and is eligible to participate in the Medicare program. (HHA: 42 CFR §488.740)*

CFR *- Code of Federal Regulations.*

CMP *- Civil money penalty. (HHA: 42 CFR 488.845; Hospice: 42 CFR §488.1245)*

CMS Location*- previously known as CMS Regional Office(s), the CMS Location(s) are part of the Survey & Operations Group (SOG) within CMS.*

Complaint investigation*, previously known as a complaint survey, means an onsite review that is conducted to investigate specific allegations of noncompliance.*

Condition-level deficiency *means noncompliance as described in 42 CFR §488.24. A condition-level deficiency is any deficiency of such character that substantially limits the provider's or supplier's capacity to furnish adequate care or which adversely affects the health or safety of patients.*

Credible allegation of compliance *is a statement or documentation that is realistic in terms of the possibility of the corrective action being accomplished between the exit conference and the date of the allegation; and that indicates resolution of the problems.*

Deficiency *is a violation of the Act and regulations contained in part 484 for HHAs, subparts A through C of this chapter, and §418 for hospice programs, subparts C and D of this chapter, is determined as part of a survey, and can be either standard or condition-level.*

Directed plan of correction *means CMS or the temporary manager (with CMS/SA approval) may direct the HHA or hospice program to take specific corrective action to achieve specific outcomes within specific timeframes. (HHA: 42 CFR §488.805; Hospice: 42 CFR §488.1250)*

Enforcement action *means the process of imposing one or more of the following alternative sanctions for HHAs or enforcement remedies for hospice programs: termination of a provider agreement; suspension of payment for all new admissions; temporary manager; civil money penalty; directed plan of correction; or directed in-service training. (HHA: 42 CFR §488.810-865; Hospice: 42 CFR §488.1200-1265)*

Extended survey (HHA only) *means a survey that reviews additional CoPs not examined during a standard survey. It may be conducted at any time but must be conducted when substandard care is identified. (42 CFR §488.705)*

Immediate jeopardy *means a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause serious injury, harm, impairment, or death to a patient(s).*

iQIES *– Internet Quality Improvement and Evaluation System.*

New admission *means an individual who becomes a patient or is readmitted to the HHA or hospice on or after the effective date of a suspension of payment sanction. (HHA: 42 CFR §488.805)*

Noncompliance *means any deficiency found at the condition-level or standard-level.*

Partial extended survey (HHA only) *means a survey conducted to determine if deficiencies and/or deficient practice(s) exist that were not fully examined during the standard survey. The surveyors may review any additional requirements which would assist in making a compliance finding. (42 CFR §488.705)*

Per day *means a CMP imposed for the number of days a facility is not in substantial compliance with the CoPs.*

Per instance *means a single event of noncompliance identified and corrected through a survey, for which the Act authorizes CMS to impose a sanction or remedy. (HHA: 42 CFR §488.805; Hospice: 42 CFR §488.1245(b)(6))*

Plan of correction *means a plan developed by the HHA or hospice program and approved by CMS that is the HHA's or hospice program's written response to survey findings detailing corrective actions to cited deficiencies and specifies the date by which those deficiencies will be corrected.*

Repeat deficiency *means a condition-level citation that is cited on the current survey and is substantially the same as or similar to, a finding of a standard-level or condition-level deficiency cited on the most recent previous standard survey or on any intervening survey since the most recent standard survey. Repeated non-compliance is not on the basis that the exact regulation (that is, tag number) for the deficiency was repeated. (HHA: 42 CFR §488.805; Hospice: 42 CFR 488.1205)*

Standard-level deficiency *means noncompliance with one or more of the standards that make up each condition of participation.*

Standard survey *means a survey conducted in which the surveyor reviews the HHA's or hospice program's compliance with a select number of standards and/or CoPs to determine the quality of care and services furnished by an HHA or hospice program. (HHA: 42 CFR §488.705)*

State survey agency (SA) *means the entity responsible for conducting most surveys to certify compliance with the Medicare participation requirements.*

Substandard care *means noncompliance with one or more CoPs identified on a standard survey, including deficiencies which could result in actual or potential harm to patients. (HHA: 42 CFR §488.705)*

Substantial compliance *means compliance with all condition-level requirements, as determined by CMS, the SA, or AO. (HHA: 42 CFR §488.705; Hospice: 42 CFR 488.1105)*

Temporary management *means the temporary appointment by CMS or by a CMS authorized agent, of a substitute manager or administrator. The HHA's or hospice program's governing body must ensure that the temporary manager has authority to hire, terminate or reassign staff, obligate funds, alter procedures, and manage the HHA or hospice program to correct deficiencies identified in the HHA's or hospice program's operation. (HHA: 42 CFR §488.805; Hospice 42 CFR 488.1235)*

Validation survey *means a survey of an accredited provider or supplier to validate the accrediting organization's CMS-approved accreditation process. These surveys are conducted on a representative sample basis, or in response to substantial allegations of non-compliance. (42 CFR 488.9(a))*

10002 – Informal Dispute Resolution (IDR) for Home Health Agencies & Hospice Programs

10002.1 – IDR Introduction & Purpose
(Rev.)

Section 488.745 and 488.1130 offers HHAs and hospice programs the option to request an informal opportunity to dispute condition-level survey findings warranting an alternative sanction following a facility's receipt of the official statement of deficiencies (Form CMS-2567). Whenever possible, we want to provide every opportunity to settle disagreements at the earliest stage, prior to a formal hearing, conserving time and money potentially spent by the facility, the SA, and CMS. The goal of IDR is to offer the facility an opportunity to refute one or more condition-level deficiencies cited on the statement of deficiencies. An IDR between an HHA or hospice program and the SA or CMS Location, as appropriate, will allow the facility an opportunity to provide an explanation of any material submitted to the SA and respond to the reviewer's questions (77 FR 67141).

This IDR will occur with the agency who conducted the survey. The IDR process, as established by the State or CMS Location, must be in writing so that it is available for review upon request.

If the survey is conducted by the CMS Location, the CMS Location may conduct the IDR.

CMS has adopted the following elements to be incorporated in all cases involving deficiencies cited as a result of Federal surveys. They are designed to clarify and expedite the resolution process. States are free to incorporate these elements into their procedures.

1. *Notice to the facility will indicate that the IDR, including any face-to-face meetings, constitutes an informal administrative process that in no way is to be construed as a formal evidentiary hearing.*

2. *Notice to the facility will indicate that counsel may accompany the HHA or hospice program. If the facility chooses to be accompanied by counsel, then it must indicate that in its request for IDR, so that CMS may also have counsel present.*

3. *CMS will verbally advise the facility of CMS's decision relative to the informal dispute, with written confirmation to follow.*

10002.2 – IDR Process
(Rev.)

When survey findings indicate a condition-level deficiency (or deficiencies), CMS or the State, as appropriate, will notify the facility in writing of its opportunity to request an IDR of those deficiencies. This notice will be provided at the time the Statement of Deficiencies is issued to the facility. The facility's request for IDR must be submitted in writing, should include the specific deficiencies that are disputed, and should be submitted within the same 10 calendar day period that the facility has for submitting an acceptable plan of correction.

A facility's initiation of the IDR process will not postpone or otherwise delay the effective date of any enforcement action. The failure to complete an IDR will not delay the effective date of any enforcement action. Further, if any findings are revised or removed based on IDR, the official Statement of Deficiencies is revised accordingly, and any enforcement actions imposed solely because of those revised or removed deficiencies are adjusted accordingly.

10002.3 - Mandatory Elements of IDR
(Rev.)

Upon their receipt of the official Form CMS-2567, agencies must be offered one informal opportunity, if they request it in writing, to dispute condition level deficiencies. Deficiencies cited at the standard level are not subject to the IDR process.

The following elements must be included in each IDR process offered:

1. *Agencies may not use the IDR process to delay the formal imposition of sanctions or to challenge any other aspect of the survey process, including:*

- *The severity assessment of a deficiency(s) at the standard level that constitutes substandard care or immediate jeopardy (IJ);*

- *Sanctions imposed by the enforcing agency;*

- *Alleged failure of the survey team to comply with a requirement of the survey process;*

- *Alleged inconsistency of the survey team in citing deficiencies among agencies; and*

- *Alleged inadequacy or inaccuracy of the IDR process.*

2. *HHAs or hospice programs must be notified of the availability of IDR in the letter transmitting the official Form CMS-2567. The letter should inform the facility of the following:*

- *It may request the opportunity for IDR, and that if it requests the opportunity, the request must be submitted in writing;*
- *The written request for IDR, from the facility, must include an explanation of the specific condition-level deficiencies that are being disputed;*
- *The written request must be made within the same 10 calendar day period the facility has for submitting an acceptable plan of correction to the surveying entity;*
- *The name and address, e-mail, and phone number of the person to contact at the CMS Location or the SA to request the IDR;*
- *The IDR process that is followed in that State, e.g., telephone conference, written communication, or face-to-face meeting; and*
- *The name and/or position title of the person who will be conducting the IDR, if known.*

***NOTE**: IDR is a process in which State agency officials make determinations of noncompliance. SAs should be aware that CMS holds them accountable for the legitimacy of the process including the accuracy and reliability of conclusions that are drawn with respect to survey findings. This means that while the SA may have the option to involve outside persons or entities they believe to be qualified to participate in this process, it is the SA, not outside individuals or entities that are responsible for IDR decisions. When an outside entity conducts IDR, the results of the IDR process may serve only as a recommendation of noncompliance or compliance to the SA. The SA will then make the IDR decision and notify the facility of that decision. CMS will look to the SA to assure the viability of these decision-making processes, and holds the SA accountable for them.*

Since CMS has ultimate oversight responsibility relative to a SA's performance, it may be appropriate for CMS to examine specific IDR decisions or the overall IDR process to determine whether the decision is consistent with CMS policy. For dually participating or Medicare-only agencies, informal dispute findings are in the manner of recommendations to CMS and, if CMS has reason to disagree with those findings, it may reject the conclusions from IDR and make its own binding determinations of noncompliance.

3. *Failure to complete IDR timely will not delay the effective date of any enforcement action against the facility.*

4. *When a facility is unsuccessful during the process at demonstrating that a deficiency should not have been cited, the SA must notify the facility in writing that it was unsuccessful.*

5. *When a facility is successful during the IDR process at demonstrating that a deficiency should not have been cited or should be revised:*

- *The deficiency citation should be marked "deleted," or "revised" as appropriate, and signed and dated by a supervisor of the surveying entity; and*

- *Any enforcement action(s) imposed solely because of that deleted or revised deficiency citation should be rescinded.*

***NOTE**: The facility has the option to request a clean (new) copy of the Form CMS-2567. However, the clean copy will be the releasable copy only when a clean (new) plan of correction is both provided and signed by the facility. The original Form CMS-2567 is disclosable when a clean plan of correction is not submitted and signed by the facility. Deficiencies pending IDR should be entered into iQIES but will not be uploaded to the national database system until IDR has been completed.*

6. *An agency may request IDR for each survey that cites condition-level deficiencies. However, if IDR is requested for deficiencies cited at a subsequent survey, a facility may not challenge the survey findings of a previous survey for which the facility either received IDR or had an opportunity for it. Condition-level deficiencies that are not corrected and that are carried forward on a subsequent survey are not eligible for the IDR process. Condition-level deficiencies identified on a subsequent survey that are new are eligible to be reviewed through the IDR process.*

Additional information related to the effect of IDR on HHA alternative sanctions and hospice program enforcement remedies, including CMPs, is addressed in the appropriate sections of this chapter.

10003 – Enforcement Actions for Home Health Agencies and Hospice Programs
(Rev.)

CMS certifies HHAs and hospice programs for participation in Medicare. The SAs then conduct standard and complaint surveys of certified providers to determine compliance with the CMS conditions of participation. If an HHA or hospice program is not in compliance with the Medicare conditions, CMS may impose an alternative sanction or enforcement remedy. The following sections describe the statutory authorities, considerations, and process for imposition of sanctions/remedies.

10003.1 - Statutory Basis
(Rev.)

Alternative Sanctions for Home Health Agencies
Sections 1891(c) through (f) establish requirements for surveying and certifying HHAs as well as authorizes the Secretary to utilize varying enforcement mechanisms to terminate participation in the Medicare program and to impose alternative sanctions if HHAs are found out of compliance with the Medicare home health CoPs. The imposition of alternative sanctions

specified in §488.820 allows for non-compliant HHAs to have additional time to come into compliance with the CoPs before being terminated.

Enforcement Remedies for Hospice Programs

Division CC, section 407 of the Consolidated Appropriations Act 2021, amended Part A of Title XVIII of the Act to add a new section 1822 of the Act, and amended sections 1864(a) and 1865(b) of the Act, establishing new hospice program survey and enforcement requirements. Section 1822(c)(5) of the Act authorizes the Secretary to utilize varying enforcement mechanisms to terminate participation in the Medicare program and to impose enforcement remedies if hospice programs are found out of compliance with the Medicare CoPs. The imposition of enforcement remedies specified in §488.1220 allows for non-compliant hospice programs to have additional time to come into compliance with the CoPs before being terminated.

10003.2 - General Provisions

(Rev.)

Under section 1891(e)(1) of the Act for HHAs and section 1822(c)(5) of the Act for hospice programs, if CMS or a SA determines that condition-level deficiencies immediately jeopardize the health or safety of its patients, then CMS must take immediate action to notify the provider of the jeopardy situation and the provider must correct the deficiencies. If the IJ is not removed because the provider is unable or unwilling to correct the deficiencies, CMS will terminate the provider's provider agreement. In addition, CMS may impose one or more specified alternative sanctions or enforcement remedies, respectively, including but not limited to CMPs and suspension of all Medicare payments before the effective date of termination.

If CMS finds that the provider is not in compliance with the Medicare CoPs and the deficiencies involved do not immediately jeopardize the health and safety of the individuals to whom the HHA or hospice program furnishes items and services, CMS may terminate the provider agreement and should consider the imposition of an alternative sanction(s)/enforcement remedy(ies)

The decision to impose one or more alternative sanctions for HHAs or enforcement remedies for hospice programs would be based on condition-level deficiencies or repeat deficiencies found in the provider during a survey.

While SAs are not required to recommend the types of sanction/remedies to be imposed, they are encouraged to do so since States may be more familiar with a facility's history and the specific circumstances in the case at hand. To ensure effective communication and exchange of information, CMS encourages that all documentation is included in iQIES or any subsequent system. The CMS Location will consider these recommendations but ultimately makes the enforcement determination.

Not all situations require the same sanctions/remedies. The CMS Location should use the enforcement sanction/remedy most appropriate in considering the level/degree of harm, the

context behind the facility noncompliance, and the type of enforcement that has the best chance of the facility achieving future compliance. While a range of sanctions/remedies are available, suspension of payment for all new admissions is likely to be the most effective at rapidly returning the provider to compliance.

10003.3 - Effect of Sanctions/Remedies on HHAs and Hospice Programs that Participate in Medicare via Deemed Status through an Accrediting Organization
(Rev.)

A deemed HHA or hospice program loses its deemed status when a condition-level finding is cited on a complaint or validation survey. When a condition-level deficiency (ies) is found, the CMS Location returns oversight of the accredited HHA or hospice program back to the SA until the HHA or hospice program can demonstrate compliance with the CoPs. During the time that the SA has jurisdiction over the HHA or hospice program, the SA, not the Accrediting Organization (AO), will follow the procedures for recommending the imposition of sanctions/remedies, if appropriate. Once the HHA or hospice program returns to compliance with the Medicare conditions and has not been terminated, the CMS Location will restore its deemed status and return oversight to the AO.

AOs are not authorized to impose federal sanctions/remedies. Therefore, HHAs or hospice programs participating in Medicare through deemed status are not directly subject to sanctions/remedies by the AO while under jurisdiction of the AO. However, the CMS location may, after reviewing the AO's survey findings and related information, authorize the SA to conduct a focused validation survey to determine whether condition-level deficiencies, cited by the AO, have been corrected. If deemed status is withdrawn and/or the HHA or hospice program is placed under the jurisdiction of the SA, as may occur following a complaint investigation by the SA, the CMS Location may impose alternative sanctions/remedies on the HHA or hospice program per the usual procedures.

10003.4 - Effect of Sanctions/Remedies on HHA Branches and Hospice Multiple Locations
(Rev.)

Regardless of whether the condition level non-compliance is identified at the branch (HHA), multiple location (hospice), or the parent location, all sanctions/remedies imposed would apply to the parent HHA or hospice and its respective branches or multiple locations.

10003.5 - Enforcement Action When IJ Exists
(Rev.)

When there is IJ to patient health or safety, CMS must complete termination procedures within 23 days from the last day of the survey which found the IJ if it is not removed before then (following guidelines in Appendix Q of the State Operations Manual). The procedure must not be postponed or stopped unless the IJ is removed, as verified through onsite verification. If there

is a written and timely credible allegation that the IJ has been removed, CMS or the State will conduct a revisit prior to termination, if possible.

In addition to termination, one or more alternative sanctions for HHAs or enforcement remedies for hospice programs may be imposed. While the use of alternative sanctions or enforcement remedies in addition to termination is permitted, the Act makes it clear that the enforcement action for noncompliant agencies with IJ deficiencies is intended to be swift. The imposition of alternative sanctions for HHAs or enforcement remedies for hospice programs in addition to termination does not extend the timeframe that the HHA or hospice program has to remove the IJ situation.

10003.6 – Enforcement Action When Condition-Level Deficiencies Exist That Do Not Pose IJ
(Rev.)

If the HHA or hospice program is no longer in compliance with the CoPs, either because the deficiency(ies) substantially limit the HHA's or hospice program's capacity to furnish adequate care but do not pose IJ, or because the HHA or hospice program has repeat noncompliance that results in a condition level deficiency based on the HHA's or hospice program's failure to correct and sustain compliance, CMS will either terminate the provider agreement following the 90 day termination track or impose one or more alternative sanctions for HHAs or enforcement remedies for hospice programs as an alternative to termination. If alternative sanctions or enforcement remedies are imposed, CMS terminates the HHA's or hospice program's provider agreement within 6 months of the last day of the survey if the HHA or hospice program is not in substantial compliance with the CoPs and the condition level deficiencies are not corrected.

10003.7 - Effect of Termination on the Patients
(Rev.)

If an HHA or hospice program fails to correct deficient practices and sustain compliance, CMS may terminate the provider agreement. When this happens, an HHA or hospice program is required to appropriately and safely transfer its patients to another local HHA or hospice within 30 days of termination (see §488.825(c) & §488.830(e) for HHAs & §488.1225(c) & §488.1230(e) for hospice programs). The HHA or hospice is responsible for providing information, assistance, and any arrangements necessary for the safe and orderly transfer of its patients. The SA is required to provide oversight for all HHAs or hospices that are terminated to ensure the safe discharge and orderly transfer of all patients to another Medicare-approved HHA or hospice. Payment to terminated HHAs or hospices for services for current patients is provided up to 30 days after termination pursuant to §489.55.

10004- Available Sanctions/Remedies
(Rev.)

To the greatest extent possible, the time between the identification of deficiencies and imposition of sanctions/remedies should be minimized. In accordance with §488.820 for HHA and §488.1220

for hospice programs, the following sanctions/remedies in addition to termination of the provider agreement are available:

- *Civil money penalties;*
- *Suspension of payment for all new admissions;*
- *Temporary management;*
- *Directed plan of correction; and*
- *Directed in-service training.*

It is important to note that imposition of an alternative sanction or enforcement remedy is an available enforcement action, but it is not required when CMS may ultimately determine that termination is the most appropriate enforcement action to ensure patient health and safety. When CMS believes that an agency cannot promptly return to compliance, termination may be preferable.

10004.1 - Factors to be Considered in Selecting Sanctions/Remedies (Rev.)

When making sanction/remedy choices, the CMS Location should consider the extent to which the noncompliance is the result of a one-time mistake, larger systemic concerns, or an action of disregard for patient health and safety. CMS bases its choice of sanction(s)/remedy(ies) on consideration of one or more factors that include, but are not limited to, the following:

- *The extent to which the deficiencies pose IJ to patient health and safety.*
- *The nature, incidence, manner, degree, and duration of the deficiencies or noncompliance.*
- *The presence of repeat deficiencies, the HHA's or hospice program's overall compliance history and any history of repeat deficiencies at either the parent or branch or multiple locations.*
- *The extent to which the deficiencies are directly related to a failure to provide quality patient care.*
- *The extent to which the HHA or hospice program is part of a larger organization with performance problems.*
- *An indication of any system-wide failure to provide quality care.*

In addition, CMS reviews other factors including, but not limited to, the history of the HHA's or hospice program's compliance with the CoPs, specifically with reference to the cited deficiencies.

Once a sanction/remedy is imposed, it becomes effective as of the date specified in the notice letter for the sanction/remedy being imposed. All sanctions/remedies remain in effect and

continue until the facility has demonstrated and is determined to be in substantial compliance with all CoPs.

The summary table below gives a high-level overview of the available sanctions/remedies and factors to consider for selection. Each of these are discussed in greater detail throughout the rest of this chapter.

Summary Table of Available Sanctions/Remedies for HHAs & Hospice Programs

Available Sanction/Remedies	***Factors to Consider for Selection***
For All Sanctions/Remedies	• *The extent to which the deficiencies pose IJ to patient health and safety.* • *The nature, incidence, manner, degree, and duration of the deficiencies or noncompliance.* • *The presence of repeat deficiencies, the hospice program's overall compliance history and any history of repeat deficiencies at either the parent hospice program or any of its multiple locations.* • *The extent to which the deficiencies are directly related to a failure to provide quality patient care.* • *The extent to which the hospice program is part of a larger organization with performance problems.* • *An indication of any system-wide failure to provide quality care.*
Civil Money Penalty (CMP)*	*When repeat deficiencies exist.* • *Upper range of CMPs for IJ situations.* • *Middle range of CMPs for noncompliance that is directly related to poor quality patient care outcomes (non-IJ).* • *Lower range of CMPs for noncompliance that is related predominately to structure or process-oriented conditions.*
Suspension of payment for all new admissions (SPNA)*	*When condition-level deficiencies relate to poor patient care outcomes.*
Temporary Management*	*When failure to comply with the CoPs is directly related to management limitations, or* *When current management oversight is likely to impair the facility's ability to return to full compliance, or* *When needed, based on the above situations, to oversee orderly involuntary termination/closure and safe transfer of patients to another local HHA or hospice.*

Directed Plan of Correction (DPOC)	*When the HHA or hospice program has deficiencies that warrant direction for the provider to take specific actions, or* *When the HHA or hospice program fails to develop an acceptable plan of correction for condition-level deficiencies.*
Directed In-Service Training	*When education is likely to correct the deficiencies and help the HHA or hospice program achieve substantial compliance.*
** For HHAs only: Please note that the imposition of one or more of these sanctions could prohibit an HHA from conducting home health aide training and competency evaluation program as noted in 42 CFR 484.80(f).*	

The following sections describe each possible alternative sanction or enforcement remedy and procedures for imposing them. In addition, the CMS Location and SA follow the procedures in Chapter 3 of the SOM if an adverse action is likely to be initiated against a Medicare participating provider.

10005 - Civil Money Penalties
(Rev.)

10005.1 - Basis for Imposing Civil Money Penalties
(Rev.)

CMS may impose a CMP against an HHA or hospice program based on noncompliance with one or more CoPs found through a survey or on the presence of repeat deficiencies (i.e., looking at the HHA's or hospice program's overall compliance history per 42 CFR 488.815(c) and 42 CFR 488.1215(c)).

Enforcement sanctions/remedies may be applied regardless of whether the HHA's or hospice program's deficiencies pose IJ to patient health and safety. CMS may impose a CMP for the number of days that an HHA or hospice program is not in substantial compliance with one or more CoPs, or for each instance that an HHA or hospice program is not in substantial compliance. In the case of unremoved IJ situations, the existing 23-day termination timeline still applies (See also Appendix Q of the State Operations Manual for IJ timelines).

The CMP amounts are based on §488.845 for HHAs and §488.1245 for hospice programs which lay out the ranges and amounts for CMPs. However, CMS is required by law to annually adjust the CMP amounts based on inflation in accordance with 45 CFR part 102. Therefore, while the original CMP amounts are located in the regulations, CMS Location staff will use the annually adjusted amounts that CMS posts on its website on the Quality, Safety & Oversight Group webpage (https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Civil-Monetary-Penalties-Annual-Adjustments.html) to calculate the penalty. The maximum CMP amount is also posted on this website and will be regularly updated when annual inflation adjustments are made.

CMS may impose a CMP against an HHA or hospice program for either the number of days (per day CMP) the facility is not in compliance with one or more CoPs or for each instance (per instance CMP) that the facility is not in compliance.

Per Day CMP

"Per day" means a CMP imposed for the number of days a facility is not in substantial compliance with the CoPs.

Surveyors may come across information during the survey that identifies past noncompliance, but evidence exists that the noncompliance was corrected and is not an issue during the current survey. While we do not cite to past noncompliance (deficiencies identified and corrected since the last survey), if a surveyor finds current noncompliance and can trace the start of noncompliance back to a specific date prior to this current survey, a per day CMP may be imposed. In general, the CMS Location may impose a per day CMP from the time when the noncompliance occurred through the time when the noncompliance was corrected. For example, CMS may impose a CMP for the number of days an IJ situation exists.

The range of per day penalties is set forth at §488.845(b)(3)-(5) for HHAs and §488.1245(b)(3)-(5) for hospice programs. These base amounts are adjusted annually for inflation and are posted on the CMS website.

The CMP range amounts are based on three levels of seriousness—upper, middle, and lower. The lower range of permitted per day CMP amounts enables CMS to better correlate the seriousness of noncompliance with the amount of the CMP. The expanded lower end of the range may be particularly important if CMS imposes a CMP that begins at the lower or middle range and then increases in amount over time the longer the noncompliance remains uncorrected. In such a case, prompt remedial action by the HHA or hospice program can limit the total amount of per day CMP that accrues (See also 77 FR 67150).

Per Instance CMP

"Per instance" is defined at §488.805 and 42 CFR 488.1205 and means a single event of noncompliance identified and corrected during a survey, for which the statute authorizes CMS to impose a sanction/remedy.

For example, during a survey, CMS or a state may identify several instances of noncompliance, each in distinct regulatory areas. Generally, we anticipate imposing per instance penalties only in the situation where a surveyor identifies a condition-level deficiency during the survey and the HHA or hospice program took sufficient action to correct the deficiency during the time of the survey (see also 77 FR 67150).

The range of per instance penalties is set forth at §488.845(b)(6) for HHA and §488.1245(b)(6) for hospice programs, and the penalty amounts are adjusted annually for inflation and are posted on the CMS website. The terminology "per instance" is not used to suggest that only one instance of condition-level noncompliance may be assigned a CMP. There can be more than one instance of condition-level noncompliance identified during a survey where the SA/CMS Location utilizes the per instance CMP as a sanction/remedy. However, the total dollar amount of the CMP for the instance or multiple instances of condition-level noncompliance may not exceed the maximum $10,000 (as adjusted for inflation) for each day of that specific survey, and may not be less than $1,000 (as adjusted for inflation) per instance.

***NOTE:** A per day and a per instance civil money penalty cannot be used simultaneously for the same deficiency in conjunction with a survey (i.e., standard, revisit, complaint). However, both types of CMPs may be used during a noncompliance cycle if more than one survey takes place, and the per day CMP was not the CMP initially imposed. When a per day CMP is the CMP sanction initially imposed, a per instance CMP cannot be imposed on a subsequent survey within the same noncompliance cycle.*

***For HHAs Only:** Please note that the imposition of a $5,000 or more CMP on an HHA would prohibit that HHA from conducting health aide training and competency evaluation program for 2 years from the date this sanction is imposed (see also 42 CFR 484.80(f)). See Appendix B of the State Operations Manual for additional information for eligible home health aide training and competency evaluation organizations at §484.80(f).*

10005.2 - Determining Amount of Civil Money Penalty
(Rev.)

CMPs are intended as a tool to encourage the HHA or hospice program to rapidly return to compliance with program requirements to protect the health and safety of individuals under their care. As with all other enforcement sanctions/remedies, CMPs are a discretionary enforcement action and not required. CMS may ultimately determine that termination is the most appropriate enforcement action to ensure patient health and safety. While a provider may be given an opportunity to correct their deficiencies and return to compliance, if CMS determines that an agency cannot promptly return to compliance, termination may be preferable to an alternative sanction or enforcement remedy.

CMS bases its choice of sanction/remedy on consideration of one or more factors that include, but are not limited to the following:

- *The extent to which the deficiencies pose IJ to patient health and safety.*
- *The nature, incidence, manner, degree, and duration of the deficiencies or noncompliance.*
- *The presence of repeat deficiencies, the HHA's or hospice program's overall compliance history and any history of repeat deficiencies at either the parent or branch or multiple location.*

- *The extent to which the deficiencies are directly related to a failure to provide quality patient care.*

- *The extent to which the HHA or hospice program is part of a larger organization with performance problems.*

- *An indication of any system-wide failure to provide quality care.*

In determining the amount of the civil money penalty, CMS considers certain factors in addition to those listed above which include:

- *The size of the HHA or the hospice program and its resources;*

- *Accurate and credible resources, such as PECOS, Medicare cost reports and Medicare/Medicaid claims information that provide information on the operation and resources of the HHA; and*

- *Evidence that the HHA or hospice program has a built-in, self-regulating quality assessment and performance improvement system to provide proper care, prevent poor outcomes, control patient injury, enhance quality, promote safety, and avoid risks to patients on a sustainable basis that indicates the ability to meet the conditions of participation and to ensure patient health and safety.*

In collaboration with other CMS components, CMS may consider an agency's financial condition on a case-by-case basis, and this evaluation may be made in part by considering the HHA's or hospice program's size and its resources. The CMS Location may need to consult with other CMS components such as Center for Program Integrity (CPI), Centers for Medicare (CM), and/or Office of Financial Management (OFM) as part of the process to consider the above factors. CMS considers whether the HHA or hospice program has the ability to pay the CMP without having to go out of business or compromise patient health and safety. An HHA or hospice program may be expected to satisfy its obligations to the federal government before making payments to its owners.

Information on the operations and resources of the HHA or hospice program may include items such as, but not limited to, historical patient census, staffing levels, and claims paid. Additionally, CMS may consider other aspects such as enforcement actions taken by CMS for enrollment or payment related issues (e.g., overpayment, pre/post-pay audits, suspensions, and revocations) and the impact these can have on HHA or hospice program resources.

When several instances of noncompliance are identified at a survey, either a per day or per instance civil money penalty could be imposed. By law, CMPs may not exceed a set maximum amount per day. The maximum is a total, comprising per day and per instance penalties. This maximum amount is set forth at §488.845(b)(2)(iii) and at §488.845(b)(6) for HHA and §488.1245(b)(2)(iii) and at §488.1245(b)(6) for hospice programs, and the current adjusted maximum amount is posted on CMS's website on the Quality, Safety & Oversight Group

webpage at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Civil-Monetary-Penalties-Annual-Adjustments.

Per the Federal Civil Penalties Inflation Adjustment Improvements Act of 2015, inflationary adjustments to the CMPs are published annually and are effective immediately upon publication. The first of these adjustments was published in the Federal Register on September 6, 2016, at 81 FR 61538. A table located at 45 CFR 102.3 shows how the CMPs are adjusted for inflation. In addition, these adjusted CMP amounts are posted on the CMS website on the Survey and Certification Group webpage and are updated when future inflation adjustments are made. Adjusted amounts that are in effect when the CMP is imposed by CMS shall be applied, regardless of when noncompliance is identified. This means that the CMP amount per day or per instance imposed should be calculated using the most current adjusted amount noted in 45 CFR 102.3. For example, if a survey identifies condition-level noncompliance but CMS has not imposed a CMP yet (i.e., sent notice of intent to impose a CMP) and the next annual adjustment is published, then CMS must impose a CMP amount, either per day or per instance, using the newly adjusted amounts. For example: During a survey, a situation of IJ that is unremoved at survey exit, is identified, and CMS sends notice of the intent to impose a CMP. Upon receipt of an acceptable plan of correction, a revisit survey is completed, revealing the situation of IJ was removed but noncompliance at the condition level remains. CMS would move to lower the amount of the CMP imposed per day considering the survey findings and changes to the severity of identified noncompliance. However, if the daily penalty assessment of the CMP is adjusted under existing Federal law prior to CMS notifying the facility of the reduction in the per day amount of the CMP, CMS must lower the amount per day only to an amount that meets the newly adjusted totals (see also 42 CFR 488.845(b)(2)(iii) for HHAs and 42 CFR 488.1245(b)(2)(iii) for hospice programs).

In the event the ranges, minimum, and/or maximum amount of a CMP is adjusted for inflation during an entity's cycle of noncompliance, CMS must calculate the amount based upon the date the notice of intent is issued, not the date noncompliance was identified. These adjusted amounts shall be used until the next effective date for CMP inflation adjustments occurs.

The CMS Location consults with the regional attorney's office to ensure compliance with section 1128A of the Act and Department of Justice requirements. Section 1128A of the Act requires CMS to offer a hearing before collecting, but not before imposing, a CMP.

10005.3 - Penalty Amounts
(Rev.)

The current adjusted penalty amounts are posted annually on the CMS website on the Quality, Safety & Oversight Group webpage at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Civil-Monetary-Penalties-Annual-Adjustments and are regularly updated when inflation adjustments are made.

10005.4 - Range of Penalty Amounts
(Rev.)

CMS bases the range of civil money penalty amounts on three levels of seriousness—upper, middle, and lower. The range of CMPs is identified at §484.485(b)(3) – (6) for HHA and §488.1245(b)(3) – (6) for hospice programs, and the amounts are adjusted annually for inflation and are posted on the CMS website. The specified CMP ranges mark the starting point in CMS's determination of the CMP amount. First, CMS looks to the specific circumstances of the survey findings to determine whether a per day or per instance CMP is warranted and whether the facts point to a CMP rate in an Upper, Middle, or Lower range. After the CMP type and range are determined, CMS considers the additional factors described above at 10012.2.

When CMS is determining the rates for multiple CMPs, the rates must be evaluated collectively. By law, CMPs may not exceed a set maximum amount per day. The maximum is a total, comprising per day and per instance penalties. This maximum is set forth at §488.845(b)(2)(iii) and at §488.845(b)(6) for HHA and at §488.1245(b)(2)(iii) and at §488.1245(b)(6) for hospice programs.

Current information on the range of CMPs and the maximum amount per day is posted on the CMS website on the Quality, Safety & Oversight Group webpage at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Civil-Monetary-Penalties-Annual-Adjustments.html.

10005.5 - Upper Range of Penalty
(Rev.)

Upper range penalty amounts are imposed for a condition-level deficiency that is IJ. The CMP upper ranges are set forth in §§488.845(b)(3)(i), (ii), and (iii) for HHA and §488.1245(b)(3)(i), (ii), and (iii) for hospice programs and will vary based on the following:

a. *If the IJ is cited for actual harm;*

b. *If the IJ is cited for potential for harm; and*

c. *If the IJ is cited for a violation of established HHA or hospice program policies and procedures*

Note: *The following examples contain findings that could become a part of an HHA's or hospice program's IJ citation. Please note that the citation of IJ is only made after careful investigation of all relevant factors as detailed in Appendix Q. An IJ decision requires a determination that the situation meets all required IJ components.*

1. *Section 488.845(b)(3)(i) for HHAs and §488.1245(b)(3)(i) for hospice programs address CMPs for a deficiency or deficiencies that are determined to be IJ and that results in actual harm.* ***Examples:*** *The facility fails to report to a physician, episodes of severe hyperglycemia, resulting in ketoacidosis and hospitalization of diabetic patient; and the facility fails to timely and accurately assess a patient's pressure ulcers, which deteriorate to Stage 4 and sepsis prior to their recognition.*

2. *Section 488.845(b)(3)(ii) for HHAs and §488.1245(b)(3)(ii) for hospice programs address CMPs for a deficiency or deficiencies that are determined to be IJ and that result in a potential for harm.* ***Examples:*** *The facility fails to intervene after patient verbalizes threats of suicide, resulting in potential for self-harm; and the facility fails to administer ordered intravenous antibiotic to patient with diagnosed infection, resulting in potential for development of sepsis.*

3. *Section 488.845(b)(3)(iii) for HHAs and §488.1245(b)(3)(iii) for hospice programs address per day penalties for an isolated incident of noncompliance that is in violation of the HHA's or hospice program's established policies and procedures.* ***Example:*** *One of the facility's nurses did not follow the infection control policies and procedures when performing wound care requiring sterile technique on an immunocompromised patient.*

Current information on the range of CMPs and the maximum amounts is posted on the CMS website on the Quality, Safety & Oversight Group webpage at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Civil-Monetary-Penalties-Annual-Adjustments.html

The penalty in this upper range will continue until the IJ is removed and substantial compliance can be determined per the usual procedures. (See Appendix Q for IJ removal process and timelines)

During the revisit survey, the SA will determine if the IJ is removed. If the IJ situation has been removed, but condition level deficiencies still exist, the penalty amount may be decreased to the middle or lower range of penalties based on the deficiency.

Note*: In accordance with 42 CFR 488.830(a)(2) for HHAs and 42 CFR 488.1230(c) for hospice programs, if one or more alternative sanctions are imposed as an alternative to termination, the delay in termination may not exceed 6 months from the last day of the survey identifying condition-level noncompliance.*

10005.6 - Middle Range of Penalty
(Rev.)

Section 488.845(b)(4) for HHA and §488.1245(b)(4) for hospice programs set forth the middle range of penalties. Middle range amounts are imposed for a repeat and/or condition-level deficiency that does not constitute IJ but is directly related to poor quality patient care outcomes.

10005.7 - Lower Range of Penalty
(Rev.)

Section 488.845(b)(5) for HHA and §488.1245(b)(5) for hospice programs set forth the lower range of penalties. CMPs in the lower range are imposed for a repeat and/or condition-level

deficiency that does not constitute IJ and that is related predominately to structure or process-oriented conditions (such as OASIS submission requirements) rather than directly related to patient care outcomes.

10005.8 – CMP Imposition and IDR in HHAs and Hospices
(New)

Per §488.745 for HHAs and §488.1130, CMS's or the State's failure to complete IDR (as described in section 10002 of this manual) shall not delay the effective date of any enforcement action, including the imposition of CMPs. In those occasions where an IDR may occur after a CMP is imposed, the IDR results will nevertheless be considered in the enforcement action. We specify at §488.745(c) for HHAs and §488.1130(c) for hospices that if any findings are revised or removed by CMS or the State (for surveys conducted by the SA) based on IDR, the CMS-2567 is revised accordingly and any enforcement actions imposed solely because of those cited deficiencies are adjusted accordingly.

10005.9 - Adjustments to Penalties
(Rev.)

CMS has the discretion to increase or reduce the amount of the CMP during the period of noncompliance depending on whether the level of noncompliance changed at the time of a revisit survey.

CMS may increase a CMP based on the following:

- *The HHA's or hospice program's inability or failure to correct deficiencies;*
- *The presence of a system-wide failure in the provision of quality care; or*
- *A determination of IJ with actual harm versus IJ with potential for harm.*

CMS may decrease a CMP to the extent that it finds, pursuant to a revisit, that substantial and sustainable improvements have been implemented even though the HHA or hospice program is not yet in full compliance with the conditions of participation.

10005.10 - Decreased Penalty Amounts
(Rev.)

If a penalty was imposed in the upper range and the IJ is removed or abated but the HHA or hospice program continues to have condition-level noncompliance that is not IJ, CMS will shift the penalty amount imposed per day from the upper range to the middle or lower range based on the conditions that are out of compliance. SAs and CMS Locations should follow the same guidelines above to determine new penalty amount. An earnest effort to correct any systemic causes of deficiencies and sustain improvement must be evident.

10005.11 - Increased Penalty Amounts
(Rev.)

Following the imposition of a lower level penalty amount (either the middle range or the lower range), CMS may increase the per day penalty amount for any condition-level deficiency or deficiencies which become sufficiently serious to pose potential harm or IJ.

CMS increases the per day penalty amount for deficiencies that are not corrected and found again at the time of revisit survey(s) for which a lower level penalty was imposed.

For repeated noncompliance with the same condition-level deficiency or for uncorrected deficiencies from a prior survey, CMS may impose an increased CMP amount.

10005.12 - Accrual and Duration of Per Day Penalty
(Rev.)

Available Sanction/Remedies	***Timeframe for Notice of Imposition***
Civil Money Penalties (CMP)*	*Notice of intent to impose – provided with statement of deficiencies* *Notice includes: the amount of the CMP being imposed, the basis for such imposition and the proposed effective date of the sanction.*

10005.13 - Duration of Per Day Penalty when there is IJ
(Rev.)

The per day CMP would begin to accrue on the last day of the survey that identified the noncompliance and would continue to accrue until the HHA or hospice program achieves substantial compliance with all requirements or the date of termination, whichever occurs first. In the case of noncompliance that poses IJ, CMS must terminate the provider agreement within 23 calendar days after the last date of the survey if the IJ is not removed.

10005.13A - Duration of Penalty when there is no IJ
(Rev.)

In the case of noncompliance that does not pose IJ, the daily accrual of per day CMP is imposed for the days of noncompliance, i.e., from the day the penalty starts (based on the survey completion date and this may be prior to the notice), until the HHA or hospice program achieves substantial compliance based on a revisit or the provider agreement is terminated, but for a period of no longer than 6 months following the last day of the survey.

If the HHA or hospice program has not achieved substantial compliance with all the conditions of participation, CMS will terminate the provider agreement. The accrual of civil

money penalty stops on the day the HHA or hospice program agreement is terminated or the HHA or hospice program achieves substantial compliance, whichever is earlier.

10005.14 – Range of Penalty Amounts - Per Instance
(Rev.)

Penalties imposed per instance of noncompliance may be assessed for one or more singular events or instances of condition-level noncompliance that are identified and where the noncompliance was corrected during the onsite survey. The terminology "per instance" is not used to suggest that only one instance of noncompliance may be the basis to assess a CMP. There can be more than one instance of noncompliance identified during a survey. The current adjusted range for per instance CMPs, as well as the adjusted maximum amount per day, is posted on the CMS website on the Quality, Safety & Oversight Group webpage at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Civil-Monetary-Penalties-Annual-Adjustments.

10005.15 – Accrual and Duration of Per Instance Penalty
(Rev.)

As set forth in §488.845(b)(6) for HHA and §488.1245(b)(6) for hospice programs, a per instance CMP is imposed for each instance of noncompliance based on a deficiency(ies) during a specific survey. It is applied to as many instances as is deemed appropriate and in a specific amount for that deficiency(ies). The current adjusted range for per instance CMPs, as well as the maximum adjusted amount per day, is posted on the CMS website on the Quality, Safety & Oversight Group webpage.

***NOTE:** The per day and per instance CMP would not be imposed simultaneously for the same CoPs in a survey. In no instance will the period of noncompliance be allowed to extend beyond 6 months from the last day of the original survey that determined the HHA's or hospice program's noncompliance. If the HHA or hospice program has not achieved substantial compliance with all the participation requirements within those 6 months, CMS will terminate the HHA or hospice program. The accrual of the per day CMP stops on the day the HHA's or hospice program's provider agreement is terminated or the HHA or hospice program achieves substantial compliance, whichever is earlier.*

***Example:** When the per instance CMP is used on the original survey, the revisit survey is used to determine compliance. If noncompliance is identified at the revisit survey and a CMP is selected as the enforcement remedy/sanction, either the per instance or per day remedy may be selected.*

10005.16 - Accrual and Duration Examples
(Rev.)

a. *Revisit Survey Identifies New Noncompliance and Same Data Tag is Selected - If the same data tag is selected to identify noncompliance, the State (or CMS Location) could choose to utilize either the per instance or per day CMP. It would not matter whether the same data tag was selected to identify the new noncompliance. The issue is whether*

noncompliance is present and whether the deficient practice rises to a level that will support selecting a CMP as a sanction. For example, noncompliance was identified at HHA Tag G406 (Condition of participation: Patient rights) during the original survey. During the revisit survey, a different problem dealing with the patient rights of three patients was cited at Tag G406. The per instance or per day CMP would be selected for the noncompliance identified at Tag G406. If the per instance civil money penalty was used, the amount of the CMP might be influenced by factors relating to the violations of patient rights. However, only one per instance CMP would be appropriate. It would not be appropriate to assign a separate CMP for each of the violations related to patient rights (findings) identified at Tag G406.

b. *Revisit Survey Identifies New Noncompliance and a Different Data Tag is Selected - If a revisit identifies new deficiencies at a different data tag, either a per instance or per day CMP could be selected as a sanction.*

c. *Noncompliance - IJ Does Not Exist (Per Day)- For noncompliance that does not pose IJ, the per day CMP is imposed for the days of noncompliance, i.e., from the day the penalty starts (and this may start accruing as early as the beginning of the last day of the survey that determines the HHA or hospice program was out of compliance), until the HHA or hospice program achieves substantial compliance, or the provider agreement is terminated. However, if the HHA or hospice program has not achieved substantial compliance at the end of 6 months from the last day of the original survey, the CMS Location terminates the provider agreement. The accrual of the CMP stops on the date that the provider agreement is terminated.*

d. *Noncompliance - IJ Does Not Exist (Per Instance)- For noncompliance that does not pose IJ, the per instance CMP is imposed for the number of deficiencies during a survey for which the per instance CMP is determined to be an appropriate sanction. For example, HHA Tag G510 (Condition of participation: Comprehensive assessment of patients) and HHA Tag G370 were cited on a survey. A per instance CMP of $2,000 is imposed for Tag G370 and a per instance CMP of $8,000 is imposed for Tag G510. No civil money penalty could then be imposed for additional deficiencies because the total "per instance CMP" may not exceed $10,000 as adjusted annually for each day of noncompliance.*

e. *Noncompliance - IJ Exists - For noncompliance that poses IJ, CMS must terminate the provider agreement within 23 calendar days after the last day of the survey that identified the IJ if the IJ is not removed. The accrual of the per day CMP stops on the date that the provider achieves substantial compliance, or the provider agreement is terminated.*

10005.17 - Computation and Notice of Total Penalty Amount
(Rev.)

*When a CMP is imposed on a **per day** basis and the HHA or hospice program achieves compliance with the conditions of participation as determined by an onsite revisit survey, CMS sends a final notice to the HHA or hospice program containing all the following information:*

- *The amount of penalty assessed per day.*
- *The total number of days of noncompliance.*
- *The total amount due.*
- *The due date of the penalty.*
- *The rate of interest to be assessed on any unpaid balance beginning on the due date. The rate of interest is the higher of either the rate fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date of the notice of the penalty amount due and this rate is published quarterly in the "Federal Register" by the Department of Health and Human Services under 45 CFR 30.13(a); or the current value of funds rate which is published annually in the "Federal Register" by the Secretary of the Treasury, subject to quarterly revisions. (The CMS Locations are notified by the CMS Office of Financial Management for the rate of interest information.)*
- *Instructions for submitting payment (see also "Method of Payment" section).*

When a CMP is imposed on a ***per day*** *basis and the HHA's or hospice program's provider agreement has been involuntarily terminated, CMS will send the penalty information, including the total amount of the CMP due, after one of the following actions has occurred:*

- *A final administrative decision is made;*
- *The HHA or hospice program has waived its right to a hearing in accordance with the regulations; or,*
- *The time for requesting a hearing has expired and CMS has not received a hearing request from the HHA or hospice program.*

When a ***per instance*** *CMP is assessed, a notice is sent to the HHA or hospice program containing all of the following information after the provider is in substantial compliance or its provider agreement has been terminated:*

- *The amount of the penalty or penalties that was assessed;*
- *The total amount due;*
- *The due date of the penalty;*
- *The rate of interest to be assessed on any unpaid balance beginning on the due date. The rate of interest is the higher of either the rate fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date of the notice of the penalty amount due and this rate is published quarterly in the "Federal Register" by the Department of Health and Human Services under 45 CFR*

30.13(a); or the current value of funds rate which is published annually in the "Federal Register" by the Secretary of the Treasury, subject to quarterly revisions. (The CMS Locations are notified by the CMS Division of Financial Management for the annual rate of interest information); and

- *Instructions for submitting payment (see also "Method of Payment" section).*

10005.18 - Notice of Imposition of Civil Money Penalty
(Rev.)

If CMS or the SA imposes a CMP, it provides the HHA or hospice program with written notice of the intent to impose the sanction/remedy, including the amount of the CMP being imposed, the basis for such imposition and the proposed effective date of the sanction/remedy. The notice includes:

I. *The nature of the noncompliance (regulatory requirements not met);*

II. *The statutory basis for the CMP;*

III. *The amount of the penalty per day of noncompliance or the amount of the penalty per instance of noncompliance during a survey;*

IV. *The factors that were considered in determining the amount of the CMP;*

V. *The date on which the per day CMP begins to accrue;*

VI. *A statement that the per day CMP will accrue until substantial compliance is achieved or until termination from participation in the program occurs.*

VII. *When the CMP payment is due;*

VIII. ***For HHAs only**: Implications of the CMP imposition on the home health aide training and competency evaluation program (see also 42 CFR 484.80(f)).*

IX. *Instructions for responding to the notice, including a statement of the HHA's or hospice program's right to a hearing and information about how to request a hearing; and*

X. *Implications of waiving the right to a hearing and information about how to waive the right to a hearing (see §10013.20 below).*

10005.19 - Sending the Notice
(Rev.)

The notice of CMP imposition shall be in writing and shall be addressed directly to the HHA or hospice program, or to an individual, an officer, managing or general agent, or other agent authorized by appointment or law to receive the notice.

The notice shall be dispatched through first-class mail, or other reliable means. Other reliable means refers to the use of alternatives to the United States mail in sending notices. Electronic communication, such as facsimile transmission or email, is equally reliable and on occasion more convenient than the United States mail. If electronic means are employed to send notice, the sender should maintain a record of the transmission to assure proof of transmission if receipt is denied.

It should be noted that in cases where the State is authorized by the CMS location, the State may send the initial notice of imposition of certain sanctions on CMS's behalf, within applicable notice requirements.

10005.20 - Appeal of Noncompliance That Led to Imposition of Civil Money Penalty

(Rev.)

Before collecting a CMP, section 1128A of the Act requires the Secretary (CMS) to conduct a hearing when properly requested by the HHA or hospice program pursuant to §498.40. An HHA or hospice program may request a hearing with the Administrative Law Judge (ALJ) on the determination of the noncompliance that is the basis for imposition of the CMP.

The procedures to request a hearing specified in 42 C.F.R. § 498.40 are followed when CMS imposes a CMP on an HHA or hospice program. Once an appeal hearing is requested, CMS cannot collect the CMP until a final agency determination. Additional procedures are set forth at 42 CFR 488.845(h) for HHA and at 42 CFR 488.1245(g) for hospice programs. Per these regulations, when an ALJ or state hearing officer (or higher administrative review authority) finds that the basis for imposing a CMP exists, the reviewing authority may not— (1) Set a penalty of zero or reduce a penalty to zero; (2) Review the exercise of discretion by CMS to impose a CMP; and (3) Consider any factors in reviewing the amount of the penalty other than those specified at §488.845(b) for HHA or §488.1245(b) for hospice programs.

10005.20A – HHA or Hospice Program Waives Right to a Hearing

(Rev.)

An HHA or hospice program may waive the right to a hearing, in writing, within 60 days from the date of the notice imposing the CMP. If an HHA or hospice program timely waives its right to an appeal hearing within 60 calendar days of their receipt of CMS' notice imposing the CMP, CMS will approve the waiver and reduce the CMP by thirty five percent (35%). Payment of the reduced CMP must be made within 15 days of the HHA's or hospice program's receipt of CMS's notice approving the waiver and reducing the CMP. If the HHA or hospice program does not waive its right to an appeal hearing in writing within 60 calendar days of their receipt of CMS original request for payment under §488.845(c)(2)(ii) for HHA and §488.1245(c)(2)(ii) for hospice programs, it will not receive the CMP reduction.

NOTE: *Each time a survey is conducted within an already running noncompliance cycle and a CMP is imposed, the HHA or hospice program is given appeal rights and may exercise its waiver of right to a hearing.*

When a per day CMP is imposed and then is increased or decreased at subsequent surveys during an already running noncompliance cycle, an HHA or hospice program may elect to either appeal each separate CMP imposition or waive the right to appeal each imposition. Each CMP imposition is computed separately for a set number of days. The final CMP amount is established after the final administrative decision.

Example: *An HHA is cited on the original recertification survey for non-compliance with 42 CFR 484.60 Condition of participation: Care planning, coordination of services, and quality of care. Findings include evidence that the HHA did not follow the plan of care, the plan of care did not include all pertinent diagnoses, and the HHA failed to notify the physician of changes in the patient's condition. On the first revisit survey, the incidence of these deficiencies increased. On both surveys, the condition is cited as out of compliance and CMPs are imposed. The CMP will be increased following the revisit survey. The HHA may choose to appeal one or both citations, or waive one or both citations, or waive one citation and appeal the other.*

When several per instance CMPs are imposed during a noncompliance cycle, an HHA or hospice program may choose to appeal or waive the right to appeal one or more of the CMPs, in the same manner as illustrated above for the per day CMPs.

After the facility achieves substantial compliance or its provider agreement is terminated, it is notified of the revised CMP amount due.

10005.21 - When a CMP is Due and Payable
(Rev.)

In accordance with HHA (42 CFR 488.845(f)) and hospice program (42 CFR 488.1245(f)) regulations, payments are due for all CMPs within 15 days from any of the following:

- *After a final administrative decision when the HHA or hospice program achieves substantial compliance before the final decision or the effective date of termination before final decision,*
    - *A final administrative decision includes an ALJ decision and review by the Departmental Appeals Board, if the HHA or hospice program requests a review of the ALJ decision.*
- *After the time to appeal has expired and the HHA or hospice program does not appeal or fails to timely appeal the initial determination,*
- *After CMS receives a written request from the HHA or hospice program requesting to waive its right to appeal the determinations that led to the imposition of a CMP,*

- *After substantial compliance is achieved, or*

- *After the effective date of termination.*

Note: *The regulations at §488.845 for HHA and §488.1245 for hospice programs do not include a provision for extended payment plans for HHA or hospice program CMPs.*

An HHA or hospice program has two options for action following the imposition of a CMP:

- *The HHA or hospice program could pay the amount due for all CMPs imposed prior to the date a CMP is due and payable; or*

- *The HHA or hospice program could request a hearing based on the determination of noncompliance with Medicare CoPs.*

When an HHA or hospice program provides timely notice waiving its right to a hearing, CMS reduces the final CMP amount by 35%. This reduction is reflected once the CMP stops accruing, that is, when the HHA or hospice program achieves substantial compliance before CMS receives its request to waive a hearing, or the effective date of the termination occurs before CMS received the waiver request.

Impact of Hearing Requests:
Within 60 days of receipt of the notice of imposition of a penalty, the HHA or hospice program may file a request directly to the Departmental Appeals Board in the Office of the Secretary, Department of Health and Human Services with a copy to the State and CMS. In accordance with §498.40(b), the HHA's or hospice program's appeal request would identify the specific issues of contention, the findings of fact and conclusions of the law with which the HHA or hospice program disagreed, and the specific basis for contending that the survey findings and determinations were invalid. A hearing would be completed before any penalty was collected. However, sanctions/remedies would continue regardless of the timing of any appeals proceedings if the HHA or hospice program had not met the CoPs.

Requesting an appeal would not delay or end the imposition of a sanction/remedy but can only affect the collection of any final CMP amounts due. A CMP would begin to accrue on the last day of the survey which identified the noncompliance. These include penalties imposed on a per day basis, as well as penalties imposed per instance of noncompliance.

10005.22 - Method of Payment
(Rev.)

HHAs and hospices may select one of the following payment options: (1) Pay.gov; or (2) Electronic transfer of funds. CMS Office of Financial Management (OFM) prefers the use of Pay.gov because it is the federal government's secure portal for web-based collection and billing services which has been implemented by OFM to collect any money due to CMS. Questions

related to use of pay.gov, please contact the OFM's Division of Collections via email at OFMDPBCCMPGeneralMailBox@cms.hhs.gov.

HHAs and hospices are not to send CMP payment checks to the CMS Locations. If an HHA or hospice requests to pay by check, it will be considered on a case-by-case basis with collaboration from the CMS Location's division of financial management.

10005.23 - Settlement of Civil Money Penalty
(Rev.)

The CMS Location has the authority to settle CMP cases at any time prior to a final administrative decision. If a decision is made to settle, the settlement should not be for a better term than had the HHA or hospice program opted for a 35 percent reduction.

10005.24 - Offsets
(Rev.)

If payment was not received by the established due date, CMS will collect the CMP through offset of monies then owed or later owing to the HHA or hospice program. To initiate such an offset, CMS will instruct the appropriate Medicare Administrative Contractors (MAC), when applicable, the State Medicaid agencies, to deduct unpaid CMP balances from any money owed to the HHA or hospice program. To maintain consistency in recovering a CMP among other types of providers who are subject to a CMP, the amount of any penalty can be deducted (offset) from any sum CMS or the State Medicaid Agency owes to the HHA or hospice program.

Interest would be assessed on the unpaid balance of the penalty beginning on the due date. The rate of interest assessed on any unpaid balance would be based on the Medicare interest rate published quarterly in the Federal Register, as specified in §405.378(d). CMS Locations are notified by CMS OFM of the current interest rate and any changes.

10005.25 - Debt Referral to the Department of the Treasury via the Debt Collection System
(New)

Those CMP amounts not recovered due to HHA or hospice program failure to pay or inadequate funds for offset will be collected through the Debt Collection Improvement Act of 1996 which requires all debt owed to any Federal agency that is more than 180 days delinquent to be transferred to the Department of the Treasury for debt collection services. Prior to initiating a CMP debt referral to the Department of the Treasury, the CMS Location must first exhaust all collection options through the MAC and the State Medicaid Agency.

The Debt Collection System (DCS) is the data system that is used by the Division of Medicare Debt Management (DMDM) in OFM to transmit debt referrals to the Department of the Treasury via the Program Support Center (PSC), a separate component within the Department of Health and Human Services.

10005.26 - Disbursement of Recovered CMP funds
(Rev.)

The CMP amounts and any corresponding interest recovered from HHAs, and hospice programs will be divided between the Medicare and Medicaid programs, based on a proportion that is commensurate with the comparative Federal expenditures under Titles XVIII and XIX of the Act, using Medicaid Statistical Information System (MSIS) and HHA or hospice program Prospective Payment System (PPS) data for a three-year fiscal period. The amounts are disbursed in accordance with § 488.845(g). Penalty funds may not be used for survey and certification operations nor can they be used as the State's Medicaid non-Federal medical assistance or administrative match. The CMS Locations are not responsible for disbursement of recovered CMP funds.

10006 - Suspension of Payment for All New Medicare Admissions
(Rev.)

10006.1 - Introduction
(Rev.)

Suspension of payment for all new Medicare admissions is conducted in accordance with §488.840 for HHA or §488.1240 for hospice programs when the provider is not in substantial compliance with the CoPs. The SA should consider recommending this sanction/remedy for deficiencies related to poor patient care outcomes, regardless of whether cited deficiencies pose IJ to patient health and safety. Suspension of payment for new admissions is likely to be the most effective sanction/remedy to influence rapid change to facilitate compliance with the CoPs and may be imposed alone or in combination with other sanctions/remedies.

10006.2 - Notice of Sanction
(Rev.)

Suspension of payment for new Medicare admissions may be imposed anytime an HHA or hospice program is found to be out of substantial compliance, as long as the HHA or hospice program is given written notice at least 2 calendar days before the effective date in IJ situations and at least 15 calendar days before the effective date in non-IJ situations. The notice of suspension of payment for new admissions must include the following: the nature of the non-compliance; the effective date of the sanction/remedy; and the right to appeal the determination leading to the sanction. In addition to notifying the HHA or hospice program of this proposed sanction/remedy, CMS will also notify the State Medicaid Agency, if applicable.

For HHAs Only: *Please note that the imposition of suspension of payment for new admissions on an HHA would prohibit that HHA from conducting health aide training and competency evaluation program for 2 years from the date this sanction is imposed (see also 42 CFR 484.80(f)). See Appendix B of the State Operations Manual for additional information for eligible home health aide training and competency evaluation organizations at §484.80(f).*

10006.3 - Effect of Sanction/Remedy on Patients Admitted before the Effective Date of Sanction/Remedy
(Rev.)

The patient's status on the effective date of the suspension of payment sanction/remedy is the controlling factor. This sanction/remedy would not apply to patients who have been receiving care from the HHA or hospice program before the effective date of this sanction/remedy. This sanction/remedy would apply only to new Medicare admissions. CMS will suspend payments for new Medicare patient admissions to the HHA or hospice program that are made on or after the effective date of the imposition of the sanction/remedy for the duration of the sanction/remedy. Payments for individuals who are already receiving services could continue. CMS defines a "new admission" as the following:

- *A patient who is admitted to the HHA or hospice program under Medicare on or after the effective date of a suspension of payment sanction/remedy; or*

- *A patient who was admitted and discharged before the effective date of the suspension of payment and is readmitted under Medicare on or after the effective date of suspension of payment sanction/remedy.*

As part of this sanction/remedy, the HHA or hospice program would be required to notify any new patient admission, before care is initiated, of the fact that Medicare payment would not be available to this HHA or hospice program because of the imposed suspension. The HHA or hospice program would be precluded from charging the Medicare patient for those services unless it could show that, before initiating the care, it had notified the patient or representative both orally and in writing in a language that the patient or representative can understand that Medicare payment is not available.

The suspension of payment sanction/remedy will end when CMS finds that the HHA or hospice program is in substantial compliance with all the CoPs or when the HHA or hospice program is terminated. That is, the suspension of payment sanction/remedy would end when the HHA or hospice program has corrected all condition-level deficiencies, and the correction has been verified by the SA. Any Medicare patients admitted during the suspension of payment period would require a new start of care (SOC) date after the suspension of payment for new admissions has ended. This is required for the HHA or hospice program to begin receiving payments for those patients.

10006.4 - Duration
(Rev.)

The suspension of payment would end when CMS terminates the provider agreement or when CMS finds the HHA or hospice program to be in substantial compliance with all of the CoPs. No payments are made to reimburse the HHA or hospice program for the time between the date the sanction/remedy was imposed and the date that substantial compliance was achieved. CMS accomplishes the suspension of payment sanction/remedy through written instructions to the appropriate MAC. The CMS Location will send the letter with instructions to the MAC

indicating the beginning or ending date of the payment suspension. Generally, if the HHA or hospice program achieves substantial compliance and it is verified by CMS, CMS will resume payments to the HHA or hospice program prospectively from the date it determines that substantial compliance was achieved.

If CMS terminates the provider agreement or determines that the HHA or hospice program is in substantial compliance with the CoPs, the HHA or hospice program would not be able to recoup any payments for services provided to Medicare patients admitted during the time the suspension was in place.

10007 - Temporary Management
(Rev.)

10007.1 – Introduction, Purpose & Imposition
(Rev.)

Temporary management is established in accordance with §488.835 for HHAs and §488.1235 for hospice programs. The following situations should be used as a general guide for imposing temporary management when:

- *CMS determines the failure to comply with the CoPs is directly related to management limitations, or*
- *Deficient management oversight that is likely to impair the HHA's or hospice program's ability to correct deficiencies and return the HHA or hospice program to full compliance within the necessary timeframe, and*
- *When needed, based on the above situations, to oversee orderly involuntary termination/closure of an HHA or hospice program including the proper and safe transfer of patients to another local HHA or hospice program.*

Notice of intent to appoint a temporary manager must be given at least 15 calendar days before the effective date of the enforcement action. When there is an IJ, notice of intent must be given at least two calendar days before the effective date of the enforcement action. The notice of intent from CMS provides the intent to impose the enforcement action, the statutory basis for the enforcement action, the nature of the noncompliance, the proposed effective date of the enforcement action, and the appeal rights. The final notice will be provided once the administrative determination is final.

***For HHAs only:** Please note that the imposition of temporary management on an HHA would prohibit that HHA from conducting health aide training and competency evaluation program for 2 years from the date this sanction is imposed (see also 42 CFR 484.80(f)). See Appendix B of the State Operations Manual for additional information for eligible home health aide training and competency evaluation organizations at §484.80(f).*

The maximum period for use of the temporary manager is six months. It is the temporary manager's responsibility to oversee correction of the deficiencies and assure the health and safety of the HHA's or hospice program's patients while the corrections are being made. An HHA or hospice program that fails to relinquish authority and control to a temporary

manager will have its provider agreement terminated in accordance with §488.865 (HHA) or §488.1265 (Hospice).

10007.2 - Selection of Temporary Manager
(Rev.)

Each SA should compile a list of individuals who are eligible to serve as temporary managers. When CMS decides to impose this sanction or remedy, it considers the SA's recommendation for a temporary manager whose work experience and education qualify the individual to oversee the correction of deficiencies to achieve substantial compliance. The temporary manager must have the experience and education that qualifies the individual to oversee the HHA or hospice program. The temporary manager can be either internal or external to the HHA/hospice program and will be appointed by CMS or the SA based on qualifications described in §§ 484.105(b) and 484.115 for HHAs and §§ 418.100 and 418.114 for hospice programs. The SA should reject a candidate who has demonstrated difficulty maintaining compliance in the past.

10007.3 – Authority and Conditions of Temporary Management
(Rev.)

CMS notifies the HHA or hospice program that a temporary manager is being appointed. The temporary manager must have the authority to hire, terminate, or reassign staff; obligate the provider's funds; alter provider policies and procedures; and otherwise manage an HHA or hospice program to correct deficiencies identified in the provider's operation. The HHA's or hospice program's management must agree to relinquish authority and control to the temporary manager and to pay his/her salary before the temporary manager can be installed in the HHA or hospice program. A contract or memorandum of understanding should be completed between the temporary manager and the HHA or hospice program prior to the temporary manager beginning any work or incurring any costs. Failure to relinquish authority and control to the temporary manager will result in termination of the HHA or hospice program.

The HHA or hospice program cannot retain final authority to approve changes of personnel or expenditures of HHA or hospice program funds and be considered to have relinquished control to the temporary manager. The temporary manager must be given access to all HHA or hospice program bank accounts. If the HHA or hospice program does not relinquish control to the temporary manager and/or provide access to bank accounts and available assets, the HHA or hospice program will be terminated. It should be noted that the HHA's or hospice program's governing body remains ultimately responsible for achieving compliance. The responsibility does not transfer to the temporary manager, SA, or CMS.

The temporary manager's salary must be at least equivalent to the prevailing annual salary of HHA or hospice program administrators in the HHA's or hospice program's geographic area based on the bureau of labor statistics, plus any additional costs that would have reasonably been incurred by the HHA or hospice program if the temporary manager had been in an employment relationship, e.g., the cost of a benefits package, prorated for the amount of time that the temporary manager spends in the HHA or hospice program. The

HHA or hospice program is also responsible for any other costs incurred by the temporary manager in furnishing services under such an arrangement or as otherwise set by the State. Failure to pay the salary and other costs is considered a failure to relinquish authority and control to temporary management and will result in termination of the provider agreement.

The State should provide the temporary manager with an appropriate orientation that includes a review of the HHA's or hospice program's deficiencies and compliance history. The State may request that the temporary manager periodically report on the actions taken to achieve compliance and, on the expenditures associated with these actions.

10007.4 - Duration of Temporary Management
(Rev.)

Temporary management continues until an HHA or hospice program is terminated by CMS, or achieves substantial compliance via an onsite survey, and is capable of remaining in substantial compliance, or decides to discontinue the sanction/remedy and reassume management control before it has achieved substantial compliance. If the HHA or hospice program reassumes control before achieving substantial compliance, CMS would initiate termination of the provider agreement and could impose additional sanctions or remedies during the time period between HHA or hospice program resumption of management and termination. Temporary management will not exceed six months from the date of the survey identifying noncompliance.

10008 - Directed Plan of Correction (DPOC)
(Rev.)

10008.1 – Purpose
(Rev.)

The purpose of the DPOC is to achieve correction and continued compliance with Federal requirements. A DPOC is a plan that the State, with CMS Location approval, or the CMS Location develops to require an HHA or hospice program to take corrective action to achieve specific outcomes within specified time frames. The requirements for DPOC are specified at §488.850 for HHA and §488.1250 for hospice programs.

10008.2 - Imposition of a Directed Plan of Correction
(Rev.)

Whether the facility has standard-level or condition-level deficiencies, an HHA or hospice program must submit an acceptable plan of correction to CMS. If the HHA or hospice program is unable to develop an acceptable plan of correction, CMS may impose a DPOC for condition level deficiencies. CMS must provide written notification of the intent to impose a DPOC sanction/remedy.

Notice of intent to impose a DPOC must be given at least 15 calendar days before the effective date of the enforcement action in non-IJ situations and at least 2 calendar days before the

effective date in IJ situations. The date the DPOC is imposed, that is, the date the sanction/remedy becomes effective, does not mean that all corrections must be completed by that date.

10008.3 - Elements of a Directed Plan of Correction
(Rev.)

A DPOC should address all of the elements required for an HHA- or hospice program-developed plan of correction. These elements include, but are not limited to, the following:

I. How an HHA or hospice program will correct each deficiency;
II. How the HHA or hospice program will act to protect patients in similar situations;
III. How the HHA or hospice program will ensure that each deficiency does not recur;
IV. How the HHA or hospice program will monitor performance to sustain solutions; and
V. The timeframe in which corrective actions will be taken.

10008.4 - Achieving Compliance
(Rev.)

Achieving compliance is the HHA's or hospice program's responsibility, whether or not a DPOC is followed. If the HHA or hospice program fails to achieve compliance within the timeframes specified in the DPOC, CMS may impose one or more additional alternative sanctions/remedies until the HHA or hospice program achieves compliance or is terminated from the Medicare program.

10009 - Directed In-Service Training
(Rev.)

10009.1 – Purpose & Imposition
(Rev.)

Directed in-service training may be used when the State, CMS, or the temporary manager believes that education is likely to correct the deficiencies and help the HHA or hospice program achieve substantial compliance. The requirements for directed in-service training are specified at §488.855 for HHA and §488.1255 for hospice programs.

Directed in-service training requires the staff of the HHA or hospice program to attend a specific in-service training program(s). The purpose of directed in-service training is to provide knowledge to achieve and remain in compliance with Federal requirements. For example, in circumstances where some, but not all, compliance problems are a result of a lack of knowledge on the part of the health care provider relative to advances in health care technology and expectations of favorable patient outcomes, directed in-service training would benefit the agency. Also, directed in-service could be used in situations where staff performance results in deficient practice. A directed in-service training program would correct

this deficient practice through retraining the staff in the use of clinically and professionally sound methods to produce quality outcomes.

Notice of intent to impose directed in-service training must be given at least 15 calendar days before the effective date of the enforcement action in non-IJ situations and at least 2 calendar days before the effective date in IJ situations.

10009.2 - Appropriate Resources for Directed In-Service Training Programs
(Rev.)

HHAs or hospice program should use programs developed by well-established centers of health education and training such as continuing education programs offered by schools of medicine, nursing, public health, community colleges, state health departments, centers for the aging, and other available area centers which have established continuing education programs for health professionals. The programs may also be conducted by consultants with background in education and training with Medicare HHA or hospice program providers, as applicable, or as deemed acceptable by CMS and/or the SA (by review of a copy of the curriculum vitas and/or resumes/references in order to determine the educator's qualifications). The SA or CMS Location may also compile a list of resources that can provide directed in-service training and may make this list available to HHAs or hospice programs.

10009.3 - Further Responsibilities
(Rev.)

The HHA or hospice program bears the expense of the directed in-service training for its staff. After the training has been completed, the SA will assess whether substantial compliance has been achieved. If directed in-service training was the sanction imposed and the HHA or hospice program does not achieve substantial compliance, CMS may impose one or more additional sanctions/remedies as specified at §488.820 for HHA or at §488.1220 for hospice programs.

Home Health (HH) Quality Reporting Program (QRP) Quick Reference Guide

The HH QRP creates Home Health Agency (HHA) quality reporting requirements, as mandated by Section 1895(b)(3)(B)(v)(II) of the Social Security Act ("the Act") and the Medicare regulations at 42 C.F.R.§484.250(a).

HHAs must report on both Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Home Health Care Survey data (HHCAHPS Survey) and Outcome and Assessment Information Set (OASIS) data. Additional data is gathered through Medicare claims. Information on measures required for the Home Health QRP can be found on the CMS Home Health Quality Measures webpage.

If the required quality data is not reported by each designated submission deadline, the HHA will be subject to a two (2) percentage point reduction in their Annual Payment Update (APU).

Frequently Asked Questions

Q: What are the data submission deadlines for OASIS data?

OASIS data must be transmitted within 30 days of the assessment date. OASIS data submitted within 30 days of the assessment date is considered to have met the requirements of submitting quality data.

The comprehensive assessment must be updated and revised (including the administration of OASIS) no less frequently than one of the following:

- The last five days of every 60 days begin with the start of care date, unless there is a beneficiary-elected transfer, significant change in condition, or discharge and return to the same HHA during the 60-day episode.
- The comprehensive assessment must be completed within 48 hours of returning home after discharge from inpatient facility, or within 48 hours of knowledge of qualifying stay in an inpatient facility. When the physician specifies a date that home care services must resume (a physician-ordered Resumption of Care date), the agency is expected to conduct the ROC (Resumption of Care) visit on that date.
- At discharge.

More information on OASIS submission deadlines can be found in the OASIS User Manual available in the Downloads section of the OASIS User Manuals webpage.

Q: What are the data submission deadlines for HHCAHPS survey data?

HHCAHPS Survey data must be reported for eligible patients monthly for four consecutive quarters. HHCAHPS Survey vendors must submit HHCAHPS data files on the third Thursday in the months of January, April, July, and October. You can view a list of HHCAHPS submission deadlines on the HHCAHPS website, homehealthcahps.org.

Q: How do I verify my submissions?

OASIS validation reports are available in the iQIES reporting application. Instructions for running these reports can be found on the iQIES portal or via the iQIES References & Manuals webpage.

HHCAHPS Survey data submission reports are available under the tab "For HHAs" on the homehealthcahps.org website. HHAs are required to check the HHCAHPS Survey data submission reports to confirm that their HHCAHPS Survey data files have been entered successfully (and conversely, entered unsuccessfully) by their respective HHCAHPS survey vendors. Additionally, under "For HHAs" home health agencies can check their quarterly HHCAHPS preview reports for data that will be posted on Care Compare. On the same website, we post the current HHCAHPS Protocols and Guidelines Manual, which contains information about public reporting measures and the public reporting schedule.

Q: How do I submit an HHCAHPS exemption request?

HHCAHPS Survey participation for every Calendar Year Annual Payment Update (CY APU) runs for a 12-month period from April 1st through March 31st. If an HHA has 59 or fewer HHCAHPS-eligible patients in the previous 12 months of April through March, then the HHA should complete an HHCAHPS Survey Participation Exemption Request (PER) form by 11:59 pm March 31 of the current CY APU period. The PER form is accessible in the "For HHAs" portal on the private side of the website https://homehealthcahps.org. The PER form is replaced annually to coincide with the data collection dates of the current CY APU period.

Help Desk Assistance

HHAPUreconsiderations@cms.hhs.gov (APU/Reconsiderations Help Desk)
For reconsideration requests and follow-up questions after the facility has received a CMS determination of non-compliance letter or for extension/exception requests.

homehealthqualityquestions@cms.hhs.gov (Home Health Quality Help Desk)
For questions about the QAO metric or the content of the QAO Historical Reports and submission of comments, questions, and suggestions about the Quality of Patient Care Star Ratings.

HHCAHPS@RTI.org or 1-866-354-0985 (HHCAHPS Technical Assistance Help Desk)
Answers to all questions about the HHCAHPS Survey.

iqies@cms.hhs.gov or 1-877-201-4721 (iQIES Help Desk)
For questions about OASIS submission reports and other provider reports.

Helpful Links

Post-Acute Care (PAC) Listserv − Sign up for the CMS PAC listserv to receive QRP updates.

OASIS References, Manuals, and Q&As − The QIES Technical Support Office (QTSO) provides several resources related to OASIS reporting, including news on report availability, manuals, training, and OASIS quarterly Questions and Answers.

HHA Quality Reporting Requirements − CMS resource containing information about the quality measures, provider compliance, and methodology.

HHCAHPS Survey Website, https://homehealthcahps.org − The official website for the HHCAHPS Survey. Many references on the website are available to the public, though HHAs can log in securely to view their data and reports via the "For HHAs" tab.

HHA Quality Reporting Training − Links to past in-person and online training as well as information on upcoming trainings.

iQIES Portal − Links to resources related to OASIS reporting, including manuals and training.

July 2024 CMS Quarterly OASIS Q&As

Category 4b

A1005, A1010, A1250, B1300, D0700

Question 1: If a patient is confused and consistently does not respond appropriately to questions, is the assessing clinician required to ask the questions for the social determinants of health (SDOH) OASIS items, such as A1005 - Ethnicity, A1010 - Race, A1250 - Transportation, B1300 - Health Literacy, and D0700 - Social Isolation?

Answer 1: Each OASIS item should be considered individually and coded based on guidance specific to that item.

For A1005 - Ethnicity, use clinical judgment to determine if the patient is able to respond. If it is determined that the patient is unable to respond, then code X - Patient unable to respond. If it is determined that the patient is unable to respond, a proxy response may be used. If neither the patient nor a proxy is able to provide a response to this item, medical record documentation may be used.

For A1010 - Race, use clinical judgment to determine if the patient is able to respond. If it is determined that the patient is unable to respond, then code X - Patient unable to respond. If it is determined that the patient is unable to respond, a proxy response may be used. If neither the patient nor a proxy is able to provide a response to this item, medical record documentation may be used.

For A1250 - Transportation, use clinical judgment to determine if the patient is able to respond. If it is determined that the patient is unable to respond, then code X - Patient unable to respond. If it is determined that the patient is unable to respond, a proxy response may be used. If neither the patient nor a proxy is able to provide a response to this item, medical record documentation may be used.

For B1300 - Health Literacy, use clinical judgment to determine if the patient is able to respond. If it is determined that the patient is unable to respond, then code 8 - Patient unable to respond. This item is intended to be a patient self-report item. No other source should be used to identify the response for this item.

For D0700 - Social Isolation, use clinical judgment to determine if the patient is able to respond. If it is determined that the patient is unable to respond, then code 8 - Patient unable to respond. This item is

intended to be a patient self-report item. No other source should be used to identify the response for this item.

M1306 - M1324

Question 2: Would a Kennedy Ulcer be considered a pressure ulcer for the purposes of coding the pressure ulcer items on the OASIS?

Answer 2: If an ulcer/injury arises from a combination of factors that are primarily caused by pressure, then the ulcer/injury should be included in pressure ulcer items as a pressure ulcer/injury.

End of life ulcers (also known as Kennedy ulcers or terminal ulcers) result from organ failure and are not considered pressure ulcers and therefore not reported on the OASIS pressure ulcer items.

M1311

Question 3: Can you please provide guidance on how to stage a pressure ulcer on the OASIS when the deepest anatomic soft tissue damage is unknown? We have a newly admitted patient who has had a pressure ulcer for over a year, but there is no documentation available to indicate the highest stage of the ulcer.

Answer 3: For M1311 - Current Number of Unhealed Pressure Ulcers/Injuries at Each Stage, code based on the findings from the first skin assessment that is conducted on or after and as close to the actual time of the SOC/ROC as possible. Do not reverse stage. Consider current and historical levels of tissue involvement.

If the pressure ulcer/injury was previously classified at a higher numerical stage than what is observed now, as long as it remains stageable, it should continue to be classified at the higher numerical stage until healed.

If historical information is not available to inform the assessment of whether the ulcer/injury was previously classified at a higher numerical stage than what it is observed as now, code based on the current observation of the wound.

Expanded Home Health Value-Based Purchasing (HHVBP) Model

QUARTERLY NEWSLETTER - SEPTEMBER 2024

This newsletter contains information for home health agencies (HHAs) related to the expanded Home Health Value-Based Purchasing (HHVBP) Model, including Model highlights, training updates, new insights, reminders, resources, and contact information.

IN THIS ISSUE:

Click Here

Instructions for Accessing HHVBP Model Reports in iQIES

Preliminary And Final Annual Performance Report (APR) For CY 2024

An agency must believe they have found an error in the Preview Report in order to submit a recalculation request.

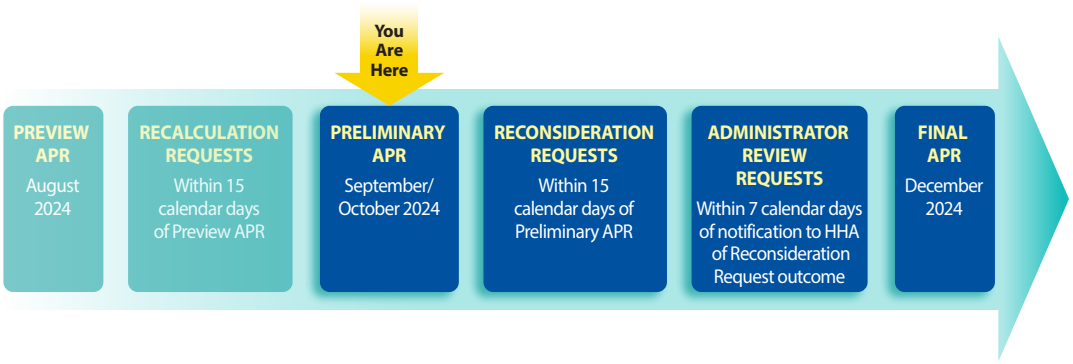
Agencies will receive their Preliminary APR in September/October 2024. This report will identify how an agency is performing with their quality measures (QMs) and expected payment adjustments. Note: HHAs can expect that this report will look the same as their Preview APR (available in August 2024), unless a recalculation request was submitted and the Centers for Medicare & Medicaid Services (CMS) made adjustments/corrections if needed and notified the HHA of the decision (i.e., request granted or denied). The Preliminary APR would reflect any of those changes granted by CMS.

Agencies that requested a recalculation (within 15 days of their August Preview APR) and do not agree with the outcome of CMS' decision may submit a reconsideration request within 15 days of the publication of their Preliminary APR. CMS will investigate the submitted request, make adjustments/corrections if needed, and notify the HHA of the decision (i.e., request granted or denied). The agency may once more appeal this decision by submitting a Request for CMS Administrator Review within 7 days of receiving the outcome notification from CMS regarding the Reconsideration Request. Requests for recalculation and reconsideration must be submitted to HHVBP_Recalculation_Requests@abtassoc.com.

Final APRs will be available in December 2024, at least 30 days before the applicable payment year (CY 2025). This report will reflect agency performance for the QMs and identify the Achievement and Improvement Points that will impact individual payment adjustments in 2025.

APR Recalculation And Reconsideration 2024 Timeline

To learn more about HHA Recalculation Requests, click here.



HHVBP Public Reporting

The expanded HHVBP Model data will be publicly reported beginning in 2025.

HHA-level HHVBP performance metrics for CY 2023 as reported in the CY 2024 APR will be published in the Provider Data Catalog (PDC) in mid-January 2025. For each CY thereafter, CMS anticipates following the same approximate timeline for public reporting.

The metrics that will be made available include but are not limited to:

- Applicable measure benchmarks and achievement thresholds for each small- and large-volume cohort.
- For each HHA that qualified for a payment adjustment based on the data for the applicable performance year:
  - ✔ The HHA's applicable measure results and improvement thresholds,
  - ✔ The HHA's Total Performance Score (TPS),
  - ✔ The HHA's TPS Percentile Ranking, and
  - ✔ The HHA's payment adjustment for a given year.

Help Desk Highlights

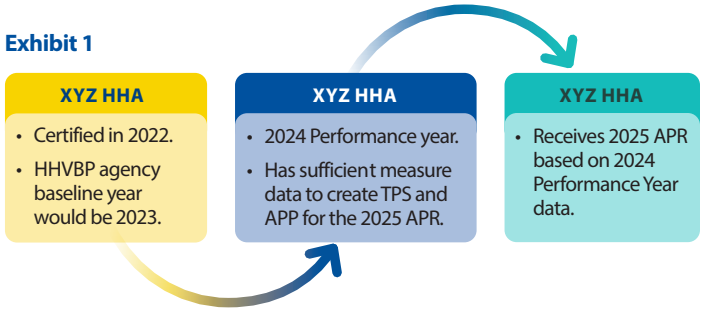
Common Help Desk questions are added to the expanded HHVBP Model FAQs. To access the updated FAQs, click here.

Who receives a CY 2024 APR?

Only active HHAs that were Medicare-certified prior to January 1, 2022, and had sufficient measure data to generate a TPS and Annual Payment Percentage (APP) will receive a CY 2024 APR. The cadence for receiving an APR is the same for an agency achieving Medicare certification in subsequent years.

For example, HHAs that were Medicare certified in 2022 would not be eligible to receive a CY 2024 APR but may be eligible to receive a CY 2025 APR based on CY 2024 performance if they have sufficient measure data to generate a TPS and APP for the CY 2025 APR (see **Exhibit 1**). Similarly, HHAs that were Medicare-certified in 2021 but did not have sufficient measure data to create a TPS and APP may be eligible to receive a CY 2025 APR based on CY 2024 performance if they meet the minimum measure data requirement for that APR.

Exhibit 1



If your agency did NOT receive a Preview APR in August 2024, this might be why…

Understanding Agency APR Eligibility

Though it is understood that the expanded HHVBP Model participation is mandatory for all HHAs, agencies may not receive a 2024 APR. For CY 2024, HHAs will receive an APR ***only*** if they were Medicare-certified prior to January 1, 2022, ***and*** had sufficient data for at least five QMs to calculate their TPS.

The APR reflects the agency's performance year data.

HHAs that become Medicare-certified must have provided a full CY of services (beginning after the date of Medicare certification) to be eligible for an APR. That first CY of services will become their HHA baseline year. This is to allow adequate time for the agency to collect the necessary data used to calculate QMs and to ensure that enough data are collected to most accurately reflect an agency's performance as displayed on an APR.

Updating Demographic Data

"I noticed that my agency name appears different on each of the reports. How can I request that it is changed so it appears the same on each?"

Information on how to update an HHA's demographic data can be found on the Home Health Quality Reporting web page: How to Update Home Health Demographic Data | CMS, and additional instructions are outlined in Provider Demographic Update Process that can be found in the Downloads section.

All HH providers are responsible for ensuring their latest demographic data are updated and available in both the iQIES and PECOS systems.

1. Complete form CMS-855A in PECOS with the updated demographic information: Welcome to the Medicare Provider Enrollment, Chain, and Ownership System (PECOS) (hhs.gov).
   - If you need assistance, contact your Medicare Administrative Contractor (MAC).
2. Contact your State OASIS Automation Coordinator (OAC) or State OASIS Education Coordinator (OEC) and request an update of your demographic data in iQIES.
   - A list of OAC/OECs and their contact information can be found here: OASIS Coordinators | CMS.

Updates to HH provider demographic information do not happen in real time and can take up to 6 months to appear on Care Compare. Should you have questions regarding this process, please contact the iQIES help desk by email at iQIES@cms.hhs.gov or by phone at (800) 339-9313.

Contact Us

HHVBP Model Help Desk
HHVBPquestions@cms.hhs.gov
Contact for information, updates, and questions about the expanded HHVBP Model.

Home Health Quality Reporting Program (HH QRP) Help Desk
homehealthqualityquestions@cms.hhs.gov
Contact for questions about the following: Home Health Quality, including Care Compare (excluding HHCAHPS), OASIS coding and documentation, quality reporting requirements and deadlines, data reported in quality reports, measure calculations, Quality of Patient Care Star Rating (excluding suppression requests), public reporting, risk adjustment, and Quality Assessment Only (QAO)/Pay for Reporting (P4P).

QIES/iQIES Service Center
iqies@cms.hhs.gov, (800) 339-9313
Contact for support with registration for the Internet Quality Improvement Evaluation System (iQIES). Alternatively, refer to the iQIES Onboarding Guide on QTSO at https://qtso.cms.gov/software/iqies/reference-manuals for registration support.

CCSQ Support Central
https://cmsqualitysupport.servicenowservices.com/ccsq_support_central
Use this link to create a ticket or to track an existing ticket.

Home Health CAHPS Help Desk
HHCAHPS@rti.org
Contact for questions related to the HHCAHPS Survey or Patient Survey Star Ratings.

HHVBP Model Expansion Listserv
Subscribe to the HHVBP Model Expansion Listserv to receive email updates related to the expanded HHVBP Model.

Not sure which help desk to use?

Check out the **Guide to Home Health Help Desks!**

HHVBP Training Updates

On August 13, 2024, CMS hosted a webinar, The HHVBP CY 2024 Annual Performance Report (APR) – What You Need to Know! A recording of this webinar and more can be found on the Expanded HHVBP Model website under Model Reports. The purpose of this webinar is to educate HH providers about the Preview APR that came out in August 2024. The webinar includes a discussion of the CY 2024 APR, how to interpret the report, the recalculation and reconsideration process, the applicable QM results and corresponding payment adjustment amounts determined by CY 2023 performance, and how the APP will be applied to Medicare Fee-For-Service (FFS) payments in CY 2025, the payment year.

In addition, CMS is offering a web-based training course that provides an overview of changes to the expanded HHVBP Model Applicable Measure Set for CY 2025 based on the HH CY 2024 Prospective Payment System (PPS) final rule. The changes to the expanded HHVBP Model's applicable measure set categories, reflecting QMs that were removed and added, are discussed. A review of measure specifications and measure weighting is also provided. The course includes interactive exercises to help you understand and apply the content presented. This program is part of a comprehensive strategy to ensure HH providers have access to the education necessary to understand and comply with changes in requirements associated with the expanded HHVBP Model.

Advancing Agency Achievement

In addition to the trainings found on the expanded HHVBP Model website, other training resources that agencies may find helpful are on the HH QRP Training Web Page.

HH QRP Education Spotlight: Section GG Training

HH providers have been collecting self-care and mobility data for several years. Since the advent of Section GG in 2017, agencies have witnessed how these data elements have impacted them in a multitude of ways. Since the Discharge Function Score measure baseline data collection began in 2023, agencies will need to ensure that accurate assessments for self-care and mobility are being conducted.

To assist agencies in the promotion of accurate data collection, CMS is offering an updated web-based training series on the *Assessment and Coding of Section GG: Functional Abilities*. This training (originally posted in 2019), has been updated to reflect OASIS-E1 guidance as of August 2024.
This training series consists of five courses:

- **Course 1:** Section GG Data Accuracy and Quality Measures.
- **Course 2:** Prior Functioning and Prior Device Use Items.
- **Course 3:** Accurate Coding for GG0130. Self-Care and GG0170. Mobility.
- **Course 4:** Understanding Admission and Discharge Performance for GG0130. Self-Care Items.
- **Course 5:** Understanding Admission and Discharge Performance for GG0170. Mobility Items.

Each of the courses contains interactive exercises to test your knowledge related to the assessment and coding of Section GG data elements. This "Train-the-Trainer" program is part of a comprehensive strategy to ensure HH providers have access to the education necessary to understand and comply with changes in Section GG guidance associated with the HH Quality Reporting Programs (QRPs).
This training series can be found on the HH QRP Training Web Page.

HH QRP Education Spotlight: HH QRP Key Program Updates Training

Is your agency up to date on the changes to the HH QRP that are being implemented this year? Some of these updates will have an impact on HHVBP. CMS has posted a web-based training specifically addressing these recent changes. What You Need to Know: PAC QRP Key Program Updates – FY/CY 2025 provides an overview of key HH QRP updates, targeting new, removed and revised QMs. There is a discussion on the Discharge Function Score measure, including a description of how the measure is calculated. This training can be found on the HH QRP Training Web Page.

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

HHVBP
EXPANDED HOME HEALTH VALUE-BASED PURCHASING MODEL

PUBLIC REPORTING TIP SHEET

Home Health Value-Based Purchasing

IN THIS TIP SHEET:

Home health agencies (HHAs) will find a brief background and overview of public reporting for the expanded Home Health Value-Based Purchasing (HHVBP) Model, including:

HHVBP Background

As authorized by Section 1115A of the Social Security Act and finalized in the Calendar Year (CY) 2016 HH Prospective Payment System (PPS) final rule (80 FR 68624), the Center for Medicare and Medicaid Innovation (CMMI) implemented the original Model in nine States on January 1, 2016. The specific goals of the original HHVBP Model were to accomplish the following:

1. Provide incentives for better quality care with greater efficiency.
2. Study new potential quality and efficiency measures for appropriateness in the HH setting.
3. Enhance the current public reporting process.

On January 8, 2021, the Centers for Medicare & Medicaid Services (CMS) announced the nationwide expansion of the HHVBP Model, which began on January 1, 2022. The expanded Model is mandatory for all Medicare-certified HHAs with a CMS Certification Number (CCN) in all 50 States, the District of Columbia, and U.S. territories. Under this expanded Model, HHAs receive adjustments to their Medicare fee-for-service (FFS) payments based on their performance against a set of applicable QMs relative to their peers' performance. For further background information regarding the expanded HHVBP Model, including the descriptions for smaller- and larger-volume-based cohorts, please refer to the expanded HHVBP Model webpage: Expanded Home Health Value-Based Purchasing Model | CMS.

Inaugural Release of HHVBP Data for Public Reporting

HHA-level performance metrics reported in the Final CY 2024 Annual Performance Report (APR) issued to HHAs in December 2024 (see **Figure 1**), will be published in the Provider Data Catalog (PDC) in January 2025. The PDC is an online data repository that provides public access to view and download official CMS data used on Care Compare and other general information.

HHA performance data will be reported annually for each HHA based on the data for the applicable performance year. Reporting of this data is important because it provides the public with insight into the quality and efficiency of care offered by Medicare-certified HHAs.

Publicly reported data for all HHAs will

- Applicable QM benchmark and achievement threshold by volume-based cohort (see **Figure 1** for applicable measures).

For HHAs that qualified for a payment adjustment, publicly reported data will also include:

- The HHA's Total Performance Score (TPS) and TPS Percentile Ranking.
- The HHA's annual Adjusted Payment Percentage (APP) for the applicable payment year.

Which HHAs will have data displayed?

- Active HHAs that were Medicare-certified prior to January 1, 2022, and had sufficient data for at least five QMs to calculate a TPS and APP.

Figure 1. Summary of Applicable QMs for CY 2023, 2024, and 2025 Performance Years

Measure Type	Quality Measure	CY 2023 & 2024	CY 2025
OASIS-based	Discharged to Community	X	
	Improvement in Dyspnea	X	X
	Improvement in Management of Oral Medications	X	X
	Total Normalized Composite (TNC) Change in Mobility	X	
	Total Normalized Composite (TNC) Change in Self-Care	X	
	Discharge Function Score (DC Function)		X
Claims-based	Acute Care Hospitalizations (ACH)	X	
	Emergency Department Use Without Hospitalization (ED)	X	
	Home Health Within-Stay Potentially Preventable Hospitalization (PPH)		X
	Discharge to Community-Post Acute Care (DTC-PAC)*		X
HHCAHPS® Survey-based	Care of Patients (Professional Care)	X	X
	Communication Between Providers and Patients	X	X
	Specific Care Issues	X	X
	Overall Rating of Home Health Care	X	X
	Willingness to Recommend the Agency	X	X
This measure spans two CYs: 2024/2025			

Which HHAs will not have their data displayed?

- Inactive HHAs.
- HHAs that were Medicare-certified on or after January 1, 2022.
- HHAs that were Medicare-certified prior to January 1, 2022, and lack sufficient data (fewer than five QMs) to calculate a TPS and APP.

HHVBP Resources

Expanded HHVBP Model Webpage: https://www.cms.gov/priorities/innovation/innovation-models/expanded-home-health-value-based-purchasing-model.

Expanded HHVBP Model FAQs: https://www.cms.gov/priorities/innovation/media/document/hhvbp-exp-faqs.

Expanded HHVBP Model Guide: https://www.cms.gov/priorities/innovation/media/document/hhvbp-exp-model-guide.

How to Access HHVBP Model Reports: https://www.cms.gov/priorities/innovation/media/document/hhvbp-exp-reports-access-instr.

CY 2024 HH PPS Final Rule: https://www.federalregister.gov/public-inspection/2023-24455/medicare-program-calendar-year-2024-home-health-prospective-payment-system-rate-update-quality.

HHVBP CY 2024 Annual Performance Report (APR) – What You Need to Know! Webinar – August 13, 2024. This training can be accessed under Model Reports on the expanded HHVBP Model website: https://www.cms.gov/priorities/innovation/innovation-models/expanded-home-health-value-based-purchasing-model.

Email questions to the HHVBP Help Desk: HHVBPquestions@cms.hhs.gov

Subscribe to the HHVBP Model Expansion Listserv: HHVBP Model Expansion listserv

Annual Performance Reports

The HHVBP APR is a confidential feedback report provided and available to HHAs via the Internet Quality Improvement & Evaluation System (iQIES). The HHVBP APR provides HHAs with their QM performance data and the APP—including how the adjustment was determined—relative to the HHA's performance, as well as when the adjustment will be applied to the HHA's Medicare FFS claims for the respective payment year.

To receive a QM score, HHAs must meet the following minimum thresholds per reporting period for each QM:

- OASIS-based measures: 20 HH quality episodes.
- Claims-based measures: 20 HH stays.
- HHCAHPS Survey-based measures: 40 completed surveys.

The HHVBP APR has three versions: Preview, Preliminary, and Final. The Preview APR is released to HHAs in August. The Preliminary APR is released to HHAs in September/October, and a Final APR is released by December. The HHVBP APRs provide HHAs with performance data they can use to help track their quality improvement efforts and offer a preview of the data prior to PR.

In August 2024, Preview CY 2024 APRs were released in iQIES for competing and eligible HHAs. This Preview APR reflected HHA performance in CY 2023 and included each HHA's APP to be applied to CY 2025, an explanation of when the payment adjustment will apply, and how CMS determined the adjustment relative to the HHA's final TPS. An example of the APR can be found here: Sample APR.

Recalculation and Reconsideration Requests

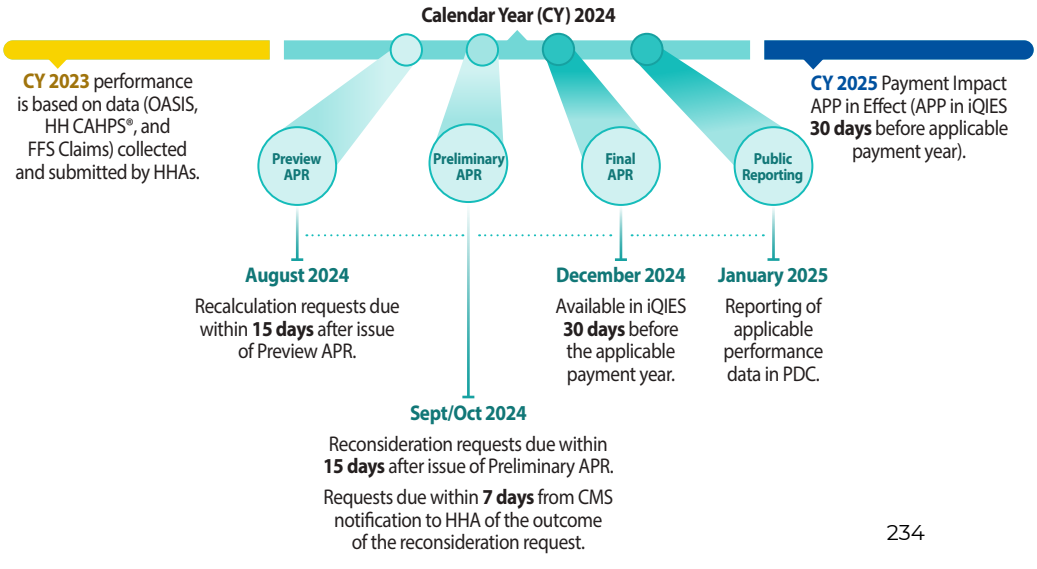
HHAs may submit requests for ***recalculation*** within 15 days after publication of the Preview APR if they wish to dispute the calculation of the Annual TPS and/or the APP.

RECONSIDERATION REQUESTS
Only HHAs that submit a recalculation request can submit a reconsideration request to CMS.

Changes resulting from CMS-approved recalculation(s) will be reflected in the Preliminary APR, which will be available to the requesting HHA via iQIES in September/October. HHAs that do not agree with the recalculation request decision can submit a request for ***reconsideration*** of that decision within 15 calendar days after CMS issues the Preliminary APR.

Upon notification to the HHA contact of CMS' reconsideration request outcome, an HHA that disagrees with CMS' decision may request an ***administrator review*** within 7 days of the CMS notification. A final decision will be issued to the HHA, and a Final APR will be available in iQIES 30 days before the applicable payment year for all HHAs regardless of whether they submitted a recalculation, reconsideration, and/or administrator review request.

Figure 2. HHVBP Lifecycle



CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 12577	**Date: April 11, 2024**
	Change Request 13543

SUBJECT: Additional Enforcement of Required County Codes on Home Health Claims

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to create an edit in Original Medicare systems to ensure required county codes are reported on all home health claims.

EFFECTIVE DATE: October 1, 2024 - Claims processed on or after this date.
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: October 7, 2024

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	10/10.1.10.3/Submission of the Notice of Admission (NOA)
R	10/40.2/HH PPS Claims

III. FUNDING:
For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

Attachment - Business Requirements

Pub. 100-04	Transmittal: 12577	Date: April 11, 2024	Change Request: 13543

SUBJECT: Additional Enforcement of Required County Codes on Home Health Claims

EFFECTIVE DATE: October 1, 2024 - Claims processed on or after this date.
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: October 7, 2024

I. GENERAL INFORMATION

A. Background: The purpose of this Change Request (CR) is to create an edit in Original Medicare systems to ensure required county codes are reported on all home health claims.

Section 50208 Bipartisan Budget Act (BBA) of 2018 required that "in the case of home health services furnished on or after January 1, 2019, the claim contains the code for the county (or equivalent area) in which the home health service was furnished." The National Uniform Billing Committee created value code 85 defined "County Where Service is Rendered" effective January 1, 2019, to enable home health agencies and Medicare to meet this requirement. Original Medicare billing instructions have required reporting value code 85 on all Home Health Prospective Payment System (HH PPS) claims (Type of Bill (TOB) 032x) since January 1, 2019. However, enforcement edits in Medicare systems returned claims to the provider when value code 85 was absent only when a rural add-on payment adjustment applied to the claim.

A recent report (A-05-20-00031) from the Office of Inspector General (OIG) noted that county code reporting on HH PPS claims was incomplete and recommended Medicare edit claims to ensure the county code is present on all claims. OIG noted that the Social Security Act at 1895(c)(3) retains a permanent requirement to report the county code on all home health claims regardless of whether a rural add-on payment adjustment is in effect.

This CR creates an edit in the Fiscal Intermediary Shared System (FISS) to require the presence of value code 85 and a Federal Information Processing System (FIPS) county code on all claims with Type of Bill 032x. Such an edit is consistent with how Medicare has implemented the other statutory payment information requirements for HH PPS claims, such as 1985(c)(2) for 15-minute increment reporting of home health visits.

This CR also makes clarifications to home health billing instructions regarding Notice of Admission timeliness exceptions, charge reporting for telehealth visits and diagnosis code reporting.

B. Policy: This CR contains no new policy. It improves enforcement of an existing statutory requirement.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
13543.1	The contractor shall return to the provider home health claims (TOB 032x other than 032A or 032D) if value code 85 and a corresponding FIPS state and county code value are not present.			X		X				
13543.1.1	The contractor shall ensure editing for the presence of value code 85 on all home health claims is performed before the claim is sent to the HH Pricer.					X				

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
13543.2	Medicare Learning Network® (MLN): CMS will develop and release national provider education content and market it through the MLN Connects® newsletter shortly after we issue the CR. MACs shall link to relevant information on your website and follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 for distributing the newsletter to providers. When you follow this manual section, you don't need to separately track and report MLN content releases. You may supplement with your local educational content after we release the newsletter.			X		

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements:

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
13543.1	The current list of FIPS state and county codes is available at www.census.gov/geographies/reference-files/2022/demo/popest/2022-fips.html.
13543.1.1	Existing editing (return code 31) for valid FIPS code values when a rural CBSA code is present will continue to be performed by the HH Pricer.

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0

10.1.10.3 - Submission of the Notice of Admission (NOA)

(Rev. 12577; Issued: 04-11-24, Effective:10-01-24; Implementation: 10-07-24)

For each admission to home health, the HHA notifies Medicare systems via submission of a Notice of Admission (NOA).

HHAs shall send the NOA to the A/B MAC (HHH) by mail, electronic data interchange (EDI), or direct data entry (DDE). EDI submissions require additional data not required by the NOA itself, to satisfy transaction standards. This data is described in a companion guide available on the CMS website. HHAs may voluntarily agree to adopt the companion guide and use it to submit EDI NOAs at any time.

The HHA can submit an NOA to Medicare when:

- The HHA has obtained a verbal or written order from the physician that contains the services required for the initial visit, and
- The HHA has conducted an initial visit at the start of care.

Only one NOA is required for any series of HH periods of care beginning with admission to home care and ending with discharge. After a discharge has been reported to Medicare, a new NOA is required before the HHA submits any additional claims.

NOAs must be submitted timely. A timely-filed NOA is submitted to and accepted by the A/B MAC (HHH) within five calendar days after admission date.

In instances where an NOA is not timely-filed, Medicare shall reduce the payment for a period of care, including outlier payment, by the number of days from the home health admission date to the date the NOA is submitted to, and accepted by, the A/B MAC (HHH), divided by 30. No LUPA per-visit payments shall be made for visits that occurred on days that fall within the period of care prior to the submission of the NOA. This reduction shall be a provider liability, and the provider shall not bill the beneficiary for it.

If an HHA fails to file a timely-filed NOA, it may request an exception, which, if approved, waives the consequences of late filing. The four circumstances that may qualify the HHA for an exception are as follows:

1. fires, floods, earthquakes, or other unusual events that inflict extensive damage to the HHA's ability to operate;

2. an event that produces a data filing problem due to a CMS or A/B MAC (HHH) systems issue that is beyond the control of the HHA;

3. a newly Medicare-certified HHA that is notified of that certification after the Medicare certification date, or which is awaiting its user ID from its A/B MAC (HHH); or,

4. other circumstances determined by the A/B MAC (HHH) or CMS to be beyond the control of the HHA.

When an NOA is submitted within the five day timely filing period, but the NOA contains inadvertent errors (such as a beneficiary identifier that has recently changed), the error may not trigger the NOA to be immediately returned to the HHA for correction. In these instances, the HHA must wait until the incorrect information is fully processed by Medicare systems before the NOA is returned for correction. Such delays in Medicare systems could cause the NOA to be late. Delays due to Medicare system constraints are outside the control of the HHA and may qualify for an exception to the timely filing requirement.
Medicare contractors shall grant an exception for the late NOA if the HHA is able to provide documentation showing:

(1) When the original NOA was submitted;
(2) When the NOA was returned for correction or was accepted and available for correction and;
(3) Evidence the HHA resubmitted the returned NOA within two business days of when it was available for correction or cancelled an accepted NOA within two business days and submitted the new NOA within two business days after the date that the cancellation NOA finalized.
The HHA shall provide sufficient information in the Remarks section of its claim to allow the contractor to research the case. If the remarks are not sufficient, Medicare contractors shall request documentation. Documentation should consist of printouts or screen images of any Medicare systems screens that contain the information shown above.
HHAs can reduce the number of errors and exception requests related changes to the beneficiary identifier by performing an eligibility check immediately before admission. This can confirm that the Medicare Beneficiary Identifier (MBI) is active and accurate since the eligibility inquiry system contains an MBI End Date field. If there is a date in that field, the MBI is not valid after that date. The HHA can contact the beneficiary or use the MBI Lookup tool to determine the current MBI to use on the NOA.

Since correct beneficiary identifier information is available to the HHA, only changes that occur shortly before the admission are beyond the HHA's control. A/B MAC (HHH) MACs will not grant exceptions based on MBI changes that were accessible to the HHA more than two weeks prior to the admission date.

An admission period will be opened on CWF with the receipt and processing of the NOA. NOAs are submitted using TOB 032A. After this admission period is recorded, the HHA can submit claims for HH periods of care in the admission.

See section 40.1 for detailed submission instructions and required information for the NOA.

40.2 - HH PPS Claims

(Rev. 12577; Issued: 04-11-24, Effective:10-01-24; Implementation: 10-07-24)

The following data elements are required to submit a claim under home health PPS. For billing of home health claims not under an HH plan of care (not under HH PPS), see §90. Home health services under a plan of care are paid based on a 30-day period of care. HHAs submit an NOA at the beginning of an admission and then submit one claim for each 30-day period of care. Claims submitted before an NOA has been received for the beneficiary will be returned to the provider.

Billing Provider Name, Address, and Telephone Number

Required – The HHA's minimum entry is the agency's name, city, state, and ZIP Code. The post office box number or street name and number may be included. The state may be abbreviated using standard post office abbreviations. Five or nine-digit ZIP Codes are acceptable. A/B MACs (HHH) use this information in connection with the provider identifier to verify provider identity.

Patient Control Number and Medical/Health Record Number

Required - The patient's control number may be shown if the patient is assigned one and the number is needed for association and reference purposes.

The HHA may enter the number assigned to the patient's medical/health record. If this number is entered, the A/B MAC (HHH) must carry it through their system and return it on the remittance record.

Type of Bill

Required - This 4-digit alphanumeric code gives two pieces of information. The first three digits indicate the base type of bill. The fourth digit indicates the sequence of this bill in this particular period of care. The types of bill accepted for HH PPS claims are:

032x - Home Health Services under a Plan of Treatment

4th Digit - Definition

> 7 - Replacement of Prior Claim - HHAs use to correct a previously submitted bill. Apply this code for the corrected or "new" bill. These adjustment claims must be accepted at any point within the timely filing period after the payment of the original claim.
>
> 8 - Void/Cancel of a Prior Claim - HHAs use this code to indicate this bill is an exact duplicate of an incorrect bill previously submitted. A replacement claim must be submitted for the period of care to be paid.
>
> 9 - Final Claim for an HH PPS Period – This code indicates an HH original bill to be processed following the submission of an HH PPS Notice of Admission (TOB 032A)

HHAs must submit HH PPS claims with the 4th digit of "9." These claims may be adjusted with code "7" or cancelled with code "8." A/B MACs (HHH) do not accept late charge bills, submitted with code "5," on HH PPS claims. To add services within the period of a paid HH claim, the HHA must submit an adjustment.

Statement Covers Period

Required - The beginning and ending dates of the period covered by this claim. For continuous care periods, the "through" date must be 29 days after the "From" date for a 30-day period of care

In cases where the beneficiary has been discharged or transferred within the period, HHAs will report the date of discharge in accordance with internal discharge procedures as the "through" date. If the beneficiary has died, the HHA reports the date of death in the "through date."

The HHA may submit claims for payment immediately after the claim "through" date. It is not required to hold claims until the end of the period of care unless the beneficiary continues under care.

Patient Name/Identifier

Required - The HHA enters the patient's last name, first name, and middle initial.

Patient Address

Required - The HHA enters the patient's full mailing address, including street number and name, post office box number or RFD, City, State, and ZIP Code.

Patient Birth Date

Required - The HHA enters the month, day, and year of birth of patient. If the full correct date is not known, leave blank.

Patient Sex

Required - “M” for male or “F” for female must be present. This item is used in conjunction with diagnoses and surgical procedures to identify inconsistencies.

Admission/Start of Care Date

Required - The HHA enters a date of admission matching the From date on the first period of care in an admission. On subsequent periods of care, the HHA continues to submit the admission date reported on the first period of care.

Point of Origin for Admission or Visit

Required - The HHA enters the appropriate NUBC point of origin code.

Patient Discharge Status

Required - The HHA enters the code that most accurately describes the patient’s status as of the “Through” date of the billing period. Any applicable NUBC approved code may be used.

Patient status code 06 should be reported in all cases where the HHA is aware that the period of care will be paid a partial period payment adjustment. These are cases in which the agency is aware that the beneficiary has transferred to another HHA within the 30-day period, or the agency is aware that the beneficiary was discharged with the goals of the original plan of care met and has been readmitted within the period. Situations may occur in which the HHA is unaware at the time of billing the discharge that these circumstances exist. In these situations, Medicare claims processing systems will adjust the discharge claim automatically to reflect the partial period payment adjustment, changing the patient status code on the paid claims record to 06.

In cases where the ownership of an HHA is changing and the CMS certification number (CCN) also changes, the service dates on the claims must fall within the effective dates of the terminating CCN. To ensure this, all periods of care with “from” dates before the termination date of the CCN that would extend beyond the termination date must be resolved by the provider submitting claims with “through” dates on or before the termination date. The provider must code the claim with patient status 06. Billing for the beneficiary is being “transferred” to the new agency ownership. In changes of ownership which do not affect the CCN, billing is unaffected.

In cases where an HHA is aware in advance that a beneficiary will become enrolled in a Medicare Advantage (MA) Organization as of a certain date, the provider should submit a claim for the shortened period prior to the MA Organization enrollment date. The provider must code the claim with patient status 06. Payment responsibility for the beneficiary is being “transferred” from Medicare fee-for-service to MA Organization, since HH PPS applies only to Medicare fee-for-service.

In cases where an HHA provides care in a 30-day period of care and then discharges the beneficiary in the next 30-day period of care, but does not provide any billable visits in the next 30-day period, special handling of the patient status code may be needed. Normally, the patient status code for 30-day period before the discharge would be 30, since the beneficiary has not yet been discharged. However, since there will not be a claim for the period in which the discharge occurred, this would result in the HH admission period remaining open in Medicare systems and prevent billing for any later HH services.

In order to close the HH admission period in these cases, the HHA should report patient status 01 on the claim for the last 30-day period in which visits occurred. This will trigger Medicare systems to close the HH admission period. If the claim has been submitted with patient status 30 before the discharge occurred, the HHA should adjust the claim to change the patient status to 01.

If the cause of the discharge in the next 30-day period is a transfer to another HHA before any visits were provided, the HHA should take care not to report patient status 06 on the claim. This would result in an

incorrect partial period payment adjustment. If the cause of the discharge in the next 30-day period is the beneficiary's death, the HHA should take care not to report patient status 20 on the claim. This would result in an incorrect date of death being recorded in Medicare systems and potentially affect claims from other providers.

Condition Codes

Conditional – The HHA enters any NUBC approved code to describe conditions that apply to the claim.

If the claim is for a patient transferred from another HHA, the HHA enters condition code 47.

If the claim is for a period of care in which there are no skilled HH visits in the billing period, but a policy exception that allows billing for covered services is documented at the HHA, the HHA enters condition code 54.

As a result of disaster conditions (such as hurricane or wildfire) that render submission of OASIS assessments impossible, Medicare may issue a waiver indicating OASIS submission is waived. In this case, HHAs should report condition code DR on their claim to indicate billing under the waiver. Since the OASIS assessment cannot be submitted, the HHA cannot report occurrence code 50 to show the assessment completion date. Claims without occurrence code 50 will be accepted if condition code DR is present.

When a provider is unable to submit a start of care OASIS for an admission period of care, they should submit the HIPPS code weighted closest to 1. For a period of continuing care, when a provider is unable to submit a follow-up OASIS, they should carry forward the last HIPPS code generated from the previous OASIS.

If as a result of disaster conditions, OASIS submission timeframes are relaxed, HHAs should submit claims without condition code DR as soon as the OASIS was submitted. In this case, matching OASIS assessment information and the occurrence code 50 date are required to ensure Medicare pays the claim accurately.

HHAs that are adjusting previously paid claims enter one of the condition codes representing Claim Change Reasons (code values D0 through E0). If adjusting the claim to correct a HIPPS code, HHAs use condition code D2 and enter "Remarks" indicating the reason for the HIPPS code change. HHAs use D9 if multiple changes are necessary.

When submitting an HH PPS claim as a demand bill, HHAs use condition code 20. See §50 for more detailed instructions regarding demand billing.

When submitting an HH PPS claim for a denial notice, HHAs use condition code 21. See §60 for more detailed instructions regarding no-payment billing.

Required - If canceling the claim (TOB 0328), HHAs report the condition codes D5 or D6 and enter "Remarks" indicating the reason for cancellation of the claim.

Occurrence Codes and Dates

Required – The HHA enters occurrence code 50 and the date the OASIS assessment corresponding to the period of care was completed (OASIS item M0090). If occurrence code 50 is not reported on a claim or adjustment, the claim will be returned to the provider for correction, unless condition code DR is present to indicate a waiver of OASIS reporting is in effect.

On claims for initial periods of care (i.e. when the From and Admission dates match), the HHA reports an inpatient admission that ended within 14 days of the "From" date by using one of the following codes.

Code	Short Descriptor	Long Descriptor

61	Hospital Discharge Date	The Through date of a hospital stay that ended within 14 days prior to the From date this HHA claim.
62	Other Institutional Discharge Date	The Through date of skilled nursing facility (SNF), inpatient rehabilitation facility (IRF), long term care hospital (LTCH) or inpatient psychiatric facility (IPF) stay that ended within 14 days prior to this HHA admission.

On claims for continuing periods of care, the HHA reports an inpatient hospital admission that ended within 14 days of the "From" date by using occurrence code 61.

To determine the 14 day period, include the "From" date, then count back using the day before the "From" date as day 1. For example, if the "From" date is January 20th, then January 19th is day 1. Counting back from January 19th, the 14 day period is January 6 through January 19. If an inpatient discharge date falls on any date in that period or on the admission day itself (January 20), it is eligible to be reported on the claim.

If more than one inpatient discharge occurs during the 14 day period, the HHA reports only the most recent applicable discharge date. Claims reporting more than one of any combination of occurrence codes 61 and 62 will be returned to the provider for correction.

Conditional - The HHA enters any other NUBC approved code to describe occurrences that apply to the claim.

Occurrence Span Code and Dates

Conditional - The HHA enters any NUBC approved Occurrence Span code to describe occurrences that apply to the claim. Reporting of occurrence span code 74 is not required to show the dates of an inpatient admission.

Value Codes and Amounts

Required - Home health payments must be based upon the site at which the beneficiary is served, *as described by a CBSA code.* For certain dates of service when required by law, payments may be further adjusted if the site is in a rural CBSA or rural county. *Value codes reporting both the CBSA and the State and County code where the beneficiary received home health services are required on all claims.*

For periods of care in which the beneficiary's site of service changes from one CBSA or county to another within the period, HHAs should submit the CBSA code or State and County code corresponding to the site of service at the end of the period.

Provider-submitted codes:

Code	Title	Definition
61	Location Where Service is Furnished (HHA and Hospice)	HHAs report the Core Based Statistical Area (CBSA) number (or rural state code) of the location where the home health or hospice service is delivered. The HHA reports the number in dollar portion of the form locator right justified to the left of the dollar/cents delimiter, add two zeros to the cents field if no cents.
85	County Where Service is Rendered	Where required by law or regulation, report the Federal Information Processing Standards (FIPS)

Code	Title	Definition
		State and County Code of the place of residence where the home health service is delivered.

Medicare-applied codes: The following codes are added during processing and may be visible in the A/B MAC (HHH)'s online claim history. They are never submitted by the HHA.

Code	Title	Definition
17	Outlier Amount	The amount of any outlier payment returned by the Pricer with this code. A/B MACs (HHH) always place condition code 61 on the claim along with this value code.
62	HH Visits - Part A	The number of visits determined by Medicare to be payable from the Part A trust fund to reflect the shift of payments from the Part A to the Part B trust fund as mandated by §1812 (a)(3) of the Social Security Act.
63	HH Visits - Part B	The number of visits determined by Medicare to be payable from the Part B trust fund to reflect the shift of payments from the Part A to the Part B trust fund as mandated by §1812 (a)(3) of the Social Security Act.
64	HH Reimbursement - Part A	The dollar amounts determined to be associated with the HH visits identified in a value code 62 amount. This Part A payment reflects the shift of payments from the Part A to the Part B trust fund as mandated by §1812 (a)(3) of the Social Security Act.
65	HH Reimbursement - Part B	The dollar amounts determined to be associated with the HH visits identified in a value code 63 amount. This Part B payment reflects the shift of payments from the Part A to the Part B trust fund as mandated by §1812 (a)(3) of the Social Security Act.
QF	Late-filed NOA penalty amount	The dollar amount that the claim payment was reduced due to the NOA being filed more than 5 days after the HH From date.
QV	Value-based purchasing adjustment amount	The dollar amount of the difference between the HHA's value-based purchasing adjusted payment and the payment amount that would have otherwise been made. May be a positive or a negative amount.

If information returned from the CWF indicates all visits on the claim are Part A, the shared system must place value codes 62 and 64 on the claim record, showing the total visits and total PPS payment amount as the values, and send the claim to CWF with RIC code V.

If information returned from CWF indicates all visits on the claim are Part B, the shared system must place value codes 63 and 65 on the claim record, showing the total visits and total PPS payment amount as the values, and send the claim to CWF with RIC code W.

If information returned from CWF indicates certain visits on the claim are payable from both Part A and Part B, the shared system must place value codes 62, 63, 64, and 65 on the claim record. The shared system also must populate the values for code 62 and 63 based on the numbers of visits returned from CWF and prorate

the total PPS reimbursement amount based on the numbers of visits to determine the dollars amounts to be associated with value codes 64 and 65. The shared system will return the claim to CWF with RIC code U.

Revenue Code and Revenue Description

Required

HH PPS claims must report a 0023 revenue code line which contains a HIPPS code. HHAs enter only one 0023 revenue code per claim in all cases.

Claims must also report all services provided to the beneficiary within the period of care. All services must be billed on one claim for the entire period. The A/B MAC (HHH) will return to the provider TOB 0329 when submitted without any visit charges.

Each service must be reported in line item detail. Each service visit (revenue codes 042x, 043x, 044x, 055x, 056x and 057x) must be reported as a separate line. Any of the following revenue codes may be used:

027x	Medical/Surgical Supplies (Also see 062x, an extension of 027x) Required detail: With the exception of revenue code 0274 (prosthetic and orthotic devices), only service units and a charge must be reported with this revenue code. If also reporting revenue code 0623 to separately identify specific wound care supplies, not just supplies for wound care patients, ensure that the charge amounts for revenue code 0623 lines are mutually exclusive from other lines for supply revenue codes reported on the claim. Report only nonroutine supply items in this revenue code or in 0623. Revenue code 0274 requires an HCPCS code, the date of service units and a charge amount. NOTE: Revenue Codes 0275 through 0278 are not used for Medicare billing on HH PPS claims.
042x	Physical Therapy Required detail: One of the physical therapy HCPCS codes defined below in the instructions for the HCPCS code field, the date of service, service units which represent the number of 15 minute increments that comprised the visit, and a charge amount.
043x	Occupational Therapy Required detail: One of the occupational therapy HCPCS codes defined below in the instructions for the HCPCS code field, the date of service, service units which represent the number of 15 minute increments that comprised the visit, and a charge amount.
044x	Speech-Language Pathology Required detail: One of the speech-language pathology HCPCS codes defined below in the instructions for the HCPCS code field, the date of service, service units which represent the number of 15 minute increments that comprised the visit, and a charge amount.

055x	Skilled Nursing Required detail: One of the skilled nursing HCPCS codes defined below in the instructions for the HCPCS code field, the date of service, service units which represent the number of 15 minute increments that comprised the visit, and a charge amount.
056x	Medical Social Services Required detail: The medical social services HCPCS code defined below in the instructions for the HCPCS code field, the date of service, service units which represent the number of 15 minute increments that comprised the visit, and a charge amount.
057x	Home Health Aide (Home Health) Required detail: The home health aide HCPCS code defined below in the instructions for the HCPCS code field, the date of service, service units which represent the number of 15 minute increments that comprised the visit, and a charge amount.

NOTE: A/B MACs (HHH) will return claims to the provider if revenue codes 058x or 059x are submitted with covered charges on Medicare home health claims. They also return to the provider if revenue code 0624, investigational devices is reported on HH claims

Revenue Codes for Optional Billing of DME

Billing of DME provided in the period of care is not required on the HH PPS claim. Home health agencies retain the option to bill these services to their A/B MAC (HHH) processing home health claims or to have the services provided under arrangement with a supplier that bills these services to the DME MAC. Agencies that choose to bill DME services on their HH PPS claims must use the revenue codes below. These services will be paid separately in addition to the HH PPS amount, based on the applicable Medicare fee schedule. For additional instructions for billing DME services see chapter 20 of this manual.

0274	Prosthetic/Orthotic Devices Required detail: The applicable HCPCS code for the item, a date of service, a number of service units, and a charge amount.
029x	Durable Medical Equipment (DME) (Other Than Renal) Required detail: The applicable HCPCS code for the item, a date of service indicating the purchase date or the beginning date of a monthly rental, a number of service units, and a charge amount. Monthly rental items should be reported with a separate line for each month's rental and service units of one. Revenue code 0294 is used to bill drugs/supplies for the effective use of DME.
060x	Oxygen (Home Health) Required detail: The applicable HCPCS code for the item, a date of service, a number of service units, and a charge amount.

Revenue Code for Optional Reporting of Wound Care Supplies

0623	Medical/Surgical Supplies - Extension of 027x Required detail: Only service units and a charge must be reported with this revenue code. If also reporting revenue code 027x to identify nonroutine supplies other than those used for wound care, the HHA must ensure that the charge amounts for the two revenue code lines are mutually exclusive.

HHAs may voluntarily report a separate revenue code line for charges for nonroutine wound care supplies, using revenue code 0623. Notwithstanding the standard abbreviation "surg dressings," HHAs use this code to report charges for ALL nonroutine wound care supplies, including but not limited to surgical dressings.

Pub. 100-02, Medicare Benefit Policy Manual, chapter 7, defines routine vs. nonroutine supplies. HHAs use that definition to determine whether any wound care supply item should be reported in this line because it is nonroutine.

HHAs can assist Medicare's future refinement of payment rates if they consistently and accurately report their charges for nonroutine wound care supplies under revenue center code 0623. HHAs should ensure that charges reported under revenue code 027x for nonroutine supplies are also complete and accurate.

HCPCS/Accommodation Rates/HIPPS Rate Codes

Required - On the 0023 revenue code line, the HHA may submit the HIPPS code they expect will be used for payment if they choose to run grouping software at their site for internal accounting purposes. If not, they may submit any valid HIPPS code in order to meet this requirement.

HHAs enter only one HIPPS code per claim in all cases. Claims submitted with additional HIPPS codes will be returned to the provider.

Medicare will determine the appropriate HIPPS code for payment based on claims and OASIS data and will replace the provider-submitted HIPPS code as necessary. If the HIPPS code further changes based on medical review or other processes, the code used for payment is recorded in the APC-HIPPS field of the electronic claim record.

For revenue code lines other than 0023, the HHA reports HCPCS codes as appropriate to that revenue code. The G- and Q- HCPCS codes listed below are for use by HHAs on Type of Bill 032x only. Claims with these HCPCS codes will be returned to the provider if submitted with Type of Bill 034x.

To report HH visits, the HHA reports one of the following HCPCS codes to represent a visit by each HH care discipline:

<u>Physical Therapy (revenue code 042x)</u>

G0151 Services performed by a qualified physical therapist in the home health or hospice setting, each 15 minutes.

G0157 Services performed by a qualified physical therapist assistant in the home health or hospice setting, each 15 minutes.

G0159 Services performed by a qualified physical therapist, in the home health setting, in the establishment or delivery of a safe and effective physical therapy maintenance program, each 15 minutes.

G2168 Services performed by a physical therapist assistant in the home health setting in the delivery of a safe and effective physical therapy maintenance program, each 15 minutes.

<u>Occupational Therapy (revenue code 043x)</u>

G0152 Services performed by a qualified occupational therapist in the home health or hospice setting, each 15 minutes.

G0158 Services performed by a qualified occupational therapist assistant in the home health or hospice setting, each 15 minutes.

G0160 Services performed by a qualified occupational therapist, in the home health setting, in the establishment or delivery of a safe and effective occupational therapy maintenance program, each 15 minutes.

G2169 Services performed by an occupational therapist assistant in the home health setting in the delivery of a safe and effective occupational therapy maintenance program, each 15 minutes.

Speech-Language Pathology (revenue code 044x)

G0153 Services performed by a qualified speech-language pathologist in the home health or hospice setting, each 15 minutes.

G0161 Services performed by a qualified speech-language pathologist, in the home health setting, in the establishment or delivery of a safe and effective speech-language pathology maintenance program, each 15 minutes.

Note that modifiers indicating services delivered under a therapy plan of care (modifiers GN, GO or GP) are not required on HH PPS claims.

Skilled Nursing (revenue code 055x)

General skilled nursing:

G0299 Direct skilled nursing services of a registered nurse (RN) in the home health or hospice setting

G0300 Direct skilled nursing of a licensed practical nurse (LPN) in the home health or hospice setting.

Care plan oversight:

G0162 Skilled services by a licensed nurse (RN only) for management and evaluation of the plan of care, each 15 minutes (the patient's underlying condition or complication requires an RN to ensure that essential non-skilled care achieves its purpose in the home health or hospice setting).

G0493 Skilled services of a registered nurse (RN) for the observation and assessment of the patient's condition, each 15 minutes (the change in the patient's condition requires skilled nursing personnel to identify and evaluate the patient's need for possible modification of treatment in the home health or hospice setting).

G0494 Skilled services of a licensed practical nurse (LPN) for the observation and assessment of the patient's condition, each 15 minutes (the change in the patient's condition requires skilled nursing personnel to identify and evaluate the patient's need for possible modification of treatment in the home health or hospice setting).

Training:

G0495 Skilled services of a registered nurse (RN), in the training and/or education of a patient or family member, in the home health or hospice setting, each 15 minutes.

G0496 Skilled services of a licensed practical nurse (LPN), in the training and/or education of a patient or family member, in the home health or hospice setting, each 15 minutes.

Medical Social Services (revenue code 056x)

G0155 Services of a clinical social worker under a home health plan of care, each 15 minutes.

Home Health Aide (revenue code 057x)

G0156 Services of a home health aide under a home health plan of care, each 15 minutes.

Regarding all skilled nursing and skilled therapy visits

In the course of a single visit, a nurse or qualified therapist may provide more than one of the nursing or therapy services reflected in the codes above. HHAs must not report more than one G-code for each visit regardless of the variety of services provided during the visit. In cases where more than one nursing or therapy service is provided in a visit, the HHA must report the G-code which reflects the service for which the clinician spent most of his/her time.

For instance, if direct skilled nursing services are provided, and the nurse also provides training/education of a patient or family member during that same visit, Medicare would expect the HHA to report the G-code which reflects the service for which most of the time was spent during that visit. Similarly, if a qualified therapist is performing a therapy service and also establishes a maintenance program during the same visit, the HHA should report the G-code that reflects the service for which most of the time was spent during that visit. In all cases, however, the number of 15-minute increments reported for the visit should reflect the total time of the visit.

Telehealth Service Reporting

Beginning on or after January 1, 2023, HHAs may voluntarily report the use of telecommunications technology in the provision of home health services on claims. This information is required on home health claims beginning on July 1, 2023. HHAs shall submit the use of telecommunications technology when furnishing home health services, on the home health claim via three G-codes.

G0320: home health services furnished using synchronous telemedicine rendered via a real-time two-way audio and video telecommunications system

G0321: home health services furnished using synchronous telemedicine rendered via telephone or other real-time interactive audio-only telecommunications system

G0322: the collection of physiologic data digitally stored and/or transmitted by the patient to the home health agency (i.e., remote patient monitoring).

HHAs shall submit services furnished via telecommunications technology in line item detail *and with covered charges*. Each service must be reported as a separately dated line under the appropriate revenue code for each discipline furnishing the service. Two occurrences of G0320 or G0321 on the same day for the same revenue code shall be reported as separate line items *with the same date of service and with service units reporting 1. Services furnished via telecommunications technology are not considered by Medicare systems when enforcing requirements for matching visit dates on home health claims.*

The use of remote patient monitoring that spans a number of days shall be reported as a single G0322 line item reporting the beginning date of monitoring and the number of days of monitoring in the service units field. If more than one discipline is using the remote monitoring information during the billing period, the HHA may choose which revenue code to report on the remote monitoring line item.

Claims with no billable visits are not submitted to Mediare, including claims for billing periods where only telehealth services are provided.

Site of Service Reporting

HHAs must report where home health services were provided. The following codes are used for this reporting:

Q5001: Hospice or home health care provided in patient's home/residence

Q5002: Hospice or home health care provided in assisted living facility

Q5009: Hospice or home health care provided in place not otherwise specified

The location where services were provided must always be reported along with the first visit reported on the claim. In addition to reporting a visit line using the G codes as described above, HHAs must report an additional line item with the same revenue code and date of service, reporting one of the three Q codes (Q5001, Q5002, and Q5009), one unit and a nominal covered charge (e.g., a penny). If the location where services were provided changes during the period of care, the new location should be reported with an additional line corresponding to the first visit provided in the new location.

Disposable Negative Pressure Wound Therapy Services

Effective for claims with statement covers Through dates on or after January 1, 2024, Medicare makes a separate payment amount for a disposable negative pressure wound therapy (NPWT) device for a patient under a home health plan of care. Payment is equal to the supply price used to determine the relative value for the service under the Medicare Physician Fee Schedule (as of January 1, 2022) for the applicable disposable device and updated by the consumer price index for all urban consumers minus the productivity adjustment for each future year.

Disposable NPWT services are billed using the following HCPCS code:

- A9272 - wound suction, disposable, includes dressing, all accessories and components, any type, each.

The HHA reports the HCPCS code with revenue code 027x (other than 0274), units representing the number of disposable devices provided during the billing period and a charge amount. Since Medicare payment no longer includes the services of the practitioner applying the device, revenue codes 042x, 043x or 0559 are not used for dNPWT HCPCS codes on Type of Bill 032x.

Modifiers

If the NOA that corresponds to a claim was filed late and the HHA is requesting an exception to the late-filing penalty (see section 10.1.10.3), append modifier KX to the HIPPS code reported on the revenue code 0023 line.

Service Date

Required - For initial periods of care, the HHA reports on the 0023 revenue code line the date of the first covered visit provided during the period. Claims and provider-submitted adjustments where the Admission Date and From Date match but the 0023 revenue code line date does not also match are returned to the provider. Contractor-submitted adjustments are excluded from this edit.

For subsequent periods, the HHA reports on the 0023 revenue code the date of the first visit provided during the period, regardless of whether the visit was covered or non-covered.

For other line items detailing all services within the period, the HHA reports service dates as appropriate to that revenue code. For service visits that begin in 1 calendar day and span into the next calendar day, report one visit using the date the visit ended as the service date.

When the claim Admission Date matches the Statement Covers "From" Date, Medicare systems ensure that the Service Date on the 0023 revenue code line also matches these dates.

Service Units

Required - Transaction standards require the reporting of a number greater than zero as the units on the 0023 revenue code line. However, Medicare systems will disregard the submitted units in processing the claim. For line items detailing all services within the period, the HHA reports units of service as appropriate to that revenue code. Coding detail for each revenue code under HH PPS is defined above under Revenue Codes.

For the revenue codes that represent home health visits (042x, 043x, 044x, 055x, 056x, and 057x), the HHA reports as service units a number of 15 minute increments that comprise the time spent treating the beneficiary. Time spent completing the OASIS assessment in the home as part of an otherwise covered and billable visit and time spent updating medical records in the home as part of such a visit may also be reported.

Visits of any length are to be reported, rounding the time to the nearest 15-minute increment. If any visits report over 96 units (over 24 hours) on a single line item, Medicare systems return the claim returned to the provider.

Covered and noncovered increments of the same visit must be reported on separate lines. This is to ensure that only covered increments are included in the per-unit based calculation of outlier payments.

Telehealth services with HCPCS codes G0320 or G0321 are reported with units of 1.

Total Charges

Required - The HHA must report zero charges on the 0023 revenue code line (the field must contain zero).

For line items detailing all services within the period of care, the HHA reports charges as appropriate to that revenue code. Coding detail for each revenue code under HH PPS is defined above under Revenue Codes. Charges may be reported in dollars and cents (i.e., charges are not required to be rounded to dollars and zero cents). Medicare claims processing systems will not make any payments based upon submitted charge amounts.

Non-covered Charges

Required – The HHA reports the total non-covered charges pertaining to the related revenue code here. Examples of non-covered charges on HH PPS claims may include:

- Visits provided exclusively to perform OASIS assessments
- Visits provided exclusively for supervisory or administrative purposes
- Therapy visits provided prior to the required re-assessments

Payer Name

Required - See chapter 25.

Release of Information Certification Indicator

Required - See chapter 25.

National Provider Identifier – Billing Provider

Required - The HHA enters their provider identifier.

Insured’s Name

Required only if MSP involved. See Pub. 100-05, Medicare Secondary Payer Manual.

Patient’s Relationship To Insured

Required only if MSP involved. See Pub. 100-05, Medicare Secondary Payer Manual.

Insured’s Unique Identifier

Required only if MSP involved. See Pub. 100-05, Medicare Secondary Payer Manual.

Insured’s Group Name

Required only if MSP involved. See Pub. 100-05, Medicare Secondary Payer Manual.

Insured’s Group Number

Required only if MSP involved. See Pub. 100-05, Medicare Secondary Payer Manual.

Treatment Authorization Code

Conditional - Treatment authorization codes are not required on all claims. The HHA submits a code in this field only if the period is subject to Pre-Claim Review. In that case, the required tracking number is submitted in the first position of the field in all submission formats.

Document Control Number (DCN)

Required - If submitting an adjustment (TOB 0327) to a previously paid HH PPS claim, the HHA enters the control number assigned to the original HH PPS claim here.

Employer Name

Required only if MSP involved. See Pub. 100-05, Medicare Secondary Payer Manual.

Principal Diagnosis Code

Required - The HHA enters the ICD code for the principal diagnosis. The code must be reported according to Official ICD Guidelines for Coding and Reporting, as required by the HIPAA. The code must be the full diagnosis code, including all five digits for ICD-9-CM or all seven digits for ICD-10 CM where applicable. Where the proper code has fewer than the maximum number of digits, the HHA does not fill it with zeros.

Medicare systems may return claims to the provider when the principal diagnosis code is not sufficient to determine the HHRG assignment under the PDGM.

Other Diagnosis Codes

Required - The HHA enters the full diagnosis codes for additional conditions if they coexisted at the time of the establishment of the plan of care. These codes may not duplicate the principal diagnosis as an additional or secondary diagnosis.

In listing the diagnoses, the HHA places them in order to best reflect the seriousness of the patient's condition and to justify the disciplines and services provided in accordance with the Official ICD Guidelines for Coding and Reporting. The sequence of codes should follow ICD guidelines for reporting manifestation codes. Medicare does not have any additional requirements regarding the reporting or sequence of the codes beyond those contained in ICD guidelines.

The following instructions apply to both Principal and Other Diagnosis Code reporting.

Diagnosis coding and claim dates:

Diagnosis codes that reflect the patient's condition as of the start of a period of care *(the claim From date)* are reflected on the claim for the current period of care. Diagnosis codes that reflect a change in the patient's condition during a period of care should be reflected on the claim for the next period.

ICD diagnosis codes are updated each year on October 1 and April 1. While the claim describes the patient's condition as of the From date, if the claim Through date spans across an ICD update, the codes that are valid after the update are reported on the claim.

For example, the HHA submits a claim spanning September 15, 2023 to October 14, 2023, for a patient that has Parkinson's Disease as a secondary diagnosis, The code in effect on September 15, 2023 is G20 (Parkinson's Disease) but effective October 1, the code that applies to the patient's condition changed to G20.C (Parkinsonism, unspecified). The G20.C code is reported on the claim.

The version of the HH Grouper logic applied to each claim is determined is based on the claim From date. In the case of a claim with a From date of September 15, 2023 and Through date of October 14, 2023, the Grouper applies the logic and codes in effect for dates of service before September 30, 2023 and not the logic and codes effective October 1. When a diagnosis code changes as describe above, the HH Grouper maps the new code back to its predecessor code to correctly determine the case-mix scoring and the HIPPS code for the claim (e.g. maps G20.C back to G20 and uses the G20 code to assign the HIPPS code).

Claim and assessment diagnosis codes:

The diagnosis codes used for payment grouping are determined from claim coding rather than the OASIS assessment. As a result, the claim and OASIS diagnosis codes are not expected to match in all cases.

Typically, the codes will match between the first claim in an admission and the start of care (Reason for Assessment –RFA 01) assessment and claims corresponding to recertification (RFA 04) assessments. Second 30-day claims in any 60-day period will not necessarily match the OASIS assessment. When diagnosis codes change between one 30-day claim and the next, there is no absolute requirement for the HHA to complete an 'other follow-up' (RFA 05) assessment to ensure that diagnosis coding on the claim matches to the assessment. However, the HHA would be required to complete an 'other follow-up' (RFA 05) assessment when such a change would be considered a major decline or improvement in the patient's health status.

Attending Provider Name and Identifiers

Required - The HHA enters the name and national provider identifier (NPI) of the attending physician who signed the plan of care.

Other Provider (Individual) Names and Identifiers

Required - The HHA enters the name and NPI of the physician who certified/re-certified the patient's eligibility for home health services.

NOTE: Both the attending physician and other provider fields should be completed unless the patient's designated attending physician is the same as the physician who certified/re-certified the patient's eligibility. When the attending physician is also the certifying/re-certifying physician, only the attending physician is required to be reported.

Remarks

Conditional – If the NOA that corresponds to a claim was filed late and the HHA is requesting an exception to the late-filing penalty (see section 10.1.10.3), enter information supporting the exception category that applied to the NOA.

The HHA shall provide sufficient information in the Remarks section of its claim to allow the contractor to research the case. If the remarks are not sufficient, Medicare contractors shall request documentation. Documentation should consist of printouts or screen images of any Medicare systems screens that contain the information shown above.

Medicare contractors shall not grant exceptions if:
• the HHA can correct the NOA without waiting for Medicare systems actions
• the HHA submits a partial NOA to fulfill the timely-filing requirement, or
• HHA with multiple provider identifiers submit the identifier of a location that did not actually provide the service

In the great majority of cases, the five day timely filing period allows enough time to submit NOAs on a day when Medicare systems are available (i.e. the period allows for ("dark days"). Additionally, the receipt date is typically applied to the NOA immediately upon submission to Medicare systems, so subsequent dark days would not affect the determination of timeliness. However, if the HHA can provide documentation showing an NOA is submitted on the day before a dark day period and the NOA does not receive a receipt date until the day following the dark days, the contractor shall grant an exception to the timely filing requirement. CMS expects these cases to be very rare.

Remarks are otherwise required only in cases where the claim is cancelled or adjusted. adjusted.

CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 12888	**Date: October 10, 2024**
	Change Request 13812

SUBJECT: Allowing Home Health (HH) Telehealth Services During an Inpatient Stay

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to revise Original Medicare claims editing to allow non-paid telehealth visits to be reported while a beneficiary is hospitalized.

EFFECTIVE DATE: April 1, 2025 - For claims processed on or after this date.
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: April 7, 2025

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	10/30.9/Coordination of HH PPS Claims Episodes With Inpatient Claim Types

III. FUNDING:

For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

Attachment - Business Requirements

Pub. 100-04	Transmittal: 12888	Date: October 10, 2024	Change Request: 13812

SUBJECT: Allowing Home Health (HH) Telehealth Services During an Inpatient Stay

EFFECTIVE DATE: April 1, 2025 - For claims processed on or after this date.
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: April 7, 2025

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to revise Original Medicare claims editing to allow non-paid telehealth visits to be reported while a beneficiary is hospitalized.

II. GENERAL INFORMATION

A. Background: Medicare beneficiaries cannot be inpatients in a hospital or skilled nursing facility and receive home health care simultaneously. If an HH Prospective Payment System (PPS) claim is received, and Medicare systems find dates of service on the HH claim that falls within the dates of an inpatient, skilled nursing facility or swing bed claim (not including the dates of admission and discharge and the dates of any leave of absence), the Common Working File (CWF) will reject the HH claim with edit 7080. The Home Health Agency (HHA) may submit a new claim removing any dates of service within the inpatient stay that were billed in error.

This date overlap editing should not apply to HH telehealth reporting, Healthcare Common Procedure Coding System (HCPCS) codes G0320, G0321 or G0322. These services are non-payable reporting items so they do not create any duplicate payment. The codes may represent the HHA remaining in contact with caregivers while the beneficiary is an inpatient. CMS has learned that these codes are currently rejecting with CWF edit 7080 in error, requiring HHAs to remove the reporting lines in order to process the claim. The requirement below corrects this error and allows HCPCS G0320, G0321 or G0322 dates on an HH PPS claim to overlap inpatient stays.

B. Policy: This CR does not contain any new policy. It corrects the implementation of existing HH telehealth reporting policy.

III. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
13812.1	The contractor shall allow an HH claim (Type of Bill 032x other than 032A or D) with line item dates of service falling within an inpatient stay if HCPCS G0320, G0321 or G0322 are present on the line.								X	

IV. PROVIDER EDUCATION

Medicare Learning Network® (MLN): CMS will develop and release national provider education content and market it through the MLN Connects® newsletter shortly after we issue the CR. MACs shall link to relevant information on your website and follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 for distributing the newsletter to providers. When you follow this manual section, you don't need to separately track and report MLN content releases. You may supplement with your local educational content after we release the newsletter.

Impacted Contractors: A/B MAC Part HHH

V. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements:

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
.1	This requirement creates a bypass condition for CWF edit 7080. All other conditions for handling dates in the edit are unchanged.

Section B: All other recommendations and supporting information:N/A

VI. CONTACTS

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VII. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not

obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0

30.9 - Coordination of HH PPS Claims Episodes With Inpatient Claim Types

(Rev. 12888; Issued:10-10-24; Effective:04-01-25; Implementation: 04-07-25)

Beneficiaries cannot be institutionalized and receive home health care simultaneously. Therefore claims for institutional inpatient services (inpatient hospital, skilled nursing facility (SNF) and swing bed claims), have priority in Medicare claims editing over claims for home health services.

If an HH PPS claim is received, and *Medicare systems find* dates of service on the HH claim that falls within the dates of an inpatient, SNF or swing bed claim (not including the dates of admission and discharge and the dates of any leave of absence), Medicare systems will reject the HH claim. The HHA may submit a new claim removing any dates of service within the inpatient stay that were billed in error.

Medicare systems allow an exception for HH telehealth reporting, HCPCS codes G0320, G0321 or G0322. An HH PPS claim may be processed if dates of service with these codes fall within an inpatient stay. This is because the services are non-payable reporting items, so they do not create any duplicate payment. The codes may represent the HHA remaining in contact with caregivers while the beneficiary is an inpatient.

If the HH PPS claim is received first and the inpatient hospital, SNF or swing bed claim comes in later, but contains dates of service duplicating dates of service on the HH PPS claim, Medicare systems will adjust the previously paid HH PPS claim to non-cover the duplicated dates of service, *excluding telehealth services*.

Guide to Home Health Help Desks

HH PROVIDER, WITH QUESTION ABOUT…

Compliance with Home Health Conditions of Participation

- ☑ Regulations & interpretive guidance
- ☑ Survey & certification
- ☑ State OASIS Education & Automation Coordinator contact updates

Home Health Survey Mailbox
hhasurveyprotocols@cms.hhs.gov

Star Rating Review Request/ Suppression Request Help Desk

- ☑ All requests for formal review of Quality of Patient Care Star Ratings
- ☑ Includes requests to suppress data

HHC Star Rating Review*
hhc_star_ratings_review_request @cms.hhs.gov

Home Health Consumer Assessment of Healthcare Providers & Systems (HHCAHPS)

- ☑ Patient Survey Star Ratings
- ☑ HHCAHPS requirements
- ☑ HHCAHPS scores on Care Compare

HHCAHPS Help Desk
hhcahps@rti.org
homehealthcahps@cms.hhs.gov
1–866–354–0985

Home Health Quality Reporting Program (QRP) Reconsiderations, Exceptions & Extensions

- ☑ Submit HH QRP APU (annual payment update) reconsideration request
- ☑ HH QRP APU reconsideration process & appeals procedures for payment determination
- ☑ HH QRP APU exception & extension requests for extraordinary circumstances

Reconsideration, Exceptions & Extensions
hhapureconsiderations @cms.hhs.gov

Home Health Quality

- ☑ OASIS coding & OASIS documentation
- ☑ Quality reporting requirements & deadlines
- ☑ Data reported in quality reports (excluding HHVBP)
- ☑ Measure calculations
- ☑ Quality of Patient Care Star Rating (excluding suppression requests)
- ☑ Public reporting/Care Compare (excluding HHCAHPS)
- ☑ Risk adjustment (excluding HHVBP)
- ☑ Quality Assessment Only (QAO)/Pay for Reporting (P4R)

Home Health Quality Help Desk
homehealthqualityquestions @cms.hhs.gov

iQIES

- ☑ OASIS data submission/ transmission
- ☑ Submission Error messages or record rejections
- ☑ Questions about submission and quality reports
- ☑ Technical support for HHA software vendors related to:
  - ☑ *OASIS Data Submission Specifications*
  - ☑ *OASIS Validation Utility Tool (VUT)*

NOTE:

iQIES User ID requests are no longer supported via the iQIES Help Desk. Users must create an account via the HARP system: https://harp.qualitynet.org/register/profile-info

iQIES Help Desk
iqies@cms.hhs.gov

1–800–339–9313

Medicare Payment for Home Health

- ☑ Payment policies:
  - ☑ *Eligibility*
  - ☑ *Coverage requirements*
  - ☑ *Patient-Driven Groupings Model (PDGM)*

Home Health Policy Help Desk
homehealthpolicy@cms.hhs.gov

Expanded Home Health Value-Based Purchasing (HHVBP) Model

- ☑ Model implementation
- ☑ Model calculations
- ☑ Model reports
- ☑ Available HHVBP resources

Expanded HHVBP Model Help Desk
HHVBPquestions@cms.hhs.gov

Updated January 2024

SUPPORT RATE INCREASES FOR NURSES

BACKGROUND

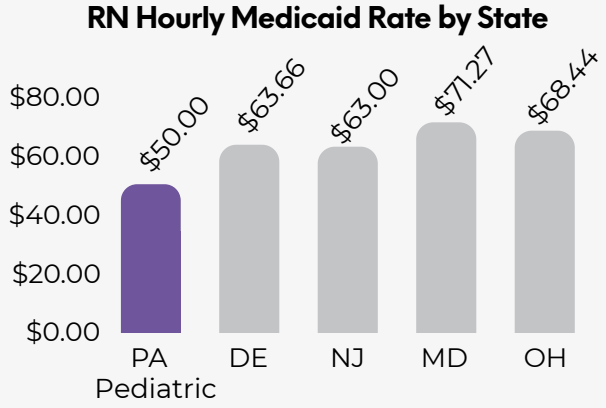
Private Duty Nursing services provide in-home long-term care for medically fragile children and adults living with chronic illness, injury or disability. Care is provided in shifts by an LPN, RN or Home Health Aide.

Pennsylvania's private duty nursing program supports more than 10,000 medically-complex and vulnerable children and more than 3,000 adults and seniors each year.

In the 2021 Mercer report titled "U.S. Health Labor Market," **Pennsylvania was ranked as having the most severe shortage of nurses in the nation.** Projections indicate that this situation will continue to deteriorate each year unless steps are taken to bolster the workforce.

OUR POSITION

- The Nursing Licensure Compact exacerbated PA's nursing crisis by allowing license reciprocity among states. PA nurses can now cross the border to states with higher rates.
- Pennsylvania's RN reimbursement rate is 46% below the weighted average of neighboring states.



- Lack of standardized rates in PA results in nurses prioritizing patient populations with higher reimbursement rates.

HOURLY NURSING REIMBURSEMENT RATES BY PROGRAM

	OMAP	OLTL	ODP
Population	*Pediatric*	*Aging and Physical Disability*	*Intellectual and Developmental Disability*
RN	$ 50.00	$ 66.20	$ 76.28
LPN	$ 50.00	$ 44.08	$ 55.08

- In the last 30 years, rate increases for pediatric care (OMAP) occurred only three times. For adults (OLTL), only once.
- Reimbursement rates have not kept pace with inflation and increased cost of care.
- Failing to adequately support in-home care WILL result in more costly Medicaid funded institutional care!

CALL TO ACTION

- **Support standardized reimbursement rates of $55.00/hour for nursing** in the Office of Medical Assistance Providers (OMAP) and Office of Long-Term Living (OLTL) programs.

  Approximate impact: $32.4M annually

- Support an increase in home health aide reimbursement rates in the same program from $27.36 to $30.10/hour.

  Approximate impact: $5.7M annually

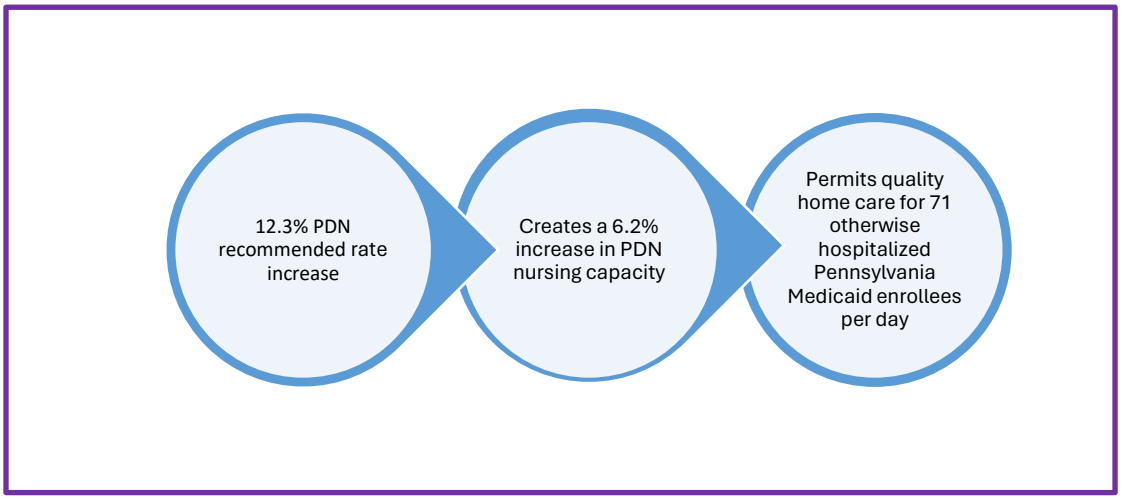
Costs and Benefits of Enhancing Shift Nursing, or Private Duty Nursing, Payment Rates in Pennsylvania's Medicaid Program

A recent study by the Menges Group, an expert in Medicaid health policy and care coordination analysis, considered a portion of Pennsylvania's Medicaid population, children and adults with complex medical conditions who require specialized home health nursing from a Shift Nurse or Private Duty Nurse (PDN), to determine potential cost savings to the state through expanded reimbursement rates.

These individuals, some of the most acute and medically fragile patients in the state, are currently being forced to spend time in costly hospital beds rather than in a more comfortable and affordable setting at home with their families.

Due to lagging Medicaid reimbursement rates, there are not enough nurses to care for the medically fragile children and adults who are able to leave the hospital. Lack of in-home nursing drives up costs through:

- Discharge delays
- Longer overall hospital stays while waiting for adequate in-home nursing coverage
- Increased chances of readmission within 90 days
- Overall increased chances of hospital admissions for individuals who are being cared for at home but not receiving enough treatment due to lack of adequate nursing coverage



The study found:

- Pennsylvania's Medicaid payment rates for shift nursing services are lower than typical Medicaid rates nationally, ranking behind New Jersey, Maryland, Delaware, and Ohio for LPN services.
- The state is (12.5%) below the average across the four peer states (using each state's Medicaid enrollment to derive the weighted average).
- 30 states have higher average Medicaid FFS payments for PDN services than Pennsylvania (when combining/averaging each state's RN and LPN rates when separate rates are used).
- Enhanced rates will add substantial capacity to deliver shift nursing services.
- 97% of the added costs to the state from increased reimbursement rates are offset with decreased inpatient hospital days.
- The remaining net annual cost of the rate increase after these offsets is estimated to be only $600,000 in state funds.
- Considerable potential cost savings exists for the rate increases to be budget neutral or even yield cost savings. If the PDN nursing capacity increases by seven percent (instead of the estimated 6.16%), for example, a net overall annual savings of $3.9 million will occur, including a $1.7 million savings in state funds.

Current and Recommended Hourly Medicaid PDN Rates

Program	Office of Long Term Living (OLTL - Adult)	Office of Medical Assistance Program (OMAP – Pediatric)
RN Rate	$66.20	$50.00
LPN Rate	$44.08	$50.00
Recommended Rates	$59.05 (blended)**	$59.05 (blended)**
Recommended Dollar Increase	*$3.91*	*$9.05*

Based on state utilization data, managed care data, and hospital costs, the study recommends changing payment methodology for Pennsylvania adult shift nursing and creating a blended rate for both RN and LPN services at $59.05. On a percentage basis, these recommended rates are 12.3 percent above the current weighted average between all of Pennsylvania's shift nursing programs.

Nearby eastern and Mid-Atlantic states are investing in PDN services to reduce Medicaid costs, increase patient access, and provide for a higher quality of life for medically fragile children and adults. Maryland raised PDN rates by 12 percent between 2023 and 2024, Delaware by 7.5 percent in 2022, and New Jersey by 2 dollars in 2023.

Medicaid rate increases for PDN nurses will allow providers to receive fair market wages and incentivize more individuals into the profession, thus providing more private duty nurses to care for Pennsylvania's medically fragile children and adults.

The Menges Group

Strategic Health Policy & Care Coordination Consulting

Costs and Benefits of Enhancing Private Duty/Shift Nursing Payment Rates in **Pennsylvania's Medicaid Program**

April 2024

Prepared for:
Pennsylvania Homecare Association

The Menges Group

Strategic Health Policy & Care Coordination Consulting

Table of Contents

The Menges Group
Strategic Health Policy & Care Coordination Consulting

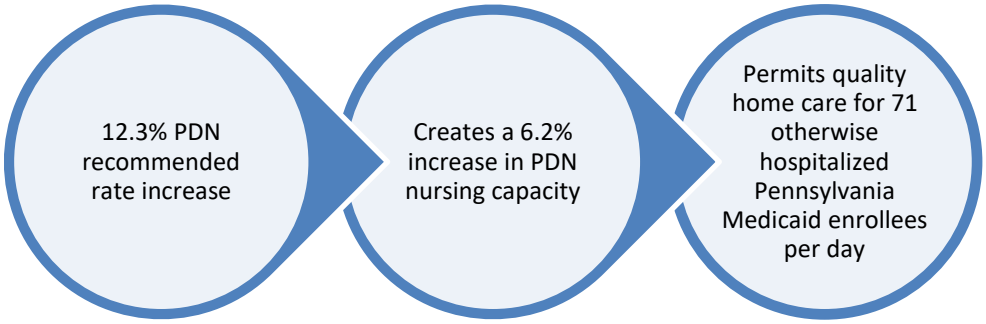
I. Executive Summary

Private Duty Nursing (PDN), often referred to as "shift nursing" in Pennsylvania, is essential in enabling many high-need Medicaid beneficiaries to be supported at home rather than via long-term hospitalization. For patients who are at home, PDN is also valuable in delivering expert care that averts clinical crises requiring hospitalization, and in freeing up family members to work and experience a better quality of life.

However, average Medicaid payment rates are below the amounts needed to attract and retain nurses into the PDN sector, and Pennsylvania's Medicaid payment rates for PDN services are *even lower* than typical Medicaid rates nationally and in the northeastern US. Many different types of organizations compete for nurses, and Pennsylvania's Medicaid rates put PDN providers at a significant disadvantage.

This report derives the payment rate increase needed to achieve a significant gain in PDN service capacity in Pennsylvania, and the net costs of taking these actions. The key components of our estimates are summarized in Exhibit ES-1 below.

Exhibit ES-1. An Essentially Cost-Neutral Path to Better Outcomes



The report also demonstrates the quality of life value of transitioning persons home when it is clinically appropriate to do so. The quote below provides an example.

> The mother of an infant/child, who came home after more than two years in the hospital, expressed that: "We spent over two years surviving and now we get to live."

Pennsylvania's current Medicaid fee-for-service (FFS) rates for PDN services, and the structure currently used for these rates, are shown in the top rows of Exhibit ES-2. The bottom rows of Exhibit ES-2 convey the report's recommended blended rate.

Exhibit ES-2. Current and Recommended Hourly Medicaid PDN Rates

Program	Office of Long Term Living (OLTL - Adult)	Office of Medical Assistance Program (OMAP – Pediatric)
RN Rate	$66.20	$50.00
LPN Rate	$44.08	$50.00
Recommended Rates	$59.05 (blended)**	$59.05 (blended)**
Recommended Dollar Increase	*$3.91*	*$9.05*

An average current hourly rate of $52.57 was derived through the following steps:

- Calculating an average adult rate of $55.14 (across the DHS Office of Long Term Living rates of $66.20 for RN services and $44.08 for LPN services); and
- Then averaging the adult figure with the DHS Office of Medical Assistance Programs pediatric rate of $50.00 (which is used for both RN and LPN services).

The above recommended blended payment rate of $59.05 simplifies the structure by averaging together current payment rates that are in some cases sending mixed signals. For example, some current rates are higher for adults than children whereas others are higher for children than adults. Also, the RN and LPN services being rendered are often identical to one another but are often generating differential payment levels.

The recommended increases were derived by:

a) tabulating an average regional Medicaid fee-for-service (FFS) payment rate for PDN services across four of Pennsylvania's neighboring peer states;

b) adjusting this average for Pennsylvania's cost of living; and

c) adjusting the rate based on an average percentage differential in Medicaid managed care organization (MCO) payments for PDN services relative to Medicaid FFS rates based on a sample of Pennsylvania's PDN providers.

The MCO payment rates represent a market-driven benchmark for balancing cost containment, access to PDN services, and quality objectives.

Based on reported experience of PDN providers in other states where rate increases were implemented, we estimate that the enhanced rates will create a 6.16% increase in the supply of PDN labor available to provide care to Pennsylvania's Medicaid population.

The combination of the increased rates and the increased labor are projected to create a 19% increase in Pennsylvania's Medicaid PDN expenditures, increasing annual Medicaid PDN costs by approximately $42 million in total Medicaid funds (federal and state share combined). However, we estimate that the above costs of the PDN rate increase will be almost entirely (97%) offset by the combination of increased PDN capacity, more home-based care, and fewer hospital days.

The inpatient savings are so large at the patient level (approximately $580,000 per person annually), that they essentially "pay for" elevating the PDN rates for the entire body of PDN care that is currently occurring at the FFS rate level. The net annual Medicaid costs are estimated to be $1.4 million for the Medicaid program overall, and $0.6 million in state funds.

Considerable cost savings potential exists for the rate increases to be budget neutral or even yield cost savings. A slight favorable variation in any of the derivation assumptions in this report will yield a net savings. For example, if the PDN nursing capacity increases by 7.0% (instead of the estimated 6.16%), a net overall annual savings of $3.9 million will occur -- including a $1.7 million savings in state funds.

II. Introduction

The Menges Group has been enlisted by the Pennsylvania Homecare Association to evaluate the state's Medicaid Private Duty Nursing (PDN) payment rates. The purpose of this report is to seek to remedy the challenges that many Pennsylvania stakeholders are currently experiencing in serving Medicaid-covered persons, particularly children with special healthcare needs who are in the inpatient setting rather than the home setting when a transition home is deemed clinically appropriate. A few statistics from a national survey are presented below:[1]

- 36% of households with a medically complex family member have experienced a hospital stay that was longer than clinically necessary due to home-based nursing support not being available.
- 87% of medically complex families had to make significant employment changes due to limited home-based nursing care being available.
- 25% of inpatient discharges for patients in medically complex families occurred with no home-based nursing care being lined up.

One nationwide PDN provider framed their challenges in Pennsylvania by noting that, "The currently established fee schedule … has prevented us from providing PDN services at scale because we simply can't afford to hire and retain nurses."

A 2019 study focused on children, published in Health Affairs, Home Health Care For Children With Medical Complexity: Workforce Gaps, Policy, and Future Directions, summarized the situation as follows:[2]

> "Home health care for children and youth with medical complexity in the United States is a patchwork of policies and programs that does not currently meet the medical needs of many patients; unnecessarily prolongs hospitalizations; and relies on an insufficient, inadequately trained workforce…. it is evident from several national surveys that family caregivers are frequently shouldering enormous burdens that lead them away from their own gainful employment and create social, emotional, and financial hardship."

In healthcare support and direct patient care occupations nationwide, workers experienced either stagnant or negative wage growth from 2001-2017[3]. According to a

[1] 2023 State of Home Health Nursing Survey, authored by K. Knight, G. Knight, and B. Jordan.
[2] Foster, Agrwal, and Davis, Children's Hospital of Chicago, published in Health Affairs, June 2019
[3] Real wage growth in the U.S. health workforce and the narrowing of the gender pay gap, authored by Janis Barry, published in Human Resources for Health, August 2021

state-specific study published by Mercer in 2021[4], Pennsylvania is currently in the top five states experiencing the most severe shortage of health care labor at the low end of the wage spectrum, limiting access to home care. Additionally, the Mercer report names Pennsylvania as the state that will experience the greatest nursing shortage over the next few years, illuminating the need for greater compensation.

Additional research in this topic area has been consistent in identifying the shortcomings of current care delivery and models, and in finding that the key opportunities for improvement involve increasing the supply of home-based care.

Examples of these research community contributions are conveyed below.

- The Joint Commission, "Home – The Best Place for Health Care," 2011
- Lindsey Paitich, BSN, RN, Chris Luedemann, MD, BSN, RN, Judy Giel, RRT, and Roy Maynard, MD, FAAP, "Allocation of Pediatric Home Care Nursing Hours – The Minnesota Experience," January, 2022.
- Jonathan Gonzalez-Smith, Montgomery Smith, William K. Bleser, and Robert S. Saunders: "Policy Opportunities To Expand Home-Based Care For People With Complex Health Needs," Health Affairs, March 18, 2022
- Barrett, DL, et al. The Gatekeeper Program. Proactive identification and case management of at-risk older adults prevents nursing home placement, saving healthcare dollars a program evaluation. Home Healthcare Nurse. March 2010;28(3):191-197.
- Leff, B, et al. "Comparison of functional outcomes associated with hospital at home care and traditional acute hospital care." Journal of the American Geriatrics Society. February 2009.
- James Howard, MD, and Tyler Kent, BS, "Improved Cost and Utilization Among Medicare Beneficiaries Dispositioned From the ED to Receive Home Health Care Compared With Inpatient Hospitalization", AJMC, March 4, 2019
- Oleg Bestsennyy, Michelle Chmielewsky, Anne Koffel, and Amit Shah, "From facility to home: How healthcare could shift by 2025, McKinsey & Company, February 2022
- Robert Nelp and Asmaa Albaroudi, "Medicaid Payment Policies to Support the Home- and Community-Based Services (HCBS) Workforce," MACPAC, November 2023

[4] US Healthcare Labor Market, authored by Tanner Bateman, Sean Hobaugh, and Eric Pridgen of Mercer, 2021.

Components of This Report

Our report conveys an array of analyses that assess the following dynamics:

a) Where Pennsylvania's Medicaid PDN payment rates compare to those in neighboring states.

b) The payment increase that would be needed to bring Pennsylvania's PDN payments in line with the neighboring peer group states' average on a cost-of-living adjusted basis for CY2024, estimating the rates paid by Medicaid MCOs.

c) The degree to which the costs of implementing this payment increase would be offset by triggering the following chain of events:

    a. Increasing the supply of PDN nurses serving Medicaid enrollees.

    b. Reducing the degree to which Medicaid-covered children are served in the inpatient setting – transitioning these patients to home-based care leveraging the additional PDN supply.

    c. Permitting additional hours of PDN care to occur at home, freeing up parents/caregivers to work more and attain a better, more multi-dimensional, quality of life.

The report also presents a compilation of patient-specific case examples demonstrating the value of PDN to patients and to their families.

III. Comparison of Medicaid PDN Payment Rates With Geographic and Demographic Peer States

We obtained Medicaid PDN payment rates for all 50 states and the District of Columbia. Exhibit 1 compares Pennsylvania's current hourly payment rates for registered nurse (RN) and licensed practical nurse (LPN) services with four neighboring states – Delaware, Maryland, New Jersey, and Ohio.[5]

Exhibit 1. 2023 Medicaid PDN Payment Rates – Pennsylvania and Neighboring Peer States

Jurisdiction	2023 PDN Hourly Payment Rate		
	RN	LPN	Average Across RN and LPN
Pennsylvania	Adult: $66.20 Pediatric: $50.00	Adult: $44.08 Pediatric: $50.00	$52.57
Delaware	$63.66	$57.04	$60.35
Maryland	$77.18	$50.02	$63.60
New Jersey	$63.00	$51.00	$57.00
Ohio	$68.44	$48.00	$58.22
Weighted Average Across Neighboring Peer States (DE, MD, NJ, OH)	**$68.60**	**$49.72**	**$59.16**

Pennsylvania currently has an array of payment rates for PDN services. The average of $52.57 was derived by first calculating an average adult rate of $55.14 (across the DHS Office of Long Term Living rates of $66.20 for RN services and $44.08 for LPN services), then averaging that with the DHS Office of Medical Assistance Programs pediatric rate of $50.00.

[5] Note that two additional neighboring states, New York and West Virginia, were not included in this peer state comparison. New York's published FFS rates are not used to a significant extent, as PDN services occur predominantly through MCOs and an array of waiver programs (with these payment levels not tied to the FFS rates). West Virginia is geographically and demographically different than all of Pennsylvania's neighboring states, with the nation's lowest cost of living and third largest percentage of its population residing in rural areas.

Note that an additional, tailored PDN rate structure for persons with developmental disabilities was not included in this average due to the relatively small volume of care that occurs at these specialized rates.

Pennsylvania's average Medicaid PDN payment rate – across RN and LPN rates, and across pediatric and adult rates – is $6.59 (12.5%) below the average across the four peer states (using each state's Medicaid enrollment to derive the weighted average).

30 states have higher average Medicaid FFS payments for PDN services than Pennsylvania (when combining/averaging each state's RN and LPN rates when separate rates are used).

"Overall, a rate of at least $60/hour is necessary to provide adequate pay to qualified staff. This rate is even higher when working with high-acuity clients ($70/hour+)"

– Pennsylvania PDN Provider

IV. Recommended Payment Increases in Pennsylvania

We made three adjustments to the figures in Table 1 to estimate appropriate Medicaid hourly rates in Pennsylvania. First, we factored in cost of living, which is 8.75% *lower* in Pennsylvania than across the four neighboring peer states.

Second, the Medicaid rates in each state were obtained as of calendar year 2023. To translate the buying power of these 2023 payments to 2024, we applied an average cost of living adjustment of 2.7% based on national Congressional Budget Office projections.[6]

Third, under Pennsylvania's Medicaid program, PDN services are often paid by managed care organizations (MCOs) rather than through the fee-for-service (FFS) setting.

The MCOs that are at dollar-for-dollar risk for health care costs have no incentive to "overpay" for PDN services. Their price differential is indicative that the health plans see/expect net value in paying above Medicaid FFS in order to secure adequate PDN nurse capacity for their enrollees requiring these services.

Data shared by more than ten PDN providers, indicates that some Medicaid MCO payment rates for PDN services are typically above – and often far above – Medicaid FFS rates in the same state. Averaging the information together, we derived Medicaid MCO payments for PDN services to be 6.0% above Medicaid FFS (for both RN and LPN services). Notwithstanding the derivation of this average differential, many Pennsylvania MCOs are paying for PDN care at the Medicaid FFS rate. It is therefore important to elevate the FFS rate, so that the health plans that are "indexing to the FFS rate" also pay the PDN providers at a level that helps deliver adequate staffing capacity.

The above rate adjustments are shown in Exhibit 2. After taking all the above factors into account, our calculations derive the recommended Medicaid FFS hourly payment rate to be $59.05. The single blended payment rate across RN and LPN services addresses the dynamic that the PDN care being rendered by RNs and LPNs is often identical – and it is more appropriate to structure the reimbursement to deliver "equal pay for equal work."

The $59.05 blended rate would actually reduce Pennsylvania's current Medicaid FFS payments when PDN services for adults are rendered by RNs, but would increase payments for those services rendered by LPNs. The recommended rate of $59.05 represents an overall rate increase of 12.33% across all PDN services that are currently reimbursed at the FFS rate levels.

[6] https://www.cbo.gov/publication/59431

The Menges Group
Strategic Health Policy & Care Coordination Consulting

Exhibit 2. Recommended Payment Rate Derivation

Item #	Description	Blended Rate (for RN and LPN Services)	Derivation
1	Average Rate Across 4 Neighboring Peer States (DE, MD, NJ, OH)	$59.16	Straight Average Calculated Within Each State's RN and LPN Rates; Medicaid Enrollment of Each State Then Used to Derive Weighted Average Across the Four States
2	Pennsylvania Cost of Living Index (relative to the four peer states' weighted average)	0.920	Source: Missouri Economic Research and Information Center, Cost of Living Data Series, Q3 2023
3	Pennsylvania Payment Rate Needed to Provide Nurses with Buying Power Equivalent to Peer State Average	$54.43	Item 1 x Item 2
4	National CPI Increase, Q4 2023 to Q4 2024	2.7%	Source: Congressional Budget Office publication
5	Payment Rate Needed to Also Capture Inflation from 2023 to 2024	$55.90	Item 3 x 1.027
6	Current Pennsylvania Payment Rate	$52.57	Exhibit 1 (averages adult and pediatric rates together)
7	Overall % Rate Increase Needed for Regional Medicaid FFS Parity	6.3%	Item 5 / Item 6 (minus 1)
8	Additional Market Increase Needed to Match Medicaid MCO Payment Rates	6.0%	Average of 15 Pennsylvania PDN providers' reported differential
9	Total Recommended Percentage Increase	12.33%	Item 7 + Item 8
10	**Recommended Payment Rate**	**$59.05**	**Item 6 x (1 + Item 9)**

We have also recommended a single blended rate across pediatric and adult patients. Pennsylvania's current rate structure creates differing rates for adults and pediatric, and these differences are in opposite directions for RN services (where adult payments are higher) and LPN services (where pediatric payments are higher). A blended rate addresses these contradictions and resolves the concerns expressed in the quotes below.

"A home health provider should not be expected to take a significant drop in reimbursement when an individual turns 21." – Pennsylvania PDN Provider

"Pediatric care pays 12% higher of a reimbursement than adult care is currently paying. If pediatric care low level is paying at a higher rate they are naturally going to choose to work where the highest money will be offered. This leaves adults across the board with having more open shifts and less viable options to cover their care, especially if they are trach and vent!"
– Pennsylvania PDN Provider

Similar Policy Approaches in Other States

The recommended payment rate increases for PDN services in Pennsylvania align with the payment policy approach being taken in multiple other states who are seeking to enhance front-line capacity to deliver quality home-based care. Two specific examples are conveyed below.

- Massachusetts recently increased its RN rate 10.8% from $64.36 to $71.32, while increasing its LPN rates by 9.3% from $53.08 to $58.00. Care delivery hours in Massachusetts increased by 22% for one PDN provider. An additional increase to these rates is pending before the Massachusetts assembly with a proposed effective date of August 14, 2024.

- Virginia increased its PDN rates in July 2022 by an average of 79%, now paying $81.62 for RN services in Northern Virginia, $71.29 for RN services in the rest of the state, $63.43 for LPN services in Northern Virginia, and $52.40 for LPN services in the rest of the state. These four current rates average to $67.19 an hour.

Overall Cost Estimates for Pennsylvania PDN Services

Pennsylvania's current Medicaid PDN costs are estimated in Exhibit 3. These costs during 2021 were provided to us by the Pennsylvania Homecare Association and a 3.0% annual cost trend was used to estimate 2024 costs.

Exhibit 3. Estimated Baseline Pennsylvania Medicaid PDN Costs

Medicaid Program Setting	SFY2021	2024 Estimate (annual 3% increase)
Fee-For-Service	$9,251,475	$10,109,337
Community HealthChoices	$115,671,533	$126,397,407
Physical HealthChoices	$461,477,264	$504,268,666
Total	**$586,400,272**	**$640,775,410**

We estimate that Pennsylvania's current Medicaid PDN costs will increase in future years for two reasons – the implementation of higher rates (in the FFS setting and which several Pennsylvania MCOs will then likely match), plus the higher volume of PDN services that occur under the higher rates (as PDN providers are able to compete more effectively for nursing labor). The key advantage of the PDN rate increases will be that they will foster greater service capacity, with PDN providers better able to attract and retain nursing labor.

Working with the data in Exhibit 3, we estimate that the 2024 baseline Medicaid PDN cost that will be affected by the increased FFS rate is $220.3 million. This estimated figure was derived through the following components:

- 100% of FFS PDN costs
- One-third of Community HealthChoices PDN costs[7]
- One-third of Physical HealthChoices PDN costs

We estimate that one-third of the PDN services paid by Medicaid MCOs is tied exactly to the Pennsylvania Medicaid FFS rate structure and amounts.

Based on information we received from PDN providers operating in other states where

[7] The Community HealthChoices (CHC) program is Pennsylvania's Long-Term Services and Supports mandatory managed care for dual-eligible individuals and individuals with physical disabilities. The Physical HealthChoices program is a separate Medicaid managed care program focused on physical health services for more than two million Medicaid adult and pediatric enrollees who are eligible for Medicaid for reasons other than disability or being age 65 or above.

significant rate increases were implemented, we have estimated that every percentage point rate increase can be expected to create roughly half this percentage in increased PDN labor capacity. Therefore, we project that a 6.16% increase in PDN service volume will occur in conjunction with a 12.33% hourly rate increase.

The additional annual Pennsylvania Medicaid payments for PDN services at these enhanced rates – including the enhanced PDN support these rates will create – are estimated in Exhibit 4 to be $42 million overall, with $17 million coming from state funds.

The overall Medicaid PDN percentage cost increase for services paid at the FFS rates, including the volume impacts, is projected at 19.3%. No cost impact is projected for PDN care that is currently being paid (by MCOs) above the FFS rate.

Exhibit 4. Pennsylvania Medicaid PDN Costs at 12.33% Rate Enhancement (Including Estimated 6.16% Increase in Supply of PDN Services)

	Pennsylvania PDN Medicaid	State Share of Costs	State Share %
Payment Rate and Current Labor Supply)	$220,331,361	$99,149,112	45.0%
SFY2024 Estimate at 12.33% Rate Enhancment	$247,498,197	$111,374,189	45.0%
Total Cost Assuming 6.16% Service Capacity Increase Occurs	$262,756,450	$118,240,402	45.0%
Additional PDN Cost at Enhanced Rate, SFY2024	**$42,425,089**	**$19,091,290**	**45.0%**

Note that the general Federal matching rate for Pennsylvania is approximately 54.12% in FY2024, and 55.09% in FY2025 -- creating a state share of approximately 45%.

V. Offsetting Savings From Inpatient Care Reductions

The previous section estimated the "gross" costs of a PDN rate increase, looking only within the silo of PDN costs. This section estimates the net costs of this increase in Pennsylvania by also taking into account what the rate increase can reasonably be expected to yield via the reduction in the volume of inpatient bed days that becomes possible when enhanced PDN nursing capacity is available.

A. Additional Persons Who Can be Supported at Home Via PDN Due to Payment Increase

As estimated in the top rows of Exhibit 5, approximately 4.2 million hours of PDN support are delivered under Pennsylvania's current Medicaid program structure at the FFS rates. A 6.16% increase in this capacity – the amount we project in conjunction with the recommended rate increases – is estimated to yield approximately 258,000 new hours of annual Medicaid PDN support in Pennsylvania.

Exhibit 5. Derivation of Number of Medicaid FFS Hospital Transition Cases that Enhanced PDN Capacity Will Be Able to Serve

Statistic	Amount
Current Pennsylvania Program Structure	
Estimated Medicaid PDN Expenditures Currently Occurring at Medicaid FFS Rate	$220,331,361
Estimated Average Hourly Payment Rate	$52.57
Estimated Annual PDN Hours Currently Provided	4,191,200
Enhanced Program	
Additional Annual PDN Hours Available (6.16% increase)	258,387
Average PDN Hours Per Patient Per Day (inpatient substitution cases)	10
Additional FFS Patients Who Can Be Served Via PDN Each Day (inpatient substitution cases: 258,387 / 365 / 12	71

The bottom half of Exhibit 5 estimates that this additional PDN labor will be sufficient to serve 71 Pennsylvania Medicaid enrollees at home who would otherwise be

hospitalized (at an assumed support level of 8 hours per calendar day). This substitution of home care for inpatient care includes two groups:

a) Hospitalized persons who can be discharged and cared for at home if additional PDN services are available; and

b) Persons receiving home-based care who can now obtain additional PDN support that prevents clinical crises and hospitalizations from occurring.

This estimate assumes the patients receiving PDN in lieu of inpatient care will receive an average of 10 hours of PDN support per day throughout the year.

C. Degree to Which Currently Hospitalized Pennsylvania Medicaid Enrollees Can be Transitioned Home (if additional PDN capacity is available)

It is challenging to discern the total number of Pennsylvania Medicaid patients who can be served safely and effectively at home in lieu of inpatient care. Piecing together the information we were able to obtain (summarized in the bulleted text below), we anticipate that there are likely over 500 persons who are in this situation at a given point in time. Therefore, the recommended rate increase – and corresponding expected increase in PDN nursing capacity – is not going to be sufficient to serve all persons who are hospitalized in Pennsylvania who could be served effectively at home. The rate increase will move Pennsylvania into a considerably better position, however.

- Another PDN provider indicated that they declined 174 referrals in the most recent calendar quarter (second quarter of 2023) where they had tabulated this information.

- Current referrals with pending or decline status since December 2023 are roughly 250 within our PDN population.

- The MCOs send weekly needs spreadsheets which is very evident of the PDN shortage crisis across the state. One MCO alone typically has more than 400 patients on its list.

- Specific to pediatrics, we currently have 10+ referrals in our division (Western Pennsylvania) that are able to come home from a facility. However, staffing is a barrier.

- Our [PDN Provider's] primary focus is pediatrics and is 95% of our service

volume. High acuity patients are the biggest risk for being stuck in hospitalizations and not being discharged to home even when they are ready for discharge. Hospitals want these patients to have full staffing before they will be discharged. The agency begins to piece staffing together but before full staffing can be secured the staffing that was secured becomes anxious at how long the discharge is taking that they bow out and the staffing that was secured falls apart. It is a vicious cycle that repeats itself.

- Our [PDN Provider's] offices receive daily referrals for both adult and pediatric clients (facility and home based) that are not able to either be discharged and start receiving PDN services or receive the full amount of service hours already authorized. These referrals are not able to be immediately accepted and often remain inpatient or not serviced status for several weeks or months until a provider is able to start care. We also have many current clients (many already shared with other agencies) who are not receiving their fully authorized PDN hours due to lack of staffing which leads to a higher hospital re-admission rate. We have also seen children sent to LTC instead of being able to remain at home due to lack of staffing.

- Approximately 50% of our Medicaid population would benefit from additional services which could decrease the number of hospitalizations. Our current Medicaid census is 210 patients.

- Our agency receives approximately 3-5 calls per day requesting skilled nursing services (PDN) for Medicaid participants in PA (children), who are unable to be discharged from the hospital due to a need for home care. Parents are trained and ready to take their children home. However, we do not have nurses available to meet their needs, due to the nursing shortage, and particularly due to the low reimbursement rates which do not allow us to attract nurses to home care.

- A considerable number of new hospitalizations will be avoided through the professional care enrollees receive at home via enhanced PDN service delivery.

D. Per Case Medicaid Savings When Home-Based PDN Is Used In Lieu of Inpatient Hospital Care

This section estimates the Medicaid savings that accrue when an individual is served at home with PDN support, in lieu of remaining hospitalized. Exhibit 6 estimates costs in the home-based setting.

Exhibit 6. Derivation of In-Home Cost Per Day Estimate

At Home Cost	Amount	Derivation
PDN Cost Per Day		
Average Hourly Rate	$59.05	Assumes 50/50 split between RN and LPN services at this report's recommended payment rates
Estimated Average Hours Per Day	10	University of Michigan publication conveys that average PDN hours are 8-12 per day (we used mid-point of 10). https://www.med.umich.edu/1libr/PedHomeVent/PrivateDutyNursing.pdf
Daily Cost, PDN	$590.52	Multiply above two rows
Estimated Pharmacy Cost/Day	$150.00	Average Medicaid cost per prescription (post rebate) in 2021 was $46; our estimate assumes average at-home patient receives 3 medications at a $50 average net cost
Estimated Other Services Cost/Day (e.g, DME)	$70.00	Ventilator cost is approximately $30/day (one-third of persons are estimated to require ventilators); other DME (hospital bed, wheelchair, etc.) estimated at approximately $30/day; other services estimated at $30/day
Total Cost/Day at Home	**$810.52**	**Sum of above three rows**

We derived an average *inpatient* daily cost of $2,400 to compare with the figures in Exhibit 6. We were not able to obtain Pennsylvania-specific data on Medicaid costs per admission or per day, and therefore used data from another state to establish this estimate – focusing on average payments within long-stay DRGs where patient transfers to home can often occur.

Exhibit 7 derives Pennsylvania's net annual Medicaid costs based on all the above figures and estimates. The cost tabulations indicate that an annual per person savings of approximately $537,000 will accrue to Pennsylvania's Medicaid program when an individual is served at home in lieu of inpatient care.

Exhibit 7. Derivation of Net Savings Impacts of PDN Rate Increase

Medicaid Cost Comparison	Daily Cost	Annualized Amount
In-Home Care	$811	$295,839
Inpatient Care	$2,400	$876,000
In-Home Savings Per Transitioned Person Per Year	$1,589	$580,161
Gross Annual Cost of PDN Rate Increase		$42,425,089
Number of Transitions Needed for Breakeven		73.1
Estimated Transitions that Recommended PDN Rate Increase Enables		70.8
Offsetting Savings Through Transitions to Home		$41,070,170
Estimated Net Annual Medicaid Cost Associated with PDN Rate Increase		**$1,354,919**
State Fund Annual Cost (45% of total)		**$609,713**

To fully offset the $42.4 million cost of the PDN payment rate increase would require that on an average day, 73 additional Pennsylvania Medicaid enrollees are cared for at home rather than in the hospital. The increased PDN capacity associated with this report's recommended rate increase is estimated to support 71 additional Pennsylvania Medicaid enrollees at home per day.

These figures result in an estimate that the costs of the PDN rate increase will be almost entirely (97%) offset by the combination of increased PDN capacity, more home-based care, and fewer hospital days.

The inpatient savings are so large at the patient level (approximately $580,000 per person annually), that they essentially "pay for" elevating the PDN rates for the entire body of PDN care that is currently occurring at the FFS rate level. The net annual Medicaid costs are estimated to be $1.4 million for the Medicaid program overall, and $0.6 million in state funds.

Considerable cost savings potential exists for the rate increases to be budget neutral or even yield cost savings. A slight favorable variation in any of the derivation assumptions in this report will yield a net savings. For example, if the PDN nursing capacity increases by 7.0% (instead of the estimated 6.16%), a net overall annual savings of $3.9 million will occur -- including a $1.7 million savings in state funds.

VI. Advantages of Home-Based Care for Patients and Families – Case Examples

High quality care delivered at home rather than in a facility setting, is the preferred model of support. From a policy perspective, the case for home-based care is furthered by the cost advantages. The following pages convey a set of case examples demonstrating the importance and value of private duty nursing in permitting effective (and cost-effective) care at home rather than in an institutional setting.

In each of these case examples, the advantages of receiving care at home versus continued hospitalization are clear, highlighting the importance of home-based care in enhancing patients' quality of life, reducing financial burden on families, and supporting workforce participation. We have grouped these case examples into three categories:

1. Patient success stories with PDN
2. PDN's positive impact on caregivers and familial socioeconomic status
3. Harmful consequences of going without PDN

1. Patient Success Stories with PDN Across the Life Course

"We have 3 babies who require a ventilator/tracheostomy to survive. In all 3 examples they have come home and been able to thrive and improve on their breathing ability and quality of life as opposed to having to spend the first 6-12 months or their lives in a hospital, away from their family and the parents having to travel back and forth daily to spend time with their newborn child." -- Pennsylvania PDN Provider

Decades-Long Use of PDN Services Allows Patient to Excel as an Educated Advocate

At 6 months of age, an individual with a genetic disease went home as one of the first tracheostomy/ventilator cases in Pennsylvania 40 years ago. At the age of 40 this individual -- who has been cared for by many stakeholders over four decades -- has thrived. This individual has earned their PHD, owns a consulting company, serves as a leader for advocacy of individuals with special needs in the state, and has a family of their own. This person continues to receive in-home PDN services, with minimal hospitalizations and continuity of PDN care across 40 years. Given the ongoing special needs (trach/vent), without in-community services over 40 years, this individual would not be healthy and living their best life today.

Long, Successful Recovery from Gunshot Injuries

At age 11 during 2019, "Brian" was an innocent bystander who got caught in the middle of gunfire while sitting in a car. He suffered a gunshot wound to the face. He was initially taken to Reading Hospital but then was transferred and admitted to two other hospitals through November of 2019. Brian underwent numerous surgeries that resulted in him being trached/vented and required a g-tube for feeding.

Brian was transferred to Good Shepherd Rehabilitation Hospital in Allentown, PA, and primarily remained there from November 2019- March 31st, 2020, until he could be discharged back home with the support of [PDN Provider's] skilled nursing services, which were coordinated through our internal RN Nursing Supervisors/Manager and Operational support teams. Our Nurses (RN/LPN) provided Brian 1 to 1 hourly private duty skilled nursing services delivering the necessary clinical oversight and medical intervention while partnering with his physician and the family to keep him safe in the comfort of his home.

Through years of excellent nursing care that Brian received in the home setting, as of March 2024, we are happy to report that he no longer requires his vent/trach or feeding tube. This is a testament to the incredibly talented nurses who provided care to him from day one, immediately following his long stint in the hospital and rehab center.

Brian was successfully transitioned to our hourly Home Health Aide (1 to 1) services, where he continues to receive the necessary level of care and service within the home setting but no longer requires that higher level of private duty nursing due to his progress and achievement of the goals outlined in his care plan.

Improved Quality of Life for Adult with Significant Respiratory Challenges

"Sarah" is a 45-year-old woman with a chronic respiratory condition that requires frequent hospitalizations for acute exacerbations. After her most recent hospitalization, Sarah's healthcare team and family members explored the option of transitioning her care to home-based management with the support of home health services.

By receiving care at home, Sarah experiences a significant improvement in her quality of life. She can sleep in her own bed, maintain a familiar routine, and enjoy the comfort and privacy of her home environment. With the support of home health nurses and respiratory therapists, Sarah can manage her condition effectively at home, reducing the need for repeated hospitalizations and allowing her to remain more independent.

"The potential for infection is reduced in the home since there are less people in and out of the home compared to being inpatient." – Pennsylvania PDN Provider

Premature Infant Successfully Transitions Out of PDN

A premature infant who was tracheostomy and ventilator dependent was transitioned home for PDN after a full year in a NICU. The in-home nurses assisted with ventilation weaning, leading to tracheostomy decannulation (removal of the tracheostomy tube). Early intervention support included working on developmental targets. At the age of 4, this child no longer required PDN support.

A similar case was highlighted in a Williamsport Sun-Gazette article.[8] The mother of the infant/child, who came home after more than two years in the hospital, expressed that: "We spent over two years surviving and now we get to live."

Supporting an Adult Diagnosed with ALS

An individual was diagnosed in their 40's with ALS leading to tracheostomy, ventilator dependency, a feeding tube and 24/7 care. The patient's significant other needs to work full-time, raise teenage daughters and maintain a home that is able to accommodate all of the patient's needs. A team of support combines to keep the individual healthy, at home and out of the hospital. PDN has been instrumental in preventing hospitalizations and averting the need to live in a long term care facility. The individual has been continually able to live with his family.

Supporting an Adolescent/Adult with Cerebral Palsy and Scoliosis

"Fred" has been diagnosed with cerebral palsy and scoliosis. Only part of his lungs function, and he has a tracheostomy and is ventilator dependent. At age 17, Fred was retained inside of the Children's Home for 359 days due to lack of nursing coverage. The lack of nursing coverage caused the patient's mother to have to quit her job and drain the family's entire life savings. Now 23 years old, Fred has progressed greatly since he has been supported by PDN at home. He hasn't been hospitalized in over 2 years.

HCBS Providing Stability for Mental and Physical Health to Thrive

A patient who, prior to receiving home and community based (HCBS) services, was hospitalized 4 times in a 12 month period (once per quarter). Since he has been receiving HCBS, he has maintained his stability at home and has not returned to inpatient status. His mental and emotional condition has improved and his family has been able to resume their lives with ease.

[8] Loyalsock 2-year-old comes home after 831 days in the hospital | News, Sports, Jobs - Williamsport Sun-Gazette (sungazette.com)

Helping Children Grow and Thrive

"Kevin", a pediatric cardio case, lives with his grandmother and grandfather, who are also his foster parents. Previously, he was unable to sit-up, stand, or walk; struggled with social interactions; and was tube-feed dependent. Since receiving one-on-one nursing, he has thrived; he is ambulatory, goes to school, interacts with children his own age and eats many foods.

Gaining Safety and Stability through Receiving PDN Services

A pediatric client with Cerebral Palsy, who was previously abused by her family, was in foster care when she began receiving skilled nursing. Nursing staff assisted with making it possible for her to attend school and helped her assimilate into the foster family. PDN allowed her to live with this loving, supportive foster family and begin healing. Due to this she was able to thrive and reach developmental milestones that she would otherwise not have met.

2. PDN's Positive Impact on Caregivers and Families

Alleviating the Financial Impact on Families

The "Sanchez" family has a young son, "Miguel," who was born prematurely and requires ongoing medical care due to complications from his premature birth. Miguel has spent the first few years of his life in and out of the hospital, placing a significant financial strain on the family.

With the assistance of a Pediatric Day Nursing (PDN) program, Miguel is able to receive the necessary medical care at home, allowing his parents to avoid the high costs associated with prolonged hospital stays. The family no longer faces expenses such as hospital parking fees, meals outside the home, and lost wages due to extended absences from work. Serving Miguel at home not only improves his health outcomes but also alleviates the financial burden on the Rodriguez family.

Allowing Caregivers to Lead Fulfilling Professional Lives

"John" is a 60-year-old man who suffered a severe stroke that left him with significant physical disabilities and requiring around-the-clock care. Initially, John was admitted to a long-term care facility, where his wife visited him daily, struggling to balance her caregiving responsibilities with her full-time job.

Recognizing the strain on their family and the desire to keep John at home, his wife explored the option of transitioning John's care to a home-based setting with the support of skilled nursing and therapy services. With the assistance of a PDN program, John can receive the necessary care at home, allowing his wife to continue working full-time without the added stress of managing John's care at a facility.

3. Negative Consequences of Going Without PDN: Case Examples

1. "George" was hospitalized in October and was re-hospitalized in December. He came home from the hospital for one week before being re-hospitalized again. Due to the lack of nurses, he has to remain in the hospital until he can be transferred to Boston. His mother has been out of work this entire time.
2. Even with significant effort made to maintain staffing, PDN services were not able to be secured in a rural area. In turn, the patient's primary guardian and single parent lost her employment since she had to work as a caregiver. This resulted in financial hardship and struggles with life resources.
3. A long-term skilled nursing admission without adequate staffing resulted in a drastic decline in health. The patient was admitted to a hospital and received surgeries resulting in tracheostomy which then necessitated much higher skilled staff in home than would initially have been required.
4. A female juvenile patient has been unnecessarily hospitalized for over 6 months due to homecare staff not being available. The patient's behavioral needs were not being met while hospitalized; her self-harming behaviors have exacerbated and become more difficult to control. The parents lost their jobs due to being at the hospital with their daughter.
5. A child was hospitalized since birth. Financially and due to distance to the facility, the family could come and go for visitation but could not be there as often as they wanted to be. This adversely affected bonding. In addition, the family suffered considerable financial strain as the child remained in the hospital, due to the loss of work, the costs of trips to the hospital, etc.
6. This patient wishes to remain at home with their family, but as their parents age, they are growing fearful that if we are unable to recruit and attract nurses for their case, they may have to placed in a facility. One of the biggest benefits of home care, is that patients are able to receive care in the safety and comfort of their own homes surrounded by their loved ones. If we as an agency are unable to remain competitive with our wages, we will not be able to attract and retain the staff we need to continue to meet the needs of our home care clients.
7. "Lauren", a SN case, t/v patient, was admitted to the hospital when loss of care occurred due to routine staffing issues. This resulted in an extended hospital stay, as her primary guardian had other work commitments and no other caregiver was identified that was trained for 24/7 high-tech care.

VII. Importance of Adequate Payments for PDN Providers to Attract and Retain an Optimal Staff Team

Pennsylvania PDN providers were asked to describe the dynamics they are confronting in terms of attracting and retaining staff to serve Medicaid patients. Excerpts from the input we received are shared below.

- We receive a weekly spread sheet from one of our MCOs that has over 400 members that are without medically warranted services due to the staffing shortage. Increase rates would draw nurses to the homecare field and help provide care for many of those members!
- We are losing staff to facilities who are paying more.
- Nurses are going to gravitate to where the money pays.
- The homecare industry has long been underpaid and therefore unable to compete with surrounding facilities which ultimately leads to an access to care problem because we are not able to attract the quality nurses needed to keep people safe while aging in place at home or allowing babies with special needs to come home from the hospital.
- A higher rate leads to more and better qualified nurses. We currently need a rate increase of $10 per hour to be competitive. We speak to several nurses every week but are unable to provide a competitive wage and benefits for them to go into Home Care.
- Home healthcare is very competitive in Western Pennsylvania and ultimately, our ability to recruit/retain staff is determined by what we can pay them.
- A $10 per hour increase in nursing rates is needed to be able to increase hourly wages and be competitive. Hundreds of cases come over from Insurance Company A each week, requesting skilled nursing hours. However, we do not have the additional staff needed to help these families.
- In instances where the reimbursement rate is greater than the Medicaid FFS fee schedule staffing levels are improved. MCO 1 High-Tech rate, ODP Waiver services, single case agreements (SCAs) for clients that face staffing challenges, and our HICU program all yield better staffing outcomes for our clients.

- In 2023, our organization received 1,227 calls or emails directly from Managed Care plans, seeking services for individual patients. 27% of these direct requests came from a plan that does not offer enhanced rates (i.e. above the current Medicaid FFS rate).

- As of 3/26/24, there are 2,266 pediatric patients statewide in need of additional hours or services (needs currently unmet).

- Just look at what hospital are offering for nurses on Indeed. This should be proof enough the [Medicaid] rates are insufficient.

"100% of clients receiving care in the home are at risk of hospitalization if we are unable to secure adequate staff to keep them home safely."
-- Pennsylvania PDN Provider

Appendix A: Methodological Observations and Limitations

This Appendix conveys further context around the quantitative estimates included in the report.

Average Medicaid PDN Payments in Fee-For-Service Setting: We have no reason to doubt the accuracy of the data the PDN providers assembled and shared with us. Data were provided from two sources and the state-by-state payment amounts were nearly identical. In several states, Medicaid PDN rates varied between RN and LPN services, urban/rural counties, high technology and low technology patients (also sometimes termed as specialty or non-specialty patients), weekday and weekend rates, and/or pediatric and adult patients. In these states, we averaged the published rates together by license (RN and LPN) by taking a straight average of the two, by urban/rural in approximate concert with a state's overall population distribution, and by severity using a 50/50 assumption (e.g., between high technology and low technology). The national average rate was derived by weighting each state's payment rates by their overall Medicaid enrollment level as of September 2023.

Average Medicaid PDN Payments in MCO Setting Relative to Fee-For-Service Setting: While it was important to understand Medicaid MCO payment rate dynamics for PDN services, we did not want to obtain or disclose the specific payment rates that PDN providers have negotiated with Medicaid MCOs. We therefore surveyed PDN providers requesting that they provide factors by which Medicaid MCO rates differed from Medicaid FFS rates in the states they serve. The data we received back were averaged within a PDN company (averaging their information across states and/or MCO data points), and these figures were then averaged together such that each PDN company contributing data received an equal weighting.

Estimated Degree to Which PDN Service Capacity Will Grow Under Enhanced Pennsylvania Medicaid Payment Rates: We received information from different PDN providers on their experience with staffing before and after Medicaid payment rate increases went into effect. There were only a few situations where large rate increases occurred, and the data we received supported a ratio of roughly 60% (i.e., any given percentage payment rate increase would yield 60% of that percentage in increased PDN nursing capacity). Due to the modest amount of data available, we lowered our estimated ratio to 50% in this report.

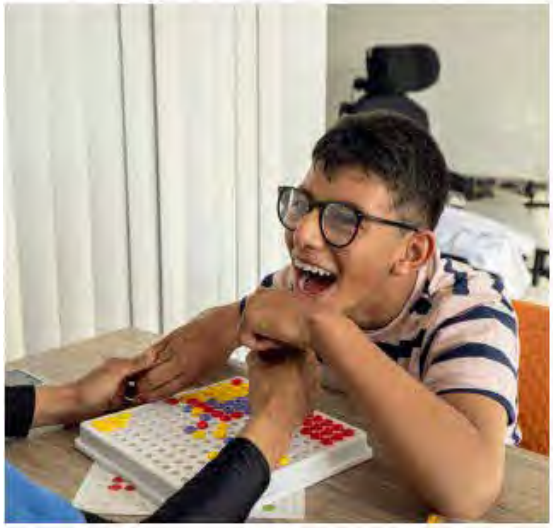
Number of Medicaid Enrollees Who Can Be Served Via PDN In Lieu of Inpatient Care: This is the component of our estimates that we felt least confident about. The data available on this issue came from too few sources to extrapolate to a reliable statewide number. The body of the report conveys this data, and our opinions around what these data mean (e.g., that there are at least 100 Pennsylvania Medicaid

enrollees in the hospital on a typical day who could be safely cared for at home if enhanced PDN capacity were available.).

Average Daily Cost of Inpatient Care: We were not able to obtain Pennsylvania data on Medicaid costs per admission (or per day). We therefore relied on the approximate figure ($2,400) from another state where we were able to tabulate costs per day within DRGs that were deemed to have a strong potential for "transferrable" days to home care.

Average Daily Cost of Home Care: Our estimates sought to match up the services that still need to be provided at home to those that occur in the inpatient setting, and these go beyond nursing care. We did not have a sound data set to estimate the daily cost for "all other services" and our assumptions – often crude ones – are conveyed in the body of the report. While these service estimates were somewhat of a "forced guess," we viewed them to be reasonable and made them objectively.



IMPROVING THE LIVES OF CHILDREN, YOUTH, AND YOUNG ADULTS WITH COMPLEX NEEDS AND THEIR FAMILIES

A report from the Blueprint Workgroup

pennsylvania
DEPARTMENT OF HUMAN SERVICES

TABLE OF CONTENTS

Acknowledgements

The creation of this document is the culmination of months of intensive discussion, hard work, honest reflection, and challenging conversations. It is the embodiment of the determination and spirit of the families and professionals who continuously strive to provide a better life for all children, youth, and young adults. A very special thank you is owed to the families and professionals who participated as members of the Blueprint Workgroup and who continually give of themselves to improve the lives of their children and those they support.

I am especially grateful to Russ Cripps and Colleen Cox from the Child Welfare Resource Center, Kaitlin Koffer and Molly Sadowsky from the ASERT Collaborative, and the DHS Team: Michael Hershey, Roseann Perry, Jenn Newman, Courtney Malecki, Emily Burger, and the many members of the DHS Complex Needs Planning Team. None of this would have been possible without their leadership, knowledge, support, and dedication.

Thank you.

Jonathan McVey
Complex Needs Planning
Office of the Secretary
Pennsylvania Department of Human Services

Blueprint Workgroup Members

Paulette Benegasi, Director, Mental Health/Intellectual Disability, Mercer County
Sandie Beren, Deputy Administrator, Montgomery County Office of Children and Youth
Emily Burger, MS, NCC, Special Populations Clinical Support, PA DHS – Office of Developmental Programs
Lauren DellaCava, Clinical Director, Community Behavioral Health, Philadelphia
Laura DeRiggi, Senior Director, Clinical Consultant Philadelphia Dept. of Behavioral Health and ID Services
Danielle DiMatteo, Director, Delaware County Juvenile Probation
Dr. Meghan Eberle, Vice President Clinical Services, Carelon Health of Pennsylvania
Judy Erb, Administrator, Mental Health/Intellectual Disability, Lancaster County
Leesa Gehman, M.Ed., Deputy Administrator, Northampton County Developmental Programs
Jalissa Gresham, Interim Assistant Program Director, United Methodist Home
Ashley Horvath, Lead Care Manager, Magellan Behavioral Health of Pennsylvania
Marlene Jennings, Program Planner, Early Intervention, Lancaster County
Ashley Johnson, Foster Parent
Shayla Jones, Youth Quality Improvement Specialist, Univ. of Pittsburgh, Child Welfare Resource Center.
Crystal Karenchak, Family Policy and Engagement Consultant, PA System of Care
Ruth Ann Koss, CASSP Coordinator, Children's Mental Health, Allegheny County
Nancy Kukovich, CEO, Adelphoi
Bethany Leas, Director, Outpatient Services, University of Pittsburgh Medical Center
Lisa Lowrie, DSW, LSW, Director of Advocacy and Consumer Relations, The Bradley Center
Herta Madder, MA, MBA CASSP Coordinator - Retired Beaver County Behavioral Health
Stefania Maiale, Adoptive Mother
Courtney Malecki, Director of Planning, Policy and Program Development, PA DHS – Office of Mental Health and Substance Abuse Services, Bureau of Children's Behavioral Health
Athena Mandros, Children and Families Business Development, Merakey
Cindy Matthews, Administrative Entity, Early Intervention, Wayne County
Dr. Kathryn McCans, Chief – Division of Pediatric Emergency Medicine, Penn State Health, Hershey Medical Center.
Beth-Ann McConnell, Interagency Coordinator, Intermediate Unit 15- Capital Area
Shari Montgomery, Intellectual Disabilities Program Director – Armstrong Indiana Behavioral and Developmental Health Program
Crystal Natan, Executive Director, Lancaster County Children and Youth Agency
Dr. Geoff Neimark, Chief Medical Officer, Community Care Behavioral Health Organization
Jennifer Newman, HSA, Cross-Systems Specialist, Office of Children, Youth, and Families
Lisa Parker, Bureau Director, PA DHS – Office of Child Development and Early Learning
Lloyd Peffer, CASSP Coordinator, Tioga County DHS
Roseann Perry, Regional Special Projects Manager, PA DHS – Office of Children, Youth, and Families
Shawn Quigley, Chief Operating Officer, Melmark
Leah M. Raker, Director, Centre County Children, Youth Services
Amy Reed, Coordinator, Early Intervention, Cumberland County
Lana Rees, Executive Director, Erie County Children, Youth and Families
Shelly Rivello, Clinical Coordinator, Behavioral Health Alliance of Rural PA
Roni Russell, PaTTAN Consultant, Pennsylvania Department of Education
Chrissy Sandacz, Manager – Care Management, PeformCare
Erica Scanlon, CASSP Coordinator, Children's Mental Health, Lancaster County

Erin Seifrit-Townsend, Deputy Administrator of Children's Mental Health, Montgomery County Department of Health and Human Services, Office of Mental Health/Developmental Disabilities/Early Intervention
Kristin Smeins, Home and School Visitor, Garnett Valley School District
Adaminah Solita Tankersly, Family Coordinator, CASSP, Philadelphia County
Deborah Tate, Assistant Administrator, Intellectual Disability/Early Intervention Centre County
Bob Tomassini, Executive Director, Juvenile Court Judges' Commission
Kevin Webber, Program Supervisor, Intermediate Unit 5 – Northwest Tri-County
Jaime Yingling, Program Specialist, Intellectual Developmental Disability, Cumberland County
Jen Zingales, Coordinator of Special Education/Early Intervention Services, Colonial Intermediate Unit 20

Executive Summary

A growing number of Pennsylvania's children, youth, and young adults with complex needs and their families often experience significant barriers to treatment, supports, and services. The current child serving systems struggle to support young people who have the most complex needs. In this report, stakeholders have come together to discuss those barriers and to identify recommendations that will improve outcomes for these youth and their families.

Consider the following three stories as an illustration of what youth with complex needs, their families, and the systems supporting them often experience. Although the stories do not capture many of the complexities, or unique circumstances, it is important to start here because these scenarios happen every day, in many different ways, across all of our child-serving systems.

> One young woman experienced significant trauma and hurt long before she reached the system. Adopted and then abandoned, bounced from placement to placement her pain manifested more and more often as aggression and anger. She landed squarely in the system with people all around her who cared and were trying to help, but they didn't know what to do next. Her team recognized she was talented and bright with her own goals. With the right support and guidance, the team talked with her about what she wanted and what her vision for her future would look like. Through that process, she chose a provider to live with, services she would use and a path in her education. She worked to catch up academically and to work towards her dreams. Because her team listened, saw her strengths, and looked for who she was beyond the heartache and pain, she now has stability and a path toward a future she controls, feels safe within, and that is her own.
>
> A young man enters a residential treatment facility because his needs have reached the point where his community-based services and family can no longer safely support him in his home. His needs are significant and cross multiple domains: behavioral, developmental, and medical. The young man's team works diligently with him, and his family is continuously supportive and engaged. As this young man grows, the team sees some positive progress. However, this young man continues to need supports beyond what his family can provide to live a full and safe life in the community. He nears adulthood and the team begins preparing and planning for the next chapter of his life. Again, despite wanting to, his family still cannot bring him home safely. The team searches for assistance and contacts many other professionals and systems, but there are delays in planning, difficulties with funding and misunderstandings between each system. All systems are engaged, but the young man is still in the same place as no provider is able to step forward to support him. Frequent and targeted outreach is completed as the days, weeks, and months pass. Eventually a provider is engaged, but additional resources are required to meet him as his level of need. The process is slow and challenging for all, but most of all for the young man and his family. There is a new home on the horizon, but there are many steps and potential missteps along the way. To the young man and his family, the journey feels like it will never end.

Planning for the future will be an evolving and ongoing process as his needs change throughout his life.

Consider another young man who was abandoned as a young child and then placed with relatives who abused him. Lacking in support and understanding, his behaviors escalated, and he became a ward of the state. Placement after placement failed him until the team connected with his true need - healing and stability. His team worked together to plan for supports in the community, developing a crisis plan and school plan, partnering with intensive services and engaging in frequent multi-system and multi-disciplinary meetings. Even when things were rough, he said he knew it would be okay because he had so many people that cared about him. His team saw his unmet needs, not just the services, but the everyday life needs that are important to everyone. The team came together and worked alongside this young man to build a life he wants to live. He has held jobs, made friends, and started to plan for his future. The process took time away from important developmental years and milestones, and he was nearly an adult by the time enough stability, treatment, and communication occurred to support him in creating this life. We wonder what trauma could have been spared if we had intervened earlier, recognized his deep needs earlier, and helped him to work towards healing sooner.

The work of supporting these three young people is by no means at an end; however, they have the support they need and deserve and are on a positive trajectory toward an everyday life. Two of these stories show us that, with the inclusion of the youth and teaming of all involved systems, it is possible. The other story shows us that even with an engaged and supportive family and a team wrapped around the young man, systems still struggle to effectively and timely support young people. All of these stories illustrate the resilience of youth with complex needs and their families.

There are other youth with complex needs and families in Pennsylvania, right now and in the future, with similar stories of hope and challenges. All of these children and families deserve assistance in navigating these challenges, and we must ease barriers and avoid delays to care and supports whenever possible. Understanding that each youth with complex needs and their families are unique, there are several characteristics that differentiate the population we seek to help through this report. The following are the most often-encountered characteristics of youth (ages 0-21) with complex needs:[1]

- Complex trauma including abuse, neglect, developmental and institutional trauma;
- Multiple and complex diagnoses across the developmental, physical, and mental health domains;
- Potential diagnostic overshadowing due to an intellectual disability and/or autism diagnosis;
- Complex communication needs;
- Inconsistent presentation of behaviors and symptoms across settings;

[1] Not all of these characteristics are required; there is wide variability in the combinations, experiences, and level of acuity of these youth. Additionally, some youth may have very few of these characteristics, but because of complex social dynamics in their lives, are considered to be a youth with complex needs.

- Lack of diagnostic clarity;
- Disrupted education;
- Limited, strained, or no natural supports;
- Multiple system involvement including justice systems; and,
- An extensive history of out-of-home care.

The following national statistics further illustrate some of the complexity of the needs of youth with disabilities, their increasing vulnerabilities, and the prevalence of these youth in our communities. Youth with disabilities are significantly more likely to experience abuse, live in institutional care and not live with kin during a child welfare placement. Research shows that youth with developmental disabilities are more likely to have co-occurring mental health needs. On top of all of that, all of these youth have experienced some form of trauma in their life. As with the stories above, these statistics do not provide a complete picture of need or prevalence.[2]

- 1 in 6 U.S. children aged 2–8 years (17.4%) had a diagnosed mental, behavioral, or developmental disorder.[3]
- Among children living below 100% of the federal poverty level, more than 1 in 5 (22%) had a mental, behavioral, or developmental disorder.[3]
- Depression and anxiety have increased over time: ever having been diagnosed with either anxiety or depression among children aged 6-17 years increased from 5.4% in 2003 to 8% in 2007 and to 8.4% in 2011-2012.[4]
- An estimated 33.6% of individuals with intellectual disabilities have co-occurring mental health conditions.[5]
- Children diagnosed with an intellectual disability were 3.7 times more likely to be neglected, 3.8 times as likely to be emotionally abused, 3.8 times as likely to be physically abused, and 4.0 times as likely to be sexually abused.[6]
- Youth aged 17+ with disabilities experience higher rates of placement instability and longer stays in placement than peers without disabilities.[7]

[2] Efforts are underway in Pennsylvania to use data to better understand the scope of need for youth with complex needs and their families.
[3] Cree RA, Bitsko RH, Robinson LR, Holbrook JR, Danielson ML, Smith DS, Kaminski JW, Kenney MK, Peacock G. Health care, family, and community factors associated with mental, behavioral, and developmental disorders and poverty among children aged 2–8 years — United States, 2016. MMWR, 2018;67(5):1377-1383.
[4] Bitsko RH, Holbrook JR, Ghandour RM, Blumberg SJ, Visser SN, Perou R, Walkup J. Epidemiology and impact of healthcare provider diagnosed anxiety and depression among US children. Journal of Developmental and Behavioral Pediatrics. Published online before print April 24, 2018
[5] Prevalence of co-occurring psychiatric disorder in adults and adolescents with intellectual disability: A systematic review and meta-analysis. Mario G. Mazza, Aurora Rosetti, Giovanna Crespi, Massimo Clerici.
[6] Sullivan, P.M. and Knutson, J.F. (2000), ‘‘Maltreatment and disabilities: a population-based epidemiological study’’, Child Abuse and Neglect, Vol. 24 No. 10, pp. 1257-73.
[7] Hill, K. (2012). Permanency and placement planning for older youth with disabilities in out-of-home placement. Children and Youth Services Review, 34, 1418–1424.

- Youth with disabilities were 2.47 times more likely to live in an institution and 2.22 times more likely to live in community-based group homes.[8]

In Pennsylvania, a good foundation of services and supports exists across all child-serving systems. However, that foundation is primarily designed around the broader population, youth who have less acute and fewer multi-system needs. As a result, well-intended systems can still miss the wants and needs of youth with complex needs and their families – meaning they are not consistently supported on a positive, personalized trajectory.

In recognition of this problem, the Pennsylvania Department of Human Services (DHS) partnered with the Autism Services, Education, Resources and Training Collaborative[9] (ASERT) to conduct a series of focus groups and surveys. Youth, families, and the child-serving systems supporting them were engaged to better understand current and future needs. These convenings highlighted common challenges these youth, families, and child-serving systems experience. Five key themes emerged across these groups:

1. Communication
2. Services and programs
3. Resource Navigation
4. Staffing / Workforce
5. Trauma-informed supports

Overarching all of the themes above is family engagement. With this new understanding, DHS partnered with the University of Pittsburgh's Child Welfare Resource Center[10] to establish and sponsor a blueprint workgroup with families with lived experience, and a multi-system and multi-disciplinary membership.[11] The workgroup kicked-off in July 2023 to develop recommendations that will improve outcomes for youth with complex needs and their families.

The workgroup met until November 2023 and using the DAPIM framework,[12] identified the recommendations starting on page 12. The foundation for the workgroup's discussion and the recommendations were the five themes from the focus groups and surveys, and the "desired future state" objective provided below:

[8] Slayter, Elspeth, 2016. "Youth with disabilities in the United States Child Welfare System," Children and Youth Services Review, Elsevier, vol. 64(C), pages 155-165.
[9] PAAutism.org
[10] University of Pittsburgh: Pennsylvania Child Welfare Resource Center
[11] Despite efforts to recruit young adults with lived experience, none were able to participate in the Blueprint Workgroup. The Department and the Blueprint Workgroup agreed to delay the release of this report to again seek the valuable input of these young adults; however, few were able to review. Any further work on this topic must include significant efforts to gain the voice of youth with lived experience.
[12] See Appendix C – DAPIM Model

Desired Future State

In Pennsylvania, we believe all youth with complex needs and their families[13] will have the opportunity to access timely supports and services that are individualized, trauma-informed, holistic, respectful of race and culture, family- and youth- driven, and available in their own communities. This will be evidenced by:

- A focus on youth and family engagement while honoring their voice and choice;
- Establishing and maintaining a well-supported and qualified workforce;
- Collaboration and shared understanding across systems to support planning and shared goals;
- Systems that prioritize early identification, proactive intervention, and service options that support family stability, safety, and the youth's healthy development and meaningful relationships which support life-long connections;
- Teams that engage in ongoing and integrated planning that supports the everyday needs of a family and youth (housing, education, transportation, scheduling, access to medical care, etc.); and,
- Service delivery that is coordinated, accessible, timely and includes support throughout the process.

Using the desired future state, the information gathered through the focus groups and surveys, the blueprint workgroup's own assessments, identification of strengths and gaps, and root cause analyses, the blueprint workgroup identified 18 recommendations which help achieve the desired future state.[14] Each numbered recommendation is connected to one or more of the five themes mentioned previously and a supporting rationale is provided. The recommendations are not listed in priority order, rather they are grouped together based on interdependencies or common threads as reflected in the table of contents.

The recommendations address a wide variety of challenges and barriers encountered by youth with complex needs, their families, and the systems supporting them. Some recommendations involve the provision of direct services, such as establishing a multi-disciplinary team of professionals for treatment and stability in the community or developing a unified and proactive approach to transitions for youth. Other recommendations reflect the need for administrative efficiencies, like improving information sharing, establishing greater uniformity in processes and forms among all insurers and health care payors, or finding a better balance in provider credentialing. Still other recommendations focus on building system capacity[15] through uniformity in trauma training, developing trainings and tools to help teams build a complete picture of the child and family, and, very importantly, the need to build and retain a qualified workforce.

All of the recommendations are intended to push the conversation forward in specific critical areas. Due to the time limited nature of the workgroup, the recommendations require further development before implementation can be achieved.[16] For example, the suggested amendments to Act 212 for Early Intervention screening and

[13] "Family" is defined by the individual.

[14] For more detailed information on the background of this effort, please see Appendix A – Background, Analysis, and Findings; and Appendix B – ASERT Final Report.

[15] The Department of Human Services is also launching the first annual Pediatric Capacity Building Institute in January 2024 to increase clinical and administrative capacity for all child-serving systems supporting youth with complex needs and their families. For more information please visit: Complex Behavioral Health Blueprint (pa.gov)

[16] For a brief list of ideas and discussion points that, due to the time limited nature of the workgroup, were not fully conceived and merit future discussion, please see Appendix D – Parking Lot Concepts.

tracking are not intended to provide exact statutory language. The blueprint workgroup recognizes that the categories in the recommendation are conceptual and that there are other potential categories and language that may be preferable. Ultimately, the blueprint workgroup seeks to ensure children with complex needs are identified as early as possible so they and their parents or caregivers can access the services and supports they need through childhood.

The blueprint workgroup also identified four recommendations that deserve separate attention because of their importance to this work:

1. Broadly, there are many young people with complex needs who are receiving interventions but are at a point in their life when they have already faced extreme challenges and adversity, have experienced significant trauma and loss, and are developing in a world without friends or family. By growing up in such an environment, imprints are being made all along the way, the challenges and adversity they were already going to experience because of their disabilities, or the circumstances of their birth are exponentially magnified and new ones are added. Many times, families, practitioners, planning team members ask themselves, what more could we have done? What could we have done differently?

   A broad systematic restructuring is needed with a commitment to implement diverse and holistic prevention activities. States, such as California and Washington, have undertaken massive initiatives to transform their systems of care for youth:

   - A statement from California's Vision for Prevention: "California is committed to the reformation of the child welfare system by shifting the mindset from a child protection and foster care system to a child and family well-being system."[17]

   A multi-year task force should be established to design and implement this restructuring to ensure all child-serving systems of care become prevention focused first and foremost.

2. Persons in state leadership roles (Governor's Office, General Assembly, regulators and/or funders) who seek to implement any of these recommendations should solicit input[18] from youth and families with lived experience. **"Nothing about us, without us."**

3. A multi-disciplinary steering team of state and system leaders, as well as youth and families, should be formed to carry these recommendations forward. Due to the breadth of this work and the time limitation on the blueprint workgroup, these recommendations require further development. Many members of the workgroup expressed a strong desire to continue developing these ideas and carrying them forward to fruition. Additionally, this steering team should leverage the knowledge and expertise of other statewide partners, such as the various associations and advocacy groups, who did not directly participate in the Blueprint Workgroup.

[17] California's Vision for Prevention
[18] In soliciting input from those with lived experience, it is critical to ensure those individuals are supported throughout that process. Safe spaces that meet their developmental, emotional, safety, and accessibility needs are required.

4. Broadly, there are two groups of youth and families in need: those who require help right now and those who will. The blueprint workgroup's recommendations will help both groups, however, the recommendations will also take time to implement. As such, the workgroup recognized the growing number of youth with complex needs who may not be in the most appropriate location for treatment and urges state, local, and system leaders to find solutions which can be implemented right now.

Ultimately, children, youth, and young adults with complex needs and their families deserve solutions that are creative, flexible, and consistently reflect the needs of the whole child and family – the following recommendations can help us achieve that.

Recommendations 1 – 3: Prioritizing Prevention and Strengthening System Response			
	Themes	**Rationale**	**Recommendation**
1.	Services & Programs, Resource Navigation	Not all children and youth with complex needs are identified at an early age and as a result, without appropriate interventions, services, and family engagement, their needs and behaviors increase requiring greater services and supports from other systems as they get older. Children who are engaged in Early Intervention services consistently experience better outcomes over the course of their life. The first opportunity to identify these children is through screening and tracking a child's development. Act 212 (Early Intervention) established six categories of children who are at particularly high-risk of requiring early intervention services, those categories include: low birth weight, neonatal intensive care, prenatal substance exposure, referral by county children and youth agency, lead exposure, or experiencing homelessness. These categories mean the child automatically qualifies for regularly occurring developmental screenings and tracking until age three. Participation is voluntary, parents or caregivers may decline at any time. Regardless of whether a	Amend Act 212 (Early Intervention) to add new categories for screening and tracking up to age 3. The following five categories[19] should be added to Act 212 for screening and tracking: 1. Children with a parent or caregiver with mental illness or SMI; 2. Children with a parent or caregiver with intellectual disabilities and/or ASD; 3. Children who live in extreme poverty; 4. Children with a parent or caregiver currently incarcerated; and, 5. Children born to individuals who had previous involvement with a county children and youth agency within the past two, three, or four years. Notably, the first four categories are all considered Adverse Childhood Experiences (ACEs) for which there is significant data showing positive outcomes when interventions are implemented. Additionally, although prenatal substance exposure (including alcohol), is a critical category that is already in use, it should be re-examined to consider a broader range of scenarios. Some examples may include: where the mother was not using substances during pregnancy, but relapses following child birth or where the father has a history of substance use.

[19] These five eligibility categories were identified without the intent of excluding other potential categories, such as Intimate Partner Violence or Domestic Violence. It should also be noted that each one of these categories can be interpreted and defined in many different ways. Lastly, there are additional methods that should be strengthened to supplement the EI screenings and tracking required in Act 212. For example, providing training to pediatricians to conduct brief screenings like ages and stages during standard well-child visits birth to three.

Recommendations 1 – 3: Prioritizing Prevention and Strengthening System Response			
	Themes	**Rationale**	**Recommendation**
		child is determined eligible for Early Intervention services as a result of these screenings and tracking, the child and family are also referred to other supports and services as they are identified. There is growing interest in expanding EI tracking categories. Children experiencing homelessness was added in 2017 and legislation has been introduced in recent years to add post-partum depression as a category. The six categories in use now should be expanded upon to ensure no children and families slip through the cracks and do not get the help they need as early as possible. The earlier a high-risk child is identified, the more likely the child will experience greater positive outcomes and require less costly supports and services later in life. Although expanding screening and tracking categories is a good start, more is needed to ensure these children do not fall through the cracks. A strong family engagement and education component is needed combined with a bridge between early childhood services and school age services. Even if these children qualify for developmental screenings and tracking, without their families engaged and without a strong bridge between systems, these children may still fall through the cracks.	In implementing these, family engagement and education is critical. Assessments should be respectful of the family culture and conducted in a thoughtful and empathetic manner. Related to family engagement and education, services like Home Visiting and Nurse Family Partnership should be examined with the goal of increasing system capacity and expanding availability to every new parent or caregiver, including access to virtual home visitation. Lastly, it is important that we also increase and strengthen the connection between Early Intervention services and school-age services – this is a critical transition period which can make a world of difference. A warm hand-off is needed between these systems – an individual who can manage this transition and ensure the holistic approach of Early Intervention is not lost.

Recommendations 1 – 3: Prioritizing Prevention and Strengthening System Response			
	Themes	**Rationale**	**Recommendation**
2.	Services & Programs, Resource Navigation	Traditional funding structures and processes were identified as a root cause of challenges related to service provision, access to services, and navigation of resources. Youth with complex needs and their families have needs that require many different types of services and support – as a result, they have to interact with many different systems and entities. Each of those systems have their own goals, rules, and processes for eligibility, service provisions, admission/discharge criteria, target ages, etc. As a result, instead of youth and families getting services to meet their unique needs, the systems try to "fit" them into each of their boxes because that is what the funding stream dictates. The current structures are designed for the general population or youth and families with low to moderate acuity. They are not flexible enough and do not allow for a more holistic approach that youth with complex needs and their families actually need.	Establish a single, dedicated funding stream outside of the human services block grant that addresses all of the developmental, physical, and mental/behavioral health requirements of youth with complex needs. By placing these domains within the same funding stream, there is greater flexibility to create programs that better meet the needs of these youth. A fully holistic approach becomes more feasible because everything will be funded and coordinated under the same funding stream. This also creates the opportunity to establish new and innovative approaches which may not be currently available or at least not available with consistency across the Commonwealth. Until this can happen, develop written guidance to all child serving systems that will aid county agencies and funders to develop programming which crosses multiple systems. Additionally, fiscal experts are needed to provide direct technical assistance to local planning entities as requested for specific youth with complex needs. (See Recommendation 14 - Needs/Gap Analysis, Recommendation 11 - Insurer Processes, Recommendation 4 – Statewide Clearinghouse, Recommendation 6 – Integrated Child/Family Team, Recommendation 7 – Integrated Family Peer Specialist, and Recommendation 13 – Billing During Teaming)

Recommendations 1 – 3: Prioritizing Prevention and Strengthening System Response			
	Themes	**Rationale**	**Recommendation**
3.	Services & Programs, Resource Navigation	Children with complex needs and families often encounter multiple providers in the community and many more through inpatient or residential treatment. Each professional provides their own assessment of the child and family, and each doctor or psychologist typically provides diagnoses or recommendations. As a result, children frequently carry multiple and sometimes conflicting diagnoses and there are no clear recommendations for the next steps. Additionally, the quality of evaluations, the reasoning for diagnoses, treatments, and recommendations may vary. Evaluations represent a snapshot in time for that child and family and there is no mechanism to revisit and revise or eliminate diagnoses that are not accurate. Standards for each profession vary by license, setting, and service, which can lead to confusing and unclear next steps. When inaccurate diagnoses remain or unclear recommendations follow the child, the child and family are at greater risk of receiving inappropriate services or not being eligible for services that are needed. There is a risk of polypharmacy at a young age and long-term impacts to the child and youth.	Form a time-limited workgroup to complete a root cause analysis on unclear and conflicting diagnoses and recommendations. Review the current standards across professions and payors to find areas of consistency and differences, and develop best practice standards for assessments, evaluations, and recommendations. Develop a guide for planning team members to use when reviewing these types of records to foster greater understanding of the content. Establish a process through which children and families can request re-evaluation or question evaluation outcomes without retribution. Provide a mechanism to provide second opinions when requested that is consistent and can be implemented across settings. (See Recommendation 14 - Needs/Gap Analysis, Recommendation 4 – Statewide Clearinghouse, Recommendation 17 – Healing Centered State, Recommendation 6 - Integrated Child/Family Team, Recommendations 11 - Insurance Processes)

Recommendations 4 – 5: Information Sharing and Resource Navigation			
	Themes	**Rationale**	**Recommendation**
4.	Resource Navigation	Finding and accessing services and supports can be very challenging for a variety of reasons. For example, many child-serving systems are structured differently between state and local levels, these different structures result in different mechanisms to find and access services. Many systems have some iteration of how to access resources, but they also have serious limitations such as compatibility with other systems, ease of navigation, or are not always up to date. As a result, it is very challenging for professionals and families to identify what resources are available near them and to access them.	Develop a statewide, comprehensive and holistic clearinghouse of information on supports, services, and program availability in Pennsylvania. This clearinghouse should compile resources from all systems[20] into a "one-stop-shop." The platform should be accessible, easy to navigate for families and professionals, and should support referrals by professionals to services and supports specific to the needs of the youth being supported. PA Navigate[21] is scheduled to launch in January 2024. PA Navigate is currently structured around social determinants of health (transportation, food insecurity, housing, homelessness, financial strain, clothing, utilities, etc.). A logical next step for PA Navigate is to expand that platform to support the service and support domains identified in the paragraph above.
5.	Communication, Services & Programs, Resource Navigation, Family Engagement	Information critical to support planning efforts is often missed or delayed when concerns about confidentiality prevent systems and planning team members from sharing information. For example, some agencies/entities/providers will not accept another entity's release form. Families are required to sign releases of information repeatedly as new systems, practitioners, and team members join the treatment and planning efforts. This is burdensome,	A time-limited, specialized workgroup with subject matter experts from across systems, including legal counsel, is needed to examine current laws, policies, practices, and tools (including infrastructure) across systems and identify opportunities to support more effective and efficient information sharing across all child serving systems.

[20] References refer to "all systems" includes, but is not limited to medical, developmental, educational, child welfare, early intervention, juvenile justice, mental health, drug and alcohol.

[21] Please visit FindHelp.org to view the platform used by PA Navigate. Please visit PA NAVIGATE - HealthShare Exchange to read a description about PA Navigate.

Recommendations 4 – 5: Information Sharing and Resource Navigation			
	Themes	**Rationale**	**Recommendation**
		frustrating, and time consuming to all parties. Meanwhile the youth is awaiting their next steps. Systems and planning teams need to be able to quickly and completely share information among themselves to make informed decisions with the family.	Potential solutions may include providing template memorandums of understanding or template releases of information, which should include the ability for families to exclude specific parties as they choose. For example, the Centers for Disease Control and Prevention provided a template Memorandum of Understanding[22] to states participating in the Autism and Developmental Disabilities Monitoring Grant program. The template designates state development disability agencies "as an authorized representative of Data Provider for the purposes of collecting information from early intervention or education records." (See Recommendation 14 - Needs/Gap Analysis, Recommendation 8 - Comprehensive Tool, and Recommendation 9 - Transitions)

[22] Memorandum of Understanding between the State Agency under the Individuals with Disabilities Act (IDEA) and the State Autism Developmental Disabilities Monitoring Program (State ADDM) (cdc.gov)

Recommendations 6 – 9: Guidance and Supporting County Multi-System Planning Efforts

	Themes	Rationale	Recommendation
6.	Communication, Resource Navigation, Family Engagement	A significant challenge for effective planning, when multiple systems are involved, is the lack of a consistent central figure or structure at the local level. This results in a variety of issues, which include, but are not limited to key partners/resources missing from the table, key information/background missing from the discussion, information being dispersed across multiple people/systems instead of centralized within the team, lack of accountability, confusion around goals, lack of effective transition planning (as described in Recommendation 9), significant family stress related to not knowing who to talk to, etc. Additionally, although there are many highly skilled individuals across various counties and in some cases successful multi-system structures that some counties have built, it isn't consistent across the state and in some cases those successful areas could still use additional support and training.	Develop guidance to counties with funding to support an Integrated Child and Family Team. The guidance should provide a template which encourages counties to utilize evidence-based teaming models to be selected at a county's discretion. Regardless of the teaming model selected, team membership should include the youth and family, a family peer specialist, all child and family serving system partners, and be multi-disciplinary. The guidance should leverage existing structures/principles (for example Child and Adolescent Service System Program (CASSP)[23] / Systems of Care (SOC)[24]; identify best practices from across the state; provide training, tools, and templates for facilitating multi-system planning meetings. Within this structure a single person/s should be identified to organize, schedule, and facilitate planning meetings. This individual/s is also responsible for maintaining the complete biopsychosocial profile of the youth and their family. (See Recommendation 8 – Comprehensive Tool, Recommendation 5 – Information Sharing, Recommendation 2 – Single Dedicated Funding, Recommendation 5 – Information Sharing, and Recommendation 13 – Billing During Teaming)
7.	Communication, Resource Navigation, Family Engagement	Families are expected to navigate extremely complex systems and communicate clearly and effectively when they are also trying to manage their own emotions, particularly coming out of crisis situations.	Catalogue and assess the types of peer supports that currently exist, identifying their role, the context and system they work within, and what types of supports and training they are provided.

[23] Child and Adolescent Service System Program (pa.gov)
[24] Systems of Care (pa.gov)

Recommendations 6 – 9: Guidance and Supporting County Multi-System Planning Efforts			
	Themes	**Rationale**	**Recommendation**
		Families struggle with having the right support to assist them when they enter system(s). Two key features of that struggle relate to emotional support and navigation. Overlapping both is the importance of clear and effective communication. Having someone who has lived experience, who knows the systems and can help families engage effectively while avoiding re-traumatization is critical. There are peer and family-peer support services currently available, however, not all are available statewide, some exist in pockets, some are more robust than others, and it is unclear whether these peer supports are available across systems to meet the needs of youth with complex needs and their families. Systems need to more broadly recognize the value of peer supports and expand resources and availability of peer support positions across the Commonwealth	Using the information from the catalogue, develop an Integrated Family Peer Specialist role to participate in the Integrated Child and Family Team (see Recommendation 6 – Integrated Child and Family Team and Recommendation 14 - Needs/Gap Analysis) to support the youth and family as they engage with that team. Consistent funding to support this role must be identified and broadly supported by all systems.
8.	Communication, Trauma-Informed Care	Children and families often must tell their stories over and over. This leads to re-traumatization and a feeling of distrust or disconnect from supports. Children and families often give up when they feel like no one knows them or understands their history. Additionally, because of having so many different systems and supports involved, contextual or historical information is frequently lost, behaviors and symptoms are misinterpreted, or inaccurate information is carried forward with no ability to confirm/correct or fully	Establish a small, time-limited work group of providers, counties, those with lived experience, and DHS staff to review available tools and assessments that chronicle a child and family's life. This should include reviewing tools like the biographical timeline, wellness recovery action plan, child profile, Early Intervention assessment, Life Course, and functional behavioral assessment.

Recommendations 6 – 9: Guidance and Supporting County Multi-System Planning Efforts			
	Themes	**Rationale**	**Recommendation**
		understand what happened. Without a thorough understanding of the child and family, we cannot support them effectively and say a child "failed" when in fact, we were missing the reason the issue was occurring or we were not addressing the root cause.	The workgroup's goal is to select or develop a process and tool that can synthesize critical contextual/historical information and be used and understood across all child-serving systems and professions. This process and tool can then be used by families to tell their story without re-traumatization and ensure a full and complete picture of the youth and the family is presented consistently to new providers or team members. This workgroup would also offer recommendations around training and support for each of these tools so that a team can choose the best tool to meet the needs of the child/family. Create a consortium of specialists across the state and across systems who are fully trained and can support the use of this tool and process in the Integrated Child and Family Team. (See Recommendation 6 - Integrated Child/Family Team, Recommendation 5 – Information Sharing, Recommendation 17 – Healing Centered State, Recommendation 9 - Transitions)
9.	Services & Programs	Transitions are consistently a time of challenges and high risks for youth and their families. This can include seemingly small transitions like graduating from a service to much larger changes such as transitioning back to their home from a residential treatment facility or group home, returning home from a juvenile justice facility, from EI to school age services, or from child serving systems to adult serving systems. Planning Team members and providers are often challenged to think about transitions as more than a move	Develop a unified and proactive approach to transitions across systems which addresses the unique needs of each child and family and considers existing regulatory requirements. Support the idea that transition is not just the move from one placement or system to another but rather any change or transition in the child and family's life – a change in therapist, change in teacher, etc. Proactive transition planning should be integral to a youth and family's long-term goals and address the immediate changes and plan for the future. Transition planning is an evolving process, the plan

Recommendations 6 – 9: Guidance and Supporting County Multi-System Planning Efforts

	Themes	Rationale	Recommendation
		from a physical location to another location rather than globally like the change from one therapist to the next, or from one teacher to another teacher. Each of these impacts the child and family, and they often find themselves in crisis afterward because the transition was not carefully thought out and prepared for and the needs of the child and family were not addressed adequately. Youth with complex needs and their families often need clearer and more supportive transition plans due to their level of need, which may not always be recognized by the larger team. Without thoughtful transition planning, we risk destabilizing a child and family further and may restart a cycle toward crisis before supports and services can be fully implemented in the home (or other settings). Every youth is unique, and their transition plan must recognize that uniqueness. Although some transition plan templates or approaches exist, they are typically limited to a particular system and do not necessarily account for the level of complexity some youth present.	should be a living document and be re-evaluated regularly with input from the child and family. Planning should establish expectations in preparation for transition, ensuring a complete understanding of the supports, interventions, and tools to be used – including family supports, managing communication, transfer of information and teaming ahead of these transitional times. Transition planning should also prepare the team for ongoing support after the transition and continuously work to identify challenges as they arise, such as during emergencies, and identify solutions for those new challenges. Establish strong and open communication between the child, family, and team to ensure supports can be fully implemented. Transition planning should also be reviewed after each transition for lessons learned and ways to prepare for transitions in the future. (See Recommendation 5 – Information Sharing and Recommendation 7 - Integrated Child/Family Peer Specialist)

Recommendations 10 – 13: Administrative Efficiencies and Supporting Our Systems			
	Themes	**Rationale**	**Recommendation**
10.	Staffing/Workforce, Trauma Informed, Services & Programs	Human service fields across service sectors are struggling to maintain a well-qualified workforce across all systems. Challenges with recruitment and staff retention impact all levels of services from case management to direct delivery. Vacancies are at an all-time high. Colleges and universities have also seen a sharp decline in the number of students enrolling in programs related to human service fields. When entities can fill a vacancy, the ability to maintain the entry level staff remains a challenge. The extensive turnover does not solely exist with entry level positions, entities are also losing long-term experienced staff. This has, at times, resulted in staff being promoted before they're ready for greater responsibility, further exacerbating staffing challenges. The ability to recruit and retain staff is impacted by the lack of a livable wage, discrepancies between wages and the cost of higher education, and inconsistencies in wages across geographic areas and between public and private agencies. Additionally, the danger of the work, the nature of the job, and the impacts of vicarious trauma	Create strong incentives to build a qualified workforce willing to enter and remain in human service fields. Consider programs that assist those who are interested in the human services field to commit to that area of study such as: • Collaboration with high schools and colleges to create innovative programming that includes opportunities for workforce training and apprenticeships, with credit. • Develop programs similar to Child Welfare Education[25] and Leadership and Child Welfare Education for Baccalaureates[26] to support broader cross-system efforts to attract candidates into the human services field. • Collaborate with colleges and universities to develop targeted and rigorous courses of study in the human services field. • Fund loan forgiveness options for child and family service providers and/or human services providers. • Identify flexibilities for employment qualifications without compromising on quality such as military service, related fields of work, and lived experience. • Create opportunities across practices and positions which support licensing and career advancement tracks. Many disciplines require advanced training or supervision that is costly and difficult to acquire. For example, social work and counseling require supervisory hours for licensing, if an employer can provide those supervisory hours in the context of the job, then employees can stay with the organization and obtain licensure. This could also look like providing an avenue for

[25] Child Welfare Education for Leadership (CWEL) | School of Social Work | University of Pittsburgh
[26] Child Welfare Education for Baccalaureates | School of Social Work | University of Pittsburgh

Recommendations 10 – 13: Administrative Efficiencies and Supporting Our Systems			
	Themes	**Rationale**	**Recommendation**
		on staff all compound the ability to retain staff. Formal education and job-related training are insufficient in preparing the workforce and equipping staff with the skills and knowledge necessary.	frontline personnel to advance such as moving from a direct support professional to a more advanced position by supporting tuition reimbursement or incentives. Supporting employee career pathways and advancement helps everyone and will increase recruitment and retention rates. Support staff already employed in the human services field through: • Standardized livable wages across the state that are equitable from county to county. • Provide retention incentives for all levels of staff such as: o Tuition assistance or comparable salary adjustments for staff pursuing higher education and/or necessary credentials; or o Longevity increases for staff who remain with their employer for certain periods of time. • Strengthen and expand upon existing benefit options for hourly and low-income workers. • Develop standards and career benchmarks that can promote competency and career advancement. • Provide staff with support and resources for self-care and work/life balance. Work with current child serving systems to develop and implement support and training opportunities for better supervision and retention of staff. Encourage the use of models of positive support, such as Sanctuary, Reflective Supervision, or Person-Centered Thinking across the board.
11.	Resource Navigation, Services & Programs	A root cause for many challenges faced by children and families is the variability with insurance coverage, navigating complex insurance mechanisms – especially	Establish a time-limited workgroup to identify challenging areas of interactions with and between insurers/healthcare payors and potential solutions to support easier and more efficient navigation of these already

Recommendations 10 – 13: Administrative Efficiencies and Supporting Our Systems			
	Themes	**Rationale**	**Recommendation**
		between insurers and healthcare payors, lack of consistency between insurers (forms, nomenclature, processes, etc.), and geographic disparities (partially a function of some system structures). The variation of responses from insurance companies results in lag times for service provision, often resulting in decompensation, thus requiring higher levels of service. This is seen in both child and adult-serving systems. While it is recognized that parent companies for insurances guide much of this, exploring this area to see what can be streamlined may provide opportunities for simplifying interactions with insurance.	complex systems. A structure is needed that supports greater consistency and alignment among insurers/healthcare payors. This recommendation applies to all insurers/healthcare payors and the relationships between those insurers: private insurers, Medicaid managed care organizations, between physical and behavioral health, between managed care entities within the same system, etc. Some examples of challenging areas to address include forms, approval/denial processes, processes in general, collaboration between insurers/healthcare payors, sharing data between insurers/healthcare payors, and nomenclature. One potential solution could be the creation of a universal form used by all insurers/healthcare payors to streamline the approval/denial process across systems. (See Recommendation 13 – Billing During Teaming, Recommendation 14 - Needs/Gap Analysis, Recommendation 12 - Provider Credentialing)
12.	Resource Navigation, Communication, Services & Programs	An important benchmark for high-quality healthcare is "credentialing," which is the process of assessing the academic qualifications and clinical practice history of a healthcare provider. This helps ensure providers have the	A better balance is needed between the burden on providers to prove their qualifications and the interests of insurers/healthcare payors to ensure funding is going toward high-quality healthcare. A time-limited workgroup of subject matter experts and stakeholders is needed to catalogue what requirements and practices are currently in place and identify potential solutions which help to balance these interests. Below are two potential solutions:

Recommendations 10 – 13: Administrative Efficiencies and Supporting Our Systems			
	Themes	**Rationale**	**Recommendation**
		appropriate qualifications, training, licensure, and ability to practice medicine.[27] In Pennsylvania, in accordance with state and federal laws, insurers/healthcare payors establish their own parameters for the types of credentials they require for a provider to enroll in their network. Notably, many, if not all, insurers in Pennsylvania are subsidiaries of larger, national companies that determine the credentialing practices and rules for their subsidiary. In addition to the variety of credentialing requirements providers must meet, the processes themselves vary from insurer to insurer. This variability is problematic because it results in providers spending a significant amount of time and resources complying with each insurer's requirements and processes, it also results in significant duplication. Rapid changes in personnel exacerbate this issue resulting in additional time away from the important work providers were trained to do.	• Establish uniform credentialing requirements across insurance companies; or, • Centralize the credentialing process for all providers and insurers. A "one-stop-shop" for providers and insurers to go for credentialing purposes. Notably, there are number of other states that have already established a centralized credentialing system and process.[28]
13.	Services & Programs,	Currently, certain practitioners cannot bill for time with a child and family if they see them concurrently with other practitioners. This results in a child and family having to	Federal and state rules and policies should be closely examined to identify and apply funding flexibilities to appropriately fund practitioner time spent

[27] Credentialing - StatPearls - NCBI Bookshelf (nih.gov)
[28] Ohio, North Carolina, Nevada (starting implementation), Mississippi, Georgia.

Recommendations 10 – 13: Administrative Efficiencies and Supporting Our Systems			
	Themes	**Rationale**	**Recommendation**
	Resource Navigation, Staffing/Workforce, Communication	share their story multiple times – something that can retraumatize all parties. This has a negative effect on the mutual understanding of the practitioners and systems interacting with the child and family. For children with complex needs and multi-system involvement, the negative impacts are compounded because of the number of practitioners with whom they interact. The teaming and planning efforts required for these children are extensive and it is reasonable to expect, especially during the staffing shortage, to compensate these practitioners when they participate in teaming efforts. Some examples of these teaming and planning scenarios include: the earlier recommendation regarding forming an Integrated Child and Family Team at the county, Family Based Mental Health Services, Intensive Interagency Meetings, Complex Needs Planning Meetings.	during intensive teaming and planning efforts specifically for youth with complex needs. Potential solutions may be teaming or bundled rates. Early Intervention uses teaming codes allowing different disciplines to meet with the child and family and to bill under that code. The Early Intervention model should be considered when examining this recommendation. (See Recommendation 11 Insurance Processes)

Recommendations 14 – 16: Understanding System Capacity and Direct Service Solutions

	Themes	Rationale	Recommendation
14.	Services & Programs	It is currently unclear what the true need for and availability of services and supports is at the local and statewide levels. We know there is disparity between rural/urban, large/small counties, etc. This is particularly true for youth with specialized treatment needs. Planners at all levels need better information to make data driven decisions regarding the services and supports needed by youth with complex needs and their families.	Conduct a comprehensive needs and gaps analysis across all relevant child serving systems. The analysis should address: • Whether there are particularly successful services or models and where they are available; • Whether and where demand may outstrip the availability of services and supports; • Whether there is a need for additional levels of care, step downs, or adjusting existing levels of care for a better bridge between facility-based care and community-based care / return to home (e.g. a setting for young adults which supports independent living, but also incorporates intensive behavior supports; • Whether there are evidence-based practices missing or which need to be expanded upon; and, • Whether and where specialty programming is needed and for what specialties (genetic disorders, fire setting, PICA, etc.). This analysis should also move beyond quantitative analysis, it should also include qualitative analysis to determine what services, supports, and models are most effective. In addition to helping local and state level planners make informed decisions, this analysis can also be used to inform the implementation of many of the recommendations contained in this report. (See Recommendation 5 – Statewide Clearinghouse, Recommendation – 2 Single Dedicated Funding)

Recommendations 14 – 16: Understanding System Capacity and Direct Service Solutions			
	Themes	**Rationale**	**Recommendation**
15.	Services & Programs	The continuum of care and transitions from facility-based care and back to the community, or moving from the child to adult system, is a consistent challenge for many youth with complex needs. Family-based services are not always equipped to respond to the myriad or acuity of the challenges these young people face. A program is needed to provide intensive supports around recovery, coordination, medication management, behavior support, and crisis support, in addition to other supports as needed. This intensive level of service can be successful in preventing re-institutionalization, loss of placement, support children and families in maintaining in the community setting and help bridge transitions to the adult system.	Create a multi-disciplinary team of professionals (e.g. a treatment service like a Dual Diagnosis Treatment Team) who are well equipped to treat and coordinate services and supports for youth with intensive multi-system needs. At a minimum this team would include a medical professional (nurse or similar), a mental health professional, behavior support, and a care coordination component. This multi-disciplinary team could be used to support individuals with complex needs. (See Recommendation 14 - Needs/Gap Analysis, Recommendation 6 - Integrated/Child Family Team)
16.	Services & Programs	Children with complex needs and their families often present to services during a crisis. They have often tried other services or have cycled through emergency rooms and inpatient hospitalizations with little time in between. They could be reintegrating into the family setting from another out of home setting and that transition can present unique needs and considerations. Family-based mental health services (FBMHS) are designed for children who are at significant risk of out of home placement. This presumes that the child has either had or is imminently at risk of no longer living in a family setting. Because of this, families with younger children may not be able to access the service and those with older children (generally, 11 years and older) may already have a long history of struggles. Because of the particular model that	Increase the flexibility and scope of Family Based Mental Health Services by: Reviewing the medical necessity criteria for FBMHS and exploring if the "at risk of out of home placement" is a required criteria or if there is a more flexible interpretation that can be applied for younger children who would benefit from this service. Consider developing tiers within FBMHS: one that is for the traditional FBMHS structure, one for a more advanced acuity and one for specialized needs such as significant trauma, problematic sexual behaviors, developmental disabilities, psychosis, etc. Explore ways to work with broader groups more consistently across the state, such as younger children or those with ID/ASD. Provide additional adjunct services within a tiered system of FBMHS to better support the family such as the addition of IBHS/ABA type supports or more robust crisis planning.

Recommendations 14 – 16: Understanding System Capacity and Direct Service Solutions			
	Themes	**Rationale**	**Recommendation**
		FBMHS uses (Eco System Structural Family Therapy) patience is needed to build relationships with a strong emphasis on gathering history, etc. Accomplishing those things takes time and may not meet the immediate needs of the family. This model also does not address behavioral interventions and parent or caregiver training around those which can be necessary when working with children with complex needs. Additionally, FBMHS does not typically provide supports for younger children (below 10) or those with ID/ASD, each of which present unique challenges to the structure of FBMHS. There also is no tract for children and families with significantly complex needs such as trauma or sexually problematic behaviors and families may be reluctant to use the service if they feel their needs are too complex for the service.[29]	The comprehensive needs and gaps analysis in recommendation 14 will inform the implementation of this recommendation. With that said it may be easier and more expedient to adjust this service as described in the meantime. (See Recommendation 14 - Needs/Gap Analysis, Recommendation – 11 - Insurance Process, Recommendation 13 – Billing During Teaming)

[29] There are FBMHS providers who do serve younger children or children with specialized needs; however, it is not consistent or widespread.

Recommendations 17 – 18: Strengthen Trauma Comprehension and Application

	Themes	Rationale	Recommendation
17.	Trauma-Informed, Services & Programs, Staffing/Workforce, Communication	Nearly all children and families that we support have experienced some level of trauma, many have experienced extreme trauma over the years. It is important that children and families are treated with a positive regard that is respectful of their lived experience. A healing-centered environment at all levels recognizes that some behaviors and outcomes that have been seen as negative are actually symptoms of underlying and unhealed trauma and must be addressed to assist the child and family in moving forward. Currently, there are many interpretations of trauma informed care across all system partners. As children and families move through these systems, they may receive trauma informed care that has been implemented with varying levels of fidelity. This inconsistency makes it difficult for children and families to find a path toward healing and engage with supports and services.	Develop uniform standards to make Pennsylvania a healing-centered state. This should include shared language, cultural competence, definitions, and technical support to ensure fidelity. Entities across all levels of service systems should commit to providing basic and advanced trauma training as well as developing internal assessment training standards and supervision consistent with trauma informed care. Additionally, recent statewide efforts, such as HEAL PA,[30] have resulted in significant forward movement with trauma-informed care in Pennsylvania. There continues to be many different groups working on trauma-informed care, and continued leadership at the highest levels is needed to bring these groups together to ensure consistency and resources are brought to bear. (See Recommendation 5 – Information Sharing, Recommendation 6 - Integrated Child/Family Team, Recommendation 18 – Judiciary Trauma Training & Application) 

[30] HEAL PA

Recommendations 17 – 18: Strengthen Trauma Comprehension and Application			
	Themes	**Rationale**	**Recommendation**
18.	Trauma Informed Communication	County judges operate differently from county to county. This applies to the use of trauma-informed language and application. Allegheny County is an example of a family court system that has applied trauma-informed strategies and could provide input to other counties.	Training should be made available for judges in both juvenile justice and child welfare systems regarding trauma and how to apply trauma-informed strategies consistently county to county. This training should include continuous opportunities for review, monitoring, and coaching to ensure fidelity. The culture of the particular workforce being trained should be accounted for with respect to content and trainer – consider whether the audience is comprised of juvenile justice professionals or child welfare professionals. (See Recommendation 17 – Healing Centered State)

Appendix A: Background, Analysis, and Findings

Background

The Pennsylvania Department of Human Services (DHS) recognized a need to understand and improve service delivery to children, youth, and young adults with complex needs and their families. Prior to making any changes, it was crucial to gather information from those families and children, as well as child and family serving systems across Pennsylvania, to learn what is and is not working. A series of surveys were sent and focus groups conducted from December 2022-May 2023 with families and youth, residential providers, behavioral health managed care organizations (BHMCO), county agencies, education system representatives, behavioral health primary contractors, and hospital systems. The surveys and focus groups were managed by ASERT (Autism Services, Education, Resources and Training)

Commissioned by DHS, ASERT is a partnership of medical centers, centers of autism research and services, universities, and other providers involved in the treatment and care of individuals of all ages with autism and their families. ASERT was developed to bring together resources locally, regionally, and statewide. Their mission is to innovate, collaborate, and lead to improve access to quality services, data, and information; to provide support, training, and education in best practices; and to facilitate the connection between individuals with autism, developmental disabilities, and special populations, families and key stakeholders at local, state, and national levels.

ASERT utilized two methods to gather data; surveys and focus groups. Data was collected around eight areas to inform this work moving forward:

- Identification of children, youth, and young adults with complex needs and the changes in this population over time;
- Barriers in service planning and provision;
- Service array;
- Education;
- Transition and discharge planning;
- Family and youth engagement;
- Social and diagnostic history; and,
- Successful strategies and opportunities for improvement.

DHS identified representatives from each of the participating child and family serving systems, as well as connections to family and child advocacy groups across PA to which ASERT sent invitations to online discussion boards and surveys. Surveys were sent to child and family organizations like Youth Advisory Board and National Alliance on Mental Illness (NAMI), then sent directly to youth and families. Hospital systems received surveys and inclusion in the focus groups through the Hospital Association of Pennsylvania (HAP). There were 97 people who participated in focus groups, 45 hospital staff respondents, and 138 family/youth

respondents. From this data collected, five themes emerged, which are communication, resource navigation, services and programs, trauma informed support, and staffing/workforce. Family engagement was included in all of the themes.

The full ASERT report can be found in **Appendix B**.

The Complex Needs Steering Committee identified what the ideal system would look. Through this process, the following Desired Future State was developed:

In Pennsylvania, we believe all youth with complex needs and their families* will have the opportunity to access timely supports and services that are individualized, trauma-informed, holistic, respectful of race and culture, family and youth driven, and available in their own communities.
This will be evidenced by:

- A focus on youth and family engagement while honoring their voice and choice.
- Establishing and maintaining a well-supported and qualified workforce.
- Collaboration and shared understanding across systems to support planning and shared goals.
- Systems which prioritize early identification, proactive intervention, and service options that support family stability, safety, and the youth's healthy development and meaningful relationships which support life-long connections.
- Teams engage in ongoing and integrated planning that supports the everyday needs of a family and youth (housing, education, transportation, scheduling, access to medical care, etc.).
- Service delivery is coordinated, accessible, timely and includes support throughout the process.

** Family is defined by the individual*

Once data collection was complete, DHS, in partnership with the University of Pittsburgh Child Welfare Resource Center (CWRC), collaborated to facilitate discussion regarding children, youth, and young adults with complex needs and their families to improve all family and youth serving systems. To ensure family and youth, as well as the systems that serve them, had a role and voice in the process, DHS provided CWRC with a large workgroup of people dedicated to working through the five theme areas.

The kickoff was held at the CWRC in Mechanicsburg on July 19-20, 2023, with small workgroup meetings held weekly thereafter. Blueprint workgroup members were facilitated through a change management framework to identify strengths and barriers, identify root causes, and make recommendations for change. Blueprint workgroup members came together at the CWRC on October 19-20, 2023, to finalize recommendations.

Themes

As discussed in Section II, focus groups and surveys were used to gather data around the needs of children and families across the state. Through the focus groups and surveys, five themes emerged from all the child and family systems. They are:

- Communication
- Services and programs
- Resource navigation
- Staffing/workforce
- Trauma informed supports

A key consideration for all five themes is the importance of family engagement throughout all five themes. Using the data collected during small workgroup meetings, employing a crosswalk of common data across all four of the groups and focus group/survey data, strengths and barriers were identified. The data collected is directly from the field and shared in the language used by those providing it, either through direct quotes or paraphrased with their permission. This is broken down by theme below and include strengths and barriers identified:

Strengths & Barriers Analysis

Communication:

- **Strengths**:
  - Systems recognize the challenges and want to work to improve communication.
  - There are mutual goals across systems to more intentionally communicate and collaborate.
  - Pennsylvania is diverse with a variety of providers and local level associations and advocacy groups, offering opportunities to come together for information sharing.
  - Child and family serving system partners value families with lived experiences.
  - Technology innovations have been implemented that can support enhanced communication.
  - Resources and access to interpreters to assist with language barriers.
  - When team members are together at the table everyone does well communicating issues and what has been tried. The passion for helping the child is there, and there is a willingness to ask and answer hard questions.
  - CASSP system when working as designed. There are other meetings similar to this that work when there is not a CASSP coordinator.
  - County team getting alerts from the Managed Care Organizations (MCO) when there is a child that is experiencing a 24 hr. Emergency Room (ER) stay.
  - Complex case conferences, and other regularly scheduled venues that bring systems together.
  - Draft OCYF regulations have been expanded to include the family and youth voice.

- **Barriers**:
  - Meeting procedures – Roles & Responsibilities
    - Not all systems are invited to the table at times and/or only those currently involved with the family. Impact on decision making and associated costs.
    - Lack of identifying roles and responsibilities of those at the table. Why are they there and what can they do? Builds trust.
    - Scripted information on what they do, but not how they can help that particular family.
    - Prioritization of stakeholders and system partners varies resulting in a certain lack of urgency.
    - Correspondence and presence in meetings don't always lead with positives. Focus on what you can bring to the table rather than what you cannot offer.
    - Definition of complex case is different between systems. Education vs. Child Welfare vs. Mental Health, etc. View on diagnosis can vary and lead to a different approach to services.
  - Confidentiality and Privacy Restrictions
    - Systems & Departments limited in what they can share with each other. Sometimes it is a perceived inability to share. Negativity can enter the collaboration.
    - Lack of sharing can lead to key information missing which may impact the services being recommended.
    - Age of consent varies from system to system.
  - Centralized Resources/Hub for Information
    - Need for an integrated plan, prioritizing needs and goals shared between systems.
    - Lack of a centralized location where cross-system and cross-county information can be stored and accessed (i.e., electronic records). System/organization databases are isolated.
    - Confusion on who regional system leadership is and how to contact them.
    - State initiatives that conflict and/or confuse professionals and families. (i.e., Trauma-informed approach).
    - Lack of a message board or listserv to reach out to system partners to share success and needs.
  - Family/Youth Engagement
    - We start with the professional's schedules, not the families.
    - Assumptions that families understand something if they are not asking about it.
    - Lack of information about the family (i.e., primary language, impairments, processing ability) leads to poor communication.
    - Lack of preparation for families prior to meetings.
    - Families/Youth feel excluded from service planning and don't feel they have a voice in services being offered.
    - Lack of purposeful and intentional check-ins with families to get feedback on how services are going for them and prioritization of services.
    - Need to consider when there are too many services in place for families.

Services and programs:

- **Strengths**:
  - There is a desire to implement successful and creative programming and supports
  - Systems share the goal to collaborate and learn about other systems' services and programs.
  - There are some very successful high-quality services and programs available in some counties for children and families (e.g., early intervention, IBHS, emotional support school placement, trauma therapy).
  - Funding to support children with complex needs exists, we just need to develop strategies to use it more effectively.
  - Pennsylvania has a robust early childhood service array.
  - Pennsylvania's five (5) children's hospitals. Some states do not have one (1) children's hospital.
  - Expansion of beds with in some 24-hour levels of care of note the beds for youth with Autism and Intellectual Diagnosis
  - The Tips program at Hershey where Primary Care physicians (PCP) can consult with a psychiatrist to triage the PCP's med management of the child until a psych appointment is available.
  - Evidence based child welfare practices like multi systemic therapy (MST) and Functional Family Parenting (FFP)
  - School based behavioral health and prevention programming.
  - Federal shift in funding (Family First) leading to increase and more services related to prevention.

- **Barriers**:
  - Service and Program availability
    - Limitation of appropriate placements and services.
    - Long waiting lists often result in decompensation and a need for higher levels of care.
    - Limited service and program availability in locations geographically close to families.
    - A lot of youth with behavioral health problems because of home challenges. If caretakers' mental health needs are addressed, it would impact challenges for youth.
    - Frequent denials or refusal of services based on the need being "too acute."
  - Transition to Adult Serving Systems
    - Moving from child to adult serving systems is a big challenge for families and older youth.
    - Many programs, including evidence-based programs, don't cross over to adult system.
    - Needs of transition-age youth are complex and include the need for housing complicated by the grey area of 18–21-year-olds caught between child and adult serving systems.
  - Funding
    - Lack of Funding flexibility to use practice to show progress and allow for new funding opportunities.
    - Funding needs to follow individual and unique family needs instead of fitting families into limited EBPs.
    - Base-funding increase needed.

- Private insurance not funding crisis services.
- Need an integrated funding model to create a stabilization home/group home that assessments can be done and not necessarily fit into a Medicaid treatment service.
- Lack of direction from State agencies about moving forward to support a child/family and making the funding work. Need for state agency action to have an impact on this work.
- Who is ultimately responsible for ensuring that the child gets what they need, funding available, waive whatever needs to be waived to secure funding?
- Is there a better way to work with counties to share funding/programs that require large populations. Ex. EBPs that cycle through children quickly and may need a large number of children serviced to secure staff/resources.

o Rules & Regulations
- Different parts of DHS licensing the same entity/provider.
- Lack of cross-system education and training.
- Various interpretations of regulations cause inconsistencies in service provision, delivery, and access.

o Assessments
- Assessments are not conducted from a holistic approach, considering the lifespan of the child and family. Child is "patient" and family dynamics are not always incorporated into the assessment and service provision. "Medical Model"
- Lack of focus on attachment and ability to establish relationships. Need to identify root causes for children and families.
- Missed diagnosis and how one system partner will translate the information.

o Education
- Servicing students' MH needs in the Least Restrictive Environment (LRE) is often limited to the availability and/or strength of a Community School-Based Behavioral Health (CSBBH) Model in schools; some schools have partnered with agencies to support this level of care, while other districts used finite ESSER Funds to develop the model, and now it's likely to be pulled from many students accessing this supports found within it.
- Others have relied heavily on other referral-based services such as School Assistance Program (SAP), and possibly outpatient care available in school to help students in need of MH (or other counseling). But as with many things, it is largely a siloed practice.
- Education around the strengths/limitations regarding med management should be more robust so that educators have a better sense of their efficacy for students accessing that as part of a treatment plan.

Resource Navigation:

o **Strengths**:
- The system can be effective with transparency and a willingness to be open, seeing families and youth holistically.
- Pennsylvania's Department of Human Services-wide Child Welfare Information System and its potential to integrate with all systems.
- Openness of PA Department of Human Services (DHS) in acknowledging insurance challenges.

- Influx of capacity building institutes and potential to enhance cross-system awareness and training.
- Insurance companies are making progress in connecting social, behavioral, and physical health services.

- **Barriers**:
  - *By professionals:*
    - Regulatory requirements, including documentation, place unnecessary burdens on staff's efforts to navigate various systems. System regulations are, at times, in conflict with one another, ex. School-based Mental Health and Education.
    - Lack of consistency in staff qualifications and need for training support.
    - Need for professionals and families to know about resources early on (preventative).
    - Evaluators/psychiatrists do not know the actual availability or timeline of the recommended service. There is often not someone who helps the family with the set-up/finding of these services and the family is left confused. No designated person to assist, similar to someone in a CASSP Coordinator role.
    - Education System – Schools are cautious in suggesting a community-based service. If it is recommended but not approved, the school may be liable to pay for the service. This can create frustration when it is a home-based service and can lead to trust and relationship challenges with the family.
    - Schools without a model that employs something like a dedicated social worker or MH liaison often struggle to bridge support across settings such as the educational environment and the community. School counselors do not have the time to provide 1:1 counseling as if often believed by the public. Often, classroom teachers do not possess adequate knowledge of systems beyond their role as educators. This is a limiting factor when we consider that educators are second only to families with time spent working with youth.
  - *By families:*
    - Need to build capacity of families early, first couple of years of parenting. Build community support and self-advocacy, natural support.
    - Families are unable to find providers who are trained and also covered by their insurance in a location that is geographically close.
    - Lack of explanation to families (what the services are, trajectory of services, why are they being referred to, etc.). IBHS vs. ABA services, combinations, etc. Informed decision-making. Services on Autism side and IDD side, families are confused about what system to access services. Complicated further by child vs. Adult serving systems. Lack of explanation around recovery and resiliency.
    - Families get lost in the system with no awareness of what is available, what is needed to access services, or how to get them in a timely manner. Identification of what resources exist and how to access them is key. Often don't understand the relationship between family and youth systems and services, as well as the role of insurance, and vice versa, system providers understanding the family needs and how it corresponds to available services and if those services are covered by insurance.

- Burden falls on families expected to repeatedly inform the school, providers, agencies and insurance about the past and current circumstances. Different points of entry to systems, this also means their story must be told multiple times.
- Multiple waiver supports in the family and no ability bring them altogether. Need someone who can understand and be broker for family in helping navigate and pull together.
- Overwhelming and Complex - Lack of information shared and also not explained in a way that a family can understand. Treatment plans are being worded too clinical and the need for them to be more family friendly.
- Resources exist, but not comprehensive and/or accessible as needed. (Ex. 211 – but does not have everything) No longer hard copies, online only. It can also be inaccurate and leads to frustration for family and workers. Need for a resource list that can be shared with providers/facilities that are located at a distance.
- Aftercare planning considerations and sharing across Counties. Central repository. Ex. Interagency coordinating council (IU 3-5) OCDEL requirement. Ex. Finding Your Way in PA. Initial intention of PA 211. If a database and repository is developed it needs to be clear about where resources are available and keep information up to date and have a warm hand off is in place.
- Complex needs children from adoption disruptions – there is limited support provided during the foster to adopt process. Following finalizing the adoption there is only a few months of support if that and then post permanency support most often can only be found through the Statewide Adoption and Permanency Network.

o *Insurance Impact:*

- Lack of awareness in navigating complex insurance processes for both families and providers with limited experience. This can create silos.
- Insurance can be a barrier due to multiple entities, geographic parameters, etc.
- MA providers not allowed in network- third-party will not provide appropriate documentation to allow MA to pay.
- HIPP- Health Insurance Premium Payment Program- have private and qualify for MA- struggles with billing when families "flip to HIPPP"- agencies passing the buck to one another, can rise to state needing to sort it out. Once involved with HIPP, getting back to managed care is nearly impossible.
- Level of clinician that can bill MA for private insurance will vary. Multiple occasions of insurance willing to pay for certain services on increased services and provider not willing to do so.
- Private insurance doesn't provide letters to confirm that a service is not covered. School and insurance play tag and there are many barriers in getting services.

Staffing/Workforce:

- **Strengths**:
  - There are dedicated practitioners striving to provide services across the state and improve the experiences for children, youth and families.
  - There are innovative efforts being made to retain and recruit staff amid the current staffing crisis.

- System partners are reassessing the qualifications of the workforce as a result of staffing shortages. Ex. Minimum requirements and how regulations impact hiring.
- Peer support in certain areas of the system allows those with lived experience to enter the workforce.
- The younger workforce encourages leaving work at work, setting better boundaries for the workday, leaving on time

- **Barriers**:

  - Lack of qualified staff results in a reluctance to take more complex cases. Turn away children due to a lack of confidence in staff's ability to manage complex youth.
  - Regulation and licensing barriers to who can provide behavioral health services and what is prohibited within that service.
  - Misconceptions around regulations and impact on staffing.
  - Care teams need more EBP trainings (not just clinicians)
  - Some young people with complex needs understand how to have staff investigated. This can then impact on other staff needing to step in to work that youth. This can lead to a youth being denied in future settings due to the history of this behavior. Complex and multilayered....one decision can have ripple effect.
  - Barriers around clinical training, workshops on actual cases, critical thinking, and clinical support on the front end of CPSL issues.
  - Impact of regulations requiring certain number of hours, topic areas. Can be up for interpretation by organization leadership. Qualifications required for what we need staff to do, BA level degree and all they do is paperwork.
  - Promotions to supervisor earlier than possibly ready due to a lack of staff, retention challenges. Situations where staff can't grow as supervisors and/or clinicians due to still carrying caseloads, managing non-supervisory work. Individuals are apprehensive, possibly do not have developed skills (ex. soft skills), and do not always have understanding for the system and families.
  - Providers have relatively low pay compared to other careers with a lack of pathways to licensure and career advancement that others in the helping field may have.
  - Salaries can't compete with other sectors.
  - Staff have debt and are unable to repay student loans in certain areas of the child/family serving system.
  - Work is dangerous, stressful, low paying.
  - Front-line work is not a career anymore. Diminishing number of students entering high ed. in general, but specifically education programs. Decrease in number of students entering human service academic programs and the field. Similar for graduate programs.
  - Professionalism is not clearly defined, resulting in a breakdown of facilitation of interventions. Profession is not valued or promoted. Need to professionalize areas of this field. Certifications in areas. Curriculum-based track towards a certification that leads to recognition, higher pay. Residential program positions are not viewed through a professional lens. They are not given the same respect or compensation as those with the "title" or "licensure,", yet they are the staff who are with the youth more than the other staff and have the greatest opportunity to impact the youth.

- Psychiatrists, even those trained in PA, are often leaving PA to work in other states. Many reporting costs of liability insurance in PA is too expensive to practice in our state.
- Lack of training focused specifically on Family Engagement, holistically looking at family dynamics and roles. Professionals not engaging in true engagement due to fear and/or capacity challenges.
- *Supervision:*
  - Lack of strong clinical supervision.
  - Need for reflective supervision to support workers, supporting families.
  - Self-care needs to be prioritized for staff, especially direct service staff, to understand their own baggage/ privilege/ trauma and how it impacts their work with families.
  - Need enhanced recruitment efforts for diverse staff.
  - Lack of shadowing and coaching of new staff. Sometimes what they learn in an academic setting doesn't translate to skills needed in the workforce.

Trauma informed supports:

- **Strengths**:
  - There are training courses available across the state to support this need.
  - There is a desire to implement creative programming and support using a trauma-informed approach.
  - Pennsylvania's plan to become trauma informed, Heal PA
  - The education system acknowledges trauma through social/emotional learning awareness. CASEL – Collaborative for Academic Social Emotional Learning. PA uses model and PA Career Ready Skills Continuum
  - Getting better at providing behavioral health support prenatally when moms are experiencing trauma, reduce cortisol levels.
  - By looking through a trauma-informed lens we are diving deeper into also looking through cultural lenses and understanding things from a point of view never acknowledged before- increased cultural humility- this leads to empowerment of the families/youth we work with.

- **Barriers**:
  - Supports and the protected time dedicated to that. Move from theoretical approach to implementation and modeling.
  - Different definitions and perspectives around trauma informed. Not accepted by all providers/staff- both in MH/SUD and outside other professional fields. There is not enough consideration of trauma history in the planning and provision of care for children and youth with complex needs. There is a lack of holistic approach to providing care. Families and children who present with complex needs often have extensive trauma histories that affect behavior, mental health, and other issues. Lack of connecting the 'dots' over the lifeline that can help understand all the adversities that a child/family may go through resulting in possible misdiagnosis and lack of appropriate treatment interventions.

- Educators have embraced this concept, but many have fallen short of applying its tenets to their school policies and classroom management styles. Public embrace of "Zero Tolerance" does not allow for a truly trauma-informed approach to thrive. "Consequences" must be dealt with for restitution to occur. Neither of these practices is trauma-sensitive, and it compounds issues for many of our youth experiencing some sort of MH concerns along the continuum of need.
- Impact on Staffing theme area: Kids with trauma are more likely to try to sever attachments which can lead to accusations and reporting. Staff who are not well trained are more likely to take this very personally and leave. It's like a cycle that cannot be broken until the root cause is addressed.
- Translating the trauma and its impact on children, youth and families is a skill that requires more cultivation. For example, no one understands the concept of 'disenfranchised grief' when children are removed from their homes and put into placement resulting in a fractured spirit, becoming identified by a diagnosis or by system status, and not ever grieving the losses associated with placement.
- Little to no support for staff in dealing with vicarious trauma or compassion fatigue Sometimes we don't acknowledge the need to take care of ourselves and give permission to colleagues to say they are not okay.
- So focused on the maladaptive or abnormal behavior, we forget what is going well, what works for families and youth, what is important for critical development for children/youth (negative things follow children for life at times)
- Lack of acknowledgement further exploration into the intersection of culture and trauma.
- Particularly for kids with complex needs, attachment is really lacking in a lot of service provision. Limitations placed on time for therapy to address trauma. Bare minimum being provided even if it is in the scope of service to extend time.

Key Findings

Once the groups identified the barriers, they were prioritized based on the areas which, if improved, would lead to the desired future state for services to children and families with complex needs (See Section III). Root cause analysis was completed with all four groups around the prioritized barriers. It should be noted, many of the root causes identified crossed over multiple theme areas with impacts intersecting between systems. These findings are highlighted below:

- Legislation impacting child and family serving systems is interpreted rigidly by system partners, resulting in the development of regulations that limit flexibility in funding.
- There is a lack of knowledge by system partners on what other systems can offer children and families, and what limitations or opportunities may exist. This may be interpreted by system partners as a reciprocal lack of cooperation and resistance.
- A family's choice in determining which system partner is engaged in the planning process is an often-overlooked barrier to working collaboratively across systems. Stigmas related to system involvement may limit the desire for family to engage with professionals.
- Expertise in navigating and supporting families in Pennsylvania's child and family serving system is underutilized. System partners value the philosophy and principles of the Child and Adolescent Service System Program (CASSP); however, they acknowledge many counties across the commonwealth are no longer resourcing the CASSP Coordinator position or have varied interpretation of the position and related duties.

- System partners define and approach children with “complex needs” differently, often driven by a diagnosis impacting service and program provisions.
- Interpretation of confidentiality laws by professionals serving children and families create communication barriers. Confidentiality laws are often not connected at the federal level (Ex. HIPPA, FERPA are not aligned with state laws). Litigious society results in a conservative approach by professionals when sharing information to support families. Engagement and communication with families around age consent laws and their impact on service delivery are areas needing particular attention.
- Cross-system, integrated plans to prioritize the needs and goals of families are underutilized. There is no centralized hub of information and/or ability for system partner’s case management systems to interact with one another. The use of data and targeted reports to identify trends and needs within the community is not occurring consistently across counties.
- Inconsistencies in types of programs available and/or willingness to fund programs from one county to the next exist, and the staffing crisis has impacted the innovation of new programming.
- Early, preventative measures to identify children and families with complex needs exist; however, those programs identifying needs can feel siloed from the child and family serving systems with an inability to navigate the most appropriate referrals for families. (ex. Early Intervention (EI) programs)
- Bridge and step-down programming exists across the Commonwealth but is not universally accessible or successful.
- There are decision-making complexities with providers determining if they have the capacity and/or space to accept children with complex needs. Children with aggressive and high-risk behaviors may be involved in confrontations with front-line staff, potentially leading to staff placed on leave while internal and CPS (Child Protective Services) investigations occur. This interaction can lead to a lack of staffing needed to support an appropriate staff/child ratio and a provider’s willingness to accept children with particular behaviors due to concerns for staff/child safety and minimizing risk. This situation can result in children being labeled as high risk, which negatively impacts their ability to be serviced in the most appropriate setting. These concerns are shared by the juvenile justice system partners and can result in children being detained in secure settings with subsequent charges being filed.
- There is a perceived lack of flexibility regarding the DSM-V meeting a family's diagnostic needs. Family and child experiences are considered and made to fit into DSM-V categories to initiate services and program eligibility. The impact of diagnosis can follow a child throughout their lifetime and impact them well into adulthood. (Ex. Military enrollment). More accountability is needed around differentiating trauma and the need for additional diagnosis to pull down funding. Outreach to the PA Psychiatric Leadership Council would be beneficial in further addressing these challenges.
- There is a perception that funding does not follow the child/family to best meet their needs, but rather the child/family needs to follow the funding to determine what program/services will best meet their needs.
- The Medicaid program does not allow for an integrated funding model to create stabilization settings for youth while comprehensive assessments are conducted as necessary to access treatment services.
- Servicing students with mental health needs is limited to availability of Community School-Based Behavioral Health models in schools. The level of funding and resources to support this service can vary throughout the community.
- Family and youth voice is often overlooked in the planning process. There is a system-wide lack of preparation of families prior to meetings, assumptions are made on the child/family’s knowledge and planning meetings often start with the coordination of professional's schedules rather than ensuring family availability first.

- While system partners value those with lived experience, there is a need to implement system-wide strategies to incorporate peer support into services and programing to help families better understand and navigate complex systems.
- There is an unspoken culture within treatment facilities that seems to support a hesitancy in complex discharge planning.
- Medicaid funding is acknowledged as the largest amount of funding supporting youth with complex needs; however, there is a lack of flexibility in funding due to the "medical model" approach, focusing on the child as the "patient" and limitations in treating treat the family through a holistic approach.
- Communication gaps exist between state and local system partners and providers regarding 3800 regulations. Feedback was solicited from county and providers; however, there has been a lack of follow-up communication around potential regulation changes.
- Quality, holistic assessments of children/families are not occurring consistently among all providers. There is a perception that assessments are completed to validate pre-conceived recommendations rather than allowing for quality assessments to inform recommendations.
- Managed Care Organizations (MCOs) do not have a standard denial process across MCOs, and they often do not honor one another's decisions. Gaps in services and extended stays in treatment settings exist when waiting through denial and appeal processes.
- Challenges exist when navigating MCOs and getting services in place for families. Non-participant agreements can take multiple weeks to get finalized and waiting lists are often identified after the agreement is in place. System partners often meet with providers who may not work with non-participant agreements and/or recommendations for a child may expire during the wait.
- There are communication gaps between The Health Insurance Premium Payment (HIPP) program and MCOs. MCOs can see when the insurance changes to the HIPP program, but they are limited in the support they can provide families moving forward.
- Challenges exist for juvenile justice partners in balancing restorative justice, keeping the community safe, while acknowledging trauma and working from a trauma-informed lens. Similar challenges exist in educational settings with zero-tolerance policies and related consequences to balance the learning environment for all students while addressing the needs and impact of trauma on students.
- The academic status of youth residing in residential settings can be challenging to identify. Academic progress with respect to credits earned towards successfully advancing academically can be impeded during transitions from inpatient and residential education settings to community-based settings.
- Many child and family-serving system partners struggle to recruit qualified front-line staff. The lack of qualified staff has a direct impact on some service providers' ability to service children with complex needs, citing a limited number of competent and qualified staff to meet the needs of the child.

System partners acknowledge that supervisors are an integral component to addressing the staffing crisis in Pennsylvania, however because of their expertise and the ongoing challenges in retaining direct-service staff, many supervisors are carrying caseloads and lack the ability to provide clinical coaching-focused strategies to develop staff skills and support retention.

Appendix B: ASERT Final Report

Final Report: Improving the Statewide System of Care for Children, Youth, and Young Adults with Complex Needs

JUNE 2023

Table of Contents

Executive Summary

This project assessed the current state of health and health-related services and programs in Pennsylvania and identified barriers in supporting children, youth, and young adults with complex needs and their families. Convenings of behavioral health managed care organizations (BHMCO), behavioral health primary contractors, county agencies, and education system representatives and surveys of hospital system staff and families and youth highlighted common challenges these groups experience. Five key themes emerged across these groups:

1. **Communication**
2. **Availability of services and programs**
3. **Awareness and navigation of resources**
4. **Staffing**
5. **Trauma-informed supports**

These themes and the barriers identified within them are interrelated. As DHS moves to the next phase of strategic planning for supporting this population, it may be helpful to consider these relationships and prioritize addressing these barriers.

Introduction and Background

The Autism Services, Education, Resources, & Training Collaborative (ASERT) Eastern Region was commissioned by the Pennsylvania Department of Human Services (DHS) to conduct an assessment to better understand current and future needs of children, youth, and young adults with complex needs, and the systems supporting them.

To support this project, focus groups and surveys were conducted with residential providers, behavioral health managed care organizations (BHMCO), behavioral health primary contractors, county agencies, education system representatives, hospital systems, and families and youth. The feedback collected through these focus groups and surveys will be used to inform DHS in future systems planning.

Methodology and Study Design

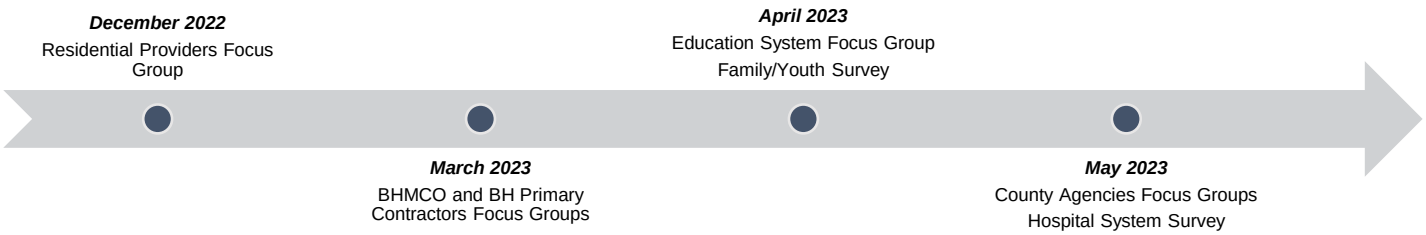
Focus groups and surveys were intentionally selected as the methodology for this project. Focus groups offer a broader and more open-ended forum for participants to describe their experiences and reactions to the topic of discussion compared to other qualitative and quantitative research methods. Qualitative research by nature, "is interactive: context dependent; holistic; flexible; evolving; inductive and descriptive. It has as its foci, perspectives, meanings, uniqueness, and subjective lived experiences. Its aim is to provide understanding" (Trudeau-Hern & Daneshpour, 2012). Focus groups are particularly useful because the moderator(s) can ask follow-up questions and probe for additional answers; this is not possible in a survey or questionnaire. There also may be topics or issues that were unknown when the initial guide questions were developed but can be probed to aid in future planning.

Surveys were intentionally selected as the methodology for emergency department personnel and family and youth for different reasons: for family and youth, the survey provided an anonymous, private way to communicate sensitive information (e.g., suicidal ideation, justice system interaction); for emergency department staff, the survey offered a more efficient method to collect information from a hard-to-reach population (DeVon et al., 2013). Focus groups would have been challenging to convene for hospital system personnel due to competing clinical priorities and limited schedule availability. Surveys were thus an appropriate alternative to collect feedback from these important stakeholder groups.

Data Collection

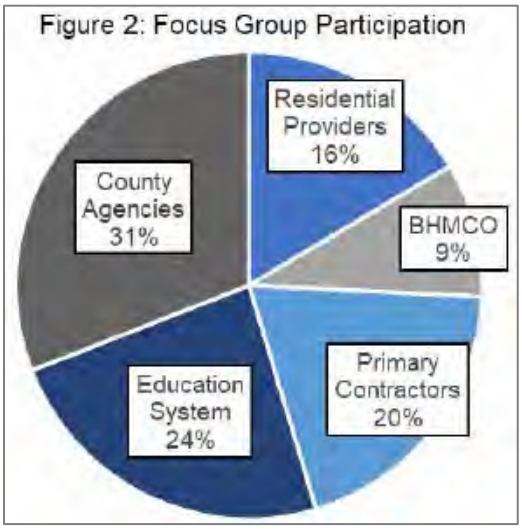
ASERT facilitated focus groups between December 2022 and May 2023 (*see Figure 1 below)* using an online discussion board through the online qualitative software, iTracks. Each iTracks online discussion board remained open for two days with each day's questions posted from the focus group moderator's guide. Participants then had the flexibility to respond to the day's (or previous day's) questions, the posts of their fellow participants, and probes or follow-ups from the moderator(s) at any time of day or night. The online discussion board forum allowed

Figure 1: Focus Group and Survey Timeline



for beneficial aspects of the focus group methodology (follow-up, probing, interaction among the group, etc.) while also accommodating for differing locations across the state, diverse schedules, and competing priorities.

Questions posed in the focus groups covered a variety of domains, including identifying children, youth, and young adults with complex needs and the changes in this population over time, barriers in service planning and provision, service array, education, transition and discharge planning, family and youth engagement, social and diagnostic history, and successful strategies and opportunities for improvement.



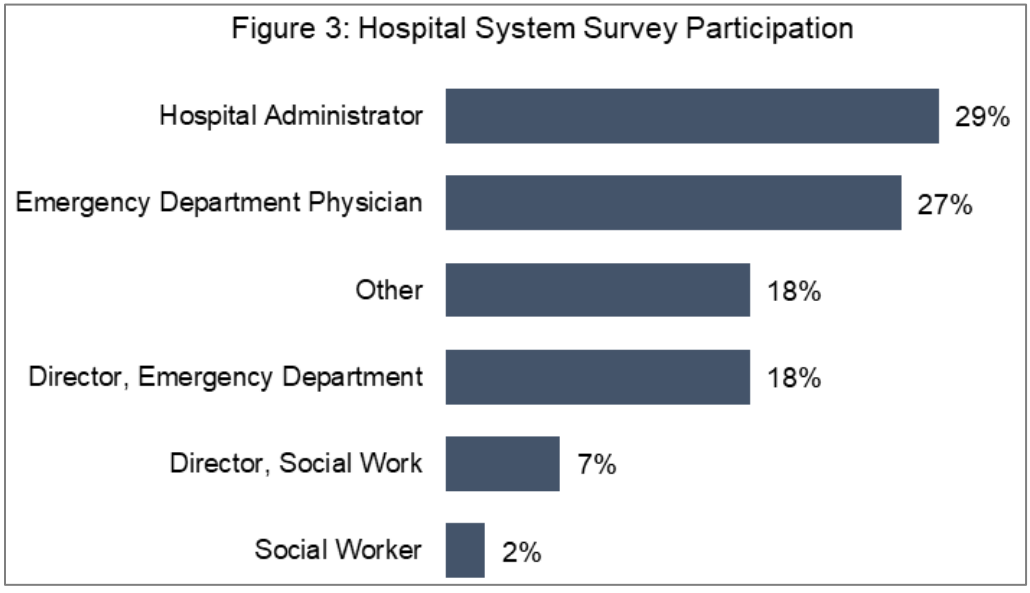
In April and May 2023, using snowball sampling methods, surveys were shared via Qualtrics links with family and youth as well as with hospital systems that serve children, youth, and young adults with complex needs. Surveys were designed with both open- and closed-ended questions to allow participants to provide detailed feedback about their experiences.

Participant Recruitment

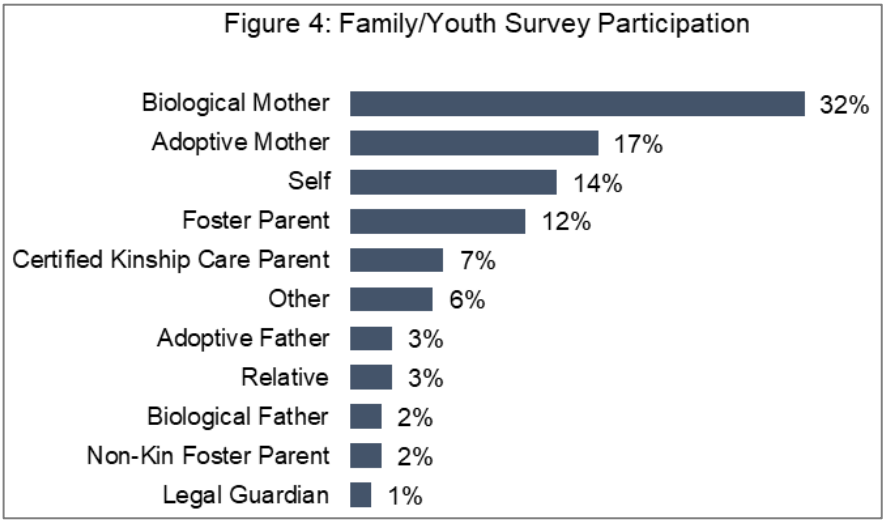
DHS identified appropriate representatives from each of the participating systems for the focus groups and ASERT invited them to participate in the online discussion boards via email link. For the youth and family survey, survey links were distributed to organizations serving this population (e.g., NAMI, YAB, Youth Move) and then sent directly to family and youth. The hospital system survey was shared with the Hospital Association of Pennsylvania (HAP) and then distributed directly to appropriate hospital system staff.

Participant Demographics

Overall, 97 people participated in six focus groups: 16 residential providers, 9 BHMCO representatives, 19 primary contractors, 23 education system representatives, and 30 county agency representatives. The county agency group was divided into two focus groups to account for its larger size (*See Figure 2*). Among the survey respondents, 45 represented hospital system staff and 138 participated as family or youth. Of the hospital system participants, 29% were administrators, 27% were Emergency Department physicians, and 18% were Emergency Department directors (*See Figure 3*). Within the "Other" category, participants identified as Operations Managers, Case and Care Management Directors, Clinical Directors, and Behavioral Health Directors. Another 10% of participants reported as Directors of Social Work or Social Workers. Of the 138



family and youth participants, 118 (86%) were family members and 20 (14%) identified as youth with complex needs (*See Figure 4*). About half of the respondents identified as biological or adoptive mothers while nearly 20% responded as foster or certified kinship care parents. The remaining 17% of participants represented adoptive and biological fathers, other relatives, non-kin foster parents, and legal guardians.



Conduct of Focus Groups

In accordance with standard focus group methodology and practice, moderators' guides were developed in collaboration with DHS to facilitate the flow of two-day online discussion boards with each participating group.

ASERT moderators posted a series of questions on the first day of the discussion boards, and participants logged on and responded to questions at times that were convenient for them. Participants were also permitted to comment on other participants' responses, allowing for a collaborative discussion. Participants were asked to log on at least three times per day during the two-day period to respond to any follow-up questions from moderators or fellow participants. DHS observed the discussions and periodically sent prompting follow-up questions to ASERT moderators to post on their behalf.

Analysis and Report Generation

The questions and responses from the moderators and focus group participants automatically generated a transcript that was used as the basis to report findings and to provide recommendations. Transcripts were read, summarized, and key themes were identified. Themes were documented after each focus group and evaluated together to inform the findings and recommendations presented in this report.

Limitations

Focus groups are a useful tool for qualitative research. However, focus group methodology has several limitations. It is important to note that the focus group findings are not generalizable to the entire target population nor are they quantitative in nature. The focus group was comprised of a targeted sample of people and does not represent an entire population. Similarly, the hospital system and family and youth surveys were distributed to a targeted sample of stakeholders belonging to these groups. Therefore, while quantitative, their responses are also not generalizable to the entire population of interest.

Findings

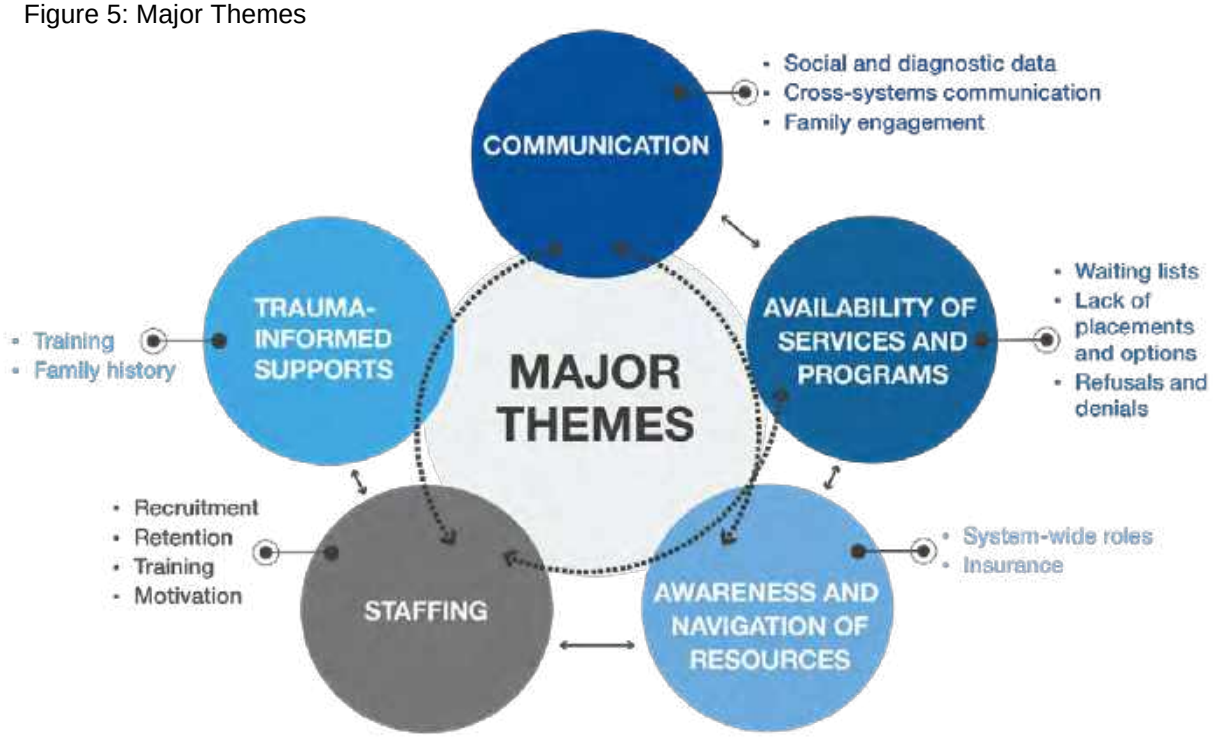
Five major themes were conceptualized across all stakeholder groups: communication, availability of services and programs, awareness and navigation of resources, staffing, and trauma-informed supports. These thematic concepts dominated discussions and were most frequently mentioned as barriers and facilitators of service planning and provision for this population.

It is also notable that many participants described existing strengths of their respective systems and of the impact of the collaborative efforts across systems to best serve children, youth, and young adults with complex needs and their families. Some strengths included:

- Staff dedicated to improving the experiences of system-involved children, youth, and young adults with complex needs and their families
- Mutual goals across systems to more intentionally collaborate, communicate, and learn about other services and programs
- Ability Desire to implement and some successful examples of creative programming and supports (e.g., peer support programs)
- Innovative efforts to retain and motivate staff amid staffing crises
- Some successful high-quality services and programs provided to children and families (e.g., ongoing therapy, early intervention, IBHS, emotional support school placements, trauma therapy)

While these strengths were mentioned in each of the groups, due to the nature of the question prompts most of the discussion and feedback was focused on the system-wide barriers that prevent them from achieving the most success. Additionally, participants recognized that the COVID-19 pandemic exacerbated existing barriers that impede system efforts to support children, youth, and young adults with complex needs which serve as a backdrop and consideration to understand the context of these findings.

Figure 5: Major Themes



Theme 1: Communication

Participants consistently noted a **lack of communication and coordination across systems** serving children, youth, and young adults with complex needs. These silos were particularly prominent throughout the initial information gathering stages and the transition and discharge processes. Participants reported that as children enter different systems or move across them, critical information is often missing or incomplete. They suggested

that improving the quality of clinical, diagnostic, social, family, and trauma histories, including the ways in which the information is shared across systems, would allow them to better serve this population.

> *"We do not always have a clear diagnosis picture for these children. Each system (MH, ID, CYFS, medical, educational, probation, etc.) have their own criteria for what they need to make them eligible for services within their program. This makes it very hard. Their needs are different for each system, and we are siloed."* – ***County Representative***

In addition to the siloes across systems, participants frequently reported barriers in communicating and engaging with families. For example, in discussing service planning, participants noted occasional disagreement about placements and levels of services across support teams and families. Focus group participants further noted that training opportunities for families to support their child with complex needs are limited.

> *"Additionally, there are times when teams will disagree with the level of supports and services that a student requires. Our IEP teams are required to make the recommendations that are most appropriate for the child based on the evaluations. At times a parent will have a differing opinion. For example, if the District recommends that a child requires an Autistic Support program, but a parent wants their child included in general education, we would need to continue to make the appropriate recommendation."* – ***School District Representative***

Families of children, youth, and young adults with complex needs echoed this sentiment of disengagement, and emphasized **feeling excluded from the service planning and provision processes**. About a quarter of family respondents (23%) disagreed or strongly disagreed that they had a voice in their child's treatment planning and the services received; similarly, among youth respondents, 23% felt they did not have a voice in their own treatment planning and the services they received.

Theme 2: Availability of services and programs

Participants noted the dearth of available services and programs as one of the most significant barriers in adequately supporting children, youth, and young adults with complex needs. They cited a **lack of appropriate placements and services, long waiting lists,** and **limited service and program availability** in locations that are geographically close to families. Similarly, across all groups, participants mentioned frequent denials or refusals of services based on individuals being "too acute."

> *"In terms of appropriate out of home placements, we see children who are recommended for RTF sitting on waitlists or being denied due to being too acute or not acute enough. We see the same with inpatient hospitalizations. We see kids who have ID or MH diagnosis unable to find an appropriate foster care placement because they are too young, too old, or their needs are too intense resulting in them being in a group home or congregate setting until a foster home can be located."* –***County Representative***

Many participants reported that they had observed or identified children who should have received other services or programming that could have prevented the need for higher levels of care or crisis placements. Specifically, they noted that residential treatment and inpatient facilities tend to become the default when other options are not available. However, participants consistently reported an overall lack of availability in both residential and community-based settings and a lack of beds available in both inpatient and RTF settings.

> *"We had a child wait over a year for ABA services and in the meantime received FBMH services but unfortunately ended up going to residential treatment. FBMH model of addressing relationships is*

*not always effective when the behaviors are not driven by relational deficits but require an ABA approach. The wait is so long to access ABA treatment that the behaviors continue to increase and the family require higher levels of care. Quicker access to the treatment, respite, parent support groups, increase the family connections within the community are all services/supports that aid better outcomes if accessed in a timely manner. a lot of our services are reactive and not preventive- the problem must manifest itself to enact services. If services can be accessed in a timely manner, have the proper training, be more creative with supports being delivered- combining FBMH and BC on cases when necessary, increase PA consults when barriers and challenges are being met, increase parent peer supports to provide insight and feedback from lived experiences." – **County Representative***

A majority (76%) of hospital system representatives reported that they have observed increases in the number of children, youth, and young adults using Emergency Department (ED) services within the past year. Almost all (91%) attributed these increases to limited resources and supports for children with complex needs. Further, they shared that they do not believe the ED is the most appropriate environment to provide services to this population.

"The ED should never be where these patients are treated. The ED is triage not ongoing care." – ***Hospital Administrator***

"It is worse than incarceration when they are in the ED." – ***Emergency Department Physician***

Families and youth reiterated challenges associated with long waiting times for services, lack of service availability entirely, and a lack of service options tailored to their needs. Nearly half (48%) of family respondents reported that they strongly disagreed or disagreed that the services provided to their child met their child's needs when they needed them. Similarly, half (47%) of the family respondents felt they did not receive services in a timely manner because there was no provider availability either among the providers in their area or staffing within an agency.

Theme 3: Awareness and navigation of resources

Family and youth respondents reported that they experience significant challenges navigating the systems they encounter. Almost half (41%) of family respondents shared that they did not have a clear understanding of the services and supports available for their child; 47% did not have a clear understanding of what the available services and supports could offer their child. Similar responses were observed among youth respondents: over one-third (36%) did not have a clear understanding of the available services and 40% did not have a clear understanding of what those services could offer. When asked to share specific challenges related to services, families and youth offered the following:

"Finding what services might be available to help our adult child is a continued challenge." – ***Biological Mother***

"We had been unable to reach our case manager and had trouble finding people to guide us in the process of finding services. My mom had to do a lot of that work on her own." – ***Young Adult***

In addition to siloes across systems, focus group participants reported a general lack of awareness and understanding about the function of the other systems that also serve children, youth, and young adults with complex needs. While some participants reported that cross-systems meetings have been effective at times,

others mentioned that they were not aware of regional partnerships that they could use to pool resources to support youth with complex needs. There was an identified need for better cross-system planning to facilitate early identification, appropriate provider training, and consistent follow-up.

> *"The system CAN be effective if all parties are open and transparent about all of the needs. At times families do not fully disclose all of their needs so we only know what we know and can assist with what we know. Involving the physical healthcare system could be improved. We always take a look at the person as a whole, not just as in need of one particular system or service. Getting everyone to the meeting is a struggle but the most beneficial and successful meetings happen when everyone is on the same page and supporting the family where they are at in their treatment process. I think holding teams meeting earlier is always a way to improve the system." –* ***County Representative***

Participants also reported a general **lack of awareness in navigating complex insurance processes**. Some noted that having multiple types of insurance introduces unique challenges for both families and providers. The lack of coordination between private insurance and Medicaid especially has at times prevented families from accessing services. Providers experience challenges submitting claims due to limited training, which then creates barriers for them to receive compensation for the services they provided.

> *"Many private insurances don't include the same levels of care within their benefit packages or have much more limited provider options. I have also learned that private MCO speak a different language regarding some levels of care." –* ***Behavioral Health Primary Contractor***

Theme 4: Staffing

Participants reported significant staffing challenges as barriers in supporting children, youth, and young adults with complex needs. They emphasized **provider availability and qualifications, burnout, recruitment and retention, training, and motivation** as primary areas of concern. Participants occasionally noted that while there is intent to meet the needs of this population, staffing challenges prevent them from doing so.

> *"Currently I see that educators are working extremely hard to meet these children's needs. However. these efforts often fall short due to overloaded schedules, lack of staffing, appropriate training opportunities, etc." –* ***IU Representative***

Further, challenges related to staffing have exacerbated shortages in services and programming.

> *"We certainly have shifted programming due to staffing. This can primarily be seen in the reduction of census. There is a delicate daily balancing of filling open beds while at the same time keeping in mind the staffing expertise and staffing levels in each treatment location. Ultimately decisions are made regarding reduction of census in each treatment location and/or closing a treatment unit." –* ***Residential Provider***

Families shared their frustrations in being able to find appropriately trained providers and caregivers for their children and emphasized that they experience challenges finding providers whose services are covered under their insurance. Approximately one-third (36%) of family respondents reported that their child did not receive timely access to services and supports due to staff not being available at a provider agency.

In addition to a lack of provider availability, many participants noted challenges related to workforce recruitment and retention. They attributed these issues to the intensity of the job, relatively low wages compared to other

roles, limited training opportunities, and a lack of opportunities for career advancement and pathways to licensure.

Theme 5: Trauma-informed supports

Across all groups, participants cited the importance of **considering trauma history in the planning and provision of care** for children, youth, and young adults with complex needs to ensure a holistic approach. Although trauma was included in the definition provided, many participants suggested that it would be helpful to have more specific information about type of trauma, including family- and community-related trauma.

> "*I would like to see under the history of trauma, a mention that not only do the youth/young adults we serve having a history of trauma, but this history of trauma is often best categorized as complex and chronic trauma. Additionally, there should be some emphasis placed on historical trauma that has occurred within the youth/young adult's support system. I also believe that noting any community trauma or violence is impactful for their treatment." – **Residential Provider***

Participants also noted an **increase in children and families with extensive trauma histories**, increases in behaviors and their intensity, and increases in mental health diagnoses like anxiety and depression. Some attributed these increases to the trauma caused by the pandemic.

> *"Yes - I think the collective and complex trauma associated with the COVID pandemic and the opioid epidemic continue to have a detrimental impact on the children we serve. We have seen an increase in critical incidents relating to suicidal ideation, emergency room referrals for psychiatric reasons and suicide attempts. In regard to suicide attempts, we are seeing attempts at younger ages, and the lethality of attempts in our adolescent population has seemed to have increased. We're also seeing a higher prevalence of anxiety, and they are often treated as behavioral problems until recognized as severe anxiety or symptoms of trauma exposure." – **Residential Provider***

Additionally, participants expressed the need for staff to receive more trauma-informed training to better understand the social and diagnostic pictures of the youth they support. County agency participants also reported that due to turnover, many providers lack the experience and knowledge to help the youth they serve with the challenges they face.

> *"We need a more holistic approach which includes qualified professionals who understand how to provide trauma informed care to both the child and their family." – **County Representative***

Conclusions

To understand how to best support children, youth, and young adults with complex needs, it is critical to periodically evaluate the systems that serve them and their families. Through focus groups and surveys, barriers across these systems were identified. Based on a reported lack of communication, limitations in service and program availability, resource awareness constraints, staffing issues, and a dearth of trauma-informed supports, DHS may wish to focus on these areas to improve the overall system of care.

The relationships between the themes presented in this report are noteworthy and may also inform future program and system planning. Challenges related to communication and coordination across systems may lead to a lack of awareness about system-wide roles and available service and program options. Relatedly, staffing concerns may impact service and program availability and the ways in which systems communicate with each other and engage with families. The availability of trauma-informed supports and related training opportunities

may affect recruitment and retention of qualified staff as well as family and youth perspectives on the availability of appropriate services and programs.

These findings are consistent with feedback DHS has previously collected from a variety of stakeholders regarding children, youth, and young adults with complex needs. The challenges that currently exist across the Pennsylvania system of care have been further exacerbated by the public health emergency. Challenges related to staffing, funding, service availability, and cross-system understanding have been previously identified. Their perceived importance by all stakeholder groups in this assessment suggests these areas could be prioritized and addressed to better serve this population.

References

DeVon, H. A., Patmon, F. L., Rosenfeld, A. G., Fennessy, M. M., & Francis, D. (2013). Implementing Clinical Research in the High Acuity Setting of the Emergency Department. *Journal of Emergency Nursing*, *39*(1), 6-12. https://doi.org/https://doi.org/10.1016/j.jen.2012.08.012

Trudeau-Hern, S., & Daneshpour, M. (2012). Cancer's Impact on Spousal Caregiver Health: A Qualitative Analysis in Grounded Theory. *Contemporary Family Therapy*, *34*. https://doi.org/10.1007/s10591-012-9211-9

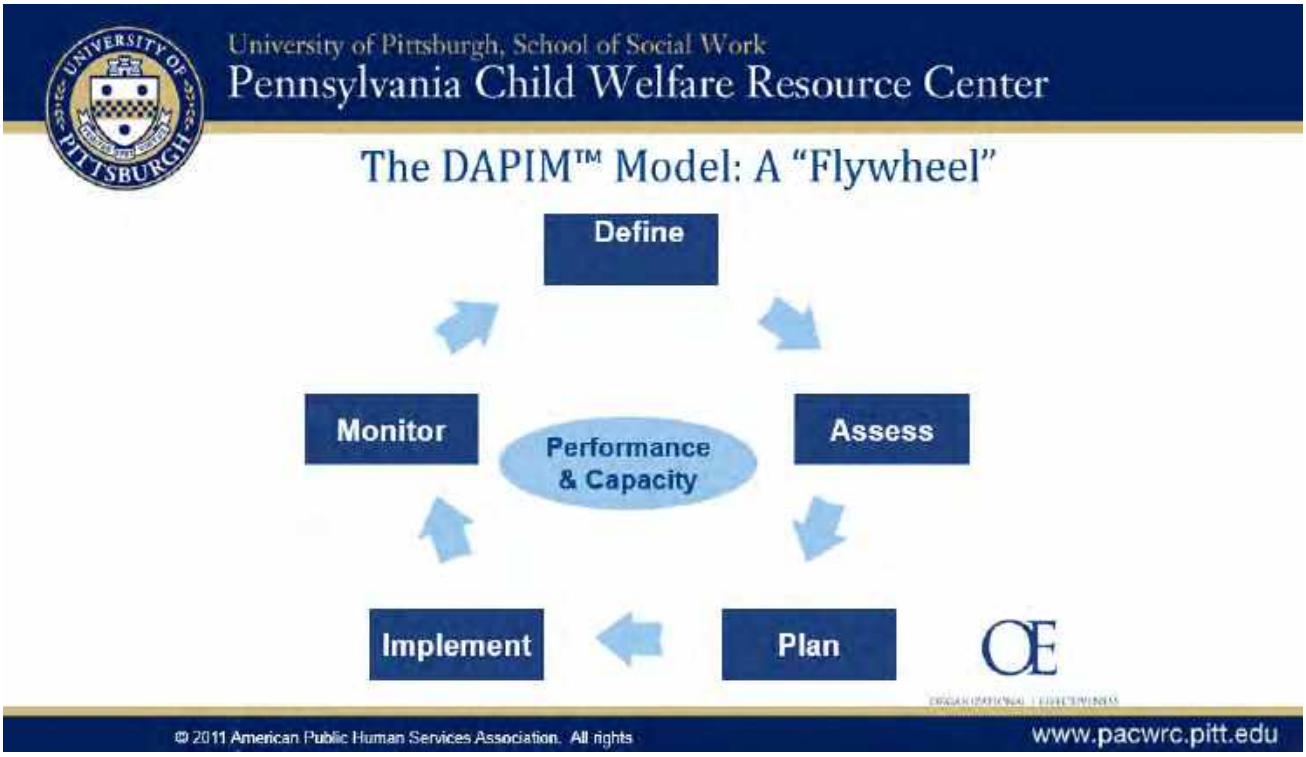
Appendix C: DAPIM Model

Blueprint for Youth with Complex Needs

A Continuous Improvement Approach

The Pennsylvania Department of Human Services (DHS), in partnership with the University of Pittsburgh - Child Welfare Resource Center (CWRC) collaborated to facilitate the Blueprint for Youth with Complex Needs Workgroup through a systemic continuous improvement approach, utilizing the American Public Human Services Association's (APHSA) DAPIM™ model.

APHSA has found that to close the gap between where we are today and achieving the results and vision we desire, we must follow a step-by-step process. It was this DAPIM process that the Complex Needs workgroup stepped through to identify system partner strengths and gaps and establish recommendations to ensure Pennsylvania's youth with complex needs and their families have access to timely supports and individualized services.



Step One: **Define** priority improvements in operational terms. Development of a Desired Future State (DFS), i.e. when child and family serving systems are working at an optimal level, supporting youth and families with timely and individualized services.

Step Two: **Assess** observable, measurable strengths, and gaps. Prioritize gaps and identify root causes.

Step Three: **Plan** and develop recommendations and remedies for priority gaps. Identify quick wins, mid-term, and longer-term improvements.

Step Four: **Implement** action plans while managing communication and capacity.

Step Five: **Monitor** progress, impact, and lessons learned for accountability and on-going adjustments.

Appendix D: Parking Lot Concepts

The Blueprint Workgroup recognized that the concerns and issues that face youth, families, and systems are multi-faceted and require more than we could offer within the time constraints of the workgroup. The workgroup developed a "parking lot" to capture ideas and potential solutions that were not completely developed. The list below captures those ideas and potential solutions for future consideration.

	Parking Lot Items
1	Explore opportunities for improvements with school-based access to mental health services, including more comprehensive service availability. There are some federal level changes in development now that may offer opportunities to strengthen services in Pennsylvania. Other states are pushing on this front as well, for example, Vermont is now allowing schools to bill Medicaid for services in school.
2	Youth with complex needs often require providers with specialized knowledge and training. Not all counties have access to providers with every specialty, it is important to develop a mechanism to share resources across counties so children and families can get what they need, when they need it. Given the specialty needs of youth with complex needs, unique approaches like regionalization of specialty services or broad access to specialist via telehealth services, including being able to consult with the onsite team may be beneficial. PA TiPS (Telephonic Psychiatric Consultation Service Program (TiPS) (pa.gov) may be a resource for youth with Medicaid, but there needs to be consideration for those with private insurance as well.
3	There is a pending state legislative bill that would prevent juvenile probation involvement for a child until age 13, which could increase the burden on other systems. New York recently implemented something similar; see House Bill 1831. It was noted that it may be challenging for this Bill to get through the Senate.
4	Other systems are developing satellite-based outpatient licenses to allow for more flexibility in providing services in the home and community environment. This could be something to explore with children's services particularly when children are located in a non-clinical setting such as a licensed group home. We would need to carefully consider how to implement this in many respects, but particularly to ensure that the setting does not become a clinical setting, but rather that the services are auxiliary in nature and have a plan to transition to a different setting.
5	Consider the accountability of team members to create environments that are conducive/favorable to change, creative, constructive, and solution focused. Notably, this also has workforce implications. Family and professional perceptions are important, and everyone involved has a responsibility to be part of the solution.

	Parking Lot Items
6	Liability is a challenge in a variety of service arenas. Some providers cannot afford the liability insurance necessary to serve certain high-risk populations. The liability issue(s) can include a need for workers compensation, litigation, and other support, particularly around CPSL. Consider offering a pool of funding to support workers comp, litigation, etc. regarding CPSL. Additionally, there needs to be a consensus on handling of incidents and reports and creation of acceptable protocols where minimal facts interviewing can help determine risk. Supporting providers in their ability to afford the insurance needed. Impact on providers' ability to accept referrals, meet staffing needs. Some insurance companies are not insuring some providers. This affects foster care and other providers, like RTF.
7	Develop statewide systems services training to support better cross-systems understanding and provide more comprehensive supports for the child and family. It promotes that the children are "our children" and not just that of one system or another. Promoting knowledge and connection among systems via learning opportunities could be a rich opportunity to connect. Several models exist for this in pocket and could be explored (DHS training systems, ASERT training etc.). These opportunities could be live and archived so they are accessible to all in the human services system. Incorporate planning with pediatric CBI as possible to engage those efforts as well.
8	Develop a mechanism for "after action reviews" of efforts to support youth/families with complex needs. This would be done in conjunction with the team and family to consider lessons learned and ways to improve experiences moving forward. Several models exist within the various systems already (e.g. Act 35 - child fatality and near fatality reviews), but it is likely a new one would need to be developed for this group and a way to manage that information that makes it applicable not only to the particular youth and family, but also benefits the broader system.
9	Children and families who are part of the adoption system experience challenges as they adjust to their new family structure. Ongoing education, resources and support are needed for both adoptive families, including siblings, as well as the adopted child. The current system does not consistently provide these opportunities and it is believed with the appropriate on-going supports such as case management, in home visitors, educational opportunities and support networks the number of failed adoptions would decrease. Providing support to everyone in the family could assist with understanding how to build the new family structure, potential challenges that might arise and specialized topics at all stages of family development.
10	Explore giving people with lived experience preference on the Civil Service just like they do for military veterans. This could improve our ability to support people through the lens of lived experience and provide more comprehensive supports informed by real life experience. There are pockets of this occurring across the state at the local level.

	Parking Lot Items
11	The safety of staff and youth supported are often an important subject of discussion. Things like accusations or reports of inappropriate treatment add trauma to an already challenging time. Can we improve safety supports using technology, training, and ongoing support for staff for how to get through false accusations, and how to get back to a healthy relationship with a youth? For example, videos could be reviewed and used as learning tools for staff.
12	How can we support providers better to take youth with these challenging behaviors? Is there a way, from a data perspective, to understand which diagnoses are resulting in the primary behaviors and/or challenges increasing incidents with staff, resulting in investigations, and so on. This, along with insurance considerations (mentioned in #6), may decrease providers refusing services due to challenging behaviors. Is there a connection to rate setting/differential rates for the level of service needed, high acuity needs, to encourage and support providers in taking youth with challenging behaviors, complex MH needs, Support staff/child ratio, education, etc.
13	More transparency is needed about those who accept Pennsylvania's Health Insurance Premium Payment program (HIPP). A close examination to ensure greater transparency is needed. Some counties/providers don't accept HIPP leaving families without resources they need. It is important to see how this is benefiting families and children and their access to services and support.

Appendix E: Blueprint Workgroup Charter and Organizational Chart

Charter: Blueprint Complex Case Planning 2023

Rationale:

The Pennsylvania Department of Human Services (DHS), in partnership with Child Welfare Resource Center (CWRC) are collaborating to facilitate discussion regarding children, youth, and young adults with complex needs and their families to improve all family and youth serving systems.

A Desired Future State was developed to guide the work and move it forward:

In Pennsylvania we believe all youth with complex needs and their families* will have the opportunity to access timely supports and services that are individualized, trauma-informed, holistic, respectful of race and culture, family and youth driven, and available in their own communities.

This will be evidenced by:

- A focus on youth and family engagement while honoring their voice and choice.
- Establishing and maintaining a well-supported and qualified workforce.
- Collaboration and shared understanding across systems to support planning and shared goals.
- Systems which prioritize early identification, proactive intervention, and service options that support family stability, safety, and the youth's healthy development and meaningful relationships which support life-long connections.
- Teams engage in ongoing and integrated planning that supports the everyday needs of a family and youth (housing, education, transportation, scheduling, access to medical care, etc.).
- Service delivery is coordinated, accessible, timely and includes support throughout the process.

* Family is defined by the individual.

The goal is to facilitate discussion with the Blueprint workgroups in identifying strengths and gaps in the system of care for youth with complex needs, identify root cause issues with gaps, and develop recommendations around strengthening those gap areas to reduce silos and streamline services to youth with complex needs.

Four groups have been identified to collaborate and include representatives from all child and family serving systems as well as families and youth with lived experience. Focus groups conducted with these systems identified five key areas for development recommendations. These are communication, services and programs, resource navigation, staffing/workforce, and trauma informed supports. Family engagement is a crucial part of the success of this work and will be highlighted in each of the five key areas.

Draft recommendations will be presented to the State Leadership (Governor's Office, Secretary of Education, Secretary of Human Services, Legislators, County Administration) by the end of November

2023.

Facilitators - University of Pittsburgh, School of Social Work, Child Welfare Resource Center (CWRC), Organization Effectiveness (OE) Staff:
Russ Cripps- Southeast (SE) OE Regional Team Supervisor, CWRC
Colleen Cox, SE OE Practice Improvement Specialist, CWRC

DHS Steering Team:
Jonathan McVey, Complex Needs Planning, Office of the Secretary, PA DHS

Roseann Perry, Regional Special Projects Manager, OCYF, PA DHS

Jennifer Newman, Human Services Analyst, OCYF, PA DHS

Emily Burger, Special Populations Clinical Support, ODP, PA DHS

Courtney Malecki, Children's MH Program Rep, OMHSAS, PA DHS

Michael Hershey, Project Manager, Office of the Secretary, PA DHS

DHS Complex Needs Planning Team:

Office	Name	Title
OCDEL	Andrea Algatt	Executive Assistant
OCYF	Roseann Perry	Regional Special Projects Manager
OCYF	Jennifer (Jenn) Newman	Human Services Analyst
OCYF	Gerry Lynn Butler	Human Services Supervisor
ODP	Nina Wall	Bureau Director Supports for Autism & Special Populations
ODP	Emily Burger	Special Populations Clinical Support
ODP	Heidi Arva	Clinical Consultant
OMAP	Katrina Becker	Manager, Special Needs/Complaints, Grievances and Fair Hearings
OMAP	Julie Escobar	Human Services Program Specialist Supervisor
OMHSAS	Scott Talley	Bureau Director Children's Behavioral Health Services
OMHSAS	Courtney Malecki	Division Director
OMHSAS	Crystal Doyle	Human Services Program Representative
Policy	Jameekia Barnett	Executive Policy Specialist
Sec. Office	Jonathan McVey	Special Assistant – Complex Needs Planning

Blueprint Workgroups:
Please see attached organizational chart.

Boundaries:
Using several change management strategies, CWRC staff will host meetings with the Blueprint Workgroups and Steering teams to help identify strengths and gaps in meeting the needs of youth with complex needs. The role of Organizational Effectiveness (OE) staff is to schedule and facilitate these meetings at the request of the Steering Team. Initial meetings will be held in person with the rest being scheduled virtually.

Non-negotiables:
- Workgroups to remain solution-focused and stay within the scope of this charter and defined expectations.
- Everyone will respect the opinions and ideas of others.
- Everyone will be open-minded, ready to learn, and willing to be inclusive of others' experience and expertise.
- Steering and Blueprint workgroups will be mindful of proprietary and intellectual properties of programs and organizations as part of the development of recommendations.
- All workgroups and subgroups will respect sensitive discussions, adhering to privacy and confidentiality expectations.

Goals:
For the group to:
- Provide an open forum for all participants to share their ideas and solutions in a collaborative manner.
- Using the information collected in the focus groups and the collective knowledge of the Blueprint workgroup, develop recommendations to improve the system of care for youth with complex needs across the state, and
- to bring families and youth with lived experience, service providers, and agencies together as a team to support better access to services for children and families with a focus on continuous quality improvement.

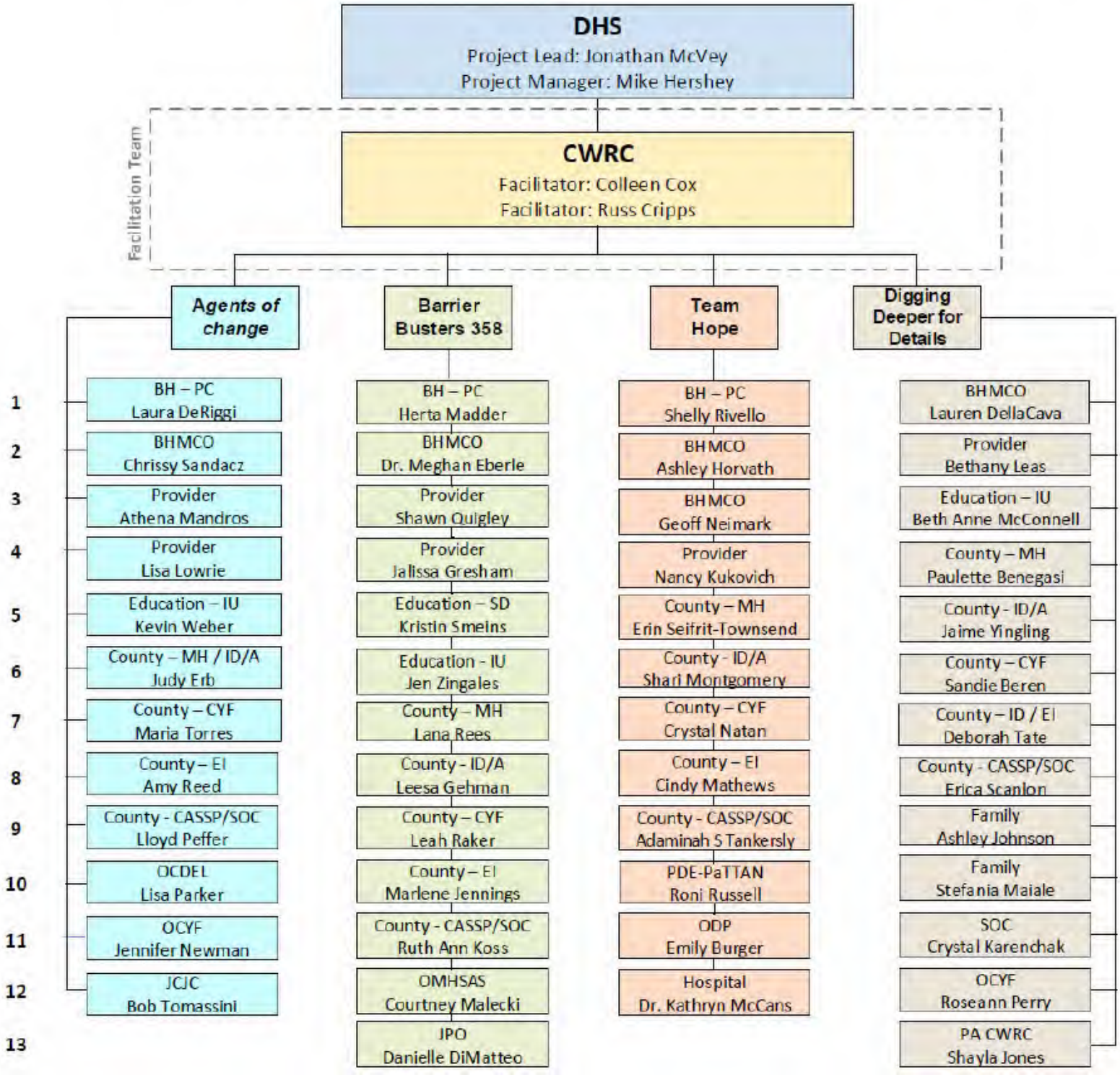
Completion Date:
The Steering and Blueprint Workgroups will be identified by April 21, 2023, with meetings to begin July 19, 2023. An initial draft of recommendations will be completed and ready for submission to the State Leadership (Governor's Office, Secretary of Education, Secretary of Human Services, Legislators, County Administration) by the end of December 2023.

Impact:
The work is designed to improve services to those youth with complex needs, bringing agencies and providers together to eradicate the silos and work collaboratively as a team to serve the children and families in need.

Commitments:
Members will be expected to prioritize meeting attendance and intersession work as needed to meet the deadline. The project will start with an in person kick off on July 19 and 20, 2023 and continue through mid- October with the groups identified. Virtual meetings will occur every other week for 2 hours. It is anticipated that groups will be assigned intersession work between meetings. A second in person wrap up is scheduled for October 19 and 20, 2023 to review and finalize recommendations to be submitted.

Communication:
There will be fluid communication from the Blueprint workgroup to the Steering Team, with key messages developed at every meeting. Information will be shared both in-person at meetings, as necessary and through email updates. Key messages after every meeting may be used to solicit feedback from external stakeholders, such as associations, advocacy organizations, and other state agencies. This will not be done without approval from the groups. Finalized recommendations will be presented to the State Leadership at the conclusion of this chartered work.

Small Workgroups Organizational Chart



Fact Sheets Jul 30, 2024

Fiscal Year (FY) 2025 Hospice Payment Rate Update Final Rule (CMS-1810-F)

Policy

Share

On July 30, 2024, the Centers for Medicare & Medicaid Services (CMS) issued a final rule (CMS-1810-F) updating Medicare hospice payment rates and the aggregate cap amount, for fiscal year (FY) 2025, in accordance with existing statutory and regulatory requirements. This rule also finalizes the proposal to adopt the most recent Office of Management and Budget (OMB) statistical area delineations, which impacts the hospice wage index and clarifies current policy related to the hospice "election statement" and the "notice of election" (NOE), as well as adds clarifying language regarding hospice admission and certification of terminal illness. The final rule summarizes public comments received related to the request for information regarding implementing a separate payment mechanism to account for high-intensity palliative care services.

This rule also finalizes that Hospice Quality Reporting Program (HQRP) measures be collected through a new collection instrument, the Hospice Outcomes and Patient Evaluation (HOPE), and finalizes two HOPE-based measures and discusses the anticipated trajectory for future refinement. The rule summarizes public comments received on the request for information regarding potential social determinants of health (SDOH) elements and provides updates on health equity, future quality measures (QMs), and public reporting requirements. Finally, the rule makes changes to the Consumer Assessment of Healthcare Providers and Systems (CAHPS) Hospice Survey.

Medicare Hospice Payment Policies

This rule finalizes the policy to adopt the most recent OMB statistical area delineations,which revise the existing core-based statistical areas (CBSA) based on data collected during the 2020 Decennial Census. Hospices negatively affected by the change to their geographic wage index will only experience a maximum 5% reduction to their 2024 wage index, as there is a 5% cap on any decrease to the wage index from the prior year. This permanent cap, finalized in the FY 2023 Hospice Final Rule, prevents a geographic area's wage index from falling below 95% of its wage index calculated in the prior FY.

The rule also summarizes comments from the public related to the comment solicitation in the proposed rule, on the potential implementation of a separate payment mechanism to account for high-intensity palliative care services (e.g., palliative dialysis, chemotherapy, radiation, and transfusions) provided under the hospice benefit.

FY 2025 Routine Annual Rate Setting Changes

The FY 2025 hospice payment update percentage is 2.9% (an estimated increase of $790 million in payments from FY 2024). This results from the 3.4% inpatient hospital market basket percentage increase, reduced by a 0.5 percentage point productivity adjustment. The FY 2025 payment rates for hospices that do not submit the required quality data would reflect the finalized FY 2025 hospice payment update percentage of 2.9%, minus four percentage points, which results in a -1.1% update.

The hospice payment update includes a statutory aggregate cap that limits the overall payments per individual that may be made annually to a hospice. The finalized hospice cap amount for FY 2025 is $34,465.34 (FY 2024 cap amount

of $33,494.01, increased by the FY 2025 hospice payment update percentage of 2.9%).

Hospice Quality Reporting Program (HQRP)

This rule finalizes two new process measures to HQRP, *Timely Follow-up for Pain Impact* and *Timely Follow-up for Non-Pain Symptom Impact,* expected to begin in FY 2028. The reporting of these two measures would be through the new HOPE instrument discussed below. These process measures address hospice care delivery as they document whether a follow-up visit occurred within 48 hours of an initial assessment where there was an impact of moderate or severe symptoms with and without pain.

The rule also adopts and implements the HOPE patient-level data collection tool, beginning with FY 2025, and functionally replaces, upon implementation, the existing Hospice Item Set (HIS) structure. HOPE will collect data at multiple time points across the hospice stay, including admission, the HOPE Update Visit (HUV), and discharge. Compared to the HIS (which only collects data at hospice admission and discharge), HOPE will enable CMS to gather patient-level data during their hospice stay to improve patient quality of care. In addition, HOPE includes several domains that are new or expanded relative to HIS, including:

- Sociodemographic (updated)
- Diagnoses (expanded)
- Symptom Impact Assessment
- Skin Conditions
- Imminent death

In addition, this rule finalizes changes to the Hospice CAHPS Survey based on the results of a mode experiment conducted in 2021. Specifically, the changes being finalized are:

- The addition of a web-mail mode (email invitation to a web survey, with mail follow-up to non-responders).
- A shortened and simplified survey.
- Modifications to survey administration protocols to include a pre-notification letter and extension of the field period from 42 to 49 days.
- The addition of a new, two-item Care Preferences measure.
- Revisions to the existing Hospice Team Communication measure and the existing Getting Hospice Care Training measure.
- The removal of three nursing home items and additional survey items impacted by other proposed changes in this rule.

The CMS Hospice Special Focus Program (SFP) will monitor hospices identified as poor performers based on selected quality indicators. Hospices selected for the SFP will be under additional oversight to enable continuous improvement.

The Hospice Special Focus Program (SFP) algorithm uses data from four measures related to caregiver experience collected by the CAHPS Hospice Survey, including Help for Pain and Symptoms, Getting Timely Help, Willingness to Recommend this Hospice, and Overall Rating of this Hospice. This final rule includes changes to the Overall Rating of this Hospice measure that are non-substantive and will not impact the SFP algorithm.

Finally, this final rule summarizes stakeholder input on potential data collection items related to four Social Determinants of Health items relevant to the HQRP (housing instability, food insecurity, utilities, and transportation challenges).

Hospice Conditions of Participation (CoPs) and Payment Requirements Technical Updates

CMS identified language discrepancies in the existing requirements for hospices as they relate to the medical director and physician designee in the Conditions of Participation (CoPs), and physician member of the interdisciplinary group

(IDG), in the payment requirements for the certification of the terminal illness and the admission to hospice care. Therefore, to align the medical director CoP and the hospice payment requirements for both clarity and consistency, CMS is finalizing technical changes to the CoPs by adding the physician member of the hospice IDG as an individual who may review the clinical information for each patient and provide written certification that it is anticipated that the patient's life expectancy is six months or less, if the illness runs its normal course. CMS made one additional change to the CoPs based on public comment: replacing “physician designated by” with “physician designee.” The finalized changes also include an update to provisions regarding certification and admission to hospice care in the hospice payment regulations to clarify that, if the medical director is unavailable, the physician designee (as defined in § 418.3) may certify the terminal illness and determine admission to hospice.

Additionally, CMS is finalizing regulation text changes to clarify the requirements related to the election statement and notice of election (NOE) in the payment regulations. These regulation text changes do not change current policy but are intended to reorganize and more clearly distinguish the separate requirements for the election statement and the NOE.

Lastly, a technical error was noted and corrected in this rule regarding the CoPs in the hospice personnel requirements. The regulation text refers to “marriage and family counselor;” however, the correct term is “marriage and family therapist.”

The final rule can be viewed at the *Federal Register* at: https://www.federalregister.gov/public-inspection.

For further information, see the hospice webpage here: http://www.cms.gov/Center/Provider- Type/Hospice-Center.html.

###

Previous Newsroom article

Next Newsroom article

Pennsylvania Homecare Association

May 27, 2024

The Honorable Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
P.O. Box 8010
Baltimore, Maryland 21244-1850
Via Electronic Submission

Re: File Code CMS-1810-P: **Medicare Program; Fiscal Year 2025 Hospice Wage Index and Payment Rate Update, Hospice Conditions of Participation, and Hospice Quality Reporting Program Requirements**

Dear Administrator Brooks-LaSure:

The Pennsylvania Homecare Association (PHA) is a statewide membership association with approximately 700 home health, homecare and hospice members across Pennsylvania. On behalf of our hospice provider members, we offer the following comments on the Medicare Program; FY 2025 Hospice Wage Index and Payment Rate Update, Hospice Conditions of Participation, and Hospice Quality Reporting Program Requirements," CMS-1810-P.

Proposed 2.6% Rate Increase

Although we recognize that CMS is limited in hospice rate setting, hospice providers are very concerned that the proposed 2.6% increase to the hospice payment rate is not fiscally sustainable in the current climate. Current and ongoing challenges include:

- **Workforce:** Hospices are facing significant staffing challenges, including difficulties recruiting and retaining nurses, social workers, aides, and other members of the interdisciplinary team/ Hospices are challenged with increased turnover and staff burnout while competing with hospitals and other healthcare providers in their communities.
- **Inflation:** Inflation has hit unprecedented levels, especially following the COVID-19 PHE. Costs for gas, drugs, supplies, PPE, and other prices continue to significantly increase each year, leaving hospices in Pennsylvania with massive cost increases. Primarily Medicare and Medicaid-paid, they are unable to pass along increased costs to patients.
- **Hospice Drives Cost Savings:** As the seminal NORC analysis showed, utilization of the hospice benefit saves the overall Medicare program billions of dollars a year – CMS

needs to recognize this dynamic value and provide appropriate and sufficient payment updates that encourage and support greater access to high-quality hospice care.

- **CMS Market Basket Forecast Errors:** CMS' own estimates of how much costs would increase over the last three fiscal years have been below the actual rate of increase. From FY2021-FY2023, the cumulative market basket forecast error is negative 4.6 percent, which creates additional cost pressures that challenges hospices' ability to serve all patients and families in need of their services and support. This further escalates the need for adequate increases to promote and continue the critical care that hospices deliver.

Updated labor market designations based on 2020 Census data (impacts hospices' wage indexes)

- PHA agrees that updating labor market designations based on the most recent Census data is a valid and appropriate step.
- However, the absence of both the rural floor and geographic reclassification protections that are afforded to hospitals leaves hospices comparatively more vulnerable to dramatic decreases in their wage indices. This means that hospices in certain counties are at a significant disadvantage, for example, where providers must contend with metropolitan costs but receive payments based on a wage index that fails to account for actual market conditions. We encourage CMS to work with PHA and similar organizations to examine the wage index development process for hospices to avoid these pitfalls.

Proposal to Implement the Hospice Outcomes & Patient Evaluation (HOPE) Assessment Instrument and Two HOPE-based Quality Measures

- PHA supports the expansion of the HQRP to include the HOPE, contributing to hospice patients receiving high quality and safe care.
- PHA urges CMS to include the full scope of patient and family services by specifically including telehealth visits and visits from all members of the IDG in the HQRP.
- PHA urges CMS to provide feedback to hospices about possible errors or problems with the completion of the tool and allow for ample time for any necessary corrections to be made. This feedback could be in the form of confidential reports for each hospice and/or a public retrospective analysis report.
- PHA asks CMS to consider its timeline, especially given the involvement of EMR providers. EMR companies need the final HOPE technical specifications before they can develop and implement the tool in their software programs. The final HOPE instrument will not be available until at least the final rule is posted and the technical specifications will likely not be available until later this year. Software vendors may need 12 months after the technical specifications are available to make the necessary software changes to their programs.

- PHA also requests that adequate time for testing of electronic submissions be allowed to ensure providers can mediate errors and issues that are bound to happen in this large-scale implementation.
- PHA seeks clarity in the final rule whether hospices are to complete the HOPE for all patients or only those over the age of 18.

Proposed CAHPS Hospice Survey and Measure Changes

- PHA commends the proposed revisions to the CAHPS Hospice Survey instrument!
- PHA asks CMS to consider using race and ethnicity in the adjusting the Hospice CAHPS case-mix to accurately reflect service experience and quality across diverse patient groups.
- The final rule is expected to be available at the beginning of August 2024, however, CMS states that the technical provisions of any finalized CAHPS Hospice Survey revisions would be available in fall 2024. This provides less than four months before the first set of decedents would be required to be collected to conduct the surveys. CAHPS Hospice Survey vendors report that the volume and complexity of the anticipated finalized changes would take far more than 4 months. We ask that implementation of the revised survey and administration protocols not begin prior to January 1, 2026 to allow for a seamless implementation and adequate planning.

Proposed Clarifying Regulation Text Changes

- CMS proposes to align regulatory and condition of participation text to clarify which physicians are able to certify terminal illness and recommend admission to hospice care. PHA supports these changes as they will bring clarity for hospice providers as well as audit contractors.
- CMS proposes to make regulatory changes to clarify and differentiate the Notice of Election (NOE) and election statement. PHA supports these changes as they will bring clarity for hospice providers as well as audit contractors.

RFI Regarding Future HQRP Social Determinants of Health (SDOH) Items

- PHA supports the addition of the following social determinants of health into the HQRP: housing instability, food insecurity, utility challenges, and barriers to transportation access.
- PHA would support language that allows the clinician gathering this data to collect feedback through verbal questioning of the patient OR through observation of the patient home for the most reliable data – this would additionally ensure trust between the patient and clinician and address cultural or language barriers that may exist.

Thank you for your consideration and the opportunity to offer comments on this proposed rule.

Sincerely,

Mia Haney, CEO
Pennsylvania Homecare Association
MHaney@pahomcare.org

mln MATTERS®
KNOWLEDGE • RESOURCES • TRAINING

Hospice Payments: FY 2025 Update

Related CR Release Date: September 11, 2024	MLN Matters Number: MM13707 Revised
Effective Date: October 1, 2024	Related Change Request (CR) Number: CR 13707
Implementation Date: October 7, 2024	Related CR Transmittal Number: R12831CP

Related CR Title: Update to Hospice Payment Rates, Hospice Cap, Hospice Wage Index and Hospice Pricer for Fiscal Year (FY) 2025

What's Changed: We made no substantive changes to the Article other than to update the related CR release date, the CR transmittal number, and the web address of the CR transmittal.

Affected Providers

- Hospices
- Other providers billing Medicare Administrative Contractors (MACs) for hospice services they provide to Medicare patients

Action Needed

Learn about updates effective October 1, 2024:

- Payment rates
- Inpatient and aggregate caps
- Wage index

Background

CMS updates payment rates for hospice care, the hospice cap amount, and the hospice wage index annually. We use the inpatient hospital market basket, adjusted for multifactor productivity (MFP) and other adjustments to get the hospice payment update percentage.

CMS CENTERS FOR MEDICARE & MEDICAID SERVICES
Medicare Learning Network®
377

Division G, Section 308 of the Consolidated Appropriations Act of 2024 (CAA, 2024) (Pub. L. 118–42) amended Section 1814(i)(2)(B) of the Social Security Act (the Act) and extended the provision that currently mandates the hospice cap be updated by the hospice payment update percentage (hospital market basket update percentage increase reduced by the MFP adjustment), rather than the Consumer Price Index for All Urban Consumers (CPI-U) for accounting years that end after September 30, 2016, and before October 1, 2033. Before the enactment of this provision, the hospice cap update was set to revert to the original methodology of updating the annual cap amount by the CPI-U starting on October 1, 2032.

We use the hospice wage index to adjust payment rates to show local differences in wages.

Section 407(b) of the CAA, 2021 changed the payment reduction for failing to meet hospice quality reporting requirements from 2% to 4% starting with FY 2024 and reduce the market basket update by 4% for any hospice that doesn't comply with the quality data submission requirements for that FY.

FY 2025 Hospice Payment Rates

We base the hospice payment update percentage for FY 2025 on the inpatient hospital market basket update of 3.4%. We then adjust the inpatient hospital market basket update of 3.4% with an MFP adjustment, which is an estimated 0.5% for FY 2025. This makes the hospice payment update for FY 2025 to be 2.9%. The final FY 2025 rates for hospices that don't submit the required quality data would be the FY 2025 hospice payment update of 2.9% minus 4%, which results in an update of –1.1%.

The FY 2025 hospice payment rates are effective for care and services you provide from October 1, 2024–September 30, 2025. We discuss the hospice payment rates further in Section 30.2 of the Medicare Claims Processing Manual, Chapter 11.

Table 1 of CR 13707 shows your FY 2025 hospice payment rates if you submit the required quality data. Table 2 of CR 13707 shows your payment rates if you don't submit the required quality data.

Hospice Inpatient and Aggregate Caps

The 2025 cap year will be October 1, 2024–September 30, 2025.

For the 2025 inpatient cap year, we'll calculate the percentage of all hospice days provided as inpatient days, including general inpatient care (GIP) and respite care, from October 1, 2024–September 30, 2025.

The hospice cap amount for the 2025 cap year is equal to the FY 2024 cap amount, which was $33,494.01, updated by the FY 2025 hospice payment update of 2.9%. This makes the FY 2025 cap amount $34,465.34.

Hospice Wage Index

The FY 2023 hospice final rule finalized the application of a permanent 5% cap on any decrease to a geographic area's wage index from its wage index in the prior year, regardless of the circumstances causing the decline starting in FY 2023. In other words, we finalized that a geographic area's wage index for FY 2023 and subsequent years wouldn't be less than 95% of its wage index calculated in the prior FY.

For FY 2025 as a transition helping reduce any significant negative impacts that hospices may experience because of the adoption of the revised Office of Management & Budget (OMB) areas, we'll calculate the permanent 5% cap on decreases on the county level and the core-based statistical area (CBSA) level, so that individual counties moving to a new area don't experience more than a 5% decrease in wage index from the previous FY.

Some counties that change OMB designations have a wage index value that's different than the wage index value assigned to the other constituent counties that make up the CBSA or statewide rural area that they're moving into because of the application of the 5% cap.

Starting in FY 2025 for hospice claims processing, counties with a different wage index value than the CBSA or rural area into which they're designated after the application of the 5% cap will use a wage index transition code to identify the county's appropriate wage index value for hospice claims. These special codes are 5 digits in length and begin with "50." The 50xxx wage index transition codes will only be used in specific counties; counties located in CBSAs and rural areas that don't correspond to a different transition wage index value will still use the CBSA number.

These counties are listed in Table 3 of CR 13707. These special 50xxx codes are also in the last column of the FY 2025 hospice wage index file.

We'll incorporate the revised payment rates and wage index in the Hospice Pricer and forward them to your MAC.

Hospice Labor Shares

The FY 2022 hospice final rule revised labor shares used to wage-adjust hospice payments for each level of care. The revised labor share for:

- Routine home care is 66.00% and the corresponding non-labor share is 34.00%
- Continuous home care is 75.20% and the corresponding non-labor share is 24.80%
- Inpatient respite care is 61.00% and the corresponding non-labor share is 39.00%
- GIP care is 63.50% and the corresponding non-labor share is 36.50%

More Information

We issued CR 13707 to your MAC as the official instruction for this change.

For more information, find your MAC's website.

Document History

Date of Change	Description
September 17, 2024	We made no substantive changes to the Article other than to update the related CR release date, the CR transmittal number, and the web address of the CR transmittal.
August 6, 2024	Initial article released.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality

Ref: QSO-25-02-Hospice

DATE: October 4, 2024

TO: State Survey Agency Directors

FROM: Directors, Quality, Safety & Oversight Group (QSOG) and Survey & Operations Group (SOG)

SUBJECT: Overview of the Hospice Special Focus Program (SFP)

Memorandum Summary

- Through increased regulatory oversight and enforcement, the SFP will address issues that could place hospice beneficiaries at risk of receiving poor quality of care.
- The memo outlines the hospice SFP criteria and the roles and responsibilities for CMS, the state survey agencies, and the accrediting organizations.
- Hospice programs that are unable to resolve the deficiencies that brought them into the SFP and cannot meet the SFP completion criteria, may be considered for termination from the Medicare program.

Background:

As required under Division CC, section 407 of the Consolidated Appropriations Act of 2021 (CAA, 2021), as codified in section 1822(b) of the Social Security Act (the "Act") and amending sections 1864(a) and 1865(b) of the Act, CMS has established a hospice special focus program (SFP) in the Calendar Year (CY) 2024 Home Health Prospective Payment System (HH PPS) final rule (88 FR 77676). Through increased regulatory oversight and enforcement of the selected poor performing hospice programs, the SFP will address issues that could place hospice beneficiaries at risk of receiving poor quality of care through increased oversight.

CMS convened a Technical Expert Panel (TEP) in the fall of CY 2022 to gain input from key partners on various aspects of the SFP development and to identify the most appropriate indicators to identify poor-performing hospices. CMS finalized the SFP methodology and an algorithm with criteria for identifying poor-performing hospices in the CY 2024 HH PPS final rule.

CMS believes the SFP will establish an equitable approach utilizing hospice survey findings and other quality indicators related to performance to ensure that hospices are accountable for providing unsafe or poor-quality care to patients. Hospice programs that do not meet the SFP

completion criteria may be considered for additional enforcement actions, including termination from the Medicare program.

Discussion:

SECTION I: SFP IDENTIFICATION AND SELECTION

To identify hospices for consideration in the SFP, CMS will use the most recent Medicare hospice data from the following sources:
1) Hospice surveys (recertification and substantiated complaint) from the last 3 consecutive years;
2) Hospice Care Index (HCI) Overall Score, based on Medicare claims data; and
3) The four Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Hospice Survey Index measures most aligned with caregiver experience: Help for Pain and Symptoms, Getting Timely Help, Willingness to Recommend the Hospice, and Overall Rating of the Hospice.

In the last quarter of each CY, CMS will apply the algorithm to all active hospice providers (i.e., has billed at least one claim to Medicare FFS in the last 12 months) and generate a list of potential SFP-eligible candidates. CMS will use this list to select the SFP participants for that CY. CMS will select 50 hospices during the fourth quarter of each calendar year for participation in the SFP during the next calendar year. The first cohort of hospices will be selected in November 2024.

If selected, the hospice will receive a letter from CMS notifying them of their inclusion in the SFP and the expectations for successful program completion. If the hospice selected is deemed by an Accrediting Organization (AO), their deemed status will be suspended, and the hospice will be placed under CMS jurisdiction until its completion of the SFP or termination from the Medicare program.

SECTION II: SFP SURVEY AND ENFORCEMENT

Hospice programs selected for the SFP will receive a standard survey not less than every six months, follow-up surveys as needed, as well as surveys for existing or new complaints.

For a hospice in the SFP that has condition-level deficiency findings, CMS may impose one or more alternate enforcement remedies, in addition to placing the provider on a termination track, and may be subject to progressive enforcement remedies, as appropriate. Please refer to the guidance in the State Operations Manual, Chapter 10 – "Informal Dispute Resolution and Enforcement Procedures for Home Health Agencies and Hospice Programs" for information on enforcement actions.

SECTION III: SFP COMPLETION OR TERMINATION

An SFP hospice that has two SFP surveys within 18 months with no uncorrected Condition Level Deficiencies (CLDs) for any survey and no pending complaint investigations triaged at the immediate jeopardy (IJ) or condition-level, or that has returned to substantial compliance with all

requirements would meet the criteria for completion of the SFP. The SFP completion date would be the date of the CMS letter informing the hospice of its removal from the SFP and reinstatement under the SA or AO jurisdiction.

Any hospice that does not achieve substantial compliance with all requirements within the prescribed timeframes may be considered for termination from the Medicare program. CMS will issue the termination letter to the hospice program in accordance with 42 CFR 489.53.

SECTION IV: PUBLIC REPORTING

CMS will post the following information at least annually on the CMS SFP website:

1) A list of eligible candidates for potential selection in the Hospice SFP;
2) Hospices selected for the SFP; and
3) Hospice status in the SFP indicated by one of the following classifications: a) In Progress; b) Completed; c) Terminated from the Medicare Program.

SECTION V: POST-SFP COMPLETION

After completing the SFP, hospice programs will receive a recertification survey within one-year from the SA or AO (as applicable), which would start a new standard 36-month survey cycle.

SECTION VI: ROLES AND RESPONSIBILITIES

The entities below are responsible for the outlined tasks for hospices selected for the SFP.

State Survey Agency

- Continue to process certification actions initiated by Form CMS-855 in accordance with Admin Memo 22-02-ALL.
- Conduct complaint investigations for allegations triaged at an IJ and Non-IJ high while the hospice program is in the SFP.
- Inform the CMS Survey and Operations Group (SOG) hospice subject-matter expert (SME) at CMS_HospiceSFP@cms.hhs.gov about all outstanding non-IJ medium and non-IJ low-level complaints (pending prior to selection in the SFP). Please include "complaint" in the subject line.
- Inform the CMS SOG hospice SME at the email address noted above when any complaint allegation is received while the provider is in the SFP for triage and investigation by the appropriate surveying entity.
- Conduct a survey within one year post-SFP completion for non-deemed hospice providers, which will start a new standard 36-month survey cycle.

CMS

- Communicate to hospice providers on their selection into SFP and copy the SAs and AOs (as applicable).

- Update applicable iQIES fields until the hospice provider has completed the SFP.
- Process informal dispute resolutions (IDRs) for hospices selected in the SFP as requested for condition-level findings.
- Impose enforcement remedies and process enforcement actions.
- Communicate the outcome of the hospice's SFP status (completion or termination) to hospice providers and copy the SAs and AOs (as applicable).

CMS Contractor

- Update applicable iQIES fields until the hospice has completed the SFP.
- Conduct SFP surveys and any applicable revisit surveys.
- Conduct complaint investigations for non-IJ medium and non-IJ low-level complaints.

Accrediting Organization

- Forward complaints received for any accredited hospice deemed provider selected for participation in the SFP to the CMS SOG hospice SME (CMS_HospiceSFP@cms.hhs.gov) and include "complaint" in the subject line.
- Conduct a survey to recommend deemed status (to the CMS Location) within one year post-SFP completion, which will start a new standard 36-month survey cycle, realigning accreditation and deeming, if requested by the hospice provider.

Contact:

For questions or concerns relating to this memorandum, please contact CMS_HospiceSFP@cms.hhs.gov.

Effective Date:

Immediately. Please communicate to all appropriate staff within 30 days.

/s/

Karen L. Tritz	David R. Wright
Director, Survey & Operations Group	Director, Quality, Safety & Oversight Group

Resources to Improve Quality of Care:

Check out CMS's new Quality in Focus interactive video series. The series of 10–15 minute videos are tailored to provider types and aim to reduce the deficiencies most commonly cited during the CMS survey process, like infection control and accident prevention. Reducing these common deficiencies increases the quality of care for people with Medicare and Medicaid. Learn to:

- *Understand surveyor evaluation criteria*
- *Recognize deficiencies*
- *Incorporate solutions into your facility's standards of care*

See the Quality, Safety, & Education Portal Training Catalog, and select Quality in Focus

Get guidance memos issued by the Quality, Safety and Oversight Group by going to CMS.gov page and entering your email to sign up. Check the box next to "CCSQ Policy, Administrative, and Safety Special Alert Memorandums" to be notified when we release a memo.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality

Ref: QSO-24-11-HHA & Hospice

DATE: May 3, 2024

TO: State Survey Agency Directors

FROM: Directors, Quality, Safety & Oversight Group (QSOG) and Survey & Operations Group (SOG)

SUBJECT: Revisions to the State Operations Manual (SOM) Chapter 10 –Informal Dispute Resolution (IDR) and Enforcement Procedures for Home Health Agencies and Hospice Programs

Memorandum Summary

- The Centers for Medicare & Medicaid Services (CMS) has revised the State Operations Manual (SOM) chapter 10 to provide procedures regarding the informal dispute resolution (IDR) process for both Home Health Agencies (HHAs) and hospice programs.
- Revisions also include guidance for State Agencies (SAs) and CMS Survey & Operations Group (SOG) Locations on recommending and imposing HHA alternative sanctions and hospice enforcement remedies.

Background:

On November 8, 2012, we published the Calendar Year (CY) 2013 Home Health Prospective Payment System (HH PPS) final rule (77 FR 67068) that set forth an IDR process for HHAs and alternative sanctions that can be imposed instead of, or in addition to, termination of an HHA's participation. On November 9, 2021, we published the CY 2022 HH PPS final rule (86 FR 62240) that set forth enforcement remedies that can be imposed instead of, or in addition to, termination of a hospice program's participation. Under these rules, CMS has the authority to impose the alternative sanctions or enforcement remedies of civil money penalties, directed in-service training, directed plans of correction, suspension of payment for new admissions, and temporary management on HHAs or hospice programs found to have condition-level deficiencies. A new hospice IDR process was also published in the CY 2024 HH PPS final rule (88 FR 77676) that offers hospice providers an informal opportunity to dispute any condition-level findings.

Discussion:

The survey and certification process provides a method for CMS to evaluate HHA and hospice programs' compliance with the Conditions of Participation (CoPs), ensuring that patient services

provided meet the minimum health and safety standards. This process is explained in Appendix B of the SOM for HHAs and Appendix M of the SOM for hospice programs. Chapter 10 provides guidance for the HHA and hospice program enforcement regulations and IDR processes at 42 CFR Part 488.

The regulations for IDR offer HHAs and hospice programs the option to request an informal opportunity to dispute condition-level survey findings warranting an alternative sanction or enforcement remedy following a facility's receipt of the Statement of Deficiencies (Form CMS-2567). Effective January 1, 2024, the IDR processes for hospices follow the same existing processes for HHAs, and Chapter 10 was updated to include hospices in the guidance.

We have also revised the SOM Chapter 10 guidance for the HHA and hospice program enforcement regulations at 42 CFR Part 488. The guidance will assist SAs in recommending, and Locations in imposing, an alternative sanction(s) or enforcement remedy(ies). CMS may terminate the provider agreement and should consider the imposition of one or more of the following sanctions/remedies. This guidance is outlined in the chapter revisions.

- Civil money penalties;
- Suspension of payment for all new admissions;
- Temporary management;
- Directed plan of correction; and
- Directed in-service training.

CMS training for Location enforcement staff on imposing the HHA alternative sanctions and the hospice program enforcement remedies is available on the CMS Quality, Safety, and Education Portal (QSEP) website. The training is titled *Enforcement Process for Home Health Agency and Hospice Programs.*

Contact:

For questions or concerns regarding HHAs, please contact hhasurveyprotocols@cms.hhs.gov.
For questions or concerns regarding hospices, please contact QSOG_Hospice@cms.hhs.gov.

Effective Date:

Immediately. Please communicate to all appropriate staff within 30 days.

/s/

Karen L. Tritz
Director, Survey & Operations Group

David R. Wright
Director, Quality, Safety & Oversight Group

Attachment- Advanced Copy of SOM Chapter 10 – Informal Dispute Resolution and Enforcement Procedures for Home Health Agencies and Hospice Programs

Resources to Improve Quality of Care:

Check out CMS's new Quality in Focus interactive video series. The series of 10–15-minute videos are tailored to provider types and intend to reduce the deficiencies most commonly cited during the CMS survey process, like infection control and accident prevention. Reducing these common deficiencies increases the quality of care for people with Medicare and Medicaid. Learn to:

- *Understand surveyor evaluation criteria*
- *Recognize deficiencies*
- *Incorporate solutions into your facility's standards of care*

See the Quality, Safety, & Education Portal Training Catalog, and select Quality in Focus

State Operations Manual

Chapter 10 – *Informal Dispute Resolution and* Enforcement Procedures for Home Health Agencies *and Hospice Programs*

Table of Contents

(Rev.)

Advanced Copy

Transmittals for Chapter 10

10000 - Introduction
(Rev.)

The Secretary has the responsibility to promote quality of care and the health and safety of patients receiving services through Medicare certified home health agencies (HHA) and hospice programs by ensuring that providers maintain compliance with the Conditions of Participation (CoP). The survey and certification process provides a method for CMS to evaluate HHA and hospice programs' compliance with the CoPs, ensuring that patient services provided meet the minimum health and safety standards and a basic level of quality. This process is explained in Appendix B of this manual for HHAs and Appendix M of this manual for hospice programs.

Chapter 10 provides guidance for the HHA and hospice program enforcement regulations at 42 CFR Part 488. No provisions contained in this chapter are intended to create any rights or sanctions not otherwise provided in law or regulation.

In accordance with 42 CFR §488.800 – §488.865 for HHAs and §488.1200-§488.1265 for hospice programs, in addition to termination of the HHA's or hospice program's provider agreement, sanctions such as civil money penalties (CMP), suspension of payment for all new admissions, temporary management, directed plans of correction, and directed in-service training can be imposed when an HHA or hospice program are out of compliance with Federal requirements.

Alternative sanctions in HHAs and enforcement remedies in hospice programs are recommended by the State survey agency (SA), and the CMS Location reviews the SA recommendation to ensure that it is supported by the SA findings. However, the CMS Location does not have the authority to delegate the imposition of sanctions to the State.

It should be noted that failure of CMS or the State to act timely does not invalidate otherwise legitimate survey and enforcement determinations.

10001 - Definitions and Acronyms
(Rev.)

Abbreviated standard *survey means a focused survey other than a standard survey that gathers information on an HHA's or hospice program's compliance with fewer specific standards or CoPs. An abbreviated standard survey may be based on complaints received or other indicators of specific concern such as reapplication for Medicare billing privileges following a deactivation. (HHA: 42 CFR §488.705; Hospice: SOM Appendix M, Task I)*

An abbreviated standard survey is a focused survey that examines any standard(s) related to the reason for the survey.

AO *– National Accreditation Organization whose program is approved by CMS. (42 CFR §488.1)*

Certification of compliance *means that the HHA or hospice program is in compliance with the CoPs and is eligible to participate in the Medicare program. (HHA: 42 CFR §488.740)*

CFR *- Code of Federal Regulations.*

CMP *- Civil money penalty. (HHA: 42 CFR 488.845; Hospice: 42 CFR §488.1245)*

CMS Location*- previously known as CMS Regional Office(s), the CMS Location(s) are part of the Survey & Operations Group (SOG) within CMS.*

Complaint investigation*, previously known as a complaint survey, means an onsite review that is conducted to investigate specific allegations of noncompliance.*

Condition-level deficiency *means noncompliance as described in 42 CFR §488.24. A condition-level deficiency is any deficiency of such character that substantially limits the provider's or supplier's capacity to furnish adequate care or which adversely affects the health or safety of patients.*

Credible allegation of compliance *is a statement or documentation that is realistic in terms of the possibility of the corrective action being accomplished between the exit conference and the date of the allegation; and that indicates resolution of the problems.*

Deficiency *is a violation of the Act and regulations contained in part 484 for HHAs, subparts A through C of this chapter, and §418 for hospice programs, subparts C and D of this chapter, is determined as part of a survey, and can be either standard or condition-level.*

Directed plan of correction *means CMS or the temporary manager (with CMS/SA approval) may direct the HHA or hospice program to take specific corrective action to achieve specific outcomes within specific timeframes. (HHA: 42 CFR §488.805; Hospice: 42 CFR §488.1250)*

Enforcement action *means the process of imposing one or more of the following alternative sanctions for HHAs or enforcement remedies for hospice programs: termination of a provider agreement; suspension of payment for all new admissions; temporary manager; civil money penalty; directed plan of correction; or directed in-service training. (HHA: 42 CFR §488.810-865; Hospice: 42 CFR §488.1200-1265)*

Extended survey (HHA only) *means a survey that reviews additional CoPs not examined during a standard survey. It may be conducted at any time but must be conducted when substandard care is identified. (42 CFR §488.705)*

Immediate jeopardy *means a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause serious injury, harm, impairment, or death to a patient(s).*

iQIES *– Internet Quality Improvement and Evaluation System.*

New admission *means an individual who becomes a patient or is readmitted to the HHA or hospice on or after the effective date of a suspension of payment sanction. (HHA: 42 CFR §488.805)*

Noncompliance *means any deficiency found at the condition-level or standard-level.*

Partial extended survey (HHA only) *means a survey conducted to determine if deficiencies and/or deficient practice(s) exist that were not fully examined during the standard survey. The surveyors may review any additional requirements which would assist in making a compliance finding. (42 CFR §488.705)*

Per day *means a CMP imposed for the number of days a facility is not in substantial compliance with the CoPs.*

Per instance *means a single event of noncompliance identified and corrected through a survey, for which the Act authorizes CMS to impose a sanction or remedy. (HHA: 42 CFR §488.805; Hospice: 42 CFR §488.1245(b)(6))*

Plan of correction *means a plan developed by the HHA or hospice program and approved by CMS that is the HHA's or hospice program's written response to survey findings detailing corrective actions to cited deficiencies and specifies the date by which those deficiencies will be corrected.*

Repeat deficiency *means a condition-level citation that is cited on the current survey and is substantially the same as or similar to, a finding of a standard-level or condition-level deficiency cited on the most recent previous standard survey or on any intervening survey since the most recent standard survey. Repeated non-compliance is not on the basis that the exact regulation (that is, tag number) for the deficiency was repeated. (HHA: 42 CFR §488.805; Hospice: 42 CFR 488.1205)*

Standard-level deficiency *means noncompliance with one or more of the standards that make up each condition of participation.*

Standard survey *means a survey conducted in which the surveyor reviews the HHA's or hospice program's compliance with a select number of standards and/or CoPs to determine the quality of care and services furnished by an HHA or hospice program. (HHA: 42 CFR §488.705)*

State survey agency (SA) *means the entity responsible for conducting most surveys to certify compliance with the Medicare participation requirements.*

Substandard care *means noncompliance with one or more CoPs identified on a standard survey, including deficiencies which could result in actual or potential harm to patients. (HHA: 42 CFR §488.705)*

Substantial compliance *means compliance with all condition-level requirements, as determined by CMS, the SA, or AO. (HHA: 42 CFR §488.705; Hospice: 42 CFR 488.1105)*

Temporary management *means the temporary appointment by CMS or by a CMS authorized agent, of a substitute manager or administrator. The HHA's or hospice program's governing body must ensure that the temporary manager has authority to hire, terminate or reassign staff, obligate funds, alter procedures, and manage the HHA or hospice program to correct deficiencies identified in the HHA's or hospice program's operation. (HHA: 42 CFR §488.805; Hospice 42 CFR 488.1235)*

Validation survey *means a survey of an accredited provider or supplier to validate the accrediting organization's CMS-approved accreditation process. These surveys are conducted on a representative sample basis, or in response to substantial allegations of non-compliance. (42 CFR 488.9(a))*

10002 – Informal Dispute Resolution (IDR) for Home Health Agencies & Hospice Programs

10002.1 – IDR Introduction & Purpose
(Rev.)

Section 488.745 and 488.1130 offers HHAs and hospice programs the option to request an informal opportunity to dispute condition-level survey findings warranting an alternative sanction following a facility's receipt of the official statement of deficiencies (Form CMS-2567). Whenever possible, we want to provide every opportunity to settle disagreements at the earliest stage, prior to a formal hearing, conserving time and money potentially spent by the facility, the SA, and CMS. The goal of IDR is to offer the facility an opportunity to refute one or more condition-level deficiencies cited on the statement of deficiencies. An IDR between an HHA or hospice program and the SA or CMS Location, as appropriate, will allow the facility an opportunity to provide an explanation of any material submitted to the SA and respond to the reviewer's questions (77 FR 67141).

This IDR will occur with the agency who conducted the survey. The IDR process, as established by the State or CMS Location, must be in writing so that it is available for review upon request.

If the survey is conducted by the CMS Location, the CMS Location may conduct the IDR.

CMS has adopted the following elements to be incorporated in all cases involving deficiencies cited as a result of Federal surveys. They are designed to clarify and expedite the resolution process. States are free to incorporate these elements into their procedures.

1. *Notice to the facility will indicate that the IDR, including any face-to-face meetings, constitutes an informal administrative process that in no way is to be construed as a formal evidentiary hearing.*

2. *Notice to the facility will indicate that counsel may accompany the HHA or hospice program. If the facility chooses to be accompanied by counsel, then it must indicate that in its request for IDR, so that CMS may also have counsel present.*

3. *CMS will verbally advise the facility of CMS's decision relative to the informal dispute, with written confirmation to follow.*

10002.2 – IDR Process
(Rev.)

When survey findings indicate a condition-level deficiency (or deficiencies), CMS or the State, as appropriate, will notify the facility in writing of its opportunity to request an IDR of those deficiencies. This notice will be provided at the time the Statement of Deficiencies is issued to the facility. The facility's request for IDR must be submitted in writing, should include the specific deficiencies that are disputed, and should be submitted within the same 10 calendar day period that the facility has for submitting an acceptable plan of correction.

A facility's initiation of the IDR process will not postpone or otherwise delay the effective date of any enforcement action. The failure to complete an IDR will not delay the effective date of any enforcement action. Further, if any findings are revised or removed based on IDR, the official Statement of Deficiencies is revised accordingly, and any enforcement actions imposed solely because of those revised or removed deficiencies are adjusted accordingly.

10002.3 - Mandatory Elements of IDR
(Rev.)

Upon their receipt of the official Form CMS-2567, agencies must be offered one informal opportunity, if they request it in writing, to dispute condition level deficiencies. Deficiencies cited at the standard level are not subject to the IDR process.

The following elements must be included in each IDR process offered:

1. *Agencies may not use the IDR process to delay the formal imposition of sanctions or to challenge any other aspect of the survey process, including:*

- *The severity assessment of a deficiency(s) at the standard level that constitutes substandard care or immediate jeopardy (IJ);*

- *Sanctions imposed by the enforcing agency;*

- *Alleged failure of the survey team to comply with a requirement of the survey process;*

- *Alleged inconsistency of the survey team in citing deficiencies among agencies; and*

- *Alleged inadequacy or inaccuracy of the IDR process.*

2. *HHAs or hospice programs must be notified of the availability of IDR in the letter transmitting the official Form CMS-2567. The letter should inform the facility of the following:*

- *It may request the opportunity for IDR, and that if it requests the opportunity, the request must be submitted in writing;*
- *The written request for IDR, from the facility, must include an explanation of the specific condition-level deficiencies that are being disputed;*
- *The written request must be made within the same 10 calendar day period the facility has for submitting an acceptable plan of correction to the surveying entity;*
- *The name and address, e-mail, and phone number of the person to contact at the CMS Location or the SA to request the IDR;*
- *The IDR process that is followed in that State, e.g., telephone conference, written communication, or face-to-face meeting; and*
- *The name and/or position title of the person who will be conducting the IDR, if known.*

***NOTE**: IDR is a process in which State agency officials make determinations of noncompliance. SAs should be aware that CMS holds them accountable for the legitimacy of the process including the accuracy and reliability of conclusions that are drawn with respect to survey findings. This means that while the SA may have the option to involve outside persons or entities they believe to be qualified to participate in this process, it is the SA, not outside individuals or entities that are responsible for IDR decisions. When an outside entity conducts IDR, the results of the IDR process may serve only as a recommendation of noncompliance or compliance to the SA. The SA will then make the IDR decision and notify the facility of that decision. CMS will look to the SA to assure the viability of these decision-making processes, and holds the SA accountable for them.*

Since CMS has ultimate oversight responsibility relative to a SA's performance, it may be appropriate for CMS to examine specific IDR decisions or the overall IDR process to determine whether the decision is consistent with CMS policy. For dually participating or Medicare-only agencies, informal dispute findings are in the manner of recommendations to CMS and, if CMS has reason to disagree with those findings, it may reject the conclusions from IDR and make its own binding determinations of noncompliance.

3. *Failure to complete IDR timely will not delay the effective date of any enforcement action against the facility.*

4. *When a facility is unsuccessful during the process at demonstrating that a deficiency should not have been cited, the SA must notify the facility in writing that it was unsuccessful.*

5. *When a facility is successful during the IDR process at demonstrating that a deficiency should not have been cited or should be revised:*

- *The deficiency citation should be marked "deleted," or "revised" as appropriate, and signed and dated by a supervisor of the surveying entity; and*

- *Any enforcement action(s) imposed solely because of that deleted or revised deficiency citation should be rescinded.*

***NOTE**: The facility has the option to request a clean (new) copy of the Form CMS-2567. However, the clean copy will be the releasable copy only when a clean (new) plan of correction is both provided and signed by the facility. The original Form CMS-2567 is disclosable when a clean plan of correction is not submitted and signed by the facility. Deficiencies pending IDR should be entered into iQIES but will not be uploaded to the national database system until IDR has been completed.*

6. *An agency may request IDR for each survey that cites condition-level deficiencies. However, if IDR is requested for deficiencies cited at a subsequent survey, a facility may not challenge the survey findings of a previous survey for which the facility either received IDR or had an opportunity for it. Condition-level deficiencies that are not corrected and that are carried forward on a subsequent survey are not eligible for the IDR process. Condition-level deficiencies identified on a subsequent survey that are new are eligible to be reviewed through the IDR process.*

Additional information related to the effect of IDR on HHA alternative sanctions and hospice program enforcement remedies, including CMPs, is addressed in the appropriate sections of this chapter.

10003 – Enforcement Actions for Home Health Agencies and Hospice Programs
(Rev.)

CMS certifies HHAs and hospice programs for participation in Medicare. The SAs then conduct standard and complaint surveys of certified providers to determine compliance with the CMS conditions of participation. If an HHA or hospice program is not in compliance with the Medicare conditions, CMS may impose an alternative sanction or enforcement remedy. The following sections describe the statutory authorities, considerations, and process for imposition of sanctions/remedies.

10003.1 - Statutory Basis
(Rev.)

Alternative Sanctions for Home Health Agencies
Sections 1891(c) through (f) establish requirements for surveying and certifying HHAs as well as authorizes the Secretary to utilize varying enforcement mechanisms to terminate participation in the Medicare program and to impose alternative sanctions if HHAs are found out of compliance with the Medicare home health CoPs. The imposition of alternative sanctions

specified in §488.820 allows for non-compliant HHAs to have additional time to come into compliance with the CoPs before being terminated.

Enforcement Remedies for Hospice Programs
Division CC, section 407 of the Consolidated Appropriations Act 2021, amended Part A of Title XVIII of the Act to add a new section 1822 of the Act, and amended sections 1864(a) and 1865(b) of the Act, establishing new hospice program survey and enforcement requirements. Section 1822(c)(5) of the Act authorizes the Secretary to utilize varying enforcement mechanisms to terminate participation in the Medicare program and to impose enforcement remedies if hospice programs are found out of compliance with the Medicare CoPs. The imposition of enforcement remedies specified in §488.1220 allows for non-compliant hospice programs to have additional time to come into compliance with the CoPs before being terminated.

10003.2 - General Provisions
(Rev.)

Under section 1891(e)(1) of the Act for HHAs and section 1822(c)(5) of the Act for hospice programs, if CMS or a SA determines that condition-level deficiencies immediately jeopardize the health or safety of its patients, then CMS must take immediate action to notify the provider of the jeopardy situation and the provider must correct the deficiencies. If the IJ is not removed because the provider is unable or unwilling to correct the deficiencies, CMS will terminate the provider's provider agreement. In addition, CMS may impose one or more specified alternative sanctions or enforcement remedies, respectively, including but not limited to CMPs and suspension of all Medicare payments before the effective date of termination.

If CMS finds that the provider is not in compliance with the Medicare CoPs and the deficiencies involved do not immediately jeopardize the health and safety of the individuals to whom the HHA or hospice program furnishes items and services, CMS may terminate the provider agreement and should consider the imposition of an alternative sanction(s)/enforcement remedy(ies)

The decision to impose one or more alternative sanctions for HHAs or enforcement remedies for hospice programs would be based on condition-level deficiencies or repeat deficiencies found in the provider during a survey.

While SAs are not required to recommend the types of sanction/remedies to be imposed, they are encouraged to do so since States may be more familiar with a facility's history and the specific circumstances in the case at hand. To ensure effective communication and exchange of information, CMS encourages that all documentation is included in iQIES or any subsequent system. The CMS Location will consider these recommendations but ultimately makes the enforcement determination.

Not all situations require the same sanctions/remedies. The CMS Location should use the enforcement sanction/remedy most appropriate in considering the level/degree of harm, the

context behind the facility noncompliance, and the type of enforcement that has the best chance of the facility achieving future compliance. While a range of sanctions/remedies are available, suspension of payment for all new admissions is likely to be the most effective at rapidly returning the provider to compliance.

10003.3 - Effect of Sanctions/Remedies on HHAs and Hospice Programs that Participate in Medicare via Deemed Status through an Accrediting Organization
(Rev.)

A deemed HHA or hospice program loses its deemed status when a condition-level finding is cited on a complaint or validation survey. When a condition-level deficiency (ies) is found, the CMS Location returns oversight of the accredited HHA or hospice program back to the SA until the HHA or hospice program can demonstrate compliance with the CoPs. During the time that the SA has jurisdiction over the HHA or hospice program, the SA, not the Accrediting Organization (AO), will follow the procedures for recommending the imposition of sanctions/remedies, if appropriate. Once the HHA or hospice program returns to compliance with the Medicare conditions and has not been terminated, the CMS Location will restore its deemed status and return oversight to the AO.

AOs are not authorized to impose federal sanctions/remedies. Therefore, HHAs or hospice programs participating in Medicare through deemed status are not directly subject to sanctions/remedies by the AO while under jurisdiction of the AO. However, the CMS location may, after reviewing the AO's survey findings and related information, authorize the SA to conduct a focused validation survey to determine whether condition-level deficiencies, cited by the AO, have been corrected. If deemed status is withdrawn and/or the HHA or hospice program is placed under the jurisdiction of the SA, as may occur following a complaint investigation by the SA, the CMS Location may impose alternative sanctions/remedies on the HHA or hospice program per the usual procedures.

10003.4 - Effect of Sanctions/Remedies on HHA Branches and Hospice Multiple Locations
(Rev.)

Regardless of whether the condition level non-compliance is identified at the branch (HHA), multiple location (hospice), or the parent location, all sanctions/remedies imposed would apply to the parent HHA or hospice and its respective branches or multiple locations.

10003.5 - Enforcement Action When IJ Exists
(Rev.)

When there is IJ to patient health or safety, CMS must complete termination procedures within 23 days from the last day of the survey which found the IJ if it is not removed before then (following guidelines in Appendix Q of the State Operations Manual). The procedure must not be postponed or stopped unless the IJ is removed, as verified through onsite verification. If there

is a written and timely credible allegation that the IJ has been removed, CMS or the State will conduct a revisit prior to termination, if possible.

In addition to termination, one or more alternative sanctions for HHAs or enforcement remedies for hospice programs may be imposed. While the use of alternative sanctions or enforcement remedies in addition to termination is permitted, the Act makes it clear that the enforcement action for noncompliant agencies with IJ deficiencies is intended to be swift. The imposition of alternative sanctions for HHAs or enforcement remedies for hospice programs in addition to termination does not extend the timeframe that the HHA or hospice program has to remove the IJ situation.

10003.6 – Enforcement Action When Condition-Level Deficiencies Exist That Do Not Pose IJ
(Rev.)

If the HHA or hospice program is no longer in compliance with the CoPs, either because the deficiency(ies) substantially limit the HHA's or hospice program's capacity to furnish adequate care but do not pose IJ, or because the HHA or hospice program has repeat noncompliance that results in a condition level deficiency based on the HHA's or hospice program's failure to correct and sustain compliance, CMS will either terminate the provider agreement following the 90 day termination track or impose one or more alternative sanctions for HHAs or enforcement remedies for hospice programs as an alternative to termination. If alternative sanctions or enforcement remedies are imposed, CMS terminates the HHA's or hospice program's provider agreement within 6 months of the last day of the survey if the HHA or hospice program is not in substantial compliance with the CoPs and the condition level deficiencies are not corrected.

10003.7 - Effect of Termination on the Patients
(Rev.)

If an HHA or hospice program fails to correct deficient practices and sustain compliance, CMS may terminate the provider agreement. When this happens, an HHA or hospice program is required to appropriately and safely transfer its patients to another local HHA or hospice within 30 days of termination (see §488.825(c) & §488.830(e) for HHAs & §488.1225(c) & §488.1230(e) for hospice programs). The HHA or hospice is responsible for providing information, assistance, and any arrangements necessary for the safe and orderly transfer of its patients. The SA is required to provide oversight for all HHAs or hospices that are terminated to ensure the safe discharge and orderly transfer of all patients to another Medicare-approved HHA or hospice. Payment to terminated HHAs or hospices for services for current patients is provided up to 30 days after termination pursuant to §489.55.

10004- Available Sanctions/Remedies
(Rev.)

To the greatest extent possible, the time between the identification of deficiencies and imposition of sanctions/remedies should be minimized. In accordance with §488.820 for HHA and §488.1220

for hospice programs, the following sanctions/remedies in addition to termination of the provider agreement are available:

- *Civil money penalties;*
- *Suspension of payment for all new admissions;*
- *Temporary management;*
- *Directed plan of correction; and*
- *Directed in-service training.*

It is important to note that imposition of an alternative sanction or enforcement remedy is an available enforcement action, but it is not required when CMS may ultimately determine that termination is the most appropriate enforcement action to ensure patient health and safety. When CMS believes that an agency cannot promptly return to compliance, termination may be preferable.

10004.1 - Factors to be Considered in Selecting Sanctions/Remedies (Rev.)

When making sanction/remedy choices, the CMS Location should consider the extent to which the noncompliance is the result of a one-time mistake, larger systemic concerns, or an action of disregard for patient health and safety. CMS bases its choice of sanction(s)/remedy(ies) on consideration of one or more factors that include, but are not limited to, the following:

- *The extent to which the deficiencies pose IJ to patient health and safety.*
- *The nature, incidence, manner, degree, and duration of the deficiencies or noncompliance.*
- *The presence of repeat deficiencies, the HHA's or hospice program's overall compliance history and any history of repeat deficiencies at either the parent or branch or multiple locations.*
- *The extent to which the deficiencies are directly related to a failure to provide quality patient care.*
- *The extent to which the HHA or hospice program is part of a larger organization with performance problems.*
- *An indication of any system-wide failure to provide quality care.*

In addition, CMS reviews other factors including, but not limited to, the history of the HHA's or hospice program's compliance with the CoPs, specifically with reference to the cited deficiencies.

Once a sanction/remedy is imposed, it becomes effective as of the date specified in the notice letter for the sanction/remedy being imposed. All sanctions/remedies remain in effect and

continue until the facility has demonstrated and is determined to be in substantial compliance with all CoPs.

The summary table below gives a high-level overview of the available sanctions/remedies and factors to consider for selection. Each of these are discussed in greater detail throughout the rest of this chapter.

Summary Table of Available Sanctions/Remedies for HHAs & Hospice Programs

Available Sanction/Remedies	***Factors to Consider for Selection***
For All Sanctions/Remedies	• *The extent to which the deficiencies pose IJ to patient health and safety.* • *The nature, incidence, manner, degree, and duration of the deficiencies or noncompliance.* • *The presence of repeat deficiencies, the hospice program's overall compliance history and any history of repeat deficiencies at either the parent hospice program or any of its multiple locations.* • *The extent to which the deficiencies are directly related to a failure to provide quality patient care.* • *The extent to which the hospice program is part of a larger organization with performance problems.* • *An indication of any system-wide failure to provide quality care.*
Civil Money Penalty (CMP)*	*When repeat deficiencies exist.* • *Upper range of CMPs for IJ situations.* • *Middle range of CMPs for noncompliance that is directly related to poor quality patient care outcomes (non-IJ).* • *Lower range of CMPs for noncompliance that is related predominately to structure or process-oriented conditions.*
Suspension of payment for all new admissions (SPNA)*	*When condition-level deficiencies relate to poor patient care outcomes.*
Temporary Management*	*When failure to comply with the CoPs is directly related to management limitations, or* *When current management oversight is likely to impair the facility's ability to return to full compliance, or* *When needed, based on the above situations, to oversee orderly involuntary termination/closure and safe transfer of patients to another local HHA or hospice.*

Directed Plan of Correction (DPOC)	*When the HHA or hospice program has deficiencies that warrant direction for the provider to take specific actions, or* *When the HHA or hospice program fails to develop an acceptable plan of correction for condition-level deficiencies.*
Directed In-Service Training	*When education is likely to correct the deficiencies and help the HHA or hospice program achieve substantial compliance.*
** For HHAs only: Please note that the imposition of one or more of these sanctions could prohibit an HHA from conducting home health aide training and competency evaluation program as noted in 42 CFR 484.80(f).*	

The following sections describe each possible alternative sanction or enforcement remedy and procedures for imposing them. In addition, the CMS Location and SA follow the procedures in Chapter 3 of the SOM if an adverse action is likely to be initiated against a Medicare participating provider.

10005 - Civil Money Penalties
(Rev.)

10005.1 - Basis for Imposing Civil Money Penalties
(Rev.)

CMS may impose a CMP against an HHA or hospice program based on noncompliance with one or more CoPs found through a survey or on the presence of repeat deficiencies (i.e., looking at the HHA's or hospice program's overall compliance history per 42 CFR 488.815(c) and 42 CFR 488.1215(c)).

Enforcement sanctions/remedies may be applied regardless of whether the HHA's or hospice program's deficiencies pose IJ to patient health and safety. CMS may impose a CMP for the number of days that an HHA or hospice program is not in substantial compliance with one or more CoPs, or for each instance that an HHA or hospice program is not in substantial compliance. In the case of unremoved IJ situations, the existing 23-day termination timeline still applies (See also Appendix Q of the State Operations Manual for IJ timelines).

The CMP amounts are based on §488.845 for HHAs and §488.1245 for hospice programs which lay out the ranges and amounts for CMPs. However, CMS is required by law to annually adjust the CMP amounts based on inflation in accordance with 45 CFR part 102. Therefore, while the original CMP amounts are located in the regulations, CMS Location staff will use the annually adjusted amounts that CMS posts on its website on the Quality, Safety & Oversight Group webpage (https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Civil-Monetary-Penalties-Annual-Adjustments.html) to calculate the penalty. The maximum CMP amount is also posted on this website and will be regularly updated when annual inflation adjustments are made.

CMS may impose a CMP against an HHA or hospice program for either the number of days (per day CMP) the facility is not in compliance with one or more CoPs or for each instance (per instance CMP) that the facility is not in compliance.

Per Day CMP

"Per day" means a CMP imposed for the number of days a facility is not in substantial compliance with the CoPs.

Surveyors may come across information during the survey that identifies past noncompliance, but evidence exists that the noncompliance was corrected and is not an issue during the current survey. While we do not cite to past noncompliance (deficiencies identified and corrected since the last survey), if a surveyor finds current noncompliance and can trace the start of noncompliance back to a specific date prior to this current survey, a per day CMP may be imposed. In general, the CMS Location may impose a per day CMP from the time when the noncompliance occurred through the time when the noncompliance was corrected. For example, CMS may impose a CMP for the number of days an IJ situation exists.

The range of per day penalties is set forth at §488.845(b)(3)-(5) for HHAs and §488.1245(b)(3)-(5) for hospice programs. These base amounts are adjusted annually for inflation and are posted on the CMS website.

The CMP range amounts are based on three levels of seriousness—upper, middle, and lower. The lower range of permitted per day CMP amounts enables CMS to better correlate the seriousness of noncompliance with the amount of the CMP. The expanded lower end of the range may be particularly important if CMS imposes a CMP that begins at the lower or middle range and then increases in amount over time the longer the noncompliance remains uncorrected. In such a case, prompt remedial action by the HHA or hospice program can limit the total amount of per day CMP that accrues (See also 77 FR 67150).

Per Instance CMP

"Per instance" is defined at §488.805 and 42 CFR 488.1205 and means a single event of noncompliance identified and corrected during a survey, for which the statute authorizes CMS to impose a sanction/remedy.

For example, during a survey, CMS or a state may identify several instances of noncompliance, each in distinct regulatory areas. Generally, we anticipate imposing per instance penalties only in the situation where a surveyor identifies a condition-level deficiency during the survey and the HHA or hospice program took sufficient action to correct the deficiency during the time of the survey (see also 77 FR 67150).

The range of per instance penalties is set forth at §488.845(b)(6) for HHA and §488.1245(b)(6) for hospice programs, and the penalty amounts are adjusted annually for inflation and are posted on the CMS website. The terminology "per instance" is not used to suggest that only one instance of condition-level noncompliance may be assigned a CMP. There can be more than one instance of condition-level noncompliance identified during a survey where the SA/CMS Location utilizes the per instance CMP as a sanction/remedy. However, the total dollar amount of the CMP for the instance or multiple instances of condition-level noncompliance may not exceed the maximum $10,000 (as adjusted for inflation) for each day of that specific survey, and may not be less than $1,000 (as adjusted for inflation) per instance.

***NOTE:** A per day and a per instance civil money penalty cannot be used simultaneously for the same deficiency in conjunction with a survey (i.e., standard, revisit, complaint). However, both types of CMPs may be used during a noncompliance cycle if more than one survey takes place, and the per day CMP was not the CMP initially imposed. When a per day CMP is the CMP sanction initially imposed, a per instance CMP cannot be imposed on a subsequent survey within the same noncompliance cycle.*

***For HHAs Only:** Please note that the imposition of a $5,000 or more CMP on an HHA would prohibit that HHA from conducting health aide training and competency evaluation program for 2 years from the date this sanction is imposed (see also 42 CFR 484.80(f)). See Appendix B of the State Operations Manual for additional information for eligible home health aide training and competency evaluation organizations at §484.80(f).*

10005.2 - Determining Amount of Civil Money Penalty
(Rev.)

CMPs are intended as a tool to encourage the HHA or hospice program to rapidly return to compliance with program requirements to protect the health and safety of individuals under their care. As with all other enforcement sanctions/remedies, CMPs are a discretionary enforcement action and not required. CMS may ultimately determine that termination is the most appropriate enforcement action to ensure patient health and safety. While a provider may be given an opportunity to correct their deficiencies and return to compliance, if CMS determines that an agency cannot promptly return to compliance, termination may be preferable to an alternative sanction or enforcement remedy.

CMS bases its choice of sanction/remedy on consideration of one or more factors that include, but are not limited to the following:

- *The extent to which the deficiencies pose IJ to patient health and safety.*
- *The nature, incidence, manner, degree, and duration of the deficiencies or noncompliance.*
- *The presence of repeat deficiencies, the HHA's or hospice program's overall compliance history and any history of repeat deficiencies at either the parent or branch or multiple location.*

- *The extent to which the deficiencies are directly related to a failure to provide quality patient care.*

- *The extent to which the HHA or hospice program is part of a larger organization with performance problems.*

- *An indication of any system-wide failure to provide quality care.*

In determining the amount of the civil money penalty, CMS considers certain factors in addition to those listed above which include:

- *The size of the HHA or the hospice program and its resources;*

- *Accurate and credible resources, such as PECOS, Medicare cost reports and Medicare/Medicaid claims information that provide information on the operation and resources of the HHA; and*

- *Evidence that the HHA or hospice program has a built-in, self-regulating quality assessment and performance improvement system to provide proper care, prevent poor outcomes, control patient injury, enhance quality, promote safety, and avoid risks to patients on a sustainable basis that indicates the ability to meet the conditions of participation and to ensure patient health and safety.*

In collaboration with other CMS components, CMS may consider an agency's financial condition on a case-by-case basis, and this evaluation may be made in part by considering the HHA's or hospice program's size and its resources. The CMS Location may need to consult with other CMS components such as Center for Program Integrity (CPI), Centers for Medicare (CM), and/or Office of Financial Management (OFM) as part of the process to consider the above factors. CMS considers whether the HHA or hospice program has the ability to pay the CMP without having to go out of business or compromise patient health and safety. An HHA or hospice program may be expected to satisfy its obligations to the federal government before making payments to its owners.

Information on the operations and resources of the HHA or hospice program may include items such as, but not limited to, historical patient census, staffing levels, and claims paid. Additionally, CMS may consider other aspects such as enforcement actions taken by CMS for enrollment or payment related issues (e.g., overpayment, pre/post-pay audits, suspensions, and revocations) and the impact these can have on HHA or hospice program resources.

When several instances of noncompliance are identified at a survey, either a per day or per instance civil money penalty could be imposed. By law, CMPs may not exceed a set maximum amount per day. The maximum is a total, comprising per day and per instance penalties. This maximum amount is set forth at §488.845(b)(2)(iii) and at §488.845(b)(6) for HHA and §488.1245(b)(2)(iii) and at §488.1245(b)(6) for hospice programs, and the current adjusted maximum amount is posted on CMS's website on the Quality, Safety & Oversight Group

webpage at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Civil-Monetary-Penalties-Annual-Adjustments.

Per the Federal Civil Penalties Inflation Adjustment Improvements Act of 2015, inflationary adjustments to the CMPs are published annually and are effective immediately upon publication. The first of these adjustments was published in the Federal Register on September 6, 2016, at 81 FR 61538. A table located at 45 CFR 102.3 shows how the CMPs are adjusted for inflation. In addition, these adjusted CMP amounts are posted on the CMS website on the Survey and Certification Group webpage and are updated when future inflation adjustments are made. Adjusted amounts that are in effect when the CMP is imposed by CMS shall be applied, regardless of when noncompliance is identified. This means that the CMP amount per day or per instance imposed should be calculated using the most current adjusted amount noted in 45 CFR 102.3. For example, if a survey identifies condition-level noncompliance but CMS has not imposed a CMP yet (i.e., sent notice of intent to impose a CMP) and the next annual adjustment is published, then CMS must impose a CMP amount, either per day or per instance, using the newly adjusted amounts. For example: During a survey, a situation of IJ that is unremoved at survey exit, is identified, and CMS sends notice of the intent to impose a CMP. Upon receipt of an acceptable plan of correction, a revisit survey is completed, revealing the situation of IJ was removed but noncompliance at the condition level remains. CMS would move to lower the amount of the CMP imposed per day considering the survey findings and changes to the severity of identified noncompliance. However, if the daily penalty assessment of the CMP is adjusted under existing Federal law prior to CMS notifying the facility of the reduction in the per day amount of the CMP, CMS must lower the amount per day only to an amount that meets the newly adjusted totals (see also 42 CFR 488.845(b)(2)(iii) for HHAs and 42 CFR 488.1245(b)(2)(iii) for hospice programs).

In the event the ranges, minimum, and/or maximum amount of a CMP is adjusted for inflation during an entity's cycle of noncompliance, CMS must calculate the amount based upon the date the notice of intent is issued, not the date noncompliance was identified. These adjusted amounts shall be used until the next effective date for CMP inflation adjustments occurs.

The CMS Location consults with the regional attorney's office to ensure compliance with section 1128A of the Act and Department of Justice requirements. Section 1128A of the Act requires CMS to offer a hearing before collecting, but not before imposing, a CMP.

10005.3 - Penalty Amounts
(Rev.)

The current adjusted penalty amounts are posted annually on the CMS website on the Quality, Safety & Oversight Group webpage at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Civil-Monetary-Penalties-Annual-Adjustments and are regularly updated when inflation adjustments are made.

10005.4 - Range of Penalty Amounts
(Rev.)

CMS bases the range of civil money penalty amounts on three levels of seriousness—upper, middle, and lower. The range of CMPs is identified at §484.485(b)(3) – (6) for HHA and §488.1245(b)(3) – (6) for hospice programs, and the amounts are adjusted annually for inflation and are posted on the CMS website. The specified CMP ranges mark the starting point in CMS's determination of the CMP amount. First, CMS looks to the specific circumstances of the survey findings to determine whether a per day or per instance CMP is warranted and whether the facts point to a CMP rate in an Upper, Middle, or Lower range. After the CMP type and range are determined, CMS considers the additional factors described above at 10012.2.

When CMS is determining the rates for multiple CMPs, the rates must be evaluated collectively. By law, CMPs may not exceed a set maximum amount per day. The maximum is a total, comprising per day and per instance penalties. This maximum is set forth at §488.845(b)(2)(iii) and at §488.845(b)(6) for HHA and at §488.1245(b)(2)(iii) and at §488.1245(b)(6) for hospice programs.

Current information on the range of CMPs and the maximum amount per day is posted on the CMS website on the Quality, Safety & Oversight Group webpage at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Civil-Monetary-Penalties-Annual-Adjustments.html.

10005.5 - Upper Range of Penalty
(Rev.)

Upper range penalty amounts are imposed for a condition-level deficiency that is IJ. The CMP upper ranges are set forth in §§488.845(b)(3)(i), (ii), and (iii) for HHA and §488.1245(b)(3)(i), (ii), and (iii) for hospice programs and will vary based on the following:

a. *If the IJ is cited for actual harm;*

b. *If the IJ is cited for potential for harm; and*

c. *If the IJ is cited for a violation of established HHA or hospice program policies and procedures*

***Note:** The following examples contain findings that could become a part of an HHA's or hospice program's IJ citation. Please note that the citation of IJ is only made after careful investigation of all relevant factors as detailed in Appendix Q. An IJ decision requires a determination that the situation meets all required IJ components.*

1. *Section 488.845(b)(3)(i) for HHAs and §488.1245(b)(3)(i) for hospice programs address CMPs for a deficiency or deficiencies that are determined to be IJ and that results in actual harm. **Examples:** The facility fails to report to a physician, episodes of severe hyperglycemia, resulting in ketoacidosis and hospitalization of diabetic patient; and the facility fails to timely and accurately assess a patient's pressure ulcers, which deteriorate to Stage 4 and sepsis prior to their recognition.*

2. *Section 488.845(b)(3)(ii) for HHAs and §488.1245(b)(3)(ii) for hospice programs address CMPs for a deficiency or deficiencies that are determined to be IJ and that result in a potential for harm.* ***Examples:*** *The facility fails to intervene after patient verbalizes threats of suicide, resulting in potential for self-harm; and the facility fails to administer ordered intravenous antibiotic to patient with diagnosed infection, resulting in potential for development of sepsis.*

3. *Section 488.845(b)(3)(iii) for HHAs and §488.1245(b)(3)(iii) for hospice programs address per day penalties for an isolated incident of noncompliance that is in violation of the HHA's or hospice program's established policies and procedures.* ***Example:*** *One of the facility's nurses did not follow the infection control policies and procedures when performing wound care requiring sterile technique on an immunocompromised patient.*

Current information on the range of CMPs and the maximum amounts is posted on the CMS website on the Quality, Safety & Oversight Group webpage at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Civil-Monetary-Penalties-Annual-Adjustments.html

The penalty in this upper range will continue until the IJ is removed and substantial compliance can be determined per the usual procedures. (See Appendix Q for IJ removal process and timelines)

During the revisit survey, the SA will determine if the IJ is removed. If the IJ situation has been removed, but condition level deficiencies still exist, the penalty amount may be decreased to the middle or lower range of penalties based on the deficiency.

Note*: In accordance with 42 CFR 488.830(a)(2) for HHAs and 42 CFR 488.1230(c) for hospice programs, if one or more alternative sanctions are imposed as an alternative to termination, the delay in termination may not exceed 6 months from the last day of the survey identifying condition-level noncompliance.*

10005.6 - Middle Range of Penalty
(Rev.)

Section 488.845(b)(4) for HHA and §488.1245(b)(4) for hospice programs set forth the middle range of penalties. Middle range amounts are imposed for a repeat and/or condition-level deficiency that does not constitute IJ but is directly related to poor quality patient care outcomes.

10005.7 - Lower Range of Penalty
(Rev.)

Section 488.845(b)(5) for HHA and §488.1245(b)(5) for hospice programs set forth the lower range of penalties. CMPs in the lower range are imposed for a repeat and/or condition-level

deficiency that does not constitute IJ and that is related predominately to structure or process-oriented conditions (such as OASIS submission requirements) rather than directly related to patient care outcomes.

10005.8 – CMP Imposition and IDR in HHAs and Hospices
(New)

Per §488.745 for HHAs and §488.1130, CMS's or the State's failure to complete IDR (as described in section 10002 of this manual) shall not delay the effective date of any enforcement action, including the imposition of CMPs. In those occasions where an IDR may occur after a CMP is imposed, the IDR results will nevertheless be considered in the enforcement action. We specify at §488.745(c) for HHAs and §488.1130(c) for hospices that if any findings are revised or removed by CMS or the State (for surveys conducted by the SA) based on IDR, the CMS-2567 is revised accordingly and any enforcement actions imposed solely because of those cited deficiencies are adjusted accordingly.

10005.9 - Adjustments to Penalties
(Rev.)

CMS has the discretion to increase or reduce the amount of the CMP during the period of noncompliance depending on whether the level of noncompliance changed at the time of a revisit survey.

CMS may increase a CMP based on the following:

- *The HHA's or hospice program's inability or failure to correct deficiencies;*
- *The presence of a system-wide failure in the provision of quality care; or*
- *A determination of IJ with actual harm versus IJ with potential for harm.*

CMS may decrease a CMP to the extent that it finds, pursuant to a revisit, that substantial and sustainable improvements have been implemented even though the HHA or hospice program is not yet in full compliance with the conditions of participation.

10005.10 - Decreased Penalty Amounts
(Rev.)

If a penalty was imposed in the upper range and the IJ is removed or abated but the HHA or hospice program continues to have condition-level noncompliance that is not IJ, CMS will shift the penalty amount imposed per day from the upper range to the middle or lower range based on the conditions that are out of compliance. SAs and CMS Locations should follow the same guidelines above to determine new penalty amount. An earnest effort to correct any systemic causes of deficiencies and sustain improvement must be evident.

10005.11 - Increased Penalty Amounts
(Rev.)

Following the imposition of a lower level penalty amount (either the middle range or the lower range), CMS may increase the per day penalty amount for any condition-level deficiency or deficiencies which become sufficiently serious to pose potential harm or IJ.

CMS increases the per day penalty amount for deficiencies that are not corrected and found again at the time of revisit survey(s) for which a lower level penalty was imposed.

For repeated noncompliance with the same condition-level deficiency or for uncorrected deficiencies from a prior survey, CMS may impose an increased CMP amount.

10005.12 - Accrual and Duration of Per Day Penalty
(Rev.)

Available Sanction/Remedies	***Timeframe for Notice of Imposition***
Civil Money Penalties (CMP)*	*Notice of intent to impose – provided with statement of deficiencies* *Notice includes: the amount of the CMP being imposed, the basis for such imposition and the proposed effective date of the sanction.*

10005.13 - Duration of Per Day Penalty when there is IJ
(Rev.)

The per day CMP would begin to accrue on the last day of the survey that identified the noncompliance and would continue to accrue until the HHA or hospice program achieves substantial compliance with all requirements or the date of termination, whichever occurs first. In the case of noncompliance that poses IJ, CMS must terminate the provider agreement within 23 calendar days after the last date of the survey if the IJ is not removed.

10005.13A - Duration of Penalty when there is no IJ
(Rev.)

In the case of noncompliance that does not pose IJ, the daily accrual of per day CMP is imposed for the days of noncompliance, i.e., from the day the penalty starts (based on the survey completion date and this may be prior to the notice), until the HHA or hospice program achieves substantial compliance based on a revisit or the provider agreement is terminated, but for a period of no longer than 6 months following the last day of the survey.

If the HHA or hospice program has not achieved substantial compliance with all the conditions of participation, CMS will terminate the provider agreement. The accrual of civil

money penalty stops on the day the HHA or hospice program agreement is terminated or the HHA or hospice program achieves substantial compliance, whichever is earlier.

10005.14 – Range of Penalty Amounts - Per Instance
(Rev.)

Penalties imposed per instance of noncompliance may be assessed for one or more singular events or instances of condition-level noncompliance that are identified and where the noncompliance was corrected during the onsite survey. The terminology "per instance" is not used to suggest that only one instance of noncompliance may be the basis to assess a CMP. There can be more than one instance of noncompliance identified during a survey. The current adjusted range for per instance CMPs, as well as the adjusted maximum amount per day, is posted on the CMS website on the Quality, Safety & Oversight Group webpage at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Civil-Monetary-Penalties-Annual-Adjustments.

10005.15 – Accrual and Duration of Per Instance Penalty
(Rev.)

As set forth in §488.845(b)(6) for HHA and §488.1245(b)(6) for hospice programs, a per instance CMP is imposed for each instance of noncompliance based on a deficiency(ies) during a specific survey. It is applied to as many instances as is deemed appropriate and in a specific amount for that deficiency(ies). The current adjusted range for per instance CMPs, as well as the maximum adjusted amount per day, is posted on the CMS website on the Quality, Safety & Oversight Group webpage.

***NOTE:** The per day and per instance CMP would not be imposed simultaneously for the same CoPs in a survey. In no instance will the period of noncompliance be allowed to extend beyond 6 months from the last day of the original survey that determined the HHA's or hospice program's noncompliance. If the HHA or hospice program has not achieved substantial compliance with all the participation requirements within those 6 months, CMS will terminate the HHA or hospice program. The accrual of the per day CMP stops on the day the HHA's or hospice program's provider agreement is terminated or the HHA or hospice program achieves substantial compliance, whichever is earlier.*

***Example:** When the per instance CMP is used on the original survey, the revisit survey is used to determine compliance. If noncompliance is identified at the revisit survey and a CMP is selected as the enforcement remedy/sanction, either the per instance or per day remedy may be selected.*

10005.16 - Accrual and Duration Examples
(Rev.)

a. *Revisit Survey Identifies New Noncompliance and Same Data Tag is Selected - If the same data tag is selected to identify noncompliance, the State (or CMS Location) could choose to utilize either the per instance or per day CMP. It would not matter whether the same data tag was selected to identify the new noncompliance. The issue is whether*

noncompliance is present and whether the deficient practice rises to a level that will support selecting a CMP as a sanction. For example, noncompliance was identified at HHA Tag G406 (Condition of participation: Patient rights) during the original survey. During the revisit survey, a different problem dealing with the patient rights of three patients was cited at Tag G406. The per instance or per day CMP would be selected for the noncompliance identified at Tag G406. If the per instance civil money penalty was used, the amount of the CMP might be influenced by factors relating to the violations of patient rights. However, only one per instance CMP would be appropriate. It would not be appropriate to assign a separate CMP for each of the violations related to patient rights (findings) identified at Tag G406.

b. *Revisit Survey Identifies New Noncompliance and a Different Data Tag is Selected - If a revisit identifies new deficiencies at a different data tag, either a per instance or per day CMP could be selected as a sanction.*

c. *Noncompliance - IJ Does Not Exist (Per Day)- For noncompliance that does not pose IJ, the per day CMP is imposed for the days of noncompliance, i.e., from the day the penalty starts (and this may start accruing as early as the beginning of the last day of the survey that determines the HHA or hospice program was out of compliance), until the HHA or hospice program achieves substantial compliance, or the provider agreement is terminated. However, if the HHA or hospice program has not achieved substantial compliance at the end of 6 months from the last day of the original survey, the CMS Location terminates the provider agreement. The accrual of the CMP stops on the date that the provider agreement is terminated.*

d. *Noncompliance - IJ Does Not Exist (Per Instance)- For noncompliance that does not pose IJ, the per instance CMP is imposed for the number of deficiencies during a survey for which the per instance CMP is determined to be an appropriate sanction. For example, HHA Tag G510 (Condition of participation: Comprehensive assessment of patients) and HHA Tag G370 were cited on a survey. A per instance CMP of $2,000 is imposed for Tag G370 and a per instance CMP of $8,000 is imposed for Tag G510. No civil money penalty could then be imposed for additional deficiencies because the total "per instance CMP" may not exceed $10,000 as adjusted annually for each day of noncompliance.*

e. *Noncompliance - IJ Exists - For noncompliance that poses IJ, CMS must terminate the provider agreement within 23 calendar days after the last day of the survey that identified the IJ if the IJ is not removed. The accrual of the per day CMP stops on the date that the provider achieves substantial compliance, or the provider agreement is terminated.*

10005.17 - Computation and Notice of Total Penalty Amount
(Rev.)

*When a CMP is imposed on a **per day** basis and the HHA or hospice program achieves compliance with the conditions of participation as determined by an onsite revisit survey, CMS sends a final notice to the HHA or hospice program containing all the following information:*

- *The amount of penalty assessed per day.*
- *The total number of days of noncompliance.*
- *The total amount due.*
- *The due date of the penalty.*
- *The rate of interest to be assessed on any unpaid balance beginning on the due date. The rate of interest is the higher of either the rate fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date of the notice of the penalty amount due and this rate is published quarterly in the "Federal Register" by the Department of Health and Human Services under 45 CFR 30.13(a); or the current value of funds rate which is published annually in the "Federal Register" by the Secretary of the Treasury, subject to quarterly revisions. (The CMS Locations are notified by the CMS Office of Financial Management for the rate of interest information.)*
- *Instructions for submitting payment (see also "Method of Payment" section).*

*When a CMP is imposed on a **per day** basis and the HHA's or hospice program's provider agreement has been involuntarily terminated, CMS will send the penalty information, including the total amount of the CMP due, after one of the following actions has occurred:*

- *A final administrative decision is made;*
- *The HHA or hospice program has waived its right to a hearing in accordance with the regulations; or,*
- *The time for requesting a hearing has expired and CMS has not received a hearing request from the HHA or hospice program.*

*When a **per instance** CMP is assessed, a notice is sent to the HHA or hospice program containing all of the following information after the provider is in substantial compliance or its provider agreement has been terminated:*

- *The amount of the penalty or penalties that was assessed;*
- *The total amount due;*
- *The due date of the penalty;*
- *The rate of interest to be assessed on any unpaid balance beginning on the due date. The rate of interest is the higher of either the rate fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date of the notice of the penalty amount due and this rate is published quarterly in the "Federal Register" by the Department of Health and Human Services under 45 CFR*

30.13(a); or the current value of funds rate which is published annually in the "Federal Register" by the Secretary of the Treasury, subject to quarterly revisions. (The CMS Locations are notified by the CMS Division of Financial Management for the annual rate of interest information); and

- *Instructions for submitting payment (see also "Method of Payment" section).*

10005.18 - Notice of Imposition of Civil Money Penalty
(Rev.)

If CMS or the SA imposes a CMP, it provides the HHA or hospice program with written notice of the intent to impose the sanction/remedy, including the amount of the CMP being imposed, the basis for such imposition and the proposed effective date of the sanction/remedy. The notice includes:

I. The nature of the noncompliance (regulatory requirements not met);

II. The statutory basis for the CMP;

III. The amount of the penalty per day of noncompliance or the amount of the penalty per instance of noncompliance during a survey;

IV. The factors that were considered in determining the amount of the CMP;

V. The date on which the per day CMP begins to accrue;

VI. A statement that the per day CMP will accrue until substantial compliance is achieved or until termination from participation in the program occurs.

VII. When the CMP payment is due;

*VIII. **For HHAs only**: Implications of the CMP imposition on the home health aide training and competency evaluation program (see also 42 CFR 484.80(f)).*

IX. Instructions for responding to the notice, including a statement of the HHA's or hospice program's right to a hearing and information about how to request a hearing; and

X. Implications of waiving the right to a hearing and information about how to waive the right to a hearing (see §10013.20 below).

10005.19 - Sending the Notice
(Rev.)

The notice of CMP imposition shall be in writing and shall be addressed directly to the HHA or hospice program, or to an individual, an officer, managing or general agent, or other agent authorized by appointment or law to receive the notice.

The notice shall be dispatched through first-class mail, or other reliable means. Other reliable means refers to the use of alternatives to the United States mail in sending notices. Electronic communication, such as facsimile transmission or email, is equally reliable and on occasion more convenient than the United States mail. If electronic means are employed to send notice, the sender should maintain a record of the transmission to assure proof of transmission if receipt is denied.

It should be noted that in cases where the State is authorized by the CMS location, the State may send the initial notice of imposition of certain sanctions on CMS's behalf, within applicable notice requirements.

10005.20 - Appeal of Noncompliance That Led to Imposition of Civil Money Penalty

(Rev.)

Before collecting a CMP, section 1128A of the Act requires the Secretary (CMS) to conduct a hearing when properly requested by the HHA or hospice program pursuant to §498.40. An HHA or hospice program may request a hearing with the Administrative Law Judge (ALJ) on the determination of the noncompliance that is the basis for imposition of the CMP.

The procedures to request a hearing specified in 42 C.F.R. § 498.40 are followed when CMS imposes a CMP on an HHA or hospice program. Once an appeal hearing is requested, CMS cannot collect the CMP until a final agency determination. Additional procedures are set forth at 42 CFR 488.845(h) for HHA and at 42 CFR 488.1245(g) for hospice programs. Per these regulations, when an ALJ or state hearing officer (or higher administrative review authority) finds that the basis for imposing a CMP exists, the reviewing authority may not— (1) Set a penalty of zero or reduce a penalty to zero; (2) Review the exercise of discretion by CMS to impose a CMP; and (3) Consider any factors in reviewing the amount of the penalty other than those specified at §488.845(b) for HHA or §488.1245(b) for hospice programs.

10005.20A – HHA or Hospice Program Waives Right to a Hearing

(Rev.)

An HHA or hospice program may waive the right to a hearing, in writing, within 60 days from the date of the notice imposing the CMP. If an HHA or hospice program timely waives its right to an appeal hearing within 60 calendar days of their receipt of CMS' notice imposing the CMP, CMS will approve the waiver and reduce the CMP by thirty five percent (35%). Payment of the reduced CMP must be made within 15 days of the HHA's or hospice program's receipt of CMS's notice approving the waiver and reducing the CMP. If the HHA or hospice program does not waive its right to an appeal hearing in writing within 60 calendar days of their receipt of CMS original request for payment under §488.845(c)(2)(ii) for HHA and §488.1245(c)(2)(ii) for hospice programs, it will not receive the CMP reduction.

NOTE: *Each time a survey is conducted within an already running noncompliance cycle and a CMP is imposed, the HHA or hospice program is given appeal rights and may exercise its waiver of right to a hearing.*

When a per day CMP is imposed and then is increased or decreased at subsequent surveys during an already running noncompliance cycle, an HHA or hospice program may elect to either appeal each separate CMP imposition or waive the right to appeal each imposition. Each CMP imposition is computed separately for a set number of days. The final CMP amount is established after the final administrative decision.

Example: *An HHA is cited on the original recertification survey for non-compliance with 42 CFR 484.60 Condition of participation: Care planning, coordination of services, and quality of care. Findings include evidence that the HHA did not follow the plan of care, the plan of care did not include all pertinent diagnoses, and the HHA failed to notify the physician of changes in the patient's condition. On the first revisit survey, the incidence of these deficiencies increased. On both surveys, the condition is cited as out of compliance and CMPs are imposed. The CMP will be increased following the revisit survey. The HHA may choose to appeal one or both citations, or waive one or both citations, or waive one citation and appeal the other.*

When several per instance CMPs are imposed during a noncompliance cycle, an HHA or hospice program may choose to appeal or waive the right to appeal one or more of the CMPs, in the same manner as illustrated above for the per day CMPs.

After the facility achieves substantial compliance or its provider agreement is terminated, it is notified of the revised CMP amount due.

10005.21 - When a CMP is Due and Payable
(Rev.)

In accordance with HHA (42 CFR 488.845(f)) and hospice program (42 CFR 488.1245(f)) regulations, payments are due for all CMPs within 15 days from any of the following:

- *After a final administrative decision when the HHA or hospice program achieves substantial compliance before the final decision or the effective date of termination before final decision,*
    - *A final administrative decision includes an ALJ decision and review by the Departmental Appeals Board, if the HHA or hospice program requests a review of the ALJ decision.*
- *After the time to appeal has expired and the HHA or hospice program does not appeal or fails to timely appeal the initial determination,*
- *After CMS receives a written request from the HHA or hospice program requesting to waive its right to appeal the determinations that led to the imposition of a CMP,*

- *After substantial compliance is achieved, or*

- *After the effective date of termination.*

Note: *The regulations at §488.845 for HHA and §488.1245 for hospice programs do not include a provision for extended payment plans for HHA or hospice program CMPs.*

An HHA or hospice program has two options for action following the imposition of a CMP:

- *The HHA or hospice program could pay the amount due for all CMPs imposed prior to the date a CMP is due and payable; or*

- *The HHA or hospice program could request a hearing based on the determination of noncompliance with Medicare CoPs.*

When an HHA or hospice program provides timely notice waiving its right to a hearing, CMS reduces the final CMP amount by 35%. This reduction is reflected once the CMP stops accruing, that is, when the HHA or hospice program achieves substantial compliance before CMS receives its request to waive a hearing, or the effective date of the termination occurs before CMS received the waiver request.

Impact of Hearing Requests:
Within 60 days of receipt of the notice of imposition of a penalty, the HHA or hospice program may file a request directly to the Departmental Appeals Board in the Office of the Secretary, Department of Health and Human Services with a copy to the State and CMS. In accordance with §498.40(b), the HHA's or hospice program's appeal request would identify the specific issues of contention, the findings of fact and conclusions of the law with which the HHA or hospice program disagreed, and the specific basis for contending that the survey findings and determinations were invalid. A hearing would be completed before any penalty was collected. However, sanctions/remedies would continue regardless of the timing of any appeals proceedings if the HHA or hospice program had not met the CoPs.

Requesting an appeal would not delay or end the imposition of a sanction/remedy but can only affect the collection of any final CMP amounts due. A CMP would begin to accrue on the last day of the survey which identified the noncompliance. These include penalties imposed on a per day basis, as well as penalties imposed per instance of noncompliance.

10005.22 - Method of Payment
(Rev.)

HHAs and hospices may select one of the following payment options: (1) Pay.gov; or (2) Electronic transfer of funds. CMS Office of Financial Management (OFM) prefers the use of Pay.gov because it is the federal government's secure portal for web-based collection and billing services which has been implemented by OFM to collect any money due to CMS. Questions

related to use of pay.gov, please contact the OFM's Division of Collections via email at OFMDPBCCMPGeneralMailBox@cms.hhs.gov.

HHAs and hospices are not to send CMP payment checks to the CMS Locations. If an HHA or hospice requests to pay by check, it will be considered on a case-by-case basis with collaboration from the CMS Location's division of financial management.

10005.23 - Settlement of Civil Money Penalty
(Rev.)

The CMS Location has the authority to settle CMP cases at any time prior to a final administrative decision. If a decision is made to settle, the settlement should not be for a better term than had the HHA or hospice program opted for a 35 percent reduction.

10005.24 - Offsets
(Rev.)

If payment was not received by the established due date, CMS will collect the CMP through offset of monies then owed or later owing to the HHA or hospice program. To initiate such an offset, CMS will instruct the appropriate Medicare Administrative Contractors (MAC), when applicable, the State Medicaid agencies, to deduct unpaid CMP balances from any money owed to the HHA or hospice program. To maintain consistency in recovering a CMP among other types of providers who are subject to a CMP, the amount of any penalty can be deducted (offset) from any sum CMS or the State Medicaid Agency owes to the HHA or hospice program.

Interest would be assessed on the unpaid balance of the penalty beginning on the due date. The rate of interest assessed on any unpaid balance would be based on the Medicare interest rate published quarterly in the Federal Register, as specified in §405.378(d). CMS Locations are notified by CMS OFM of the current interest rate and any changes.

10005.25 - Debt Referral to the Department of the Treasury via the Debt Collection System
(New)

Those CMP amounts not recovered due to HHA or hospice program failure to pay or inadequate funds for offset will be collected through the Debt Collection Improvement Act of 1996 which requires all debt owed to any Federal agency that is more than 180 days delinquent to be transferred to the Department of the Treasury for debt collection services. Prior to initiating a CMP debt referral to the Department of the Treasury, the CMS Location must first exhaust all collection options through the MAC and the State Medicaid Agency.

The Debt Collection System (DCS) is the data system that is used by the Division of Medicare Debt Management (DMDM) in OFM to transmit debt referrals to the Department of the Treasury via the Program Support Center (PSC), a separate component within the Department of Health and Human Services.

10005.26 - Disbursement of Recovered CMP funds
(Rev.)

The CMP amounts and any corresponding interest recovered from HHAs, and hospice programs will be divided between the Medicare and Medicaid programs, based on a proportion that is commensurate with the comparative Federal expenditures under Titles XVIII and XIX of the Act, using Medicaid Statistical Information System (MSIS) and HHA or hospice program Prospective Payment System (PPS) data for a three-year fiscal period. The amounts are disbursed in accordance with § 488.845(g). Penalty funds may not be used for survey and certification operations nor can they be used as the State's Medicaid non-Federal medical assistance or administrative match. The CMS Locations are not responsible for disbursement of recovered CMP funds.

10006 - Suspension of Payment for All New Medicare Admissions
(Rev.)

10006.1 - Introduction
(Rev.)

Suspension of payment for all new Medicare admissions is conducted in accordance with §488.840 for HHA or §488.1240 for hospice programs when the provider is not in substantial compliance with the CoPs. The SA should consider recommending this sanction/remedy for deficiencies related to poor patient care outcomes, regardless of whether cited deficiencies pose IJ to patient health and safety. Suspension of payment for new admissions is likely to be the most effective sanction/remedy to influence rapid change to facilitate compliance with the CoPs and may be imposed alone or in combination with other sanctions/remedies.

10006.2 - Notice of Sanction
(Rev.)

Suspension of payment for new Medicare admissions may be imposed anytime an HHA or hospice program is found to be out of substantial compliance, as long as the HHA or hospice program is given written notice at least 2 calendar days before the effective date in IJ situations and at least 15 calendar days before the effective date in non-IJ situations. The notice of suspension of payment for new admissions must include the following: the nature of the non-compliance; the effective date of the sanction/remedy; and the right to appeal the determination leading to the sanction. In addition to notifying the HHA or hospice program of this proposed sanction/remedy, CMS will also notify the State Medicaid Agency, if applicable.

For HHAs Only: *Please note that the imposition of suspension of payment for new admissions on an HHA would prohibit that HHA from conducting health aide training and competency evaluation program for 2 years from the date this sanction is imposed (see also 42 CFR 484.80(f)). See Appendix B of the State Operations Manual for additional information for eligible home health aide training and competency evaluation organizations at §484.80(f).*

10006.3 - Effect of Sanction/Remedy on Patients Admitted before the Effective Date of Sanction/Remedy
(Rev.)

The patient's status on the effective date of the suspension of payment sanction/remedy is the controlling factor. This sanction/remedy would not apply to patients who have been receiving care from the HHA or hospice program before the effective date of this sanction/remedy. This sanction/remedy would apply only to new Medicare admissions. CMS will suspend payments for new Medicare patient admissions to the HHA or hospice program that are made on or after the effective date of the imposition of the sanction/remedy for the duration of the sanction/remedy. Payments for individuals who are already receiving services could continue. CMS defines a "new admission" as the following:

- *A patient who is admitted to the HHA or hospice program under Medicare on or after the effective date of a suspension of payment sanction/remedy; or*

- *A patient who was admitted and discharged before the effective date of the suspension of payment and is readmitted under Medicare on or after the effective date of suspension of payment sanction/remedy.*

As part of this sanction/remedy, the HHA or hospice program would be required to notify any new patient admission, before care is initiated, of the fact that Medicare payment would not be available to this HHA or hospice program because of the imposed suspension. The HHA or hospice program would be precluded from charging the Medicare patient for those services unless it could show that, before initiating the care, it had notified the patient or representative both orally and in writing in a language that the patient or representative can understand that Medicare payment is not available.

The suspension of payment sanction/remedy will end when CMS finds that the HHA or hospice program is in substantial compliance with all the CoPs or when the HHA or hospice program is terminated. That is, the suspension of payment sanction/remedy would end when the HHA or hospice program has corrected all condition-level deficiencies, and the correction has been verified by the SA. Any Medicare patients admitted during the suspension of payment period would require a new start of care (SOC) date after the suspension of payment for new admissions has ended. This is required for the HHA or hospice program to begin receiving payments for those patients.

10006.4 - Duration
(Rev.)

The suspension of payment would end when CMS terminates the provider agreement or when CMS finds the HHA or hospice program to be in substantial compliance with all of the CoPs. No payments are made to reimburse the HHA or hospice program for the time between the date the sanction/remedy was imposed and the date that substantial compliance was achieved. CMS accomplishes the suspension of payment sanction/remedy through written instructions to the appropriate MAC. The CMS Location will send the letter with instructions to the MAC

indicating the beginning or ending date of the payment suspension. Generally, if the HHA or hospice program achieves substantial compliance and it is verified by CMS, CMS will resume payments to the HHA or hospice program prospectively from the date it determines that substantial compliance was achieved.

If CMS terminates the provider agreement or determines that the HHA or hospice program is in substantial compliance with the CoPs, the HHA or hospice program would not be able to recoup any payments for services provided to Medicare patients admitted during the time the suspension was in place.

10007 - Temporary Management
(Rev.)

10007.1 – Introduction, Purpose & Imposition
(Rev.)

Temporary management is established in accordance with §488.835 for HHAs and §488.1235 for hospice programs. The following situations should be used as a general guide for imposing temporary management when:

- *CMS determines the failure to comply with the CoPs is directly related to management limitations, or*
- *Deficient management oversight that is likely to impair the HHA's or hospice program's ability to correct deficiencies and return the HHA or hospice program to full compliance within the necessary timeframe, and*
- *When needed, based on the above situations, to oversee orderly involuntary termination/closure of an HHA or hospice program including the proper and safe transfer of patients to another local HHA or hospice program.*

Notice of intent to appoint a temporary manager must be given at least 15 calendar days before the effective date of the enforcement action. When there is an IJ, notice of intent must be given at least two calendar days before the effective date of the enforcement action. The notice of intent from CMS provides the intent to impose the enforcement action, the statutory basis for the enforcement action, the nature of the noncompliance, the proposed effective date of the enforcement action, and the appeal rights. The final notice will be provided once the administrative determination is final.

***For HHAs only:** Please note that the imposition of temporary management on an HHA would prohibit that HHA from conducting health aide training and competency evaluation program for 2 years from the date this sanction is imposed (see also 42 CFR 484.80(f)). See Appendix B of the State Operations Manual for additional information for eligible home health aide training and competency evaluation organizations at §484.80(f).*

The maximum period for use of the temporary manager is six months. It is the temporary manager's responsibility to oversee correction of the deficiencies and assure the health and safety of the HHA's or hospice program's patients while the corrections are being made. An HHA or hospice program that fails to relinquish authority and control to a temporary

manager will have its provider agreement terminated in accordance with §488.865 (HHA) or §488.1265 (Hospice).

10007.2 - Selection of Temporary Manager
(Rev.)

Each SA should compile a list of individuals who are eligible to serve as temporary managers. When CMS decides to impose this sanction or remedy, it considers the SA's recommendation for a temporary manager whose work experience and education qualify the individual to oversee the correction of deficiencies to achieve substantial compliance. The temporary manager must have the experience and education that qualifies the individual to oversee the HHA or hospice program. The temporary manager can be either internal or external to the HHA/hospice program and will be appointed by CMS or the SA based on qualifications described in §§ 484.105(b) and 484.115 for HHAs and §§ 418.100 and 418.114 for hospice programs. The SA should reject a candidate who has demonstrated difficulty maintaining compliance in the past.

10007.3 – Authority and Conditions of Temporary Management
(Rev.)

CMS notifies the HHA or hospice program that a temporary manager is being appointed. The temporary manager must have the authority to hire, terminate, or reassign staff; obligate the provider's funds; alter provider policies and procedures; and otherwise manage an HHA or hospice program to correct deficiencies identified in the provider's operation. The HHA's or hospice program's management must agree to relinquish authority and control to the temporary manager and to pay his/her salary before the temporary manager can be installed in the HHA or hospice program. A contract or memorandum of understanding should be completed between the temporary manager and the HHA or hospice program prior to the temporary manager beginning any work or incurring any costs. Failure to relinquish authority and control to the temporary manager will result in termination of the HHA or hospice program.

The HHA or hospice program cannot retain final authority to approve changes of personnel or expenditures of HHA or hospice program funds and be considered to have relinquished control to the temporary manager. The temporary manager must be given access to all HHA or hospice program bank accounts. If the HHA or hospice program does not relinquish control to the temporary manager and/or provide access to bank accounts and available assets, the HHA or hospice program will be terminated. It should be noted that the HHA's or hospice program's governing body remains ultimately responsible for achieving compliance. The responsibility does not transfer to the temporary manager, SA, or CMS.

The temporary manager's salary must be at least equivalent to the prevailing annual salary of HHA or hospice program administrators in the HHA's or hospice program's geographic area based on the bureau of labor statistics, plus any additional costs that would have reasonably been incurred by the HHA or hospice program if the temporary manager had been in an employment relationship, e.g., the cost of a benefits package, prorated for the amount of time that the temporary manager spends in the HHA or hospice program. The

HHA or hospice program is also responsible for any other costs incurred by the temporary manager in furnishing services under such an arrangement or as otherwise set by the State. Failure to pay the salary and other costs is considered a failure to relinquish authority and control to temporary management and will result in termination of the provider agreement.

The State should provide the temporary manager with an appropriate orientation that includes a review of the HHA's or hospice program's deficiencies and compliance history. The State may request that the temporary manager periodically report on the actions taken to achieve compliance and, on the expenditures associated with these actions.

10007.4 - Duration of Temporary Management
(Rev.)

Temporary management continues until an HHA or hospice program is terminated by CMS, or achieves substantial compliance via an onsite survey, and is capable of remaining in substantial compliance, or decides to discontinue the sanction/remedy and reassume management control before it has achieved substantial compliance. If the HHA or hospice program reassumes control before achieving substantial compliance, CMS would initiate termination of the provider agreement and could impose additional sanctions or remedies during the time period between HHA or hospice program resumption of management and termination. Temporary management will not exceed six months from the date of the survey identifying noncompliance.

10008 - Directed Plan of Correction (DPOC)
(Rev.)

10008.1 – Purpose
(Rev.)

The purpose of the DPOC is to achieve correction and continued compliance with Federal requirements. A DPOC is a plan that the State, with CMS Location approval, or the CMS Location develops to require an HHA or hospice program to take corrective action to achieve specific outcomes within specified time frames. The requirements for DPOC are specified at §488.850 for HHA and §488.1250 for hospice programs.

10008.2 - Imposition of a Directed Plan of Correction
(Rev.)

Whether the facility has standard-level or condition-level deficiencies, an HHA or hospice program must submit an acceptable plan of correction to CMS. If the HHA or hospice program is unable to develop an acceptable plan of correction, CMS may impose a DPOC for condition level deficiencies. CMS must provide written notification of the intent to impose a DPOC sanction/remedy.

Notice of intent to impose a DPOC must be given at least 15 calendar days before the effective date of the enforcement action in non-IJ situations and at least 2 calendar days before the

effective date in IJ situations. The date the DPOC is imposed, that is, the date the sanction/remedy becomes effective, does not mean that all corrections must be completed by that date.

10008.3 - Elements of a Directed Plan of Correction
(Rev.)

A DPOC should address all of the elements required for an HHA- or hospice program-developed plan of correction. These elements include, but are not limited to, the following:

I. *How an HHA or hospice program will correct each deficiency;*
II. *How the HHA or hospice program will act to protect patients in similar situations;*
III. *How the HHA or hospice program will ensure that each deficiency does not recur;*
IV. *How the HHA or hospice program will monitor performance to sustain solutions; and*
V. *The timeframe in which corrective actions will be taken.*

10008.4 - Achieving Compliance
(Rev.)

Achieving compliance is the HHA's or hospice program's responsibility, whether or not a DPOC is followed. If the HHA or hospice program fails to achieve compliance within the timeframes specified in the DPOC, CMS may impose one or more additional alternative sanctions/remedies until the HHA or hospice program achieves compliance or is terminated from the Medicare program.

10009 - Directed In-Service Training
(Rev.)

10009.1 – Purpose & Imposition
(Rev.)

Directed in-service training may be used when the State, CMS, or the temporary manager believes that education is likely to correct the deficiencies and help the HHA or hospice program achieve substantial compliance. The requirements for directed in-service training are specified at §488.855 for HHA and §488.1255 for hospice programs.

Directed in-service training requires the staff of the HHA or hospice program to attend a specific in-service training program(s). The purpose of directed in-service training is to provide knowledge to achieve and remain in compliance with Federal requirements. For example, in circumstances where some, but not all, compliance problems are a result of a lack of knowledge on the part of the health care provider relative to advances in health care technology and expectations of favorable patient outcomes, directed in-service training would benefit the agency. Also, directed in-service could be used in situations where staff performance results in deficient practice. A directed in-service training program would correct

this deficient practice through retraining the staff in the use of clinically and professionally sound methods to produce quality outcomes.

Notice of intent to impose directed in-service training must be given at least 15 calendar days before the effective date of the enforcement action in non-IJ situations and at least 2 calendar days before the effective date in IJ situations.

10009.2 - Appropriate Resources for Directed In-Service Training Programs
(Rev.)

HHAs or hospice program should use programs developed by well-established centers of health education and training such as continuing education programs offered by schools of medicine, nursing, public health, community colleges, state health departments, centers for the aging, and other available area centers which have established continuing education programs for health professionals. The programs may also be conducted by consultants with background in education and training with Medicare HHA or hospice program providers, as applicable, or as deemed acceptable by CMS and/or the SA (by review of a copy of the curriculum vitas and/or resumes/references in order to determine the educator's qualifications). The SA or CMS Location may also compile a list of resources that can provide directed in-service training and may make this list available to HHAs or hospice programs.

10009.3 - Further Responsibilities
(Rev.)

The HHA or hospice program bears the expense of the directed in-service training for its staff. After the training has been completed, the SA will assess whether substantial compliance has been achieved. If directed in-service training was the sanction imposed and the HHA or hospice program does not achieve substantial compliance, CMS may impose one or more additional sanctions/remedies as specified at §488.820 for HHA or at §488.1220 for hospice programs.

Hospice Certification / Recertification Requirements

CMS Medicare Benefit Policy Manual (Pub. 100-02), chapter 9 PDF, section 20.1

To be eligible to elect hospice care under Medicare, an individual must be entitled to Medicare Part A benefits and certified as terminally ill. An individual is considered to be terminally ill if the medical prognosis is that the individual's life expectancy is 6 months or less if the illness runs its normal course.

Timeframe for Certification/Recertification

The hospice must obtain, no later than 2 calendar days (that is, by the end of the third day), and after the start of each benefit period an oral or written certification of the terminal illness. Initial certifications may be completed up to 15 days before hospice care is elected. For the subsequent periods, recertifications may be completed up to 15 days before the next benefit period begins.

If the hospice cannot obtain written certification within 2 calendar days, it must obtain oral certification within 2 calendar days. When making an oral certification, the certifying physician(s) should state that the patient is terminally ill, with a prognosis of 6 months or less. In addition, the hospice must ensure the written certification/recertification is signed and dated prior to billing Medicare, or their claim(s) may be denied.

Content of the Certification/Recertification

Section 1814(a)(7) of the Social Security Act (the Act) specifies that certification of terminal illness for hospice benefits shall be based on the clinical judgment of the hospice medical director or physician member of the interdisciplinary group (IDG) and the individual's attending physician, if he/she has one, regarding the normal course of the individual's illness. Nurse practitioners and physician assistants cannot certify or re-certify an individual as terminally ill. In the event that a beneficiary's attending physician is a nurse practitioner or a physician assistant, the hospice medical director or the physician member of the hospice IDG certifies the individual as terminally ill. In addition to the initial certification for hospice, the patient must be recertified for each subsequent hospice benefit period.

The written certification/recertification must include:

- The statement that the individual's medical prognosis is that their life expectancy is 6 months or less if the terminal illness runs its normal course
- The physician's brief narrative explanation of the clinical findings that supports a life expectancy of 6 months or less as part of the certification and recertification forms, or as an addendum to the certification and recertification forms
  - If the narrative is part of the certification or recertification form, then the narrative must be located immediately above the physician's signature.
  - If the narrative exists as an addendum to the certification or recertification form, in addition to the physician's signature on the certification or recertification form, the physician must also sign immediately following the narrative in the addendum.
  - The narrative must reflect the patient's individual clinical circumstances and cannot contain check boxes or standard language used for all patients. The physician must synthesize the patient's comprehensive medical information in order to compose this brief clinical justification narrative.
  - The narrative shall include a statement directly above the physician signature attesting that by signing, the physician confirms that he/she composed the narrative based on his/her review of the patient's medical record or, if applicable, his or her examination of the patient. The physician may dictate the narrative.
- The signature(s) of the physician(s), the date signed, and the benefit period dates that the certification or recertification covers (for more on signature requirements, see the CMS Medicare Program Integrity Manual (Pub. 100-08), chapter 3 PDF, section 3.3.2.4).
- For recertifications on or after January 1, 2011, the narrative associated with the third benefit period recertification and every subsequent recertification must include an explanation of why the clinical findings of the face-to-face encounter support a life expectancy of 6 months or less. Documentation must include the date of the encounter, an attestation by the physician or nurse practitioner that he/she had an encounter with the beneficiary. If the encounter was done by a nurse practitioner, he/she must attest that clinical findings were provided to the certifying physician.

Signature Requirements for Certification

- CMS Medicare Benefit Policy Manual (Pub. 100-02), chapter 9 PDF, section 20.1
- CMS Medicare Program Integrity Manual (Pub. 100-08), chapter 3 PDF, section 3.3.2.4

Acceptable signatures

- Handwritten signatures
- Electronic signatures
- Facsimile of original written or electronic signatures

NOTE: All signatures must be dated. Handwritten signatures must be hand dated.

Unacceptable signatures

- Stamped signatures

Signatures for Initial Certifications

For the first benefit period after election of the Medicare hospice benefit, the certification must be signed and dated by the:

- Medical director of the hospice or the physician member of the hospice interdisciplinary group (IDG); and

- The beneficiary's attending physician (if they have one).

Note: To sign the certification, the attending physician must be a Doctor of Medicine or osteopathy and be identified by the beneficiary at the time he/she elects to receive hospice care as having the most significant role in the determination and delivery of the individual's medical care.

Signatures for Recertifications

For the recertification (and subsequent hospice benefit periods), only the hospice medical director or the physician member of the IDG is required to sign and date the certification. The beneficiary's attending physician is not required to sign and date the recertification.

Face-to-Face Encounter

For recertifications on or after January 1, 2011, a hospice physician or hospice nurse practitioner must have a face-to-face encounter with each hospice patient prior to the beginning of the patient's third benefit period, and each subsequent benefit period.

Face-to-Face Timeframe

The encounter must occur no more than 30 calendar days before the third benefit period recertification and each subsequent recertification.

Timeframe exceptional circumstances

For new hospice admissions in the third or later benefit period: In cases where a hospice newly admits a patient who is in the third or later benefit period, exceptional circumstances may prevent a face-to-face encounter prior to the start of the benefit period.

An emergency weekend admission and the patient cannot be seen by the hospice physician or the nurse practitioner (NP) until the following Monday.

Unavailable CMS data systems resulting in the inability for the hospice to determine if the patient is in the 3rd benefit period.

In addition, if the patient dies within 2 days of admission, a FTF encounter is considered to be complete.

Untimely Face-to-Face Encounter

When a required face-to-face (FTF) encounter does not occur timely, the beneficiary is no longer certified as terminally ill, and therefore, is not eligible for the Medicare hospice benefit. In these cases, the hospice must discharge the beneficiary from the Medicare hospice benefit because he/she is no longer considered terminally ill for Medicare purposes. When a discharge occurs due to failure to perform a required FTF encounter timely, the claim should include appropriate billing information. For additional information about how to bill correctly, refer to the CGS "Untimely Face-To-Face Encounter" Web page.

Who Performs and Signs the FTF Encounter

The FTF encounter must be performed by a hospice physician or a hospice NP. The hospice physician must be employed by the hospice, a volunteer, or working under contract. The hospice NP must be employed by the hospice (receives a W-2 form from the hospice or volunteers for the hospice). Physician Assistants (PAs), clinical nurse specialists, and outside attending physicians are not authorized by section 1814(a)(7)(D)(i) of the Act to perform the face-to-face encounter for recertification.

FTF Requirements

The hospice physician or NP must attest in writing that he or she had a FTF encounter with the patient, including the date of the encounter. The attestation, which must be a separate and distinct part of the recertification, or as an addendum to the recertification associated with the 3rd benefit period, must meet the following criteria:

- Clearly titled
- Accompanying signature, and date signed by the individual who performed the visit
- Date of the visit
- Clinical findings to determine continued hospice eligibility
- When the hospice NP/non-certifying physician performs the FTF, the attestation must also state that the clinical findings were provided to the certifying physician.

Billing Responsibilities

Before submitting claims to CGS, hospice agencies should ensure:

- All FTF requirements are met; and
- The written certification, including the narrative and FTF, is signed prior to billing the claim.

Additional Resources

- CMS Medicare Benefit Policy Manual (Pub. 100-02), chapter 9 PDF, §20.1
- CMS Medicare Claims Processing Manual (Pub. 100-04), chapter 11 PDF, § 30.3
- November 17, 2010 "Home Health Prospective Payment System Rate Update for Calendar Year 2011 PDF" Final Rule, Pgs. 70435-70454
- August 4, 2011, "Medicare Program: Hospice Wage Index for Fiscal Year 2012" Final Rule PDF"
- "Hospice Face-to-Face (FTF) Encounters for Recertification PDF" Quick Resource Tool

Common Hospice Certification Errors

Medicare cannot make appropriate payment without correct dates, signatures and identifying roles of the physician(s). The following list identifies the common types of missing and inadequate information:

- Predating physician(s) certification signatures.
- Not having both the hospice medical director and attending physician (if applicable) sign the initial certification as required.
- The physician's narrative is missing.
- The physician's narrative does not include a statement attesting that it was composed by the physician.
- The attestation statement is missing.
- Not having verbal certifications by both the medical director and attending physician (if applicable).
- No physician(s) signatures.
- Illegible physician signatures.
- Physician did not date his/her signature.
- Not clearly stating the dates the certification period encompasses.

mln MATTERS®
KNOWLEDGE • RESOURCES • TRAINING

Hospice Claims Edits for Certifying Physicians

Related CR Release Date: September 13, 2024	MLN Matters Number: MM13531 Revised
Effective Date: June 3, 2024	Related Change Request (CR) Number: CR 13531
Implementation Date: October 7, 2024, for all BRs except 13531.3, 13531.3.1, and 13531.4; November 18, 2024, for remaining BRs	Related CR Transmittal Number: R12847CP

Related CR Title: Additional Implementation Edits on Hospice Claims for Hospice Certifying Physician Medicare Enrollment

What's Changed: We added an exception to the edit logic for when a nurse practitioner or physician assistant is serving as an attending. We also revised the CR implementation date, CR release date, transmittal number, and CR link. Substantive content changes are in dark red.

Affected Providers

- Hospices
- Physicians and other providers billing Medicare Administrative Contractors (MACs) for hospice services they provide to Medicare patients

Action Needed

Make sure your billing staff knows about these updates effective June 3, 2024:

- We pay for hospice services if certifying physicians, including hospice physicians and hospice attending physicians, are enrolled in or opted-out of Medicare
- We subject the hospice attending and certifying physicians to ordering and referring denial edits except if the designated attending is a nurse practitioner (NP) or a physician assistant (PA)
- Updates to Sections 20 and 30 in the Medicare Claims Processing Manual, Chapter 11

Background

We're making sure certifying physicians, including hospice physicians and hospice attending physicians, are enrolled in or opted-out of Medicare before paying for their hospice services. This requirement is in the FY 2024 Hospice Payment Rate Update Final Rule.

CMS CENTERS FOR MEDICARE & MEDICAID SERVICES
Medicare Learning Network®
422

We'll deny hospice claims if the certifying physician, including hospice physician and hospice attending physician, isn't on our PECOS hospice ordering and referring files. This addresses hospice program integrity and quality of care per Section 6405 of the Affordable Care Act.

We're implementing these changes on October 7, 2024, unless noted in CR 13531. For claims you submit on or after October 7, 2024, with dates of service as of June 3, 2024, or later, we'll check the REF PHYS NPI field and the ATT PHYS NPI field on hospice claims to make sure the certifying physicians, including hospice physicians and hospice attending physicians, are enrolled in or opted-out of Medicare. We'll subject both physicians, if different, to the ordering and referring denial edits for the initial certification period. If an NP or a PA is serving as the designated attending, we will only subject the certifying physician in the REF PHYS NPI field to the ordering and referring denial edits.

If the certifying or recertifying physician and the attending physician are the same individual, we apply the edits only to the "Attending" field.

For subsequent certifications, if both physicians are listed, we'll check the REF PHYS NPI field for the certifying physician. You should enter the attending physician in the ATT PHYS NPI field and the certifying physician in the REF PHYS NPI field. If the patient doesn't have an attending physician, you should report the hospice certifying or recertifying physician in the ATT PHYS NPI field.

CR 13531 also makes the following changes for claims reporting to Section 20.1.1 of the Medicare Claims Processing Manual, Chapter 11:

- Attending Physician I.D. – The hospice enters the name and provider identifier of the attending physician designated by the patient at the time of election as having the most significant role in the determination and delivery of the patient's medical care. The patient's designated attending physician could be an independent physician, a hospice physician, an NP, or a PA. If there is no attending physician listed, then the hospice shall report the hospice certifying or recertifying physician.
- Other Physician I.D. – A hospice enters the name and NPI of the hospice physician responsible for certifying or recertifying that the patient is terminally ill, with a life expectancy of 6 months or less if the disease runs its normal course. For electronic claims, this information is reported in Loop ID 2310F – Referring Provider Name. You should complete both the attending physician and other physician fields unless the patient's designated attending physician is the same as the physician certifying or recertifying the terminal illness. When the attending physician is also the physician certifying or recertifying the terminal illness, then you should only populate the attending physician field; the other physician field isn't required.

More Information

We issued CR 13531 to your MAC as the official instruction for this change. For more information, find your MAC's website.

Document History

Date of Change	Description
September 19, 2024	We added an exception to the edit logic for when a nurse practitioner or physician assistant is serving as an attending. We also revised the CR implementation date, CR release date, transmittal number, and CR link.
May 14, 2024	We revised the effective date and the web address of CR 13531. We also added coding information for the referring provider name on page 2.
April 18, 2024	Initial article released.

Hospice Certifying Enrollment

Questions and Answers (Q & A) Document

September 19, 2024

NOTE: In the event of any inconsistency, the policies in this Q & A document supersede those in the March 26, 2024, Medicare Learning Network update regarding the hospice certifying requirement at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-NetworkMLN/MLNProducts/html/medicare-payment-systems.html#Hospice.

Q: What is the hospice certifying requirement?

A: Starting June 3, 2024, under Section 6405 of the Affordable Care Act, the following physicians must be enrolled in or opted-out of Medicare for the service to be paid:

1. Hospice medical director or the physician member of the hospice interdisciplinary group who certifies the patient's terminal condition (hereafter occasionally referenced as "hospice physician").
2. Patient-designated attending physician (if they have one) who certifies their terminal condition. The attending physician must meet the definition of "physician" specified in 42 CFR § 410.20(b).

Under 42 CFR § 418.22(c), these two categories of physicians must initially certify the patient's terminal condition. For subsequent coverage periods, only the hospice physician must certify the patient's terminal condition.

Q: Does this new requirement change who can certify for hospice services?

A: Except for the new enrollment or opt-out requirement, nothing is changing under 42 CFR § 418.22 regarding who may certify the patient's terminal illness.

Q: If the physician is enrolling in Medicare to satisfy the new requirement, which enrollment form should be submitted?

A: Unless the physician is planning to also bill Medicare for Part B services (in which case the Form CMS-855I should be submitted), he/she should submit the Form CMS-855O. In other words, if the physician is enrolling solely to certify hospice services under § 418.22(c) and will not bill Medicare for services furnished, the Form CMS-855O should be submitted.

Q: To further clarify the prior Q/A, is a physician (Physician X) employed by or under contracted with a hospice and not performing any services outside of the hospice ineligible for enrollment via the Form CMS-855I or the Form CMS-855O?

A:

- Form CMS-855I - If Physician X will not bill Medicare Part B for services and only Part A hospice services are involved, he/she cannot enroll via the Form CMS-855I.

- Form CMS-855O – Since Form CMS-855O enrollment is for physicians who wish to order/certify services (including providing the § 418.22(c) certifications) but do not intend to bill Medicare for services, Physician X can enroll via the Form CMS-855O.

Q: What, if anything, do currently enrolled or opted-out physicians need to do regarding this requirement?

A: If the physician is currently enrolled or opted-out, the physician does not need to do anything. The physician already meets the enrollment/opt-out requirement. In addition, it is unnecessary for the physician to have designated "hospice" as their specialty on their enrollment application. If the physician is enrolled or opted-out, they meet the new enrollment/opt-out requirement regardless of the specialty listed on their application.

Q: How can one check to see: (1) whether a physician is enrolled or opted-out; and (2) when a physician is due to revalidate his/her enrollment? Also, concerning the latter, the Medicare Revalidation List webpage at https://data.cms.gov/tools/medicare-revalidation-list includes the following note: "*No revalidation due dates will be issued for individual practitioners starting with the January 2024 due dates until further notice*." Does CMS have an expected timeframe for when revalidation due dates will be issued for physicians?

A: Hospices can verify a physician's enrollment or opt-out status using the CMS ordering and referring data file (ORDF), which lists all Medicare-enrolled and opted-out physicians. The ORDF has a separate column for hospice enrolled/opted-out physicians.

The Revalidation List will be updated (and the physician himself/herself will be notified by the MAC) when it is time for the physician to revalidate his/her enrollment. CMS does not have an expected timeframe for issuing revalidation due dates for physicians.

Q: A physician is enrolled and intends to certify for hospice services. However, the "Y" box in the Hospice column next to the physician's name in the ORDF is not checked. Does this mean the physician cannot certify for hospice services?

A: If an individual is listed on the ORDF, it means that he/she meets the requirement to enroll or opt-out as a prerequisite for ordering or certifying the services/items outlined in 42 CFR 424.507. These are hospice services, home health services, DMEPOS items, clinical laboratory services, and imaging services. Meeting the requirement to enroll/opt-out under 42 CFR § 424.507 is different, however, than the individual qualifying as a provider/supplier type under Medicare regulations that can order or certify the service/item. For example, suppose an individual provider – Practitioner Smith -- is enrolled in Medicare to order/certify. He/she may meet the regulatory requirements to order DMEPOS items for patients but not to certify for hospice services per § 418.22(c). Whether an enrolled/opted-out individual listed in the ORDF is of a provider type that can order/certify for the services/items in § 424.507 may be denoted by a "Y" or "N" in the ORDF column for that service. Using our above example, the ORDF DMEPOS column next to Smith's name may indicate "Y" while the Hospice column may indicate "N."

To reiterate, it is critical to distinguish the enrollment/opt-out requirement under § 424.507 from the ability of a certain provider type to order or certify a particular service or item. Simply because a non-physician practitioner type is enrolled or opted-out does not in and of itself mean that said type can order/certify a service/item under Medicare regulations. Moreover, although the ODRF will often indicate whether an individual is of a provider/supplier type that can order/certify services, hospices should NOT rely exclusively on the ORDF for this determination. It is ultimately the hospice's responsibility to ensure that the individuals who certify the services the hospice furnishes are eligible to do so under § 418.22(c).

Q: Must the certifying or recertifying physician remain enrolled for the patient's entire certification and benefit period?

A: The hospice physician and attending physician only need to be enrolled or opted-out at the time they make the certification or recertification. The physician does not need to remain enrolled or opted-out during the patient's entire certification and benefit period. Moreover, if the physician becomes unenrolled and non-opted-out, the hospice does not need to get a new certification to replace the one the previously enrolled or opted-out physician signed.

In a similar vein, the edits will only apply to claims with dates of service on or after June 3, 2024. If the service began prior to June 3 but continues through and after June 3, the edits will not apply until a claim is submitted with dates of services on or after June 3.

Q: For the enrollment/opt-out requirement, how should the claim form be completed and what will be validated?

A: We address this matter at CMS Pub. 100-04, Chapter 11, Section 30.3 and CMS Change Request (CR) 13531.

(1) Attending Physician field - The hospice shall enter the name and provider identifier of the attending physician, which could be an independent physician, hospice physician, a nurse practitioner, or physician assistant. If there is no attending physician listed, the hospice shall report the hospice certifying/recertifying physician.

(2) Other Physician field - The hospice shall enter the name and provider identifier of the hospice physician responsible for certifying/recertifying that the patient is terminally ill.

Both the attending physician and other physician fields should be completed unless the patient's designated attending physician is the same as the physician certifying/recertifying the terminal illness. When the attending physician is also the physician certifying/recertifying the terminal illness, only the attending physician field is required to be populated; the other physician field would not need to be populated.

From June 3, 2024, through October 6, 2024, CMS is only verifying the enrollment/opt-out status of the physician listed in the claim's "Attending Physician" field when the claim is submitted for the initial certification/recertification. Accordingly, hospices should enter the certifying physician in the "Attending Physician" field. So long as the hospice enters a physician in the "Attending Physician" field and that physician is in the PECOS record that is valid for edit dates, the claim will not edit.

Beginning October 7, 2024, CMS will begin verifying the enrollment/opt-out status of physicians listed in the "Other Physician" field. Once that occurs, CMS will check both the "Attending Physician" field and the "Other Physician" field. Additional details regarding the verification checks beginning on October 7, 2024, are in CR 13531.

Q: When is occurrence code 27 and the date required?

A: The OC 27 code/date is only required on claims where initial certification or recertification occurs. CMS will not be conducting certifying/recertifying physician enrollment checks on physicians reported on claims that do not have occurrence code 27 and date reported.

Q: Are physician assistants (PAs) and nurse practitioners (NPs) subject to this new enrollment/opt-out requirement concerning hospice services?

A: PAs and NPs cannot certify or recertify a patient for hospice as referenced in § 418.22(c). We stated this in CMS-1787-F, which is the regulation that finalized our new provision (88 FR 51164). Accordingly, they need not be enrolled for purposes of meeting the enrollment/optout requirements of § 424.507(b) regarding hospice certifications under § 418.22(c).

Q: Do VA physicians need to do anything other than apply using the Form CMS-855O to certify hospice services?

A: If the VA physician (1) is not currently enrolled in/opted-out of Medicare, (2) wishes to furnish the Medicare certifications described in § 418.22(c), and (3) will not bill Medicare for services furnished, he/she need only submit the Form CMS-855O.

mln MATTERS®
KNOWLEDGE • RESOURCES • TRAINING

Provider Enrollment Changes to the Medicare Program Integrity Manual

Related CR Release Date: November 9, 2023
MLN Matters Number: MM13331
Effective Date: January 1, 2024
Related Change Request (CR) Number: CR 13331
Implementation Date: January 2, 2024
Related CR Transmittal Number: R12356PI
Related CR Title: Incorporation of Recent Provider Enrollment Regulatory Changes into Chapter 10 of CMS Publication (Pub.) 100-08 - Physician Fee Schedule (PFS) Final Rule

Affected Providers

- Marriage and family therapists (MFTs)
- Mental health counselors (MHCs)
- Physicians and other practitioners paid under the PFS
- All other Medicare provider and supplier types

Action Needed

Make sure your billing staff knows about these changes effective January 1, 2024:

- Medicare enrollment of MFTs and MHCs
- Other provider enrollment policy updates like denial reasons and revocations

Background

CR 13331 updates Chapter 10 of the Medicare Program Integrity Manual. These changes for MFTs, MHCs, and other regulatory changes are in the CY 2024 PFS final rule.

The key updates are:

- Section 10.1.1.1:
    - Authorized official (per 42 CFR 424.502) is currently defined as an appointed official (for example, chief executive officer, chief financial officer, general partner, chairman of the board, or direct owner) to whom the organization has granted the legal authority to:
        - Enroll it in the Medicare Program
        - Make changes or updates to the organization's status in Medicare

- Commit the organization to fully abide by the statutes, regulations, and program instructions of Medicare

The PFS rule clarifies that, for the authorized official definition only, the term organization means the enrolling entity as identified by its legal business name and tax identification number.

- Indirect ownership interest means any ownership interest in an entity that has an ownership interest in the enrolling or enrolled provider or supplier, or any ownership interest in an indirect owner of the enrolling or enrolled provider or supplier.
- Supplier means all of the following:
  - The individuals and entities that qualify as suppliers
  - Physical therapists in private practice
  - Occupational therapists in private practice
  - Speech-language pathologists

- Section 10.2.3.17: Medicare covers services that MFTs provide, effective January 1, 2024. An MFT is a person who:
  - Possesses a master's or doctor's degree which qualifies for licensure or certification as an MFT pursuant to state law of the state in which such a person provides MFT services
  - Has performed at least 2 years or 3,000 hours of post master's degree clinical supervised experience in marriage and family therapy in an appropriate setting such as a hospital, skilled nursing facility (SNF), private practice, or clinic after obtaining such degree
  - Is licensed or certified as an MFT by the state in which the MFT performs the services

- Section 10.2.3.18: Medicare covers MHC services effective January 1, 2024. An MHC is person who:
  - Possesses a master's or doctor's degree which qualifies for licensure or certification as an MHC, clinical professional counselor, or professional counselor under the state law of the state in which such person provides the MHC services
  - Has performed at least 2 years or 3,000 hours of post master's degree clinical supervised experience in mental health counseling in an appropriate setting such as a hospital, SNF, private practice, or clinic after obtaining such a degree
  - Is licensed or certified as an MHC, clinical professional counselor, professional counselor, addiction counselor, or alcohol and drug counselor by the state in which the services are performed.

Like certain other practitioners, MFTs and MHCs may:

- Opt-out of Medicare
- Form groups
- Reassign their benefits

- Receive reassigned benefits
- Order or certify services to the extent otherwise permitted by law

They'll complete the Form CMS-855I to bill for services and be subject to limited-risk screening. Section 10.6.12 has more details.

Other changes in Chapter 10 regarding provider enrollment regulations include:

- Section 10.4.2.2 has complete details on 2 more denial reasons
- Section 10.4.7.2 has new details on revocations and their effective dates

More Information

We issued CR 13331 to your MAC as the official instruction for this change. CMS encourages providers to review all the updates to Chapter 10, which is part of CR 13331.

For more information, find your MAC's website.

Document History

Date of Change	Description
November 9, 2023	Initial article released.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality

Ref: QSO-24-12-Hospice & FQHC/RHC

DATE: May 28, 2024

TO: State Survey Agency Directors

FROM: Directors, Quality, Safety & Oversight Group (QSOG) and Survey & Operations Group (SOG)

SUBJECT: **State Operations Manual (SOM) Appendix M-Hospice and Appendix G-Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Revisions to Include Marriage and Family Therapists (MFTs) and Mental Health Counselors (MHCs)**

Memorandum Summary

- The Calendar Year 2024 Physician Fee Schedule final rule updated the Hospice Conditions of Participations, the Rural Health Clinic Conditions for Certification, and the Federally Qualified Health Center Conditions for Coverage to implement provisions of the Consolidated Appropriations Act, 2023.
- The hospice interdisciplinary team must now include at least one social worker, marriage and family therapist or mental health counselor as part of the team and the hospice personnel requirements were also updated to add these disciplines. The Rural Health Clinic and Federally Qualified Health Center staffing and personnel requirements were updated to include marriage and family therapists and mental health counselors as part of the collaborative team approach to providing services. Additionally, definitions of several health care professionals who are already eligible to provide services at RHCs and FQHCs were updated, including the definition of "nurse practitioner," to align with current standards of professional practice.
- The State Operations Manual appendices are being updated to reflect the final rule requirements.

Background:

The Calendar Year (CY) 2024 Physician Fee Schedule (PFS) final rule was published on November 16, 2023, titled *Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program* (88 FR 78818). The regulations in the final rule became effective as of January 1, 2024.

Among other things, the final rule provides updates to the Hospice Conditions of Participation (CoPs), and the Rural Health Clinic (RHC) Conditions for Certification (CfCs), and the Federally Qualified Health Center (FQHC) Conditions for Coverage (CfCs) to implement provisions included in the Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117–328, December 29, 2022).

The hospice CoPs were updated to implement division FF, section 4121(b) of the CAA, 2023, that requires the hospice interdisciplinary group to include at least one social worker, marriage and family therapist (MFT) or mental health counselor (MHC). Additionally, the hospice personnel requirements were updated to add the MFT and MHC as new disciplines along with the education and training qualifications required for each discipline.

Additionally, the RHC and FQHC CfCs were updated to implement section 4121(b) of the CAA, 2023 modifying the staffing and personnel requirements to include MFTs and MHCs as part of the collaborative team approach to providing services. The RHC and FQHC CfC definitions were updated to include MFTs and MHCs as recognized staff alongside other healthcare professionals who are already eligible to provide services, and the definition of "nurse practitioner" was revised to align with current standards of professional practice.

Discussion:

Hospice

The hospice interdisciplinary group (IDG), care planning, and coordination of services CoP at 42 CFR 418.56 was updated to require that the IDG must include at least a social worker (SW), MFT, or MHC. The hospice is not required to include all three of these professions as members of the IDG and may choose (though is not required) to select more than one of these professions to serve as member(s) of the IDG. The definitions of the MFT and MHC disciplines (as defined at 42 CFR 410.53 and 410.54, respectively) have also been added to the hospice personnel qualifications CoP at 42 CFR 418.114(b).

RHC and FQHC

The RHC and FQHC CfC definitions at 42 CFR 491.2 were updated to add the terms "clinical psychologist (CP)," "clinical social worker," and "certified nurse midwife (CNM)." This rule also finalizes changes to the CfCs to define MFT and MHC services to indicate that RHCs and FQHCs can offer these services under their Medicare certification. Additionally, the existing "nurse practitioner (NP)" definition was revised to accurately reflect current professional standards by removing the reference to specific certifying bodies as they are now outdated. This revision will ensure the requirement reflects the breadth of currently available certifications.

Finally, the RHC and FQHC CfCs at 42 CFR 491.8 was updated to add MFT and MHC to the list of practitioners who may be the owner or an employee of the clinic or center, or may furnish services under contract to the clinic or center, as well as included as staff available to furnish patient care services at all times the clinic or center operates. If an

RHC or FQHC provides services furnished by an MFT or MHC, they will be required to update their patient care policy, as set out in 42 CFR 491.9(b)(2).

SOM Updates
An advance copy of the State Operations Manual (SOM) Appendix M – Hospice and Appendix G – RHC is attached, reflecting updates to the regulation text.

The revisions to Appendix M and Appendix G indicating the regulation changes made by the final rule will be reflected in the SOM's online version shortly following the release of this memorandum.

Resource:
On November 29, 2023, CMS hosted a Hospice Open Door Forum call. On that call, questions were asked regarding the new requirements for marriage and family therapists and mental health counselors effective January 1, 2024. The responses provided to the hospice stakeholders are available as a resource at https://www.cms.gov/files/document/hospice-open-door-forum-qa.pdf.

Contact:
For questions or concerns relating to this memorandum for hospice, please contact QSOG_Hospice@cms.hhs.gov.
For questions or concerns relating to this memorandum for RHC/FQHC, please contact QSOG_RHC-FQHC@cms.hhs.gov.

Effective Date:
Immediately. Please communicate to all appropriate staff immediately.

/s/

Karen L. Tritz
Director, Survey & Operations Group

David R. Wright
Director, Quality, Safety & Oversight Group

Attachments A and B-
Advance Copy of SOM Appendix M – Guidance to Surveyors: Hospice
Advance Copy of SOM Appendix G – Guidance to Surveyors: Rural Health Clinics (RHCs)

Resources to Improve Quality of Care:
Check out CMS's new Quality in Focus interactive video series. The series of 10–15 minute videos are tailored to provider types and aim to reduce the deficiencies most commonly cited during the CMS survey process, like infection control and accident prevention. Reducing these common deficiencies increases the quality of care for people with Medicare and Medicaid. Learn to:

- *Understand surveyor evaluation criteria*
- *Recognize deficiencies*
- *Incorporate solutions into your facility's standards of care*

See the Quality, Safety, & Education Portal Training Catalog, and select Quality in Focus

Get guidance memos issued by the Quality, Safety and Oversight Group by going to CMS.gov page and entering your email to sign up. Check the box next to "CCSQ Policy, Administrative, and Safety Special Alert Memorandums" to be notified when we release a memo.

CMS Manual System **Pub. 100-07 State Operations Provider Certification**	**Department of Health & Human Services (DHHS)** **Centers for Medicare & Medicaid Services (CMS)**
Transmittal- *Advanced Copy*	**Date:**

SUBJECT: Revisions to the State Operations Manual (SOM) Appendix M-Hospice

I. SUMMARY OF CHANGES: This transmittal includes revisions to the SOM Appendix M based on the recent federal regulation changes based on the CY 2024 Physician Fee Schedule final rule that was published on November 16, 2023, and titled *Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program*. The regulations in the final rule are effective as of January 1, 2024

NEW/REVISED MATERIAL - EFFECTIVE DATE*: Upon Issuance
IMPLEMENTATION DATE:

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (*N/A if manual not updated.*)
(R = REVISED, N = NEW, D = DELETED) – (*Only One Per Row.*)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix M/L541/§418.56(a)(1) The interdisciplinary group must include, but is not limited to, individuals who are qualified and competent to practice in the following professional roles: (i) A doctor of medicine or osteopathy (who is an employee or under contract with the hospice). (ii) A registered nurse. (iii) A social worker, marriage and family therapist, or a mental health counselor. (iv) A pastoral or other counselor.
N	Appendix M/L901/§418.114(b)(9) - Marriage and family counselor as defined at § 410.53.

N	Appendix M/L902/§418.114(b)(10) – Mental health counselor as defined at § 410.54.

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.
Or
Funding for implementation activities will be provided to contractors through the regular budget process.

IV. ATTACHMENTS:

	Business Requirements
X	**Manual Instruction**
	Confidential Requirements
	One-Time Notification
	One-Time Notification -Confidential
	Recurring Update Notification

***Unless otherwise specified, the effective date is the date of service.**

State Operations Manual
Appendix M - Guidance to Surveyors: Hospice
Advance Copy

L541
(Rev.)

§418.56(a)(1) …The interdisciplinary group must include, but is not limited to, individuals who are qualified and competent to practice in the following professional roles:

(i) A doctor of medicine or osteopathy (who is an employee or under contract with the hospice).
i. (ii) A registered nurse.
ii. (iii) A social worker*, marriage and family therapist, or a mental health counselor*.
iii. (iv) A pastoral or other counselor.

Interpretive Guidelines §418.56(a)(1)(i)-(iv)

The number of individuals on the IDG is not as important as their qualifications and abilities. For example, if a group member meets the hospice criteria and is licensed as a RN and also meets the Medicare criteria to be considered a social worker under the hospice benefit, he/she would be qualified to serve on the IDG as both a nurse and a social worker.

L901
(Rev.)

§418.114(b)(9) Marriage and family counselor as defined at § 410.53.

L902
(Rev.)

§418.114(b)(10) Mental health counselor as defined at § 410.54.

CMS Manual System **Pub. 100-07 State Operations Provider Certification**	**Department of Health & Human Services (DHHS)** **Centers for Medicare & Medicaid Services (CMS)**
Transmittal- *Advanced Copy*	**Date:**

SUBJECT: Revisions to the State Operations Manual (SOM) Appendix G - RHC

I. SUMMARY OF CHANGES: This transmittal includes revisions to the SOM Appendix G based on the recent federal regulation changes based on the CY 2024 Physician Fee Schedule final rule that was published on November 16, 2023, and titled *Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program*. The regulations in the final rule are effective as of January 1, 2024

NEW/REVISED MATERIAL - EFFECTIVE DATE*: Upon Issuance
IMPLEMENTATION DATE:

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (*N/A if manual not updated.*)
(R = REVISED, N = NEW, D = DELETED) – (*Only One Per Row.*)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix G/J-0082/[§ 491.8(a) Staffing.]/§491.2 Definitions. As used in this subpart, unless the context indicates otherwise: Nurse practitioner means a person who meets the applicable State requirements governing the qualifications of nurse practitioners, and who meets one of the following conditions: (1) Is certified as a nurse practitioner by a recognized national certifying body that has established standards for nurse practitioners and possesses a master's or doctoral degree in nursing practice; or…

R	Appendix G/J-0083/[§ 491.8(a) Staffing.]/(3) The . . . certified nurse-midwife, clinical social worker, clinical psychologist, marriage and family therapist, or mental health counselor member of the staff may be the owner or an employee of the clinic or center, or may furnish services under contract to the clinic or center… §491.2 Definitions. As used in this subpart, unless the context indicates otherwise: Certified nurse-midwife (CNM) means an individual who meets the applicable education, training, and other requirements at § 410.77(a) of this chapter. Clinical psychologist (CP) means an individual who meets the applicable education, training, and other requirements of § 410.71(d) of this chapter. Clinical social worker means an individual who meets the applicable education, training, and other requirements at § 410.73(a) of this chapter. Marriage and family therapist means an individual who meets the applicable education, training, and other requirements at § 410.53 of this chapter. Mental health counselor means an individual who meets the applicable education, training, and other requirements at § 410.54 of this chapter.
R	Appendix G/J-0085/[§ 491.8(a) Staffing.]/(6) A physician, nurse practitioner, physician assistant, certified nurse-midwife, clinical social worker, clinical psychologist, marriage and family therapist, or a mental health counselor is available to furnish patient care services at all times the clinic or center operates. . . .

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

Or

Funding for implementation activities will be provided to contractors through the regular budget process.

IV. ATTACHMENTS:

	Business Requirements
X	**Manual Instruction**
	Confidential Requirements
	One-Time Notification
	One-Time Notification -Confidential

	Recurring Update Notification

***Unless otherwise specified, the effective date is the date of service.**

State Operations Manual
Appendix G - Guidance for Surveyors: Rural Health Clinics (RHCs)
Advance Copy

J-0082
(Rev.)

[§ 491.8(a) Staffing.]

(1) . . . Rural health clinic staffs must also include one or more physician's assistants or nurse practitioners.

(3) The physician assistant, nurse practitioner, . . . may be the owner or an employee of the clinic . . ., or may furnish services under contract to the clinic . . . In the case of a clinic, at least one physician assistant or nurse practitioner must be an employee of the clinic.

§491.2 Definitions. As used in this subpart, unless the context indicates otherwise:

Nurse practitioner means a *person* who meets the *applicable* State requirements governing the qualifications of nurse practitioners, and who meets *at least* one of the following conditions:

(1) Is certified as a nurse practitioner by *a recognized national certifying body that has established standards for nurse practitioners and possesses a master's or doctoral degree in nursing practice*; or

(2) Has satisfactorily completed a formal 1 academic year educational program that:

(i) Prepares registered nurses to perform an expanded role in the delivery of primary care;

(ii) Includes at least 4 months (in the aggregate) of classroom instruction and a component of supervised clinical practice; and

(iii) Awards a degree, diploma, or certificate to persons who successfully complete the program; or

(3) Has successfully completed a formal educational program (for preparing registered nurses to perform an expanded role in the delivery of primary care) that does not meet the requirements of paragraph (2) of this definition, and has been performing an expanded role in the delivery of primary care for a total of 12 months during the 18-month period immediately preceding the effective date of this subpart.

Physician assistant means a person who meets the applicable State requirements governing the qualifications for assistants to primary care physicians, and who meets at least one of the following conditions:

(1) Is currently certified by the National Commission on Certification of Physician Assistants to assist primary care physicians; or

(2) Has satisfactorily completed a program for preparing physician's assistants that:

(i) Was at least 1 academic year in length;

(ii) Consisted of supervised clinical practice and at least 4 months (in the aggregate) of classroom instruction directed toward preparing students to deliver health care; and

(iii) Was accredited by the American Medical Association's Committee on Allied Health Education and Accreditation; or

(3) Has satisfactorily completed a formal educational program (for preparing physician assistants) that does not meet the requirements of paragraph (2) of this definition and assisted primary care physicians for a total of 12 months during the 18-month period that ended on December 31, 1986.

Interpretative Guidelines § 491.8(a)(1) & (3)

In addition to having a physician on staff, the RHC's health care staff must also include one or more nurse practitioner(s) (NP) or physician assistant(s) (PA), as defined at § 491.2. The RHC's NP and/or PA must meet the Medicare definition of an NP or PA and be licensed in accordance with the law of the State in which the RHC is located and practicing within their permitted State scope of practice.

At least one NP or PA must be an employee of the RHC (note that a clinic's owner may also be an employee; this is at the owner's discretion). CMS interprets an "employee" to mean an individual to whom the clinic issues an IRS Form W-2, Wage and Tax Statement. (See 79 FR 25462, May 2, 2014). However, once the clinic has employed at least one NP or PA, the other practitioners may furnish services under contract to the clinic instead of being employees. These

other NPs or PAs may contract directly with the clinic or may have an arrangement with a third party that contracts with the clinic to furnish the practitioner's services.

In all cases the RHC must have sufficient practitioners, both physician and non-physician, to furnish the volume of RHC services it provides to its patients, consistent with accepted standards of practice.

- As provided by § 1861(aa)(7) of the Act, and implemented in Section 2248 of the SOM, an existing RHC may request a waiver of the requirement to employ a NP or PA. The mid-level staffing waiver is applicable to Medicare-participating RHCs only. Initial applicants to participate in Medicare as an RHC are **not** eligible for staffing waivers. CMS grants a currently certified RHC a one-year waiver of the requirement to employ a NP or PA if:

- The RHC submits the written request for a waiver to the appropriate SA;

- The RHC demonstrates that it has been unable, despite reasonable efforts, to hire a NP or PA in the previous 90-day period; and

- The RHC's request is submitted six months or more after the date of the expiration of any previous such waiver for the RHC.

The SA is responsible for reviewing the evidence the RHC provides regarding its efforts to hire an NP or PA in the previous 90 days and recommending approval or disapproval of the requested waiver to the RO. The SA must complete its review and recommendation within 30 calendar days of receiving the written waiver request from the RHC.

The waiver is deemed to have been granted, unless the waiver request is denied by the RO within 60 calendar days after the date the SA received the RHC's waiver request. In cases where the waiver request is deemed to have been approved, the effective date of the 1-year waiver is the 61st day after the date the request was received by the SA.

See Section 2248 for more details on the waiver process and the expectations for RHCs and SAs

Survey Procedures § 491.8(a)(1) & (3)

- Determine that the clinic has at the time of the survey at least one NP or PA who is an employee of the clinic, as evidenced by the clinic issuing a W-2.

- If the clinic already participates in Medicare as an RHC and does not employ a NP or PA, check whether there is a valid waiver in effect.

J-0083
(Rev.)

[§ 491.8(a) Staffing.]

(3) The . . . *certified* nurse-midwife, clinical social worker, clinical psychologist, *marriage and family therapist, or mental health counselor* member of the staff may be the owner or an employee of the clinic or center, or may furnish services under contract to the clinic . . . .

§491.2 Definitions. As used in this subpart, unless the context indicates otherwise:

Certified nurse-midwife (CNM) means an individual who meets the applicable education, training, and other requirements at § 410.77(a) of this chapter.

Clinical psychologist (CP) means an individual who meets the applicable education, training, and other requirements of § 410.71(d) of this chapter.

Clinical social worker means an individual who meets the applicable education, training, and other requirements at § 410.73(a) of this chapter.

*****

Marriage and family therapist means an individual who meets the applicable education, training, and other requirements at § 410.53 of this chapter.

Mental health counselor means an individual who meets the applicable education, training, and other requirements at § 410.54 of this chapter.

*****

Interpretative Guidelines § 491.8(a)(3)

The clinic is not required to have a nurse-midwife, clinical social worker or clinical psychologist on staff. If it does have any of these on staff, they must be licensed as required by State law of the State in which the clinic is located, and must be practicing within their permitted scope of practice.

A nurse midwife, clinical social worker or clinical psychologist who is on the clinic's staff may be the clinic's owner (who may also be an employee at the same time), an employee of the clinic, or providing services to the clinic under a contractual agreement. These types of practitioners may contract directly with the clinic or may have an arrangement with a third party that contracts with the clinic to furnish the practitioner's services.

Survey Procedures § 491.8(a)(3)

- If the clinic has a nurse midwife, clinical social worker, or clinical psychologist on staff, verify that the individual has a current State license when one is required under State law.

J-0085
(Rev.)

[§ 491.8(a) Staffing.]

(5) The staff is sufficient to provide the services essential to the operation of the clinic . . . .

(6) A physician, nurse practitioner, physician assistant, certified nurse-midwife, clinical social worker, clinical psychologist*, marriage and family therapist, or a mental health counselor* is available to furnish patient care services at all times the clinic . . . operates. . . .

Interpretative Guidelines § 491.8(a)(5) & (6)

The clinic must be sufficiently staffed to provide the services offered by the RHC. Specifically, this means that the clinic has sufficient staff practicing within their permitted scope of practice to provide RHC services to the clinic's patients at all hours that the clinic is open and operating. Consistent with § 491.9(c), the RHC services the clinic furnishes are diagnostic and therapeutic services and supplies similar to those furnished in a physician office, including, but not limited to, performing history and physical examinations, assessment of health status, and treatment for a variety of medical conditions. The clinic must also furnish specified laboratory services and first responder-type emergency services to individuals in the clinic experiencing a medical emergency. The clinic must have sufficient staff members who are qualified to furnish these services to the volume of patients the RHC sees. Even when staffing meets the minimum requirement in terms of practitioner time at the RHC, the staffing may be insufficient for the volume of services the RHC provides.

The clinic may only be open and furnishing RHC services if there is a physician, NP, PA, certified nurse midwife, clinical social worker, or clinical psychologist on site and available to furnish services. Although the physician medical director may perform many, not all, of his/her responsibilities remotely via telecommunications, this does not mean the clinic can be open and furnishing services without any practitioner on-site. With the exception of services, the clinic's medical director or other MDs or DOs may provide by telemedicine, the clinic may only furnish those services that are within the scope of practice of the practitioners who are on site at the time the services are offered. The loss of a PA or NP staff member may require the RHC to request a temporary staffing waiver via its SA. It may also require a temporary adjustment of the clinic's operating hours or services and an adjustment in visits by the physician(s) providing medical direction. It is the responsibility of the clinic to promptly advise the SA of any changes in staffing which would affect its certification status.

(NOTE: See the guidance for § 491.8(a)(3) and Section 2248 for more details on the waiver process and the expectations for RHCs and SAs.)

RHCs may allow beneficiary entry to the waiting room or other non-patient care areas to handle billing inquiries or to get out of the weather when the mid-level practitioner as defined in §493.2, clinical social worker, clinical psychologist or physician staff member is not present to provide health care services. However, the clinic is not considered to be in operation as an RHC during this period. No health care services may be provided until a mid-level practitioner, clinical social worker, clinical psychologist or physician staff member is present onsite. There should be a reasonable timeframe between administrative transactions conducted on the premises outside the hours of operation of the RHC and the commencement of RHC operations with the healthcare professional's arrival. Any RHC that choose to exercise this flexibility should post the hours of administrative services only versus the hours of RHC operations. Signage should clearly delineate times the healthcare professional staff member is present onsite. If State law does not allow access to the RHC premises when the clinic is not in operation as an RHC, the facility must adhere to such laws.

Survey Procedures § 491.8(a)(5) & (6)

- Determine whether there is a physician or a non-physician practitioner on-site at all times the RHC is open. Review staff schedules and the clinic's hours of operation to confirm. Ask staff members if the RHC is ever open and providing services when no practitioner is present.
- Verify posted hours to confirm appropriate professional healthcare staffing within the RHC's hours of operation.

MFT and MHC Benefit

1. Does Medicare recognize Marriage and Family Therapists (MFTs) and Mental Health Counselors (MHCs)?

Section 4121 of Division FF of the Consolidated Appropriations Act, 2023 (CAA, 2023), establishes a new Medicare benefit category for MFT and MHC services furnished by and directly billed by MFTs and MHCs. Payment for MFT and MHC services under Part B of the Medicare program will begin January 1, 2024.

2. How does Medicare define MFTs?

Section 4121 Division FF of the CAA, 2023, defines MFT services as services for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital). An MFT is an individual who:

- Possesses a master's or doctor's degree which qualifies for licensure or certification as a MFT pursuant to State law of the State in which the individual furnishes the services defined as marriage and family therapist services,
- Performed at least 2 years or 3,000 hours of post master's degree clinical supervised experience in marriage and family therapy in an appropriate setting such as a hospital, skilled nursing facility, private practice, or clinic,
- Is licensed or certified as a marriage and family therapist by the State in which you perform services.

3. How does Medicare define MHCs?

Section 4121 Division FF of the CAA, 2023, defines MHC services as services for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital). An MHC is an individual who:

- Possesses a master's or doctor's degree which qualifies for licensure or certification as a MHC, clinical professional counselor, or professional counselor under State law of the State in which the individual furnishes the services defined as mental health counselor services,
- Performed at least 2 years or 3,000 hours of post master's degree clinical supervised experience in mental health counseling in an appropriate setting such as a hospital, SNF, private practice, or clinic
- Is licensed or certified as an MHC, clinical professional counselor, or professional counselor by the State in which you perform services

Additionally, addiction counselors and alcohol and drug counselors who meet all the applicable requirements of an MHC may enroll in Medicare as MHCs and bill Medicare for MHC services.

4. Where can I find more information about Medicare coverage for MFTs/MHCs?

Providers can refer to the MFT/MHC webpage and the Medicare and Mental Health Coverage MLN Booklet.

National Provider Identifier (NPI) and Taxonomy Codes

5. What is an NPI?

The NPI is a unique, 10-digit identification number for covered health care providers and must be used in the administrative and financial transactions adopted under HIPAA.

To enroll in Medicare, you must first obtain an NPI and provide it on the Medicare enrollment application. NPIs are issued through the National Plan & Provider Enumeration System (NPPES). You can apply for an NPI on the NPPES website. If you are not sureif you have an NPI, search the NPI Registry.

6. What taxonomy code do I select in NPPES for MFTs and MHCs?

A taxonomy code is a unique 10-character code that designates your classification and specialization. You will select this code when applying for an NPI in NPPES. The MFT taxonomy code is 106H00000X. The MHC taxonomy code is 101YM0800X.

7. I'm currently enrolled in Medicaid and have an NPI. Do I need a new NPI for Medicare?

Practitioners may only have one Type 1 NPI. Use your existing NPI to enroll in Medicare.

Enrolling as an MFT or MHC

8. What is a Medicare Administrative Contractor (MAC)?

A MAC is a private health care insurer that has been awarded a geographic jurisdiction to process Medicare Part A and Part B (A/B) enrollment applications and Medicare Fee-For-Service (FFS) claims, respond to provider inquiries, and educate providers about Medicare FFS enrollment and billing requirements.

Find your designated MAC and their contact and mailing address at MAC Contact Information.

9. When can I start enrolling in Medicare?

MFTs and MHCs can begin submitting their enrollment applications after the Calendar Year (CY) 2024 Physician Fee Schedule (PFS) final rule is displayed at the Federal Register, usually around November 1, 2023. However, as the new benefits authorized by Section 4121(a) of the

Division FF of CAA, 2023, do not take effect until January 1, 2024, MFTs/MHCs will not be granted an effective date earlier than January 1, 2024, and claims with dates of service prior to January 1, 2024, will not be payable.

10. What enrollment application do I complete to enroll in Medicare?

MFTs and MHCs can enroll electronically using the Provider Enrollment, Chain, and Ownership System (PECOS) or the paper CMS-855I enrollment application.

PECOS is the online Medicare enrollment system. It offers a scenario-driven application, asking questions to obtain the required information for your specific enrollment scenario. Use PECOS for faster and easier enrollment into Medicare.

The CMS-855I application is completed by physicians and non-physician practitioners who render Medicare Part B services to beneficiaries. This includes a physician or practitioner who (1) is the sole owner of a professional corporation, professional association, or limited liability company and (2) will bill Medicare through this business entity.

11. How do I access PECOS?

You must create a user account in the Identity & Access Management System (I&A). The I&A system allows you to:

- Use NPPES to apply for and manage NPIs
- Use PECOS to enroll in Medicare, update or revalidate your current enrollment information
- Register to get EHR incentive payments for eligible professionals and hospitals that adopt, use and upgrade, or show meaningful use of certified EHR technology

12. The paper CMS-855I application does not list the MFT and MHC specialties. How do I identify my specialty on the application?

MFTs and MHCs should select the Undefined Non-Physician Practitioner Specialty option in section 2H of the CMS-855I application and specify MFT or MHC in the space provided. A future update of the paper CMS-855I will include the MFT and MHC specialties.

The specialties are available in PECOS for online application submissions.

13. Can mental health professionals enroll as MHCs?

Per 42 CFR § 410.54(a)(3), an MHC must be licensed or certified as an MHC, clinical professional counselor, professional counselor, addiction counselor, or alcohol and drug counselor

by the state in which the services are performed. Individuals who meet all the applicable statutory and regulatory qualifications to be an MHC --- even though they may be licensed or certified by their state under a different title to furnish mental health counseling --- may enroll as an MHC. This list of mental health professionals is not exhaustive and will vary by state.

These individuals should select the Undefined Non-Physician Practitioner Specialty option in section 2H of the CMS-855I application and specify MHC in the space provided instead of the title they are licensed or certified by their state.

14. Do I have to submit multiple applications if I render services in multiple states?

A separate CMS-855I enrollment is required in each state where services are rendered. For example, the MAC's jurisdiction consists of States X, Y, and Z. Dr. Jones is enrolled in State X with 2 locations. He wants to add a third location in State Y. A separate, initial CMS-855I application is required for the State Y location.

In addition, the practitioner must be licensed and/or certified in each state where services are rendered. The applicable license must be included on the application.

15. Does Medicare recognize compact licenses?

Medicare recognizes licenses obtained through the interstate license compact pathway as valid, full licenses for the purposes of meeting federal license requirements. For more information on compact licenses refer to SE20008.

16. Who can sign the PECOS application or paper CMS-855I?

The enrolling or enrolled practitioner is the only person who can sign the PECOS application or paper CMS-855I. A practitioner may not delegate the authority to sign the CMS-855I on his/her behalf to any other person.

17. How long does it take to process an enrollment application?

Generally, all clean web applications will be processed within 15 calendar days following receipt, and all clean paper applications will be processed within 30 calendar days following receipt. The timeframes may be extended if the application is incomplete or missing information or documentation.

The MAC will send a development letter to the provider requesting the additional information. The provider will have 30 calendar days to respond. If no response is received, the application will be rejected. Providers should respond to all MAC requests for additional information timely, to avoid further delays.

18. Who can be listed as the contact person on the enrollment application?

If questions arise during the processing of the enrollment application, your MAC will contact the individual reported in the contact person section of PECOS or the paper CMS-855I. The individual practitioner may choose to designate themselves as the contact person or someone with knowledge of the application (e.g., office staff, credentialing staff).

The contact person will only be authorized to discuss issues concerning the pending enrollment application. Your MAC will not discuss any other Medicare issues about you with the contact person.

If the section is left blank, the MAC will contact the practitioner directly using the information in Section 2: Correspondence Mailing Address.

19. What risk category are MFTs and MHCs?

CMS established three levels of provider and supplier enrollment risk-based screening: limited, moderate, high. The risk levels denote the MAC's level of screening when the provider initially enrolls in Medicare, adds a new practice location, revalidates its enrollment information, or, in certain circumstances, changes all or part of its ownership.

MFTs and MHCs are limited risk. Providers and suppliers designated in the limited risk category undergo verification of licensure and a wide range of database checks to ensure compliance with all provider or supplier specific requirements.

20. Do MFTs/ MHCs have to pay an application fee?

MFTs and MHCs are not required to pay an application fee.

21. What is a Provider Transaction Access Number (PTAN)?

A PTAN is a Medicare-only number issued to providers by MACs upon enrollment. The Medicare approval letter will include the assigned PTAN.

The approval letter will note that the NPI must be used to bill the Medicare program and that the PTAN will be used to authenticate the provider when using MAC self-help tools such as the Interactive Voice Response (IVR) phone system, internet portal, on-line application status, etc.

The PTAN's use should generally be limited to the provider's interactions with their MAC.

If you enroll in multiple states, you will receive separate PTANs.

22. Am I required to receive payment through Electronic Funds Transfer (EFT)?

CMS requires that providers and suppliers, who are enrolling in the Medicare program or making a change in their enrollment data, receive payments via electronic funds transfer. Submit the EFT

Agreement with your enrollment application, along with a voided check or bank letter confirming your account information.

If you reassign all Medicare benefits you do not need to submit an EFT agreement.

23. If I am enrolled in Medicaid, do I have to separately enroll in Medicare?

If you plan to provide services to Medicare beneficiaries, you must separately enroll in Medicare. Enrolling in Medicaid does not automatically enroll you in Medicare.

Reassigning Medicare Benefits

24. What does it mean to reassign your Medicare benefits?

Reassigning your Medicare benefits allows an eligible organization/group to submit claims and receive payment for Medicare Part B services that you have provided as a member of the organization/group. An eligible organization/group may be an individual, a clinic/group practice or other health care organization.

25. How do I report a reassignment on the CMS-855I?

You can report a reassignment through PECOS or the CMS-855I paper application. If submitting via paper, select the submittal reason, "You are reporting a change to your Medicare enrollment information" and complete the applicable sections. The reassignment information is reported in section 4F. The practitioner must sign section 15B and the Authorized or Delegated Official of the organization/group must sign Section 15C to establish the reassignment. If you reassign benefits to multiple organizations/groups, copy and complete section 4F and 15C, as applicable.

Both the individual practitioner and the eligible organization/group must be currently enrolled or concurrently enrolling in the Medicare program to establish the reassignment. The organization/group must be enrolled or enrolling through PECOS or the CMS-855B.

26. I render services in a private practice and as an employee of a group. How do I report this in PECOS or on the paper CMS-855I?

In PECOS report your private practice in the Physical Location and Specialty Payments Address topic and the reassignment in the Reassignment topic. Complete the appropriate signatures for the practitioner and the Authorized or Delegated Official of the organization/group accepting the reassigned benefits during the submission process.

On the paper CMS-855I report your private practice in section 4B and the reassignment in 4F of the CMS-855I. Complete section 15 with the appropriate signatures for the practitioner and the Authorized or Delegated Official of the organization/group accepting the reassigned benefits.

27. Can I practice independently as an MFT/MHC but also be an owner of a group?

Yes. A provider can be enrolled as an individual practitioner and an owner of a group. The practitioner completes the CMS-855I application. The group completes the CMS-855B. Ownership information is reported in sections 5 and 6 of the CMS-855B.

28. My group is currently enrolled with a PTAN we use to bill for Licensed Clinical Social Worker (LCSW) services. Do we need a new PTAN to bill for MFTs/MHCs services as part of the group?

The group's PTAN will not change. The MAC will issue a PTAN to the individual practitioner that links them to your group once they have enrolled as an MFT/MHC.

29. Can I work for a rural health clinic and federally qualified health center and be paid by Medicare?

Services furnished by an MFT and MHC are covered when furnished in a rural health clinic and federally qualified health center.

30. Are MFT and MHC services excluded from consolidated billing requirements under the skilled nursing facility prospective payment system (SNF PPS)?

Section 4121(a)(4) of the CAA 2023, requires Medicare to exclude MFT and MHC services from SNF consolidated billing. Exclusion from consolidated billing allows these services to be billed separately by the performing clinician rather than being included in the Medicare Part A SNF payment. We finalized the regulatory text changes required to codify this new legislative requirement to exclude MFT and MHC services from SNF consolidated billing for services furnished on or after January 1, 2024, in the FY 2024 SNF PPS final rule (88 FR 53200).

31. Can MFTs and MHCs serve as members of the hospice interdisciplinary team?

Yes, the hospice interdisciplinary team is required to include at least one social worker, MFT or MHC.

32. Is Medicare enrollment mandatory?

Section 1848(g)(4)(A) of the Social Security Act requires that you submit claims for all your Medicare patients for services rendered. This requirement applies primarily to physicians, non-physician practitioners and suppliers who provide covered services to Medicare beneficiaries. To submit Medicare claims and receive payment for covered Medicare items or services, you must be enrolled under Medicare regulations.

For the mandatory claim submission requirements refer to Medicare Claims Processing Manual, Chapter 1.

Telehealth

33. Can MFTs and MHCs perform telehealth services?

Yes. MFTs and MHCs have been added to the list of practitioners who can furnish Medicare telehealth services.

During the COVID-19 public health emergency (PHE), CMS used emergency waiver and other regulatory authorities so you could provide more services to your patients via telehealth. Section 4113 of the CAA, 2023 extended many of these flexibilities through December 31, 2024, and made some of them permanent. For more information refer to Telehealth Services Fact Sheet.

34. How do I enroll to perform telehealth services to patients located in my home state or another state?

Practitioners who perform telehealth services should enroll based on their enrollment scenario. Refer to the scenarios below as a guide for completing the paper application. For faster and easier enrollment, providers are encouraged to submit their applications electronically through PECOS.

a. **Practitioner Only Renders Services in a Private Practice:** The practitioner renders telehealth services from his/her home in Florida. The practitioner completes all applicable sections of the paper CMS-855I. In section 4B of the CMS-855I, enter the location where the telehealth service is performed (e.g., office, home). Select the practice location type as "Business Office for Administrative/Telehealth Use Only" or "Home Office for Administrative/Telehealth Use Only." This option prevents the practitioner's home address from being published on Care Compare, a tool for Medicare beneficiaries to find and compare different Medicare providers.

   The practitioner submits the completed application to First Coast Services Options, the MAC that processes enrollment applications for Florida.

b. **Practitioner reassigns all benefits to a group. Practitioner and group are in the same state:** The practitioner reassigns benefits to a group In Maryland but will be rendering telehealth services from his/her home in Maryland. The practitioner completes all applicable sections of the CMS-855I. In section 4F of the CMS-855I, the practitioner lists the group accepting the new reassignment of benefits from the practitioner. If the group is already enrolled, no further action is needed. If the group is not enrolled, they will complete all applicable sections of the CMS-855B and list their office locations in section 4A. The practitioner does not list his/her home address on the CMS-855I or on the group's CMS-855B application. Physicians/practitioners who bill for Medicare telehealth services should report place of service (POS) code 02 or 10 beginning January 1, 2024.

The practitioner and group submit the CMS-855I and CMS-855B to Novitas Solutions, the MAC that processes enrollment applications for Maryland.

c. **Practitioner reassigns all benefits to a group. Practitioner and Group are in different states:** The practitioner reassigns benefits to a group in Maryland but will be rendering telehealth services from his/her home in Florida. The practitioner must enroll in the state where the group is located because they are submitting claims on behalf of the practitioner. The practitioner completes all applicable sections of the CMS-855I. In section 4F of the CMS-855I, the practitioner lists the group accepting the new reassignment of benefits from the practitioner. If the group is already enrolled, no further action is needed. If the group is not enrolled, they will complete all applicable sections of the CMS-855B and list their office locations in section 4A. The practitioner does not list his/her home address on the CMS-855I or on the group's CMS-855B application. The practitioner can continue to bill as if he/she furnished the service in person, through December 31, 2024.

   The practitioner and group submit the CMS-855I and CMS-855B to Novitas Solutions, the MAC that processes enrollment applications for Maryland.

Supervision Requirements

35. Do I need two years of supervision prior to enrolling in Medicare?

Section 4121 of the CAA, 2023 requires MFTs and MHCs have 2 years of clinical supervised experience to enroll in Medicare.

36. What documentation should I submit to verify I meet the clinical supervision requirements?

Some states require the clinical supervised experience as a requirement to be fully licensed. In this case no additional action is necessary. The MAC will validate your license and clinical supervised experience during application processing.

If the clinical experience is not part of obtaining a license, the practitioner will need to submit documentation with their application confirming the 2-year requirement is met. Such documentation must include:

- A statement from the provider/supplier where the MFT/MHC performed the services (e.g., hospital, clinic) verifying that the MFT/MHC performed services at that setting for the required number of years. The statement must be:
  - On the provider's/supplier's letterhead (e-mail is not acceptable); and
  - Signed by: (1) the supervisor under whom the MFT/MHC performed the services; (2) an applicable department head (e.g., chief of psychology) of the provider/supplier; or (3) a current authorized or delegated official of the provider/supplier (i.e., the AO/DO

has already been approved as such in the provider/supplier's enrollment record if the provider/supplier is Medicare-enrolled).

- A statement verifying that the MFT/MHC meets the year or hour requirements from a: (1) licensing or credentialing body for the state in which the MFT/MHC is enrolling; or (2) national MFT/MHC credentialing organization. The statement can be signed by any official of the state licensing/credentialing or national credentialing body and must be on the body's letterhead (email is not acceptable).

Revalidation

37. What does it mean to revalidate?

You are required to revalidate—or renew—your enrollment record periodically to maintain Medicare billing privileges. In general, providers and suppliers revalidate every five years, but DMEPOS suppliers revalidate every three years. CMS also reserves the right to request off-cycle revalidations.

38. How are providers notified when it's time to revalidate?

You can search the Medicare Revalidation List to find your revalidation due date. CMS posts revalidation due dates seven months in advance.

Your MAC will also send a revalidation notice to you via email or U.S. postal mail about three to four months prior to your due date.

39. What happens if I don't revalidate on time?

Failing to revalidate on time could result in a hold on your Medicare reimbursement or deactivation of your Medicare billing privileges.

If your Medicare billing privileges are deactivated, you'll need to submit a complete Medicare enrollment application to reactivate your billing privileges. Medicare won't reimburse you for any services during the period that you were deactivated.

Opt-Out of Medicare

40. If I don't enroll, do I need to opt-out to continue to see Medicare beneficiaries**?**

Physicians and non-physician practitioners who see Medicare beneficiaries but do not want to enroll and submit claims to Medicare, are required to opt-out. Opting out means that you do not want to bill Medicare for your services, but instead want your Medicare patients to pay out-of-pocket. You enter private contracts with your Medicare patients where you agree that nobody will submit the bill to Medicare for reimbursement. To opt-out you must submit an opt-out

affidavit to your MAC. For more information refer to Opt Out of Medicare.

Some Medicare Advantage (MA) plans and/or State Medicaid Agencies may require you to enroll in Medicare before enrolling in their programs. Opting out of Medicare could impact your participation in these programs. Refer to https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Downloads/opt-out-decision-matrix-%5BOctober-2015%5D.pdf for the impacts of opting out.

Physicians and non-physician practitioners who will not see Medicare patients, are not required to enroll or opt-out of Medicare.

41. Is there a standard opt-out form?

A standard opt-out form is not available. However, some MACs have a template on their website that you can use. Find your designated MAC and their contact and mailing address at MAC Contact Information.

42. How long does the opt-out period last?

The opt-out period lasts for 2 years. Your opt-out status will automatically renew every 2-years unless you terminate. To terminate your opt-out status, you must submit a written notice (no later than 30 days before the end of your current 2 year opt-out period) to your MAC indicating that you do not want to extend his opt-out status for a subsequent 2-year period. Otherwise, your opt-out will automatically renew for another 2-year period.

Physicians or practitioners who have not previously opted out may terminate their opt-out period early, but notification must be given to the MAC(s) no later than 90 days after the effective date of the initial 2-year opt-out period.

For more information on opting-out refer to Opting Out of Medicare.

Getting Started with the Hospice Quality Reporting Program

This document provides detailed information on the requirements of the Hospice Item Set (HIS) and Consumer Assessment of Healthcare Providers and Systems® (CAHPS®) Hospice Survey. It is designed especially for new hospice providers and staff and provides comprehensive detail on the background of each requirement, data submission deadlines, possible exemptions, tips for compliance, and links to useful resources, including Help Desks.

The Hospice Quality Reporting Program (HQRP) promotes the delivery of person-centered, high-quality, and safe care by hospice providers. Currently, the HQRP uses three data sources for the calculation of quality measures (QMs):

1. Hospice Item Set (HIS)
2. Consumer Assessment of Healthcare Providers and Systems® (CAHPS®) Hospice Survey
3. Administrative Data (Claims)*

*The data source for the claims-based measures will be Medicare claims data that are already collected and submitted to CMS.

There are four (QMs) associated with the HQRP, one from HIS data, two from Medicare claims, and one from CAHPS® Hospice Survey.

The HQRP was established under section 1814(i)(5) of the Social Security Act (SSA). Data collection of the HIS began on July 1, 2014. To be compliant with the HQRP currently, hospices must comply with both the individual requirements of HIS and CAHPS®, and the submission of administrative data (Medicare claims). Individual compliance requirements for HIS and CAHPS® are discussed in greater detail, below. Since administrative data is collected from claims, hospices are automatically considered 100% compliant with this requirement. The SSA also directed the Secretary to reduce the market basket update (also known as the Annual Payment Update, or APU) for any hospice that does not comply with the quality data submission requirements with respect to that FY. Effective with the FY 2022 Final Rule, beginning with the

FY 2024 APU and for each subsequent year, the reduction increased from 2 to 4 percentage points for hospices who do not comply with the HQRP for that FY. The CMS HQRP website is the official website of the HQRP. Hospices should bookmark this website and check it often for updates.

Section 1: HIS

Who is required to submit data: As of July 1, 2014, all Medicare-certified hospice providers must submit HIS data (HIS-Admission and HIS-Discharge records) on all patient admissions and discharges. HIS data are collected and submitted on all patient admissions, regardless of the payer, patient's age, or location of the receipt of hospice services.

For new hospice providers: There are two considerations: when to begin submitting HIS data and when you may be subject to the APU reduction for HIS purposes.

- When to begin HIS data submission: New hospice providers must submit HIS data (HIS-Admission and HIS Discharge records) for all patient admissions on or after the date in the CMS Certification Number (CCN) notification letterhead.
- APU determination: New hospice providers are required to submit HIS data for patient admissions on or after the date in the CCN letterhead. A new hospice with a CCN notification letter dated on or after November 1st will not be subject to the 4 percentage-point APU reduction for that first year only. In this situation, if a hospice is found non-compliant, then it will need to follow the reconsideration process and attach the CCN notification letter and any other relevant documents to support their new status.

- **HIS Data Collection:** HIS data collection consists of collecting or abstracting data from patient clinical records to complete HIS Items. To ensure successful HIS data collection, hospices should review materials available on the CMS HQRP website, including:
  - Read the HIS Manual (available on the HIS webpage), which provides instructions for completing HIS items, as well as clinical examples for each item.
  - Watch HIS data collection trainings, which are available on the HQRP Training and Education Library webpage.
  - Contact the Quality Help Desk at HospiceQualityQuestions@cms.hhs.gov for questions about HIS data collection processes.

- **HIS Data Submission:** Hospices must convert HIS data into the proper electronic file format (XML) and submit all HIS records to CMS via Quality Improvement and Evaluation System (QI ES) Assessment Submission and Processing (ASAP). Hospice providers do not need to have an electronic medical record to convert/submit HIS data.
  - To convert HIS records, acquire the appropriate software either Hospice Abstraction Reporting Tool (HART) or a vendor-designed software. The decision to use HART or a vendor software is your decision. Hospices who wish to use the free of charge HART should refer to the HIS Technical webpage to download the latest version.
  - To submit HIS data to QIES ASAP, hospices need to register for two User IDs: a CMSNet User ID and a QIES User ID.

- Register for the CMSNet User ID here using the "Hospice CMSNet Online Registration" application link.
- Once successfully logged onto the CMS Network using the CMSNet User ID, providers can register for a QIES User ID. Further information on registering for the QIES User ID can be found here under "QIES User ID."
- For questions about registering for User IDs and the HART or QIES ASAP systems, contact the Technical Help Desk at (877) 201-4721 (Monday–Friday from 7:00 AM – 7:00 PM CT), or by email at iqies@cms.hhs.gov.

- **Ensuring Successful Data Submission:** After each data submission to QIES ASAP, providers MUST verify that the data submitted were **ACCEPTED** by QIES ASAP.
  - When an HIS file is uploaded to QIES ASAP, you will receive two confirmation messages: an "Upload Completed" message and a "Submission Received" message. These initial two confirmation messages only indicate that the file has been **SUBMITTED** to QIES ASAP; they do not indicate that the file has been successfully **ACCEPTED** by QIES ASAP and CMS.
  - To ensure a file has been **ACCEPTED** without error, check the Final Validation Report in Certification And Survey Provider Enhances Reports (CASPER). For instructions on how to check the submission status of a file in the Final Validation Report, please refer to the CASPER Reporting Hospice Provider User's Guide located on the Hospice provider page of the QIES technical support office (QTSO) website.
  - If, 1) a Final Validation Report is not received following the submission of HIS records; or 2) a Final Validation Report is received with fatal errors listed, the data submission was not successful, and you must correct any errors and resubmit relevant HIS records to QIES ASAP.
  - Print and retain your Final Validation Reports as evidence of successful submission and processing of HIS records.
  - Contact the QTSO Help Desk at iQIES@cms.hhs.gov or call 1-877-201-4721, for questions about verifying that a submission was successfully received and processed.

- **Data Submission Deadlines:** HIS data is submitted on a rolling basis; HIS-Admission records and HIS Discharge records must be **SUBMITTED** and **ACCEPTED** by the Admission Date + 30 calendar days and the Discharge Date + 30 calendar days, respectively.

- **HIS Compliance:** HIS compliance for APU is based on timeliness of data submission. To be compliant for all reporting years, **hospices must submit at least 90% of their HIS records in accordance with the 30-day submission deadline specified above.**

Determinations of timeliness compliance are made based on records with a target date within the appropriate calendar year (Jan 1 – Dec 31). For example, for the FY 2026 APU reporting year, hospices must submit a minimum of 90% of records with a target date within the reporting period (HIS records with a target date 1/1/24 – 12/31/24) on time.

For more information on HIS timeliness requirements, please refer to the "Timeliness Compliance Threshold Fact Sheet" located in the Downloads section of the HQRP Requirements and Best Practices webpage.

Section 2: Hospice CAHPS®

Who is required to submit data: All Medicare-certified hospices are required to submit Hospice CAHPS® data. However, there are two exemptions for Hospice CAHPS® reporting: newness exemption and size exemption.

- **Newness exemption:** For hospices who received their CCN on/after January 1st of the data collection year. This is a one-time exemption that will be automatically granted by CMS, no action is required from hospice providers to receive this exemption. We recommend that you keep the CMS letter informing you of the assignment of your CCN.
- **Size Exemption:** For hospices with fewer than 50 survey-eligible decedents in the prior calendar year. This exemption is not automatically granted; hospices must complete the request form annually by the size exemption form deadline. The size exemption form is available on the CAHPS® Hospice Survey website. Hospice providers must submit the form annually, by the specified deadline, to be eligible for the exemption.
- For questions about the CAHPS® Hospice Survey and data submission requirements, please contact the CAHPS® Help Desk at hospicecahpssurvey@hsag.com or call 1-844-472-4621.

Data Collection and Submission: Eligible hospices must contract with a CMS-approved vendor to conduct their CAHPS® surveys and submit their CAHPS® data. CAHPS® data is submitted by your vendor to the CAHPS® data warehouse.

- A list of approved survey vendors can be found by accessing the Approved Vendor List navigation button on the left-hand side of the CAHPS® Hospice Survey website.
- After contracting with an approved survey vendor, the hospice will need to complete and submit a CAHPS® Hospice Survey Vendor Authorization Form. To view or download the CAHPS® Hospice Survey Vendor Authorization Form, visit the Technical Specifications webpage.

Data Submission Deadlines: Your vendor must submit data quarterly. The deadlines are the second Wednesday of February, May, August, and November.

Ensuring Successful Data Submission: Maintain close contact with your vendor to ensure it is meeting quarterly deadlines and to ensure data submitted by the vendor has been **ACCEPTED** by CMS.

- Contact your vendor to ensure it is submitting data in ample time to meet the quarterly deadlines. We cannot accept late submissions.
- Sign up for data submission reports at the Information for Hospices webpage to monitor your vendor's actions and ensure submitted data have been accepted.

CAHPS® Compliance: CAHPS® compliance is determined based on whether your vendor successfully submits a total of 12 months of data to the CAHPS® data warehouse, with each submission made by the quarterly deadline. This means:

- Each quarterly submission must be complete (have 3 months or 1 quarter's worth of data)
- Each quarterly submission must be **SUBMITTED AND ACCEPTED** by the quarterly data submission deadline

For More Information: For more information about the CAHPS® Hospice Survey, please access the survey website or contact the technical assistance project team at hospicecahpssurvey@hsag.com or call 1- 844472-4621.

Getting Started with Hospice CASPER Quality Measure Reports

This fact sheet contains information about the two Certification and Survey Provider Enhanced Reporting (CASPER) Quality Measure (QM) reports available to hospice providers. Additionally, this fact sheet includes one potential model hospices could employ to use the QM reports for quality improvement.

I. Understanding the Hospice CASPER Quality Measure Reports

Two Confidential Provider Feedback Reports are available in the CASPER reporting application: **Hospice-Level Quality Measure Report** and **Hospice Patient Stay-Level Quality Measure Report**. These two reports fall under the class of CASPER reports known as "QM reports." CASPER QM reports are on-demand and are intended to provide hospice providers with feedback on their quality measure scores, helping them to improve the quality of care delivered. The information available in these reports in CASPER is for internal purposes only and is not for public display.

- **The Hospice-Level QM Report** includes the Hospice item Set (HIS) Comprehensive Assessment at Admission (CBE #3235), Hospice Care Index (HCI), and Hospice Visits in the Last Days of Life (HVLDL-CBE #3645) measure scores. The claims-based measures were added in September 2021. The report includes hospice specific scores, national and state averages. Details of the seven component process measures are included for the HIS Comprehensive Assessment at Admission Measure, as well as the details for the 10 individual HCI indicators.
- **The Hospice Patient-Level QM Report** identifies each patient with a qualifying HIS record used to calculate the hospice-level quality measure values for a select period. The report displays each patient's name and indicates how/if the patient's assessment affected the hospice's quality measure. The details of the seven component process measures are also included at the patient level for the HIS Comprehensive Assessment at Admission Measure. Claims-based measures are not included in these reports.

What measures are reported and how are these data collected?

The Hospice Quality Reporting Program (HQRP) was established under Section 1814(i)(5) of the Social Security Act. Since 2014, Medicare-certified hospice providers are required to submit an HIS Admission record for all patient admissions and an HIS-Discharge record for their subsequent discharges. Hospices are required to submit the appropriate HIS record for each patient admission and discharge, regardless of the patient's payer source, age, or location where hospice services are received. Hospices submit HIS data to CMS through the Quality Improvement and Evaluation System (QIES) Assessment Submission and Processing (ASAP), or it's replacement system.

HIS data are used to calculate one HQRP process measure, and administrative data (i.e., Medicare claims) are used to calculate two claims-based quality measures *(Table 1).* These three of the four HQRP quality measures are reported on the Hospice CASPER Quality Measure Reports. The Consumer

Assessment of Healthcare Providers and Systems (CAHPS®) Hospice Survey (Consensus-Based Entity (CBE) # 2651) [1] measure is not included on these QM reports.

Table 1. Quality Measures Reported on CASPER QM Reports

Measure Title (CBE ID)	Measure Description
HIS Comprehensive Assessment at Admission (CBE #3235)	The percentage of hospice stays during which patients received a comprehensive patient assessment at hospice admission.
Hospice Visits in the Last Days of Life (HVLDL) (CBE #3645) *	A claims-based measure indicating visits in the last 3 days of life
Hospice Care Index (HCI)	A single score measure that combines the results of 10 claims-based indicators

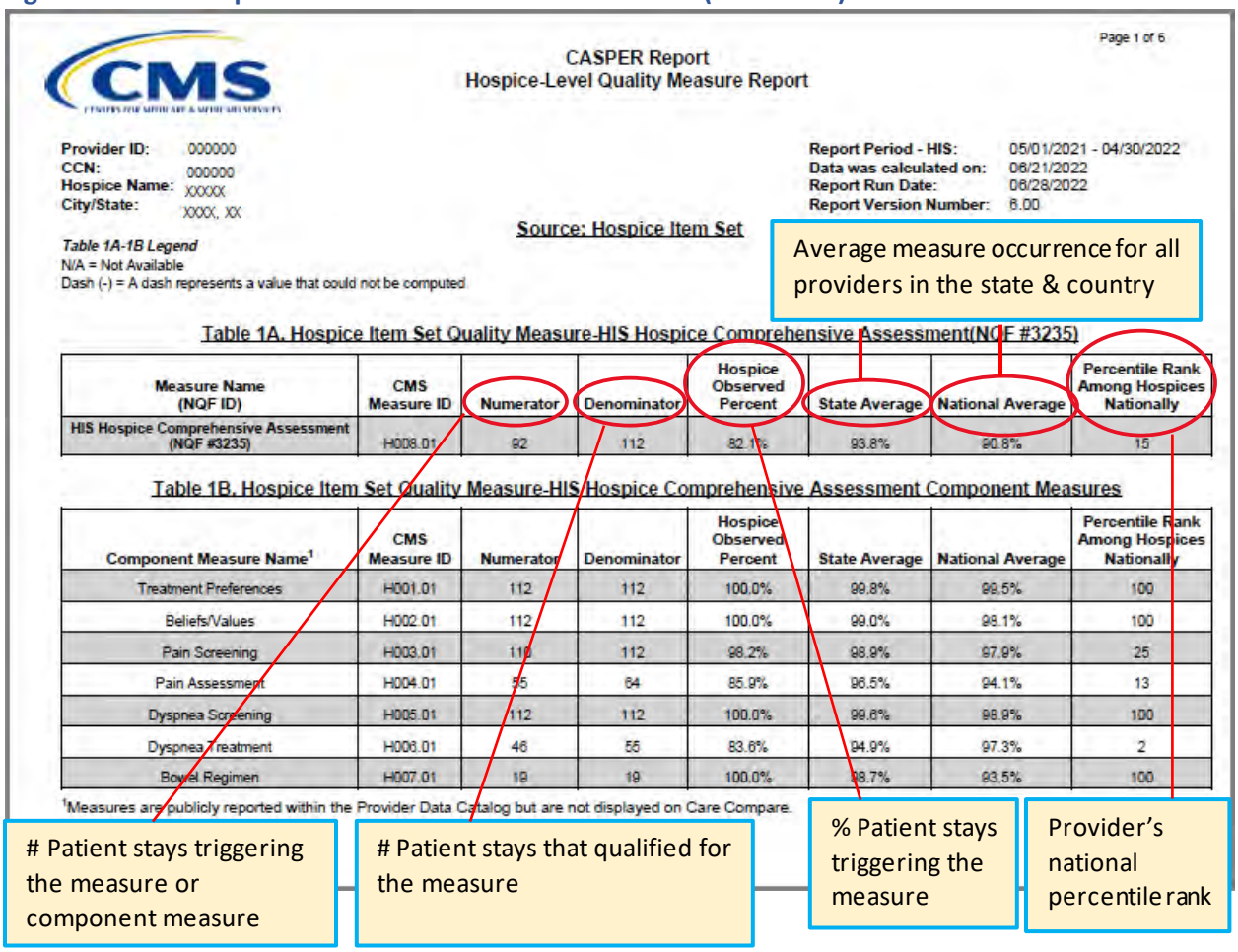
Hospice-Level Quality Measure Report

This report enables hospice providers to review their QM scores at the hospice-level and compare their organization's overall performance to their state and national average scores. *Figure 1A illustrates how to read this report.*

- Use as a quality improvement tool:
  - Hospice providers can identify which QMs they perform well on and which they might develop quality improvement interventions to improve performance.
  - QM results can be trended by comparing QM scores and percentiles across multiple reporting periods. Trending QM scores enables hospice providers to monitor the progress of their quality improvement interventions.
  - For the HIS Comprehensive Assessment at Admission, providers can trend consecutive quarters, while for the claims-based measures, providers can trend by the eight quarters (2 years) of data.
- Understanding data calculations:
  - For the HIS Comprehensive Assessment at Admission, the data are calculated monthly, approximately mid-month. Any assessments submitted after the calculation date will be included in the next monthly calculation. The *"Data was calculated on"* date shows you the most recent calculation date.
  - For claims-based measure scores, the data is updated annually in November.

[1] For information about the CAHPS® Hospice Survey, a description of the survey, its measures, and requirements visit the survey webpage, www.hospicecahpssurvey.org.

Figure 1a. HIS Comprehensive Assessment at Admission (CBE #3235)



Page 1 of 6

CASPER Report
Hospice-Level Quality Measure Report

Provider ID: 000000
CCN: 000000
Hospice Name: XXXX
City/State: XXXX, XX

Report Period - HIS: 05/01/2021 - 04/30/2022
Data was calculated on: 06/21/2022
Report Run Date: 06/28/2022
Report Version Number: 6.00

Source: Hospice Item Set

Table 1A-1B Legend
N/A = Not Available
Dash (-) = A dash represents a value that could not be computed

Average measure occurrence for all providers in the state & country

Table 1A. Hospice Item Set Quality Measure-HIS Hospice Comprehensive Assessment(NQF #3235)

Measure Name (NQF ID)	CMS Measure ID	Numerator	Denominator	Hospice Observed Percent	State Average	National Average	Percentile Rank Among Hospices Nationally
HIS Hospice Comprehensive Assessment (NQF #3235)	H008.01	92	112	82.1%	93.8%	90.8%	15

Table 1B. Hospice Item Set Quality Measure-HIS Hospice Comprehensive Assessment Component Measures

Component Measure Name[1]	CMS Measure ID	Numerator	Denominator	Hospice Observed Percent	State Average	National Average	Percentile Rank Among Hospices Nationally
Treatment Preferences	H001.01	112	112	100.0%	99.8%	99.5%	100
Beliefs/Values	H002.01	112	112	100.0%	99.0%	98.1%	100
Pain Screening	H003.01	110	112	98.2%	98.9%	97.9%	25
Pain Assessment	H004.01	55	64	85.9%	96.5%	94.1%	13
Dyspnea Screening	H005.01	112	112	100.0%	99.6%	98.9%	100
Dyspnea Treatment	H006.01	46	55	83.6%	94.9%	97.3%	2
Bowel Regimen	H007.01	19	19	100.0%	98.7%	93.5%	100

[1]Measures are publicly reported within the Provider Data Catalog but are not displayed on Care Compare.

Patient stays triggering the measure or component measure

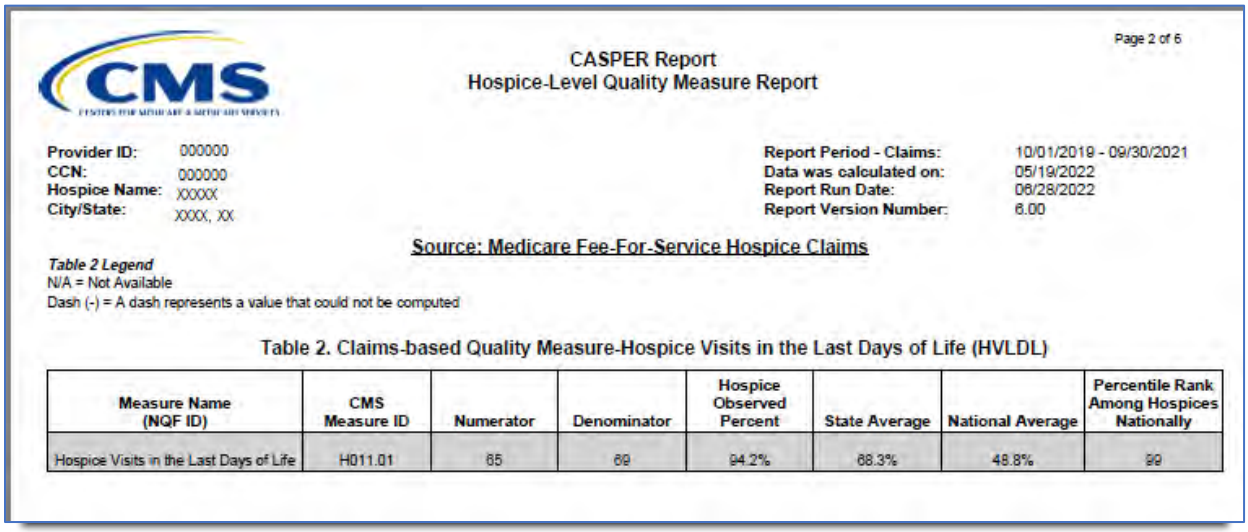
Patient stays that qualified for the measure

% Patient stays triggering the measure

Provider's national percentile rank

Figure 1A provides detailed explanations to help you interpret the columns in the report.

Figure 1b. HVLDL (CBE #3645)



Page 2 of 6

CASPER Report
Hospice-Level Quality Measure Report

Provider ID:	000000	**Report Period - Claims:**	10/01/2019 - 09/30/2021
CCN:	000000	**Data was calculated on:**	05/19/2022
Hospice Name:	XXXXX	**Report Run Date:**	06/28/2022
City/State:	XXXX, XX	**Report Version Number:**	6.00

Source: Medicare Fee-For-Service Hospice Claims

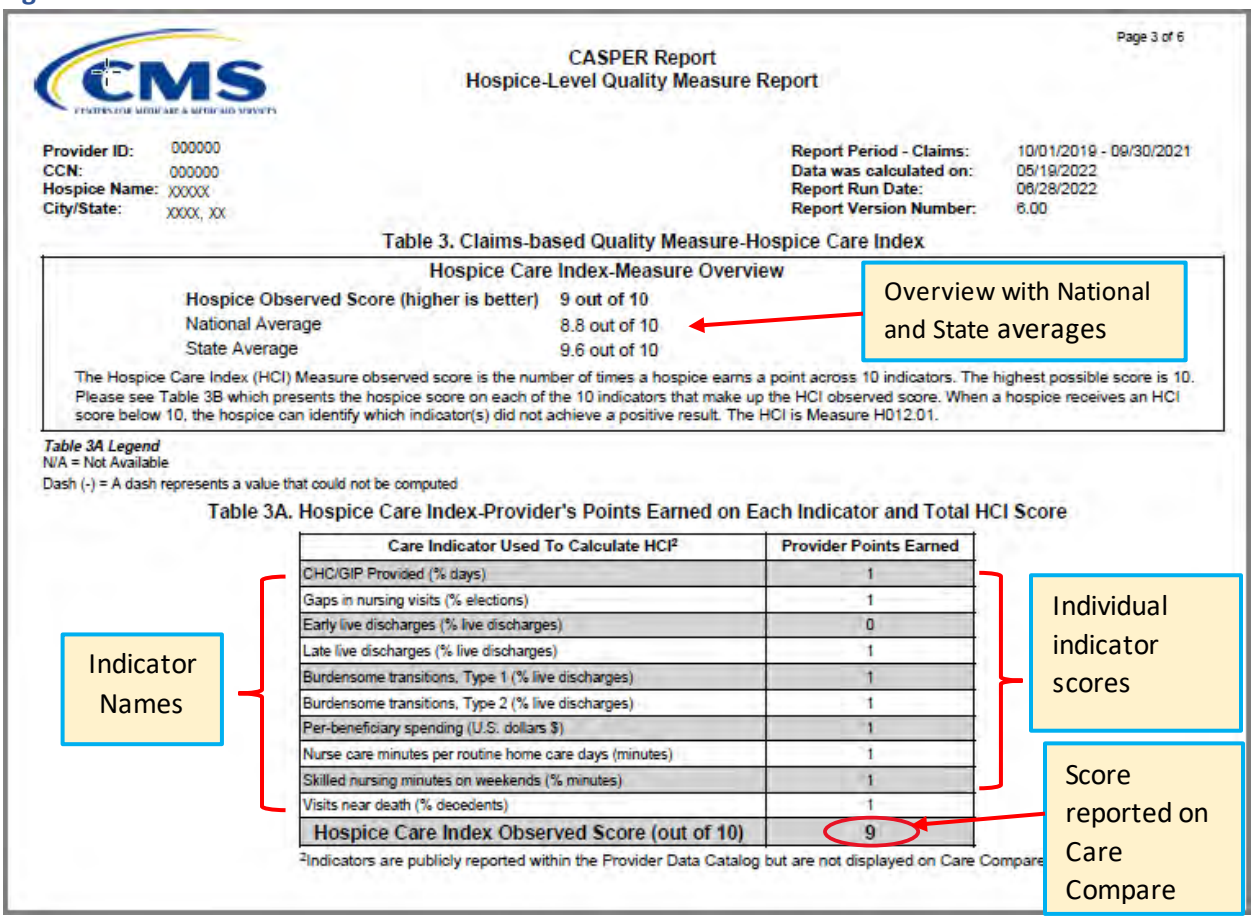
Table 2 Legend
N/A = Not Available
Dash (-) = A dash represents a value that could not be computed

Table 2. Claims-based Quality Measure-Hospice Visits in the Last Days of Life (HVLDL)

Measure Name (NQF ID)	CMS Measure ID	Numerator	Denominator	Hospice Observed Percent	State Average	National Average	Percentile Rank Among Hospices Nationally
Hospice Visits in the Last Days of Life	H011.01	65	69	94.2%	68.3%	48.8%	99

Figure 1b displays a sample of the HVLDL measure on Table 2 of the report. This table includes the same columns of information as HIS Comprehensive Assessment at Admission.

Figure 1c. HCI Overview



Page 3 of 6

CASPER Report
Hospice-Level Quality Measure Report

Provider ID:	000000	**Report Period - Claims:**	10/01/2019 - 09/30/2021
CCN:	000000	**Data was calculated on:**	05/19/2022
Hospice Name:	XXXX	**Report Run Date:**	06/28/2022
City/State:	XXXX, XX	**Report Version Number:**	6.00

Table 3. Claims-based Quality Measure-Hospice Care Index

Hospice Care Index-Measure Overview

Hospice Observed Score (higher is better)	**9 out of 10**
National Average	8.8 out of 10
State Average	9.6 out of 10

The Hospice Care Index (HCI) Measure observed score is the number of times a hospice earns a point across 10 indicators. The highest possible score is 10. Please see Table 3B which presents the hospice score on each of the 10 indicators that make up the HCI observed score. When a hospice receives an HCI score below 10, the hospice can identify which indicator(s) did not achieve a positive result. The HCI is Measure H012.01.

Overview with National and State averages

Table 3A Legend
N/A = Not Available
Dash (-) = A dash represents a value that could not be computed

Table 3A. Hospice Care Index-Provider's Points Earned on Each Indicator and Total HCI Score

Care Indicator Used To Calculate HCI[2]	Provider Points Earned
CHC/GIP Provided (% days)	1
Gaps in nursing visits (% elections)	1
Early live discharges (% live discharges)	0
Late live discharges (% live discharges)	1
Burdensome transitions, Type 1 (% live discharges)	1
Burdensome transitions, Type 2 (% live discharges)	1
Per-beneficiary spending (U.S. dollars $)	1
Nurse care minutes per routine home care days (minutes)	1
Skilled nursing minutes on weekends (% minutes)	1
Visits near death (% decedents)	1
Hospice Care Index Observed Score (out of 10)	**9**

[2]Indicators are publicly reported within the Provider Data Catalog but are not displayed on Care Compare

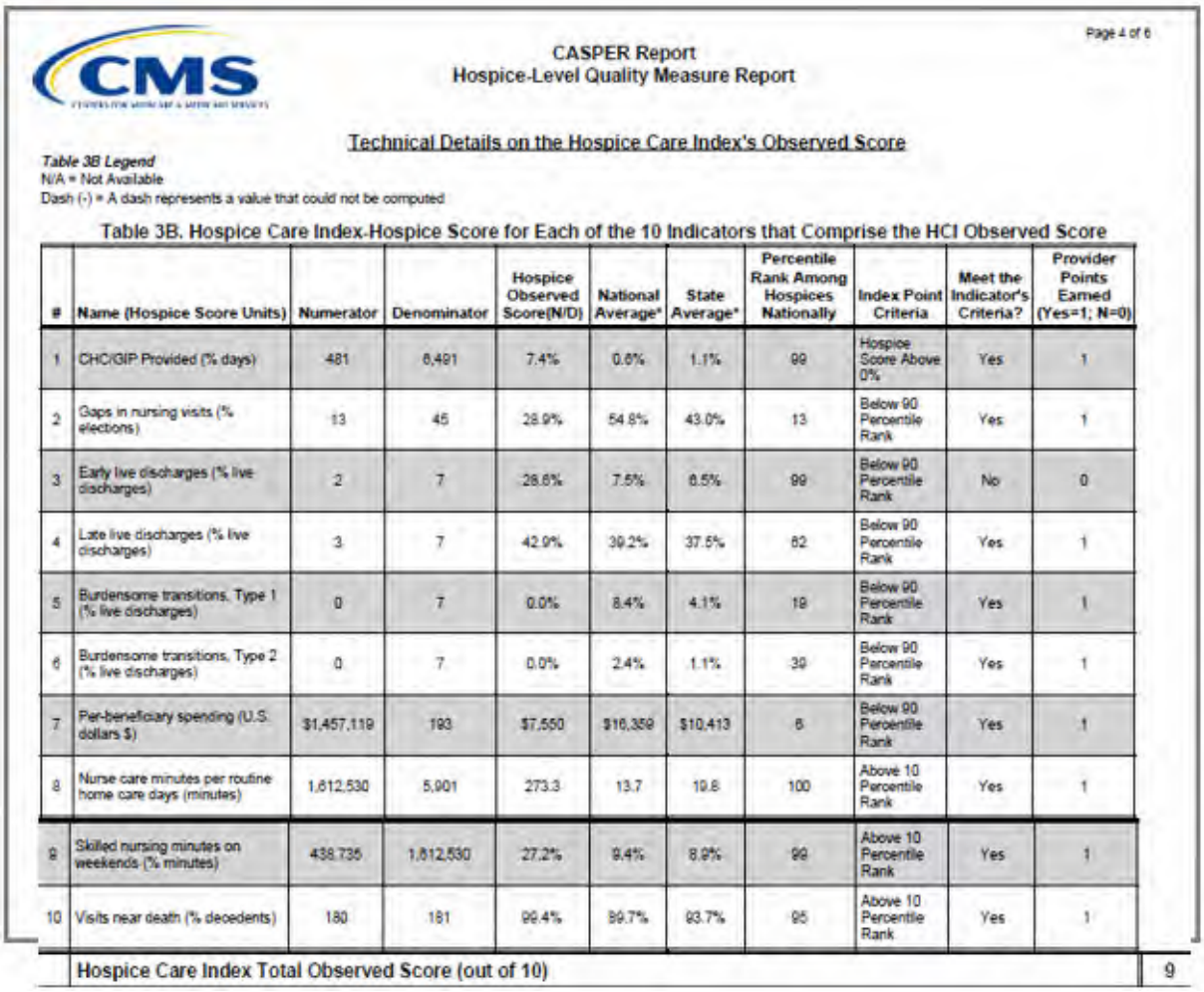
Indicator Names

Individual indicator scores

Score reported on Care Compare

Figure 1c. depicts Table 3 and 3A of the report for the HCI claims-based measure. The top box highlighted in blue displays the hospice's score, 9 out of 10. For reference, the national and state averages are also given; (8.8 out of 10), and (9.6 out of 10) respectively. For this measure, a higher observed score is better; a hospice with a 10 out of 10 would have the highest score. Since the HCI score is an index reflecting multiple indicators, the report also contains indicator-level data in the chart shown at the bottom. Table 3A shows that the provider earned 1 point for 9 of the ten indicators, resulting in the 9 out of 10 Hospice Observed Score. This provider did not meet the criteria for one of the indicators, thus did not earn a point for that indicator.

Figure 1d. HCI - Details for the 10 Indicators



Page 4 of 6

CASPER Report
Hospice-Level Quality Measure Report

Technical Details on the Hospice Care Index's Observed Score

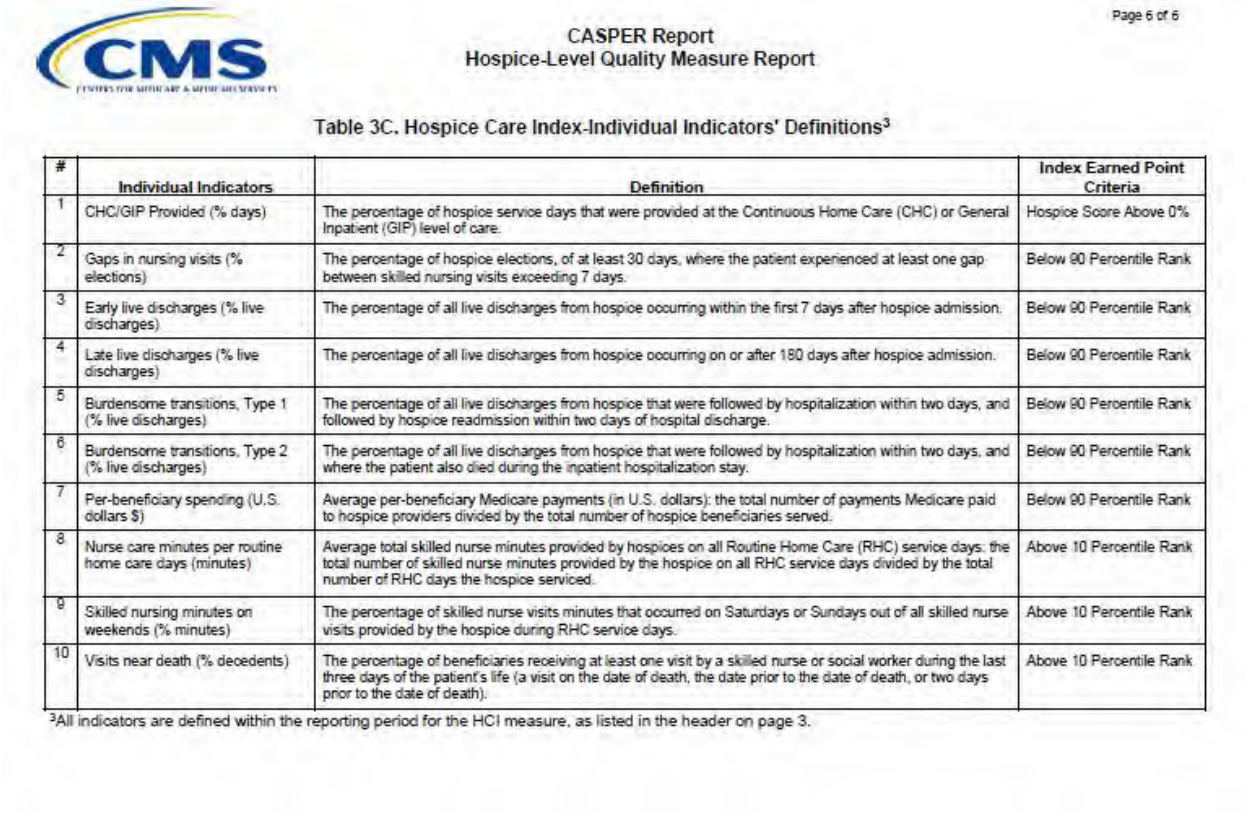
Table 3B Legend
N/A = Not Available
Dash (-) = A dash represents a value that could not be computed

Table 3B. Hospice Care Index-Hospice Score for Each of the 10 Indicators that Comprise the HCI Observed Score

#	Name (Hospice Score Units)	Numerator	Denominator	Hospice Observed Score(N/D)	National Average*	State Average*	Percentile Rank Among Hospices Nationally	Index Point Criteria	Meet the Indicator's Criteria?	Provider Points Earned (Yes=1; N=0)
1	CHC/GIP Provided (% days)	481	6,491	7.4%	0.6%	1.1%	99	Hospice Score Above 0%	Yes	1
2	Gaps in nursing visits (% elections)	13	45	28.9%	54.8%	43.0%	13	Below 90 Percentile Rank	Yes	1
3	Early live discharges (% live discharges)	2	7	28.6%	7.5%	6.5%	99	Below 90 Percentile Rank	No	0
4	Late live discharges (% live discharges)	3	7	42.9%	39.2%	37.5%	82	Below 90 Percentile Rank	Yes	1
5	Burdensome transitions, Type 1 (% live discharges)	0	7	0.0%	8.4%	4.1%	19	Below 90 Percentile Rank	Yes	1
6	Burdensome transitions, Type 2 (% live discharges)	0	7	0.0%	2.4%	1.1%	39	Below 90 Percentile Rank	Yes	1
7	Per-beneficiary spending (U.S. dollars $)	$1,457,119	193	$7,550	$16,359	$10,413	6	Below 90 Percentile Rank	Yes	1
8	Nurse care minutes per routine home care days (minutes)	1,612,530	5,901	273.3	13.7	19.8	100	Above 10 Percentile Rank	Yes	1
9	Skilled nursing minutes on weekends (% minutes)	438,735	1,612,530	27.2%	9.4%	8.9%	99	Above 10 Percentile Rank	Yes	1
10	Visits near death (% decedents)	180	181	99.4%	89.7%	93.7%	95	Above 10 Percentile Rank	Yes	1
	Hospice Care Index Total Observed Score (out of 10)									9

Figure 1d depicts an example of Table 3B in the report. This table presents the detail for each indicator of the HCI measure. Each row represents one of the ten indicators.

Figure 1e. HCI Definitions



Page 6 of 6

CASPER Report
Hospice-Level Quality Measure Report

Table 3C. Hospice Care Index-Individual Indicators' Definitions[3]

#	Individual Indicators	Definition	Index Earned Point Criteria
1	CHC/GIP Provided (% days)	The percentage of hospice service days that were provided at the Continuous Home Care (CHC) or General Inpatient (GIP) level of care.	Hospice Score Above 0%
2	Gaps in nursing visits (% elections)	The percentage of hospice elections, of at least 30 days, where the patient experienced at least one gap between skilled nursing visits exceeding 7 days.	Below 90 Percentile Rank
3	Early live discharges (% live discharges)	The percentage of all live discharges from hospice occurring within the first 7 days after hospice admission.	Below 90 Percentile Rank
4	Late live discharges (% live discharges)	The percentage of all live discharges from hospice occurring on or after 180 days after hospice admission.	Below 90 Percentile Rank
5	Burdensome transitions, Type 1 (% live discharges)	The percentage of all live discharges from hospice that were followed by hospitalization within two days, and followed by hospice readmission within two days of hospital discharge.	Below 90 Percentile Rank
6	Burdensome transitions, Type 2 (% live discharges)	The percentage of all live discharges from hospice that were followed by hospitalization within two days, and where the patient also died during the inpatient hospitalization stay.	Below 90 Percentile Rank
7	Per-beneficiary spending (U.S. dollars $)	Average per-beneficiary Medicare payments (in U.S. dollars): the total number of payments Medicare paid to hospice providers divided by the total number of hospice beneficiaries served.	Below 90 Percentile Rank
8	Nurse care minutes per routine home care days (minutes)	Average total skilled nurse minutes provided by hospices on all Routine Home Care (RHC) service days: the total number of skilled nurse minutes provided by the hospice on all RHC service days divided by the total number of RHC days the hospice serviced.	Above 10 Percentile Rank
9	Skilled nursing minutes on weekends (% minutes)	The percentage of skilled nurse visits minutes that occurred on Saturdays or Sundays out of all skilled nurse visits provided by the hospice during RHC service days.	Above 10 Percentile Rank
10	Visits near death (% decedents)	The percentage of beneficiaries receiving at least one visit by a skilled nurse or social worker during the last three days of the patient's life (a visit on the date of death, the date prior to the date of death, or two days prior to the date of death).	Above 10 Percentile Rank

[3]All indicators are defined within the reporting period for the HCI measure, as listed in the header on page 3.

Figure 1e depicts Table 3c, which includes the definition for each HCI indicator along with the corresponding Index Earned Point Criterion.

Note: *For more information on how the numerator and denominator are determined and how quality measures are calculated, see the QM User's Manual ("Current Measures" link provided in Resources section, below)*

Hospice Patient Stay-Level Quality Measure Report

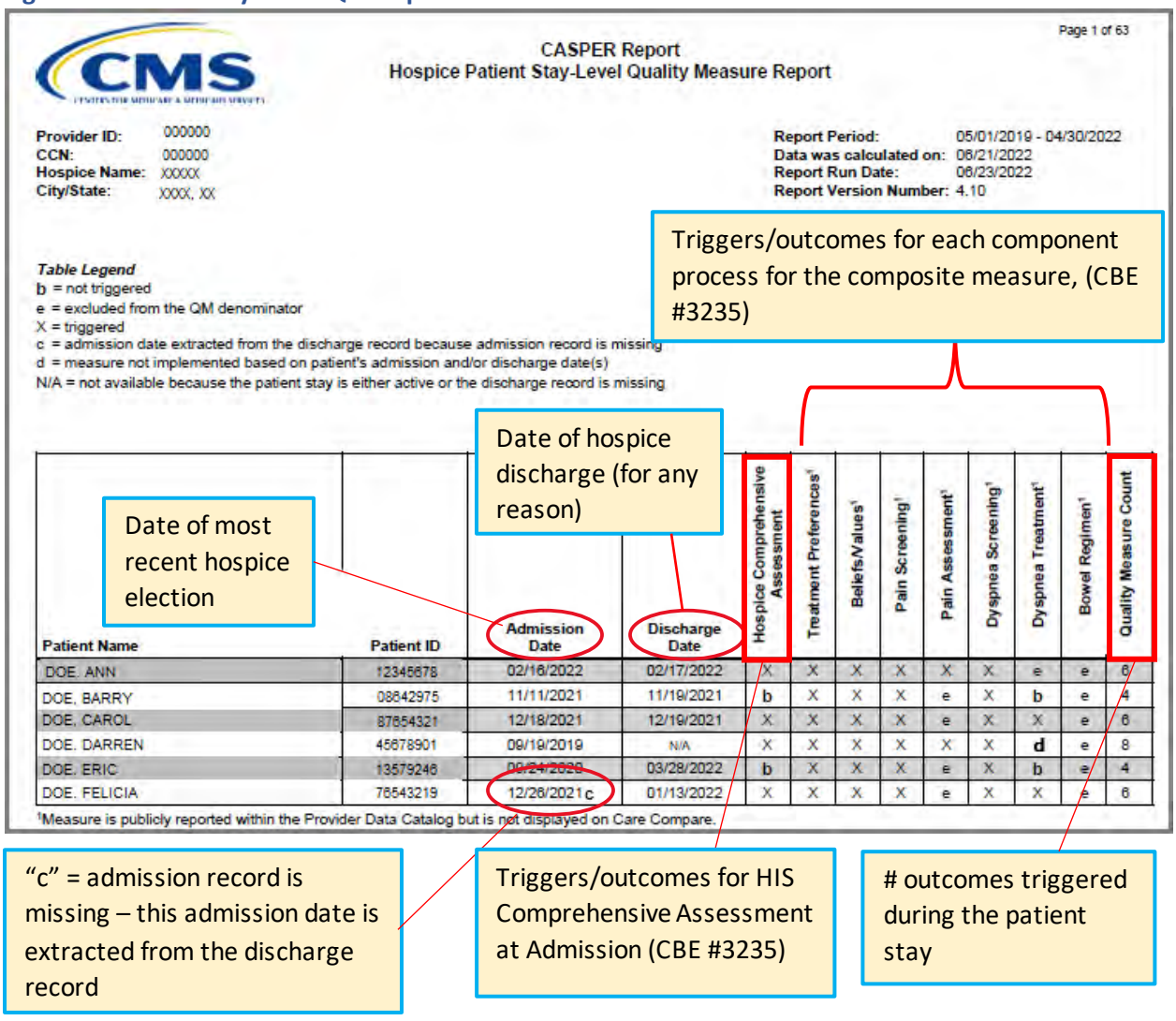
This report enables hospice providers to review the quality measure outcomes for the HIS Comprehensive Assessment at Admission for all patient stays during the reporting period. The report shows which patient stays triggered each quality measure. *Figure 2* illustrates how to read this report.

- As a companion report to the Hospice-Level Quality Measure Report, this report drills down to patient-stay level information for each of the seven component quality measures that comprise the HIS Comprehensive Assessment at Admission.
- Use as a quality improvement tool:
    - This report can assist a hospice to review the individual components for the HIS Comprehensive Assessment at Admission measure, should results on the Hospice-Level Quality Measure Report be less favorable than anticipated. Providers can quickly assess which patient stays contributed to the unfavorable results. Hospices can then implement process improvements to address the issues identified.

- Quality of care concerns for specific patient populations can also be assessed (e.g., based upon length of stay). For example, to look at short stay patients, a hospice provider could review cases in which the admission and discharge date were within the same month and year. It can then be determined which patients did not achieve three or more of the component process measures. Thus, the hospice could decide whether there are general quality of care concerns for patients with a short length of stay.
- Missing records: This report indicates when an admission record was not submitted with a corresponding HIS discharge record (Type 2 Stay). This information could assist a provider to identify when a missing admission record should be submitted to the QIES ASAP system. A link to the HIS Manual is provided in the Resources section below.

- Claims-based measures are not included in these reports.

Figure 2. Patient Stay-Level QM Report



Page 1 of 63

CASPER Report
Hospice Patient Stay-Level Quality Measure Report

Provider ID: 000000
CCN: 000000
Hospice Name: XXXXX
City/State: XXXX, XX

Report Period: 05/01/2019 - 04/30/2022
Data was calculated on: 06/21/2022
Report Run Date: 06/23/2022
Report Version Number: 4.10

Table Legend
b = not triggered
e = excluded from the QM denominator
X = triggered
c = admission date extracted from the discharge record because admission record is missing
d = measure not implemented based on patient's admission and/or discharge date(s)
N/A = not available because the patient stay is either active or the discharge record is missing

Patient Name	Patient ID	Admission Date	Discharge Date	Hospice Comprehensive Assessment	Treatment Preferences[1]	Beliefs/Values[1]	Pain Screening[1]	Pain Assessment[1]	Dyspnea Screening[1]	Dyspnea Treatment[1]	Bowel Regimen[1]	Quality Measure Count
DOE, ANN	12345678	02/16/2022	02/17/2022	X	X	X	X	X	X	e	e	6
DOE, BARRY	08642975	11/11/2021	11/19/2021	b	X	X	X	e	X	b	e	4
DOE, CAROL	87654321	12/18/2021	12/19/2021	X	X	X	X	e	X	X	e	6
DOE, DARREN	45678901	09/19/2019	N/A	X	X	X	X	X	X	d	e	8
DOE, ERIC	13579246	[illegible]	03/28/2022	b	X	X	X	e	X	b	e	4
DOE, FELICIA	76543219	12/26/2021 c	01/13/2022	X	X	X	X	e	X	X	e	6

[1]Measure is publicly reported within the Provider Data Catalog but is not displayed on Care Compare.

Triggers/outcomes for each component process for the composite measure, (CBE #3235)

Date of hospice discharge (for any reason)

Date of most recent hospice election

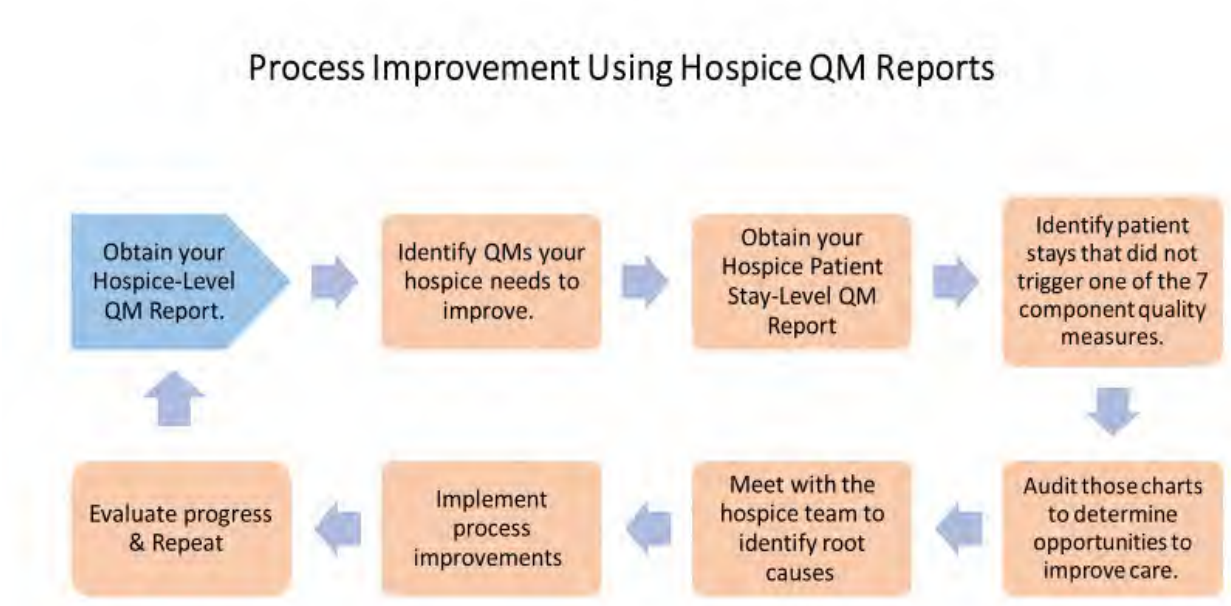
"c" = admission record is missing – this admission date is extracted from the discharge record

Triggers/outcomes for HIS Comprehensive Assessment at Admission (CBE #3235)

outcomes triggered during the patient stay

II. Sample Process for Using the Measure Reports for Quality Improvement

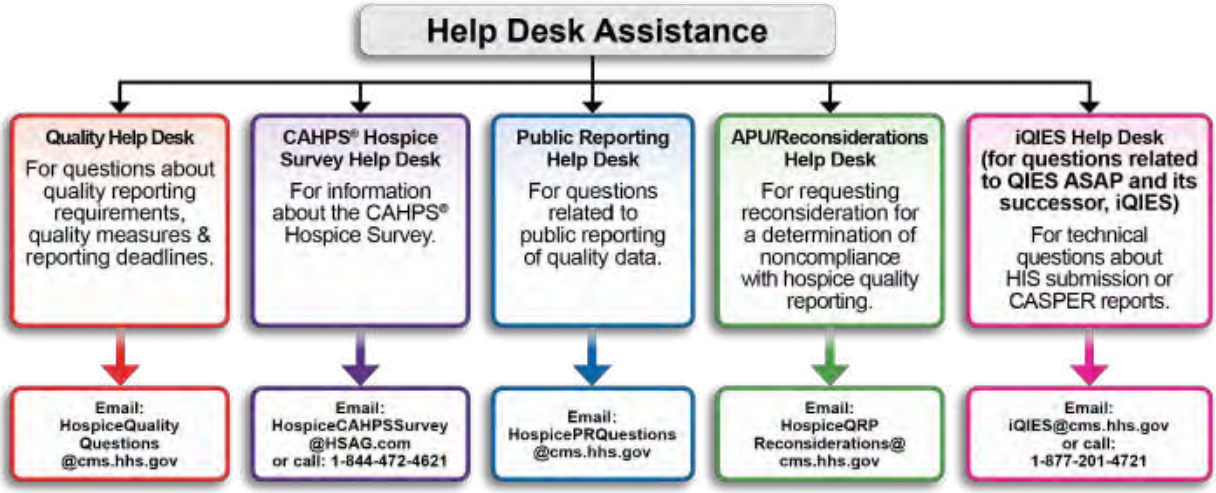
1) Obtain your Hospice-Level QM Report.
2) Use this report to identify which QMs need improvement.
3) Obtain the Hospice Patient Stay-Level QM Report for the same report period that was selected for the Hospice-Level QM Report to analyze the details for the HIS Comprehensive Assessment at Admission.
4) Analyze your Hospice Patient Stay-Level QM Report.
5) Identify a sample of patient stays that did not trigger (i.e., did not meet the numerator criteria) for one of the seven component quality measures for the HIS Comprehensive Assessment at Admission. This may reflect opportunities for quality improvement.
6) Audit the medical records for those patient stays that did not trigger the measure. This will help to determine where the opportunities are to improve care and where a defined care process may not have been followed.
7) Meet with your hospice team to identify root causes. Ask why these care processes were not followed? This may require looking beyond chart data.
   a) For example, if all patient stays in a poor-performing component measure were found to be under the care of one nurse, explore with the nurse why this occurred and why sub-optimal care may have been delivered.
   b) In cases where excellent care was identified (patient stays triggered the measure), explore with the hospice team how those processes could be replicated.
8) Implement process improvements related to the findings of the chart audits.
9) Repeat this cycle regularly to drive quality improvement



III. Resources Available to Hospice Providers

- For more detailed instruction on accessing CASPER reports, please view the CASPER Reporting Hospice Provider User's Guide.
- For Training on all topics related to the HQRP, including how to use provider reports, visit the HQRP Training and Education Library.
- For more information, resources, and updates related to HIS data submission specifications and other technical information, visit the HIS Technical Information webpage on the CMS HQRP website.
- For more information on the QMs and how the measures are calculated review the current HQRP QM User's Manual located in the Downloads section of the Current Measures webpage on the CMS HQRP website.

IV. Help Desk Resources



Getting Started with Hospice CASPER Review and Correct Reports

This overview of the Review and Correct Reports is intended to help providers understand what they are and how to interpret and use the Hospice Item Set (HIS) data contained within them. These reports are confidential and contain details about the HIS-based quality measure (QM), Comprehensive Assessment at Admission (Consensus-Based Entity (CBE) #3235). Review and Correct Reports provide information at the hospice-level, and about individual patients, if desired.

Sections

I. Understanding the Hospice CASPER Review and Correct Reports

The CASPER Review and Correct Reports are designed to give hospices an opportunity to:

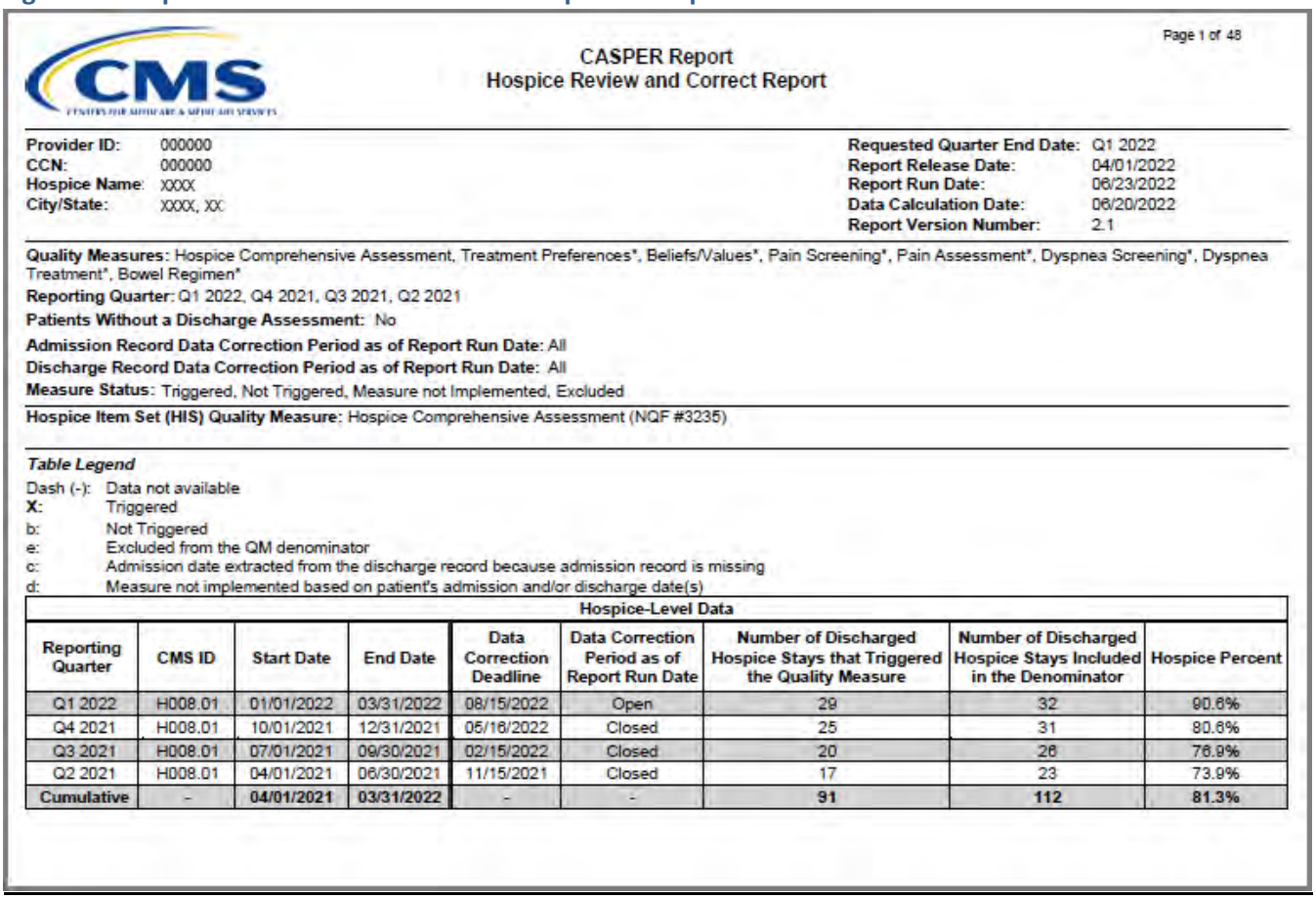
- Confirm the accuracy of their HIS-based QM data
- Track quarterly data cumulatively
- View data that is both "Open" and "Closed" for data correction over 12 months
- Access QM data prior to the Data Correction Deadline for public reporting.

What information does the hospice-level Review and Correct Report display?

The hospice level Review and Correct Report displays the number of patient-stays that trigger the quality measure (the numerator) and the number of eligible patient discharges (the denominator) for the HIS Comprehensive Assessment at Admission in the Hospice Quality Reporting program (HQRP), as well as the seven individual components for the measure. It also displays the observed performance rate, which is simply the numerator divided by the denominator multiplied by 100. These results are not risk-adjusted. While the seven individual component measures are publicly reported within the Provider Data Catalog, these are not displayed on Care Compare. The report also includes the status of the data correction period determined by the Data Correction Deadline for each quarter. The correction period will be either Open or Closed depending on whether the Data Correction Deadline for the displayed data has passed.

Any corrections hospice providers make to the HIS data during an Open data correction period will be reflected in public reporting of the QM. Please see *Figure 1* below for an example of the hospice- level Review and Correct Report display, with data for four quarters that would typically be included.

Figure 1: Hospice-Level Review and Correct Report Example



Page 1 of 48

CASPER Report
Hospice Review and Correct Report

Provider ID: 000000
CCN: 000000
Hospice Name: XXXX
City/State: XXXX, XX

Requested Quarter End Date: Q1 2022
Report Release Date: 04/01/2022
Report Run Date: 06/23/2022
Data Calculation Date: 06/20/2022
Report Version Number: 2.1

Quality Measures: Hospice Comprehensive Assessment, Treatment Preferences*, Beliefs/Values*, Pain Screening*, Pain Assessment*, Dyspnea Screening*, Dyspnea Treatment*, Bowel Regimen*
Reporting Quarter: Q1 2022, Q4 2021, Q3 2021, Q2 2021
Patients Without a Discharge Assessment: No
Admission Record Data Correction Period as of Report Run Date: All
Discharge Record Data Correction Period as of Report Run Date: All
Measure Status: Triggered, Not Triggered, Measure not Implemented, Excluded
Hospice Item Set (HIS) Quality Measure: Hospice Comprehensive Assessment (NQF #3235)

Table Legend
Dash (-): Data not available
X: Triggered
b: Not Triggered
e: Excluded from the QM denominator
c: Admission date extracted from the discharge record because admission record is missing
d: Measure not implemented based on patient's admission and/or discharge date(s)

Hospice-Level Data

Reporting Quarter	CMS ID	Start Date	End Date	Data Correction Deadline	Data Correction Period as of Report Run Date	Number of Discharged Hospice Stays that Triggered the Quality Measure	Number of Discharged Hospice Stays Included in the Denominator	Hospice Percent
Q1 2022	H008.01	01/01/2022	03/31/2022	08/15/2022	Open	29	32	90.6%
Q4 2021	H008.01	10/01/2021	12/31/2021	05/16/2022	Closed	25	31	80.6%
Q3 2021	H008.01	07/01/2021	09/30/2021	02/15/2022	Closed	20	26	76.9%
Q2 2021	H008.01	04/01/2021	06/30/2021	11/15/2021	Closed	17	23	73.9%
Cumulative	-	**04/01/2021**	**03/31/2022**	-	-	**91**	**112**	**81.3%**

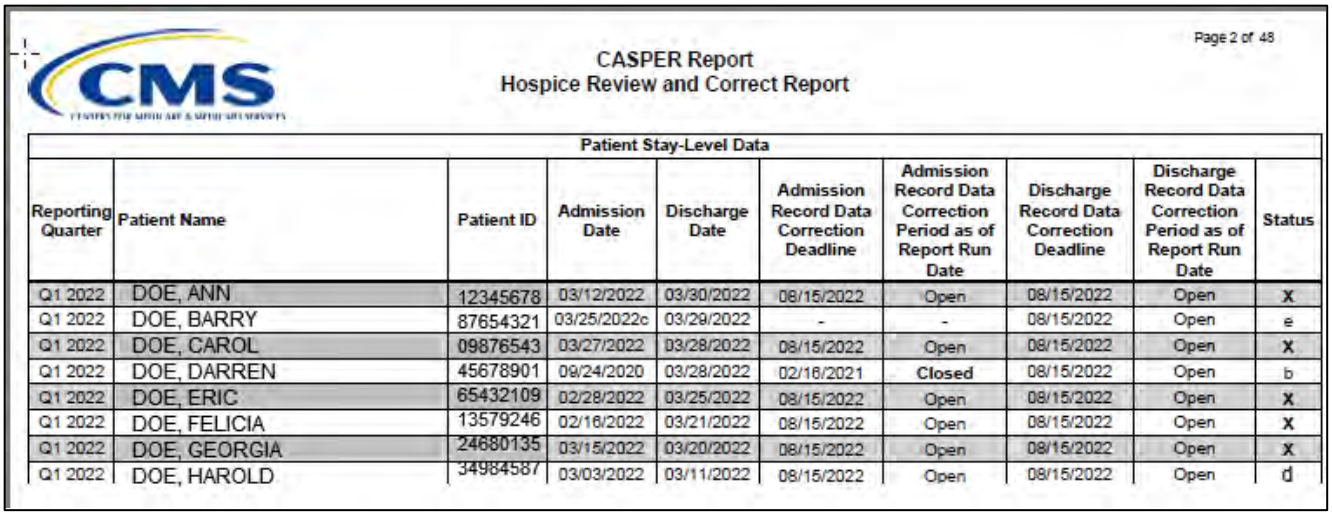
What patient stay-level information is displayed on the Review and Correct Report?

If included in the report request, patient-stay level results will display along with the hospice-level aggregated data in the same report. The patient-stay level information displayed includes a list of individual hospice patients with their admission and discharge dates for the stay and for whom the HIS data was submitted. The report indicates whether or not each patient was included in the numerator for the QM. *Table 1* below shows the letters used in the "Status" column to communicate information about each stay in relation to the measure included in the report. *Figure 2* presents an example of a patient-level information.

Table 1: Letters used in Review and Correct Reports

Letter	What the Information Indicates
X	The patient-stay *triggered the measure* (included in both the numerator and the denominator)
b	The patient-stay *did NOT trigger the measure* (included in the denominator, but not the numerator)
e	This patient was *excluded* from the denominator
c	The admission record is missing; the *Admission Date listed was extracted from the discharge record.*
d	The measure was not implemented based on patient's admission and/or discharge date(s).

Figure 2: Patient-Level Example



CASPER Report
Hospice Review and Correct Report

Page 2 of 48

Patient Stay-Level Data

Reporting Quarter	Patient Name	Patient ID	Admission Date	Discharge Date	Admission Record Data Correction Deadline	Admission Record Data Correction Period as of Report Run Date	Discharge Record Data Correction Deadline	Discharge Record Data Correction Period as of Report Run Date	Status
Q1 2022	DOE, ANN	12345678	03/12/2022	03/30/2022	08/15/2022	Open	08/15/2022	Open	x
Q1 2022	DOE, BARRY	87654321	03/25/2022c	03/29/2022	-	-	08/15/2022	Open	e
Q1 2022	DOE, CAROL	09876543	03/27/2022	03/28/2022	08/15/2022	Open	08/15/2022	Open	x
Q1 2022	DOE, DARREN	45678901	09/24/2020	03/28/2022	02/16/2021	Closed	08/15/2022	Open	b
Q1 2022	DOE, ERIC	65432109	02/28/2022	03/25/2022	08/15/2022	Open	08/15/2022	Open	x
Q1 2022	DOE, FELICIA	13579246	02/16/2022	03/21/2022	08/15/2022	Open	08/15/2022	Open	x
Q1 2022	DOE, GEORGIA	24680135	03/15/2022	03/20/2022	08/15/2022	Open	08/15/2022	Open	x
Q1 2022	DOE, HAROLD	34984587	03/03/2022	03/11/2022	08/15/2022	Open	08/15/2022	Open	d

When can providers run their Review and Correct Reports? And for what quarters?

Providers can run their Review and Correct Reports on-demand – that is, *at any time*. Reports display four consecutive quarters of data. Hospices can select which four quarters they would like to include. The reports populate data based on the user-specified "quarter end date" and automatically fills the "begin date" to include the three quarters preceding the specified "end date" quarter. For example, if the user selects Q1 2024 as the end date, the report will populate and display HIS QM results for discharges that occurred during Q2 2023 – Q1 2024. *Table 2* below shows this and other examples of how the Review and Correct Report data may be displayed for four possible quarterly end dates.

Table 2: Data Display by User-Selected End Date

User-Specified Quarter End Date	Quarters Included in Report
Q1 2024	Q1 2024, Q4 2023, Q3 2023, Q2 2023
Q2 2024	Q2 2024, Q1 2024, Q4 2023, Q3 2023
Q3 2024	Q3 2024, Q2 2024, Q1 2024, Q4 2023
Q4 2024	Q4 2024, Q3 2024, Q2 2024, Q1 2024

How often are the Review and Correct Reports updated?

New quarterly data are available for these reports on the first business day following the last day of the calendar year quarter.[1] As new quarterly data become available, hospices can include them in their Review and Correct Reports. HIS-based QM data are updated weekly. The updates reflect any changes made by providers, including modifications, as well as HIS records submitted and accepted after the

[1]For admission and discharge record data submitted at the end of the preceding quarter, data from these records will be included in the quarterly data after a subsequent weekly refresh. *Example: a provider may have a patient who is discharged at the end of the Q1 on March 31st, and will submit the HIS discharge record April 3rd, which is already in Q2. In this example, the discharge record will not appear if the report is run during the first week of April but will appear if the report is run during the following weeks.*

HQRP's 30-day submission deadline.[2] For all user-specified end quarter displayed in *Table 2* above, *Table 3* shows the date when those quarterly data become available in the Review and Correct Reports.

[2] As stated in the FY2018 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements Final Rule (FR36670), 90% of all required HIS records must be submitted and accepted within the 30- day submission deadline to avoid the percentage point reduction in the FY 2020 Annual Payment Unit (APU) and beyond. Starting with FY 2024, the penalty increased from 2% to 4%.

Table 3: Data Release Dates and Associated Quarterly Data

User-Specified Quarter End Date	Quarters Included in Report	Release Date
Q1 2024	Q1 2024, Q4 2023, Q3 2023, Q2 2023	**April 1, 2024**
Q2 2024	Q2 2024, Q1 2024, Q4 2023, Q3 2023	**July 1, 2024**
Q3 2024	Q3 2024, Q2 2024, Q1 2024, Q4 2023	**October 1, 2024**
Q4 2024	Q4 2024, Q3 2024, Q2 2024, Q1 2024	**January 1, 2025**

How can hospice providers use the Review and Correct reports?

If you access your reports early, you have more opportunity to make changes. For example, hospices may identify a need to correct data, and thus submit, modify, and/or inactivate HIS records in the Quality Improvement and Evaluation System (QIES) Assessment Submission And Processing (ASAP) system. In some cases, hospices may identify opportunities to provide staff education to ensure the accuracy of HIS data submissions or to initiate or update quality improvement strategies. A hospice can follow this sequence of activities to make use of the Review and Correct Reports:

1. Access the reports and investigate measure results
2. Identify opportunities for data correction and/or initiating or updating quality improvement strategies
3. Submit, modify, and/or inactivate HIS records in the ASAP system, as needed
4. Access the reports again to verify updates or corrections from the previous week

How do the CASPER Review and Correct Reports differ from QM Reports and Preview Reports?

The CASPER reports all have specific functions**.**

- **QM Reports** provide hospices with data to support quality improvement, including throughcomparison of hospice-level QM data with the national and state averages
- **Review and Correct Reports** give hospice providers a resource to monitor performance rates andthe opportunity to make required edits or corrections to their submitted HIS data
- **Preview Reports** provide previews of QM results prior to public display on Care Compare. Corrections to the underlying data for the measure calculations can no longer be made. A provider may request a CMS review of the calculations contained within the Provider Preview Report, should they believe the denominator or another quality metric to be inaccurate. Once reviewed, if CMS agrees that one or all of the data components are inaccurate, CMS may grant suppression of those measure results on Care Compare.

The reports differ in specific ways to fulfill these functions. *Table 4* highlights some of the key similarities and differences QM Reports and Preview Reports have with the Review and Correct Reports.

Table 4. Overview of Reports for Hospice Quality Reporting

Report Title	Always includes a full year of data	Includes patient stay-level data	Includes hospice-level data	Affected by data correction deadlines	Underlying data can be changed	Run on-demand
CASPER QM Reports	No*	Yes	Yes	No	Yes	Yes
Review and Correct Reports	Yes	Yes	Yes	Yes	**	Yes
HIS Provider Preview Reports	Yes	No	Yes	Yes	No	No

* The report may include a full year of data if requested by the provider. ** If the data correction period is "Open," provider corrections to HIS records will appear in a future release of the Review and Correct Reports. If the data correction period is "Closed," provider corrections to HIS records will NOT appear in a future release.

II. Report Example and Overview

Please see a mock-up example of Review and Correct Report sections below. Providers are encouraged to keep the following points in mind when reviewing their reports:

- Hospice Level Data Section: Includes the QM numerator, denominator, and score for patients who have been *discharged* within the selected four quarter reporting period. This section doesnot include patient records which are ongoing at the end of the selected four quarter reportingperiod.

- The Patient Stay-Level Section: Includes record-level data and provides an opportunity to quickly identify records that may require further investigation by the hospice, such as possible data inaccuracies or quality of care concerns.

The examples below include records that are still "Open" for data correction prior to the public reporting deadline on Care Compare at which time records are "Closed" or "frozen" for any data correction. In addition, the mock-up example includes:

- Twelve months of data indicating when the data is re-calculated (on a weekly basis) so providerscan capture edits or changes to HIS records submitted prior to the data correction deadline.
- Filters providers can select when running this report. For example, if a provider would like to see only data for patients without a discharge assessment, a selected filter will provide those records.
- The hospice-level section shows the number of discharged patients during the indicated quarter that met the QM's denominator criteria and numerator criteria and provides a *quarterly and cumulative* QM score.

Example of Hospice-Level Section on the Review and Correct Report

Report shows a rolling 12 months of data. This is the newest quarter of data that will appear on this report. The newest quarter of data doesn't automatically display; data for that quarter and the date in the requested quarter end date only display the latest quarter if it was selected by the user.

CASPER Report
Hospice Review and Correct Report

Provider ID: 000000
CCN: 000000
Hospice Name: XXXX
City/State: XXXX, XX

Shows the date on which this data was recalculated.

Requested Quarter End Date: Q1 2022
Report Release Date: 04/01/2022
Report Run Date: 06/23/2022
Data Calculation Date: 06/20/2022
Report Version Number: 2.1

Quality Measures: Hospice Comprehensive Assessment, Treatment Preferences*, Beliefs/Values*, Pain Screening*, Pain Assessment*, Dyspnea Screening*, Dyspnea Treatment*, Bowel Regimen*
Reporting Quarter: Q1 2022, Q4 2021, Q3 2021, Q2 2021
Patients Without a Discharge Assessment: No
Admission Record Data Correction Period as of Report Run Date: All
Discharge Record Data Correction Period as of Report Run Date: All
Measure Status: Triggered, Not Triggered, Measure not Implemented, Excluded

Providers can select certain filters when running this report (e.g., if the provider would like to see only data for patients without a discharge assessment). Selected filters will appear.

Hospice Item Set (HIS) Quality Measure: Hospice Comprehensive Assessment (NQF #3235)

Measure or component measure being reviewed

Table Legend
Dash (-): Data not available
X: Triggered
b: Not Triggered
e: Excluded from the QM denominator
c: Admission date extracted from the discharge record because admission record is missing
d: Measure not implemented based on patient's admission and/or discharge date(s)

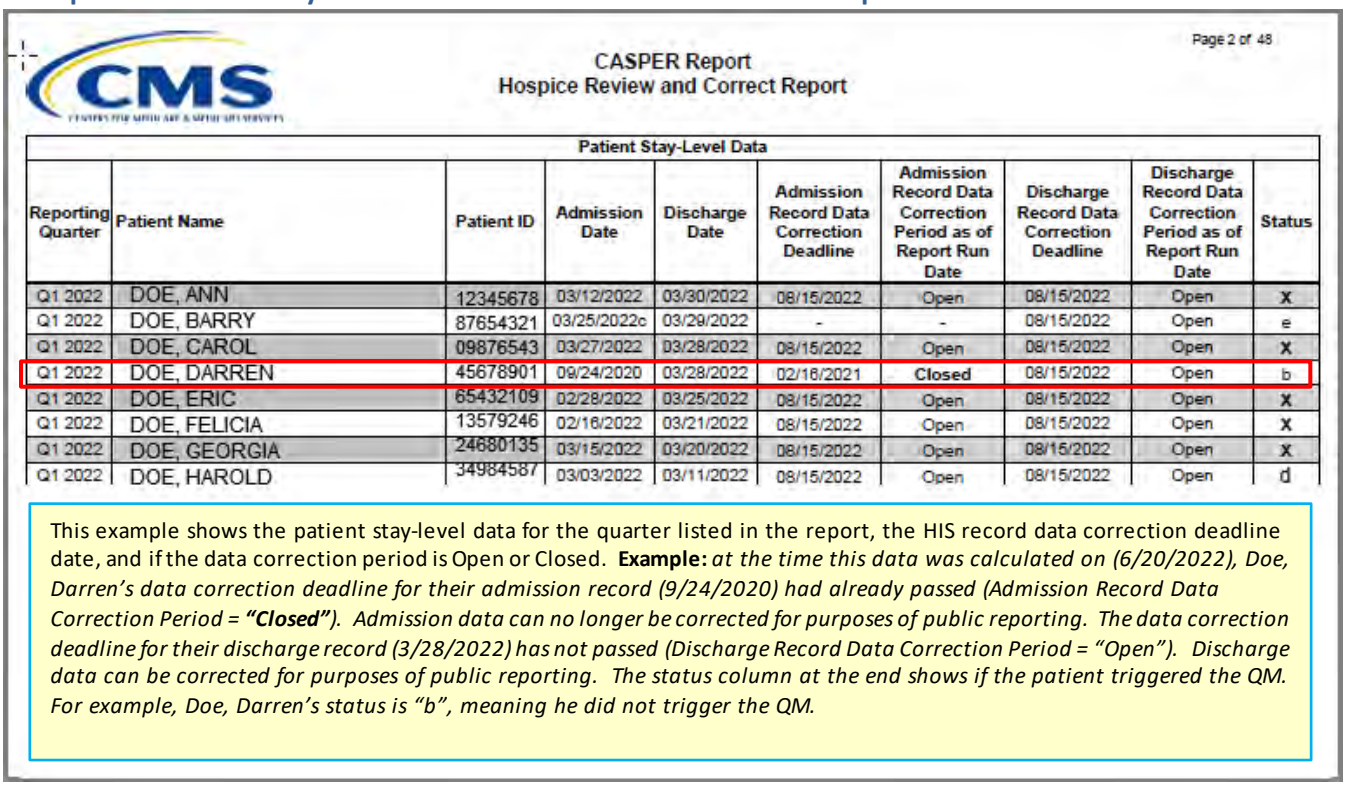
Shows the number of discharged patients during the indicated quarter that met the QMs denominator and numerator criteria. Provides a quarterly QM score.

Hospice-Level Data

Reporting Quarter	CMS ID	Start Date	End Date	Data Correction Deadline	Data Correction Period as of Report Run Date	Number of Discharged Hospice Stays that Triggered the Quality Measure	Number of Discharged Hospice Stays Included in the Denominator	Hospice Percent
Q1 2022	H008.01	01/01/2022	03/31/2022	08/15/2022	Open	29	32	90.6%
Q4 2021	H008.01	10/01/2021	12/31/2021	05/16/2022	Closed	25	31	80.6%
Q3 2021	H008.01	07/01/2021	09/30/2021	02/15/2022	Closed	20	26	76.9%
Q2 2021	H008.01	04/01/2021	06/30/2021	11/15/2021	Closed	17	23	73.9%
Cumulative	-	**04/01/2021**	**03/31/2022**	-	-	**91**	**112**	**81.3%**

Shows the number of discharged patients during the indicated 4 quarters that met the QMs denominator and numerator criteria. Provides a cumulative QM score.

Example of a Patient Stay-Level Section of the Review and Correct Report



CASPER Report
Hospice Review and Correct Report

Patient Stay-Level Data

Reporting Quarter	Patient Name	Patient ID	Admission Date	Discharge Date	Admission Record Data Correction Deadline	Admission Record Data Correction Period as of Report Run Date	Discharge Record Data Correction Deadline	Discharge Record Data Correction Period as of Report Run Date	Status
Q1 2022	DOE, ANN	12345678	03/12/2022	03/30/2022	08/15/2022	Open	08/15/2022	Open	x
Q1 2022	DOE, BARRY	87654321	03/25/2022c	03/29/2022	-	-	08/15/2022	Open	e
Q1 2022	DOE, CAROL	09876543	03/27/2022	03/28/2022	08/15/2022	Open	08/15/2022	Open	x
Q1 2022	DOE, DARREN	45678901	09/24/2020	03/28/2022	02/16/2021	Closed	08/15/2022	Open	b
Q1 2022	DOE, ERIC	65432109	02/28/2022	03/25/2022	08/15/2022	Open	08/15/2022	Open	x
Q1 2022	DOE, FELICIA	13579246	02/16/2022	03/21/2022	08/15/2022	Open	08/15/2022	Open	x
Q1 2022	DOE, GEORGIA	24680135	03/15/2022	03/20/2022	08/15/2022	Open	08/15/2022	Open	x
Q1 2022	DOE, HAROLD	34984587	03/03/2022	03/11/2022	08/15/2022	Open	08/15/2022	Open	d

This example shows the patient stay-level data for the quarter listed in the report, the HIS record data correction deadline date, and if the data correction period is Open or Closed. **Example:** *at the time this data was calculated on (6/20/2022), Doe, Darren's data correction deadline for their admission record (9/24/2020) had already passed (Admission Record Data Correction Period =* ***"Closed"****). Admission data can no longer be corrected for purposes of public reporting. The data correction deadline for their discharge record (3/28/2022) has not passed (Discharge Record Data Correction Period = "Open"). Discharge data can be corrected for purposes of public reporting. The status column at the end shows if the patient triggered the QM. For example, Doe, Darren's status is "b", meaning he did not trigger the QM.*

III. Resources Available to Hospice Providers

For specifics about the HQRP QMs, including access to the current HQRP QM User's Manual, visit the Current Measures page of the CMS HQRP website: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Current-Measures.

For helpful documents about the CASPER QM Reports, or to just get started with the HQRP, visit the *"Provider Toolkit section"* of the Requirements and Best Practice webpage: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/HQRP-Requirements-and-Best-Practices.

For technical information including questions about registration for User IDs, technical questions regarding HIS data transmission, error messages, or accessing reports in the CASPER Reporting application, contact the iQIES Technical Help Desk at: iQIES@cms.hhs.gov or by phone: 800-339-9313.

For the current HIS Manual, visit the Downloads section of the Hospice Item Set webpage on the HQRP website at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/Hospice-Item-Set-HIS.

For general questions about the HQRP program, reporting requirements, quality measures, and reporting deadlines, contact the Quality Help Desk at: hospicequalityquestions@cms.hhs.gov

Hospice Quality Reporting Program (HQRP) Quick Reference Guide

This document is for HQRP data impacting FY2023 payment updates and all subsequent years.

The Hospice QRP creates hospice quality reporting requirements, as established under section 1814(i)(5) of the Social Security Act (SSA). Each year, by October 1, CMS publishes the quality measures a hospice must report.

Hospices must submit the required Hospice Item Set (HIS) data to CMS. HIS includes HIS-Admission and HIS-Discharge records. The HIS data must be transmitted to CMS via the Quality Improvement Evaluation System (QIES) through the Assessment Submission and Processing (ASAP) system.

In addition, hospices are required to participate in the Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Hospice Survey. The CAHPS® Hospice Survey was designed to measure and assess the experiences of patients who died while receiving hospice care, as well as the experiences of their informal primary caregivers.

The HQRP also includes administrative data (Medicare claims). The FY 2022 Final Rule added administrative data to the HQRP, and these are used to calculate two claims-based measures (Hospice Visits in Last Days of Life (HVLDL) and Hospice Care Index (HCI)). Since CMS obtains this data through claims submitted by hospice providers, hospices with claims are 100% compliant with this requirement.

If the required quality data is not reported by each designated submission deadline, the hospice will be subject to a four (4) percentage point reduction in their Annual Payment Update (APU).

Frequently Asked Questions

Q: What are the data submission deadlines for CAHPS® Hospice Survey data?

The data submission deadlines for *CAHPS® Hospice Survey data* are the second Wednesday of the month for the months of February, May, August, and November. It is important for hospices to submit their patient counts to their selected vendor monthly. Approved CAHPS vendors submit data on behalf of their client hospices on or before that date. Late data is not accepted. More information is available on the official CAHPS® Hospice Survey website.

Q: What are the data submission deadlines for HIS data?

The submission deadline for HIS records is 30 days from the event date (admission or discharge). More information is available on the Timeliness Compliance Threshold Fact Sheet, available in the Downloads box on the CMS Hospice Item Set (HIS) webpage. For FY2022 and all subsequent fiscal years, the HIS threshold is 90%. This means 90% of all HIS assessments must be submitted within 30 days of the event date (admission or discharge).

Q: How do I verify my submissions?

One of the best methods to monitor successful HIS submissions is through Final Validation Reports. Instructions on reports for validating HIS are available on the iQIES portal.

A hospice and its vendors can monitor CAHPS® Hospice Survey data submissions through reports posted to the CAHPS® Hospice Survey Data Warehouse. These reports are available by 5:00 PM Eastern Time on the next business day after submission. More details on the CAHPS® Hospice Survey, including podcasts about data submission and other key items, can be found in the Information for Hospices section of the CAHPS® Hospice Survey website.
CMS provides multiple educational resources and training opportunities on Hospice Quality Reporting Program and CAHPS® Hospice Survey websites to help providers be successful.

Q: How do I submit a CAHPS® Hospice Survey size exemption request?

In order to file a size exemption request, go to the CAHPS® Hospice Survey Participation Exemption for Size webpage. There is more information on the page and a form to fill out and submit online.
Exemption requests must be submitted on an annual basis.

Q: How do I submit the data for the claims-based measures?

The data source for the claims-based measures will be Medicare claims data that is already collected and submitted to CMS. There is no additional submission requirement for administrative data (Medicare claims).

Help Desk Assistance

iqies@cms.hhs.gov or 1-877-201-4721 (iQIES Help Desk)
For questions about HIS submission reports and CASPER reports.

HospiceQualityQuestions@cms.hhs.gov (Quality Help Desk)
For questions about quality reporting requirements, quality measures, and reporting deadlines.

HospiceQRPReconsiderations@cms.hhs.gov(APU/Reconsiderations Help Desk)
For requesting reconsideration for a determination of non-compliance with hospice quality reporting

HospicePRquestions@cms.hhs.gov (Public Reporting Help Desk)

For questions related to public reporting of quality data.

hospicecahpssurvey@hsag.com (CAHPS® Hospice Survey Help Desk) For information about the CAHPS® Hospice Survey.

Helpful Links

Post-Acute Care (PAC) Listserv— Sign up for the official CMS PAC listserv to receive important QRP updates.

HQRP Requirements and Best Practices webpage - CMS resources containing information about quality measures, provider compliance, and best practice methodology.

CAHPS® Hospice Survey webpage - The official website for information on the CAHPS® Hospice Survey, including current measures and size exemption forms.

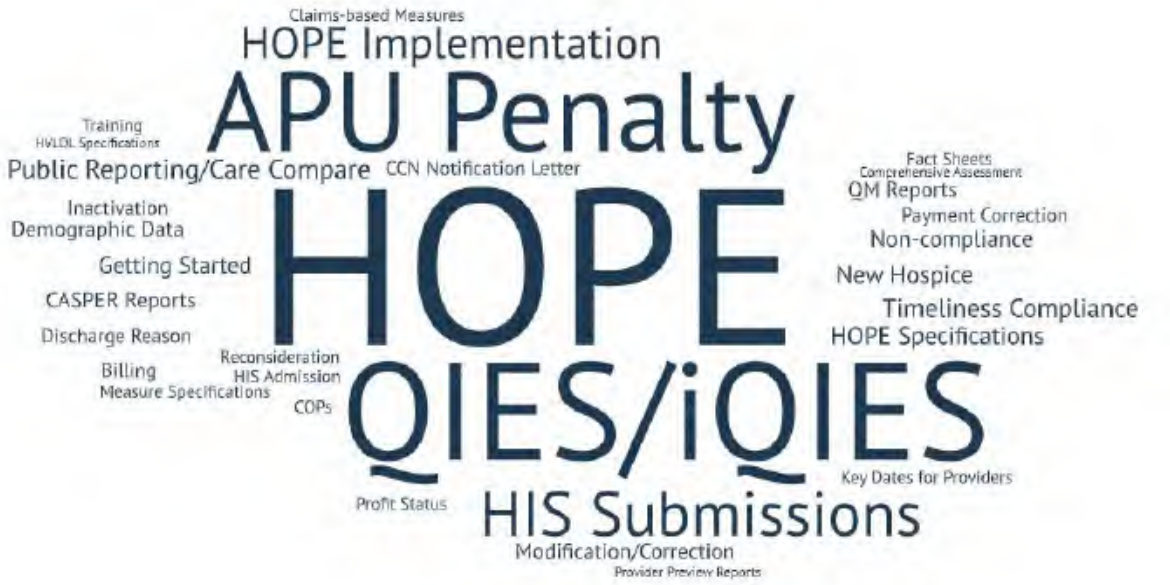
Hospice Item Set (HIS) webpage - Resources containing the HIS Manual, HIS for admission and discharge, and information on final validation reports.

HQRP Training and Education Library - Links to past in-person and online training as well as information on upcoming trainings.

Current Measures - Details on the current quality measures for the QRP and the link to the HQRP QM User's Manual v4.00 is in the Downloads section.

iQIES Portal – Provides numerous resources related to Hospice reporting, including news on report availability, manuals, and training.

Hospice Quality Reporting Program (HQRP)



Help Desk Questions and Answers: Quarter 2, 2024

Word cloud reflects frequency of keywords for questions received during the quarter.

The HQRP Help Desk responded to **66** questions in the second quarter of 2024. This quarter covers questions received between April 1 and June 30, 2024. The questions below reflect newer and/or more common questions.

Question 1:

Low Scores on Hospice and Palliative Care Composite Process Measure - Comprehensive Assessment at Admission (CBE #3235)

Our hospice is very small with a low average daily census (ADC). Although we conduct a complete and comprehensive assessment on every new patient, (including pain, spiritual, and psychosocial assessments), our scores do not reflect the care and services we deliver. Does a low ADC affect the scores on this measure?

Answer 1:

We suggest you review your **Patient Stay-Level Quality Measure Report** in CASPER to understand the details of the *Hospice and Palliative Care Composite Process Measure – Comprehensive Assessment at Admission (CBE #3235)* QM. You can learn about these QM reports in the document - Getting Started with Hospice CASPER Quality Measure Reports: August 2022**,** which is located on the Requirements and Best Practices webpage in the Provider Toolkit or Downloads section. There are also other useful fact sheets on this webpage.

Additionally, a training on the composite measure was conducted in June 2021 - ***Understanding the Composite Quality Measure.*** This training discussed how individual scores differ from composite scoring and it can be found in the *Downloads* section of the HQRP Training and Education Library page.

Lastly, to understand how CBE #3235 is actually calculated, you can refer to the HQRP Quality Measure Specifications User's Manual which can be found in the *Downloads* section of the Current Measures page.

Question 2:

Data Specifications for HOPE Implementation

Software vendors need technical data specifications to program EHR software for HOPE implementation. When will CMS publish the data specifications for HOPE, and does the user interface in our software need to look like the forms in the draft HOPE Guidance Manual?

Answer 2:

The technical data specifications and other materials related to HOPE, including the final HOPE Guidance Manual and the item sets will be available soon **after the publication of the FY2025 Hospice Final Rule (CMS-1810-F).** Regarding your EHR user interface, CMS does not provide guidance on what that interface should look like. CMS requires that the software comply with the final HOPE data specifications.

Question 3:

HIS Timeliness Compliance Threshold Report

I am able to access my hospice's FY2025 and FY2026 HIS threshold reports in CASPER, however I am looking for the previous reports from FY2024 and FY2023. Is there any way to retrieve these older reports?

Answer 3:

The **HIS threshold report is only available for the current and prior year** within CASPER. Therefore, the FY2024 and FY2023 Timeliness Compliance Threshold Reports are not available. For these reports, there is no access to historical CY data.

Question 4:

HIS Submission Process

Does CMS have instructions or a checklist available to ensure that we are submitting all of the items required for the HQRP?

Answer 4:

Please visit the HQRP Requirements and Best Practices webpage and review the document, ***Getting Started with the HQRP*** available under "Provider Toolkit." This document provides information about the HQRP, HIS, and CAHPS® Hospice Survey submissions. For more detailed information about HIS submission, you can refer to the *HIS Submission Users Guide* available on the QIES Technical Support Office website under "References & Manuals."

There are also useful resources on the HQRP Training and Education Library. We suggest Course 1: Getting Started with the HQRP and Public Reporting which provides a general overview of the HQRP and Course 2: HQRP Data Submissions and Reports provides an introduction to the HQRP data submission requirements and reports available to providers.

If you have any further questions, please reach out to the Technical Help Desk. They provide assistance with technical issues and questions regarding data transmission and submission, error messages, and registration for User IDs. The Technical Help Desk email is: iqies@cms.hhs.gov. You can also reach them by phone at: 1-877-201-4721, Monday-Friday from 7:00 a.m. – 7:00 p.m. Central Time.

Question 5:

Hospice Provider Preview Reports and Claims-based Measures

I have a question about our May 2024 Hospice Provider Preview Report. The Claims based measures reporting period still says January 1, 2021, through December 31, 2022. Why is this the same reporting period used for the last hospice provider preview report?

Answer 5:

The claims-based measures are only updated annually, in November. The data will not change until November 2024. To understand the dates for Public Reporting, we suggest you access the Key Dates for Providers webpage.

Hospice Quality Reporting Program Quality Measure Specifications User's Manual

Draft HOPE-Based Timely Reassessment Process Measures

Process Measures Calculated from the Hospice Outcome & Patient Evaluation (HOPE): Timely Follow-up for Pain Impact (#01795-02-C-HQR) and Timely Follow-up for Non-Pain Symptom Impact (#01796-01-C-HQR)

Section 1: Measure Description

The purpose of this chapter is to describe *Timely Follow-up for Pain Impact* (#01795-02-C-HQR) and *Timely Follow-up for Non-Pain Symptom Impact* (#01796-01-C-HQR). These quality measures are calculated from data collected through the Hospice Outcomes & Patient Evaluation (HOPE) and submitted to CMS under the Hospice Quality Reporting Program (HQRP). Both measures capture the percent of hospice patient assessments that have a symptom follow-up visit within two (2) days when the symptom impact was initially assessed as moderate or severe, as follows:

- *Timely Follow-up for Pain Impact* measure captures the percent of hospice patient assessments that have a symptom follow-up visit within two (2) days after pain impact was initially assessed as moderate or severe; and
- *Timely Follow-up for Non-Pain Symptom Impact* measure captures the percent of assessments that have a symptom follow-up visit within two (2) days after non-pain symptom impact was initially assessed as moderate or severe.

Data for these measures are collected by hospice clinicians using HOPE. Symptom impact assessments are administered at fixed timepoints during a hospice election: at admission (ADM) and the two HOPE Update Visits (HUVs). The Symptom Impact item (J2051) may trigger the need for the Symptom Follow-up Visit (SFV). When the patient's pain or non-pain symptom impact is assessed as moderate or severe, a HOPE SFV is expected within two (2) calendar days. For these measures, the measurement time window is defined as the date of the symptom impact screening (J2050B) where the impact is assessed as moderate or severe to two (2) calendar days thereafter. Depending upon responses to the Symptom Impact item (J2051) at ADM and the two HUVs (each at specified timeframes), up to three SFVs may be required over the course of the hospice stay. If during an SFV, there is evidence of ongoing moderate or severe symptom impact, no additional HOPE SFV is required. Although multiple SFVs are not required for the purpose of the HQRP, it is expected that the hospice staff will continue to follow up with the patient, based on their clinical and symptom management needs.

Section 2 below describes the method in which eligible records are selected. **Section 3** describes the steps for calculating the measure. **Section 4** and **Section 5** discuss considerations for public reporting, the minimum quality denominator threshold count for a hospice to have publicly reported data, and methods for calculating state and national measure scores, respectively.

Section 2: Data Sources

The eligible records for both hospice process measures are selected as follows (note that bold italic text indicates terms defined in **Appendix 1: Definitions**):

1. Determine the two-year/eight-quarter ***reporting period.***
2. Identify ADM records (A0250. = 01) and HUV records (A0250. = 02 or 03).
3. Select ADM and HUV records to be included in the ***hospice process measure sample*** if the record has an assessment completion date (Z0350.) within the ***reporting period***. A patient can have multiple records included in the sample (up to three records per hospice admission).
4. Apply the measure specifications (see Section 3 below) to the selected ADM and HUV records. Round all measure scores using the rounding rule.

Section 3: Measure Calculation

Steps to calculate each measure and data elements used in each step are as follows. Note that in the notation, numbers in brackets index a data element located on the ADM or HUV record (initial assessments) [1] or on the SFV record [2].

Step	Calculation of *Timely Follow-up for Pain Impact*	Calculation of *Timely Follow-up for Non-Pain Symptom Impact*
Step 1: Calculate the denominator	Total number of HOPE ADM or HUV assessments where pain impact was assessed as moderate or severe. • At ADM or HUV (A0250. = 1. Admission, 2. HUV #1, or 3. HUV #2) [1], o Symptom Impact - Pain (J2051.A.) [1] = 2. Moderate or 3. Severe	Total number of HOPE ADM or HUV assessments where any non-pain symptom impact was assessed as moderate or severe. • At ADM or HUV (A0250. = 1. Admission, 2. HUV #1, or 3. HUV #2) [1], o Symptom Impact - Shortness of Breath (J2051.B.) [1] = 2. Moderate or 3. Severe, or o Symptom Impact - Anxiety (J2051.C.) [1] = 2. Moderate or 3. Severe, or o Symptom Impact - Nausea (J2051.D.) [1] = 2. Moderate or 3. Severe, or o Symptom Impact - Vomiting (J2051.E.) [1] = 2. Moderate or 3. Severe, or o Symptom Impact - Diarrhea (J2051.F.) [1] = 2. Moderate or 3. Severe, or o Symptom Impact - Constipation (J2051.G.) [1] = 2. Moderate or 3. Severe, or o Symptom Impact - Agitation (J2051.H.) [1] = 2. Moderate or 3. Severe
Step 2: Remove any denominator exclusions	Remove if: • Patient was discharged from hospice for any reason before an SFV could be completed → exclude o Symptom Follow-up in-person visit was not completed (Symptom Follow-up Visit (J2052.A.) [2] = 0, and o Discharge Date (A0270.) [2] ≤ Date of Symptom Impact Screening (J2050.B.) [1] + two days • Hospice was unable to complete the SFV → exclude o Symptom Follow-up in-person visit was not completed (Symptom Follow-up Visit (J2052.A.) [2] = 0, and	Remove if: • Patient was discharged from hospice for any reason before an SFV could be completed → exclude o Symptom Follow-up in-person visit was not completed (Symptom Follow-up Visit (J2052.A.) [2] = 0, and o Discharge Date (A0270.) [2] ≤ Date of Symptom Impact Screening (J2050.B.) [1] + two days • Hospice was unable to complete the SFV → exclude o Symptom Follow-up in-person visit was not completed (Symptom Follow-up Visit (J2052.A.) [2] = 0, and

Step	Calculation of *Timely Follow-up for Pain Impact*	Calculation of *Timely Follow-up for Non-Pain Symptom Impact*
	○ Hospice Unable to Visit (J2052.C.) [2] = 1. Patient and/or caregiver declined an in-person visit, 2. Patient unavailable (e.g., in ED, hospital, travel outside of service area), or 3. Attempts to contact patient and/or caregiver were unsuccessful.	○ Hospice Unable to Visit (J2052.C.) [2] = 1. Patient and/or caregiver declined an in-person visit, 2. Patient unavailable (e.g., in ED, hospital, travel outside of service area), or 3. Attempts to contact patient and/or caregiver were unsuccessful.
Step 3: Calculate the numerator	Number of HOPE ADM or HUV assessments for which a symptom follow-up visit date was within two days of the initial/triggering assessment date. • Date of in-person SFV (J2052.B.) [2] - Date of Symptom Impact Screening (J2050.B.) [1] ≤ Two (2) days when a Symptom Impact Screening occurred (J2050.A. = 1. yes) [1]	Number of HOPE ADM or HUV assessments for which a symptom follow-up visit date was within two days of the initial/triggering assessment date. • Date of in-person SFV (J2052.B.) [2] - Date of Symptom Impact Screening (J2050.B.) [1] ≤ Two (2) days when a Symptom Impact Screening occurred (J2050.A. = 1. yes) [1]
Step 4: Express the measure score as a proportion	Divide the hospice's numerator count by its denominator count to obtain the hospice's observed score; that is, divide the result of step 3 by the result of step 2. The score is converted to a percent value by multiplying by 100. Round the score using the rounding rule, as defined in Appendix 1.	Divide the hospice's numerator count by its denominator count to obtain the hospice's observed score; that is, divide the result of step 3 by the result of step 2. The score is converted to a percent value by multiplying by 100. Round the score using the rounding rule, as defined in Appendix 1.

Section 4: Public Reporting Threshold

Hospices must have at least 20 qualifying denominator cases (i.e., 20 HOPE ADM or HUV assessments where symptom impact was assessed as moderate or severe) during the reporting period in each respective measure for scores to be publicly reported on the Care Compare site. Hospices that do not meet this threshold will have measure scores suppressed. If there are 20 qualifying denominator cases for one measure but not the other, then the measure above the threshold will be reported but the other with below 20 qualifying denominator cases will be suppressed.

Section 5: National and Average State Calculation

To calculate the national average for each measure, take the national sum of all the hospices' individual numerators and divide by the total summation of nationwide hospices' individual denominators. Statewide averages are calculated by dividing the statewide summations of numerators by statewide summation of denominators among all hospices located in that state. Round the national and state averages using the ***rounding rule***, as defined in **Appendix 1**. Note that both state and national averages include the numerators and denominators of hospices that are publicly suppressed individually because the denominator size did not meet the minimum threshold for public reporting.

Value-Based Insurance Design Model: Hospice Benefit Component

Calendar Year (CY) 2024 Technical and Operational Guidance on the Conclusion of the Hospice Benefit Component

Table of Contents

1. Background

In 2021, the Centers for Medicare & Medicaid Services (CMS) began testing the inclusion of the Part A Hospice Benefit within the Medicare Advantage (MA) benefits package through the Hospice Benefit Component of the Value-Based Insurance Design (VBID) Model. This test has allowed CMS to assess the impact on costs, care delivery and quality of care, especially for palliative and hospice care, when participating MA plans are financially responsible for Medicare-covered hospice care along with the vast majority of other Parts A and B benefits. On March 4, 2024, CMS announced that the Hospice Benefit Component will conclude as of December 31, 2024 at 11:59 PM.[1]

This document serves as technical guidance for Medicare Advantage Organizations (MAOs) currently participating or that formerly participated in the Hospice Benefit Component and Medicare certified hospice providers ("hospice providers").

This document covers the following topics:

- Financial Responsibility for Care Provided During and Immediately After a Hospice Election
- Network Adequacy Requirements
- MAO Communication to Enrollees and Providers
- Transitional Concurrent Care
- Hospice Supplemental Benefits
- Palliative Care
- Operations and Claims
- Monitoring and Data Collection

The guidance covers CMS's requirements and expectations for the remainder of the Hospice Benefit Component's operations through Calendar Year (CY) 2024 along with requirements and expectations for operations on and after January 1, 2025. This document supplements the Amendment to Addendum to Medicare Managed Care Contract for Participation in the Medicare Advantage Value-Based Insurance Design Model CY 2024 ("Amendment to the CY 2024 Contract Addendum"). Certain sections from the Amendment to the CY 2024 Contract Addendum are referenced below, but note that these references may not be applicable to the amendments to the CY 2021, CY 2022, and/or CY 2023 contract addenda because those provisions are either labelled differently or do not exist in the other versions. Defined terms used in this guidance have the meanings given in the Addendum.

Unless explicitly identified and revised by this guidance, the various guidance about the Hospice Benefit Component remains in effect through CY 2024. This includes the CY 2024 Request for Applications for the Hospice Benefit Component of the VBID Model, VBID Hospice Benefit Component Monitoring Guidelines, VBID Model Hospice Benefit Component Phase 2 Network Adequacy Guidance, VBID Communications and Marketing Guidelines, and Final Hospice Capitation Payment Rate Actuarial Methodology. The most recent versions of these documents can be found here:
https://innovation.cms.gov/innovation-models/vbid.

MAOs, hospice providers, and others are encouraged to email the VBID Model team (VBID@cms.hhs.gov) directly with questions on this technical and operational guidance.

[1] https://www.cms.gov/priorities/innovation/innovation-models/vbid/vbid-hospice-announcement

2. Financial Responsibility for Care Provided During and Immediately After a Hospice Election

As per the CY 2024 Addendum to the Medicare Managed Care Contract for Participation in the MA VBID Model (CY 2024 Addendum), throughout CY 2024 participating MAOs must continue to provide the full scope of hospice care, as defined at Section 1861(dd) of the Act and required by implementing regulations at 42 CFR Part 418 to all hospice enrollees in VBID Plan Benefit packages (PBPs) participating in the Hospice Benefit Component; provide hospice care in accordance with each enrollee's choice to elect or revoke the hospice benefit in accordance with Section 1812(d) of the Act and 42 CFR §§ 418.24 and 418.28; and treat hospice care as a basic benefit for purposes of compliance with regulations in 42 CFR Part 422, except for regulations that have been expressly waived.

Per Article I Section D of the Amendment to the CY 2024 Contract Addendum, MAOs participating in the Hospice Benefit Component must continue to cover all hospice elections for beneficiaries in participating PBPs for care delivered through December 31, 2024. Starting with services provided on or after January 1, 2025, financial responsibility for hospice coverage for MA enrollees that were covered through the Hospice Benefit Component will revert to Original Medicare (that is, the Medicare FFS program). More details are available in the Operations and Claims section of this document. For any hospice election on or after January 1, 2025, by an MA enrollee, Medicare-covered hospice benefits will be through the Medicare FFS program, consistent with applicable law, including 42 CFR §§ 418.1 through 418.405.

CMS will continue to make the hospice capitation payment to MAOs for hospice enrollees whose Hospice Election started under the Model as per Appendix 3 of the CY 2024 Addendum. CMS shall pay the Hospice capitation amount in a lump-sum retrospectively to the MAO on a periodic basis determined at CMS's sole discretion.

Beginning January 1, 2025, the regulation at 42 CFR § 422.320 will apply as to payment to MAOs that have participated in the Hospice Benefit Component for any MA enrollee that elects or has elected hospice.

3. Network Adequacy Requirements

In CY 2024, MAOs with Mature-Year PBPs will no longer be subject to the Model Phase 2 Network Adequacy requirements minimum number of providers for mature year PBPs.[2] All Model participants will be held to the Model Phase 1 network adequacy requirements as outlined in the Section 2.6 of the CY 2024 VBID Hospice Request for Applications (RFA). To satisfy Model Phase 1 Network Adequacy Requirements, participating MAOs must offer access to in-network hospice providers by contracting with at least one hospice provider for the service area, regardless of whether the MAO has a Mature-Year PBP, and by covering hospice care furnished by out-of-network hospice providers consistent with Article III of the Amendment to the CY 2024 Contract Addendum.[3]

All participating MAOs must continue through CY 2024 to provide access to a network of hospice providers that are certified by Medicare to provide hospice care. Participating MAOs must cover all hospice care furnished by either in-network hospice providers or out-of-network (non-contracted) hospice providers to a hospice enrollee who is enrolled in a VBID PBP that is participating in the Hospice Benefit Component. MAOs must notify CMS of any hospice provider terminations that meet any of the following:

(i) go beyond individual or limited provider terminations that occur during the routine course of plan operations; or

[2] https://www.cms.gov/files/document/vbidhospicephase2networkadequacyguidance.pdf
[3] https://www.cms.gov/priorities/innovation/media/document/vbid-cy-2024-rfa

(ii) affect or would affect the MAO's ability to meet the minimum requirement of one in-network hospice provider for a PBP.

Notification to CMS must happen at least 90 calendar days prior to the effective date of the termination in the same manner as if the change were a significant change to the provider network under Chapter 4, Section 110.1.2 of the Medicare Managed Care Manual[4] regardless of whether such changes are considered "significant" with respect to the network-at-large. This notice must be provided via email to VBID@cms.hhs.gov. More communication details can be found in the Communication Requirements section below.

4. MAO Communications to Enrollees and Providers

All MAOs participating in the Hospice Benefit Component in CY 2024, as well as MAOs that participated in previous years and have hospice enrollees with ongoing hospice elections that have continued into 2024, are required to notify all hospice providers that have billed them about the conclusion of the Hospice Benefit Component. For beneficiaries who are on hospice while covered by previously or currently participating PBPs, the MAO must notify beneficiaries of changes to hospice coverage through personalized outreach. Additionally, MAOs will be required to notify beneficiaries of changes to hospice coverage through the annual notice of change (ANOC) for CY 2025 as per the CY 2025 Communication and Marketing Guidelines. As part of the ANOC, as described in the CY 2025 Communication and Marketing Guidelines, MAOs must communicate differences in cost-sharing between the plan's cost-sharing structure for hospice care, supplemental benefits, transitional concurrent care, and/or palliative care in CY 2024 compared to CY 2025 in Original Medicare. Article IV of the Amendment to the CY 2024 Contract Addendum contains these requirements. Please reference Appendix 3 of the CY 2025 VBID Model Communications and Marketing Guidelines for more information.[5]

MAOs must comply with 42 CFR 422.111(e) and make a good faith effort to provide written notice of a termination of a contracted hospice provider at least 30 calendar days before the termination effective date to all enrollees who are patients seen on a regular basis by the provider whose contract is terminating, irrespective of whether the termination is for or without cause. The Model-participating MAO must provide documentation to the enrollee, their representative, and providers as needed to ensure a smooth transition without interruptions to care or billing.

Under 42 CFR 422.112(b), MAOs offering coordinated care plans, including Model-participating MAOs, must ensure continuity of care and integration of services through arrangements with contracted providers, including policies that specify under what circumstances services are coordinated and the methods for coordination that include specific items listed in the regulation. Model-participating MAOs must ensure that such policies include notifying the enrollee's hospice provider and other providers that the MAO's coverage of the hospice election has ended, including for any transitional concurrent care or hospice supplemental benefits. CMS encourages hospice and other healthcare providers furnishing services to an enrollee who has elected hospice to participate actively in the continuity of care process to ensure the enrollee faces limited disruptions and no barriers to care. The enrollee's access to the Medicare-participating hospice provider of their choice must be maintained.

In addition to communications with enrollees and hospice providers, transitioning MAOs are required to inform other members of their provider network about the MAO's transition out of the Hospice Benefit

[4] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf
[5] https://www.cms.gov/files/document/vbid-cy25-marketing-guidelines.pdf

Component VBID Model participation if notification could enhance or increase beneficiary engagement and care transitions such as around the availability of continuity of care for a period of time.

5. Transitional Concurrent Care

Transitional concurrent care must continue to be provided to qualifying beneficiaries until the termination of the Hospice Benefit Component on December 31, 2024. Due to the termination of the Hospice Benefit Component, transitional concurrent care will not be available after December 31, 2024. As set forth in section 1812(d)(2) of the Act and reflected at 42 CFR 418.24(b)(2), beneficiaries who elect hospice care waive all rights to have payment made for any services "related to the treatment of the individual's condition with respect to which a diagnosis of terminal illness has been made" except for services provided by the beneficiary's designated hospice, or another hospice under arrangements made by his or her designated hospice or the individual's attending physician (if the attending physician is not an employee of the designated hospice).

As per the CY 2024 VBID Hospice RFA, and as reflected in participating MAOs' approved proposals for participation in the Hospice Benefit Component for CY 2024, participating MAOs must continue to offer transitional concurrent care throughout CY 2024. Participating MAOs must work with in-network hospice providers and in-network non-hospice providers to make available transitional concurrent care services necessary to address continuing care needs, as clinically appropriate, for the treatment of hospice enrollees' terminal illness and related conditions. Section 2.3 of the CY2024 VBID Hospice RFA and Appendix 3, section 4(a) of the CY2024 Addendum include additional details on the transitional concurrent care strategy and network limitation. Model-participating MAOs may only provide coverage for transitional concurrent care services when an enrollee chooses an in-network hospice provider, as such services are intended to be provided to the enrollee on a transitional basis in a setting where the enrollee's care can be closely coordinated.

6. Hospice Supplemental Benefits

Hospice Supplemental Benefits must continue to be provided to qualifying beneficiaries through the termination of the Hospice Benefit Component on December 31, 2024. As per section 2.4 of the CY 2024 VBID Hospice Benefit Component RFA, participating MAOs may offer a broad set of mandatory supplemental benefits for enrollees who elect hospice (hereafter "hospice supplemental benefits") in addition to any mandatory supplemental benefits offered to all or other targeted enrollees in the plan. Hospice supplemental benefits will only be available through the termination of the Hospice Benefit Component on December 31, 2024.

Under the Hospice Benefit Component, CMS may, consistent with the waiver of uniformity in the Addendum, Appendix 1, permit participating MAOs to limit these hospice supplemental benefits to enrollees who have elected hospice and use in-network hospice providers. If approved in an MAOs application that hospice supplemental benefits are to be available to enrollees who have elected hospice and use in-network hospice providers, then these supplemental benefits must continue to be limited to in-network providers as per the approved CY 2024 application.

7. Palliative Care

As required by Appendix 3, section B(3) of the CY 2024 Addendum, Model-participating MAOs must develop and implement a strategy regarding access to and delivery of palliative care services for enrollees with serious illness who are either not eligible for or who have chosen not to (or not yet chosen to) receive hospice services. Participating MAOs must continue to provide palliative care services as described in their approved proposals for participation in the Hospice Benefit Component throughout CY 2024.

In April 2018, CMS provided guidance for all MAOs that home-based palliative care services not covered under Original Medicare could instead be covered as a supplemental benefit.[6] Specifically, this guidance continues to apply to stand-alone services provided to enrollees of Model-participating MAOs with serious illness who are not eligible for hospice services (e.g., stand-alone palliative nursing and social work services in the home not covered by Medicare Part A or Part B). Palliative care offerings through the Model will only be available through the termination date of December 31, 2024. If MAOs are interested in continuing to offer palliative care in future years, CMS can offer technical guidance upon request.

8. Operations and Claims

For hospice care that began under a participating PBP, for services provided prior to January 1, 2025, hospices should follow current Model billing procedures and requirements. Consistent with the Model to date, Notices of Election (NOE), Notices of Termination/Revocation (NOTR), and all hospice claims must be submitted (1) to the Medicare contractor for informational purposes, monitoring and evaluation (irrespective of network status), and (2) to Model-participating plans so that they can to make timely payment to hospice providers (in the case of in-network hospice providers, if in alignment with contractual agreements). Aligned with Original Medicare claims processing, Model-participating MAOs may include similar timely filing requirements for hospice providers stated in 42 CFR 418.24 and described in further guidance within the Medicare Claims Processing Manual, Ch. 11.

For hospice elections that extend beyond the termination date (December 31, 2024), of the Hospice Benefit Component, hospice providers should not discharge any patient solely because of their coverage in a plan participating in the Hospice Benefit Component prior to CY 2025. For those hospice elections that continue, no new NOEs will be required, and timely filing requirements for hospice providers stated in 42 CFR 418.24 and described in further guidance within the Medicare Claims Processing Manual, Ch. 11 will continue to apply. For hospice elections that began under the Model and continue into CY 2025, for services that occur in CY 2025 and beyond hospices must follow the requirements under Original Medicare as described in the Medicare Claims Processing Manual, Ch. 11.

Under Original Medicare, hospice providers are subject to two payment caps—one for inpatient care, and another for aggregate payments. The number of days of inpatient care a hospice provider furnishes is limited to not more than 20% of total patient care days. The hospice aggregate cap amount limits payments to a hospice provider to the cap amount (updated annually by CMS pursuant to 42 CFR 418.309) multiplied by the number of Medicare patients served. Of importance, Model-participating MAOs' enrollees' hospice experience will not be included in either payment cap calculation. In CY 2025, Original Medicare retains responsibility for the hospice coverage and the payment caps will apply.

9. Monitoring and Data Collection

Participating MAOs continue to be required to submit all monitoring data and information as described in the CY 2024 VBID Hospice benefit Component Monitoring Guidelines.[7] As per the CY 2024 Addendum, participating MAOs shall ensure the timely transfer of any data or files to CMS necessary for evaluation, transition or close-out of the MAO's model-related activities, and shall comply with all other CMS-specified close-out procedures and related Model Technical and Operational Guidance. This data reporting may continue into CY 2025 and beyond until all participation data has been collected.

[6] CMS HPMS Memo. Reinterpretation of "Primarily Health Related" for Supplemental Benefits. April 27, 2018. https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/HPMS-Memos-Archive-Weekly-Items/SysHPMS-Memo-2018-Week4-Apr-23-27

[7] https://www.cms.gov/files/document/vbid-cy24-hospice-monitoring-guidelines.pdf

CMS will continue to make Hospice Utilization Reports for CY 2024 hospice enrollee detailed claim data available to participating MAOs as per Appendix 3 section G(2) of the CY 2024 Addendum.

HOUSE AMENDED

PRIOR PRINTER'S NO. 1396 PRINTER'S NO. 1940

THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 1080 Session of 2024

INTRODUCED BY CULVER, PENNYCUICK, CAPPELLETTI, J. WARD, SCHWANK AND FARRY, FEBRUARY 23, 2024

AS AMENDED ON SECOND CONSIDERATION, HOUSE OF REPRESENTATIVES, OCTOBER 7, 2024

AN ACT

Amending the act of June 29, 1953 (P.L.304, No.66), entitled "An act providing for the administration of a statewide system of vital statistics; prescribing the functions of the State Department of Health, the State Advisory Health Board and local registrars; imposing duties upon coroners, prothonotaries, clerks of orphans' court, physicians, midwives and other persons; requiring reports and certificates for the registration of vital statistics; regulating the disposition of dead bodies; limiting the disclosure of records; prescribing the sufficiency of vital statistics records as evidence; prescribing fees and penalties; and revising and consolidating the laws relating thereto," ~~in death and fetal death registration, providing for pronouncement of death by a practical nurse.~~ IN GENERAL PROVISIONS, FURTHER PROVIDING FOR DEFINITIONS; IN DEATH AND FETAL DEATH REGISTRATION, PROVIDING FOR PRONOUNCEMENT OF DEATH BY A PRACTICAL NURSE; AND, IN RECORDS, FURTHER PROVIDING FOR FEES FOR COPIES. <-- <--

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

~~Section 1. The act of June 29, 1953 (P.L.304, No.66), known as the Vital Statistics Law of 1953, is amended by adding a section to read:~~ <--

SECTION 1. SECTION 105 INTRODUCTORY PARAGRAPH OF THE ACT OF JUNE 29, 1953 (P.L.304, NO.66), KNOWN AS THE VITAL STATISTICS <--

LAW OF 1953, IS AMENDED TO READ:

SECTION 105. GENERAL PROVISIONS: DEFINITIONS.--AS USED IN THIS ACT, THE FOLLOWING WORDS AND PHRASES SHALL HAVE THE MEANINGS GIVEN TO THEM IN THIS SECTION UNLESS THE CONTEXT CLEARLY INDICATES OTHERWISE--

* * *

SECTION 2. THE ACT IS AMENDED BY ADDING A SECTION TO READ:

Section 508. Death and Fetal Death Registration: Pronouncement of Death by a Practical Nurse.--(a) A practical nurse shall have the authority to pronounce death if all of the following are met:

(1) The patient is in the care of a licensed hospice.

(2) The patient has a valid Do Not Resuscitate Order issued in accordance with the laws of this Commonwealth.

(3) The practical nurse is conducting a focused assessment to identify the cessation of circulatory and respiratory functions as provided under the act of December 17, 1982 (P.L.1401, No.323), known as the "Uniform Determination of Death Act."

(4) The practical nurse has received training in accordance with subsection (e).

(b) A practical nurse shall have the authority to release the body of the deceased to a funeral director after notice has been given to the attending physician or certified registered nurse practitioner, if the deceased has an attending physician or certified registered nurse practitioner, and to a family member, as soon as practicable.

(c) If circumstances surrounding the nature of death are not anticipated and require a coroner's investigation, the practical nurse shall notify the county coroner, and the

authority to release the body of the deceased to the funeral director shall be that of the coroner.

(d) Except as provided for under sections 502 and 503, this section provides for the pronouncement of death by a practical nurse in accordance with the "Uniform Determination of Death Act," but in no way authorizes a nurse to determine the cause of death. The responsibility for determining the cause of death remains with the physician, certified registered nurse practitioner or the coroner as provided under this act.

(e) The following shall apply to training:

(1) In accordance with 42 CFR 418.100 (relating to condition of participation: organization and administration of services) in effect on the effective date of this clause, a hospice shall conduct an initial training upon hiring, an annual training and an annual assessment of the skills and competence of a practical nurse who will assess the vital signs of a patient to determine cessation of circulatory and respiratory function.

(2) Each practical nurse must be trained for a minimum of three hours in vital signs training, postmortem care, grief training and circumstances requiring a coroner's investigation.

(3) A hospice shall have written policies and procedures describing its method of assessment of competency and maintain a written description of the in-service training provided during the previous twelve months.

(f) The following shall apply:

(1) A practical nurse and an employing agency of a practical nurse acting in good faith and in compliance with the provisions of this act, THE REGULATIONS OF the State Board of Nursing and THE REGULATIONS OF the Department of Health shall be immune from liability claims by reason of pronouncing death under this <-- <--

section.

(2) Nothing under this section shall impose an obligation on a practical nurse to carry out the function authorized by this section.

(3) Nothing under this section is intended to relieve a practical nurse of civil or criminal liability that might otherwise be incurred for failing to follow the rules and regulations of the State Board of Nursing.

(4) Nothing under this section shall preempt the requirements of 20 Pa.C.S. Ch. 86 (relating to anatomical gifts).

(g) A practical nurse shall have the authority to pronounce death in accordance with ~~procedural~~ regulations as may be promulgated by the State Board of Nursing within eighteen months of the effective date of this subsection. <--

(h) As used in this section, the term "practical nurse" shall mean a practical nurse who is employed by a licensed hospice, involved in the direct care of a patient of the licensed hospice and is:

(1) licensed under the act of March 2, 1956 (1955 P.L.1211, No.376), known as the "Practical Nurse Law"; or

(2) authorized to practice practical nursing in this Commonwealth.

SECTION 3. SECTION 807(C) OF THE ACT IS AMENDED AND THE SECTION IS AMENDED BY ADDING SUBSECTIONS TO READ: <--

SECTION 807. RECORDS: FEES FOR COPIES.--* * *

[(C) NO FEE SHALL BE CHARGED FOR CERTIFIED COPIES OF RECORDS OR PARTS THEREOF FURNISHED MEMBERS OF THE ARMED FORCES OF THE UNITED STATES AND THEIR DEPENDENTS DURING THEIR TERM OF ACTIVE SERVICE AND AFTER THEIR DEATH IN SERVICE OR HONORABLE DISCHARGE

THEREFROM.]

(D) SUBJECT TO SUBSECTION (E), NO FEE SHALL BE CHARGED FOR CERTIFIED COPIES OF RECORDS OR PARTS THEREOF FOR ANY OF THE FOLLOWING:

(1) AN INDIVIDUAL WHO CURRENTLY SERVES IN THE UNITED STATES ARMED FORCES, INCLUDING A RESERVE COMPONENT OR THE NATIONAL GUARD.

(2) A MEMBER OF THE UNITED STATES ARMED FORCES, INCLUDING A RESERVE COMPONENT OR THE NATIONAL GUARD, WHO WAS KILLED OR DIES AS A RESULT OF INJURIES RECEIVED WHILE ON OFFICIAL DUTY STATUS AUTHORIZED UNDER FEDERAL OR STATE LAW.

(3) A VETERAN.

(4) A SPOUSE OF AN INDIVIDUAL SPECIFIED UNDER PARAGRAPH (1), (2) OR (3).

(5) A DEPENDENT OF AN INDIVIDUAL SPECIFIED UNDER PARAGRAPH (1), (2) OR (3).

(E) THE FEE WAIVER UNDER SUBSECTION (D) SHALL ONLY APPLY TO THE FOLLOWING APPLICANTS FOR CERTIFIED COPIES OF RECORDS OR PARTS THEREOF:

(1) AN APPLICANT WHO IS AN INDIVIDUAL SPECIFIED UNDER SUBSECTION (D)(1) OR (3).

(2) AN APPLICANT WHO IS A SPOUSE OF AN INDIVIDUAL SPECIFIED UNDER SUBSECTION (D)(1), (2) OR (3).

(3) AN APPLICANT WHO IS A REPRESENTATIVE OF A DEPENDENT CHILD OF A DECEASED VETERAN OR AN INDIVIDUAL SPECIFIED UNDER SUBSECTION (D)(2). THIS PARAGRAPH SHALL ONLY APPLY TO A REQUEST MADE FOR A CERTIFIED COPY OF A CERTIFICATE OF DEATH.

(4) AN APPLICANT WHO IS A REPRESENTATIVE OF THE ESTATE OF AN INDIVIDUAL SPECIFIED UNDER SUBSECTION (D)(1), (2), (3) OR (4). THIS PARAGRAPH SHALL ONLY APPLY TO A REQUEST MADE FOR A

CERTIFIED COPY OF A CERTIFICATE OF DEATH.

(5) AN APPLICANT THAT IS A FUNERAL ESTABLISHMENT RESPONSIBLE FOR FILING THE DEATH RECORD OF AN INDIVIDUAL SPECIFIED UNDER SUBSECTION (D). THIS PARAGRAPH SHALL ONLY APPLY TO A REQUEST MADE FOR A CERTIFIED COPY OF A CERTIFICATE OF DEATH.

(F) THE FEE WAIVER UNDER SUBSECTION (D) SHALL APPLY REGARDLESS OF WHETHER AN INDIVIDUAL SPECIFIED UNDER SUBSECTION (D)(2) OR (3) PREDECEASED OR SURVIVED ANY OTHER INDIVIDUAL WHO QUALIFIES FOR THE FEE WAIVER.

(G) THE FEE WAIVER UNDER SUBSECTION (D) SHALL APPLY TO THE FIRST TEN (10) CERTIFIED COPIES OF THE SAME RECORD OR PARTS THEREOF ISSUED BY, OR ON BEHALF OF, THE DEPARTMENT DURING A CALENDAR YEAR FOR AN APPLICANT UNDER SUBSECTION (E).

(H) AS USED IN THIS SECTION, THE TERM "VETERAN" MEANS AN INDIVIDUAL WHO SERVED IN THE UNITED STATES ARMED FORCES, INCLUDING A RESERVE COMPONENT OR THE NATIONAL GUARD, AND WHO WAS DISCHARGED OR RELEASED FROM SERVICE UNDER CONDITIONS OTHER THAN DISHONORABLE.

Section ~~2~~ 4. This act shall take effect in 60 days. **<--**

ALLOW HOSPICE LPNS TO PERFORM DEATH PRONOUNCEMENTS

BACKGROUND

Licensed practical nurses (LPNs) provide critical, hands-on-care for hospice patients across the Commonwealth. However, they are unable to make death pronouncements for their hospice patients.

The Vital Statistics Law of 1953 currently limits the ability to pronounce death to registered nurses (RNs), medical doctors, physician assistants, and coroners.

CALL TO ACTION

Support Senate Bill 1080 sponsored by Sen. Lynda Culver allowing hospice LPNs to make death pronouncements for their patients.

This will help to alleviate workforce strains and allow agencies to allocate care and resources to best meet the needs of their patients and families.

OUR POSITION

- LPNs are not prohibited from pronouncing death in the applicable scope of practice law, deeming them competent to perform this work.
- Hospices across the state face workforce shortages and must allocate finite resources to best serve their patients.
- LPNs are more than qualified to perform death pronouncements, allowing hospices to allocate resources as deemed most appropriate for patient care.
- Virginia enacted legislation in 2022 to permit hospice nurses to pronounce death for hospice patients.

Pennsylvania Homecare Association

The Honorable Michele Brooks
Chairwoman
Health & Human Services Committee
Pennsylvania State Senate
Room 168 Main Capitol
Harrisburg, PA 17120-3050

The Honorable Art Haywood
Chairman
Health & Human Services Committee
Pennsylvania State Senate
Room 10 East Wing
Harrisburg, PA 17120-3004

Dear Chairpersons Brooks and Haywood,

We are writing to express the Pennsylvania Homecare Association's strong support for Senate Bill (SB) 1080, sponsored by Sen. Lynda Schlegal Culver, which addresses an important issue for hospice care across the Commonwealth. SB 1080 is currently pending consideration by the Senate Health and Human Services Committee. The Pennsylvania Homecare Association, representing over 700 home health, hospice, and homecare members, advocates for policies that enhance the quality of care for patients and support the dedicated professionals who provide this care.

Licensed Practical Nurses (LPNs) provide intimate, hands-on care for hospice patients throughout Pennsylvania. Their role is critical, offering compassionate and essential services to patients and families during the hospice experience. However, under the current Vital Statistics Law of 1953, the ability to pronounce a patient's death is restricted to Registered Nurses (RNs), medical doctors, physician assistants, and coroners. This limitation prevents LPNs from performing a function for which they are more than qualified, causing unnecessary delays and resource allocation challenges for hospice providers.

LPNs are not prohibited from pronouncing death under the applicable scope of practice law and are competent to serve this function. Virginia enacted legislation in 2022 to permit hospice LPNs to pronounce death for hospice patients, setting a precedent for similar action in Pennsylvania.

Hospices across the state are facing workforce shortages and must allocate finite resources efficiently to serve their patients best. We urge you to support Senate Bill 1080. This legislative change will help alleviate workforce strains and allow hospice agencies to allocate care and resources more effectively, ultimately benefiting patients and their families during a most critical time.

Thank you for your attention to this matter and your commitment to improving hospice care in Pennsylvania. We appreciate your support for this important legislation.

Sincerely,

Mia Haney

Alex McMahon

Mia Haney
CEO

Alexandra McMahon
Director – Government Relations

Fact Sheets Apr 26, 2023

Ensuring Access to Medicaid Services (CMS 2442-P) Notice of Proposed Rulemaking

Medicaid & CHIP

Share

Summary of Key Home and Community-Based Services (HCBS) Provisions

Ensuring beneficiaries can access covered services is a critical function of the Medicaid program and a top priority of the Centers for Medicare & Medicaid Services (CMS). The proposed rule, *Ensuring Access to Medicaid Services,* outlined in this fact sheet, includes both proposed changes to current requirements and newly proposed requirements that would advance CMS's efforts to improve access to care, quality, and health outcomes, and better promote health equity for Medicaid beneficiaries across fee-for-service (FFS) and managed care delivery systems, including for home and community-based services (HCBS) provided through those delivery systems. These proposed requirements are intended to increase transparency and accountability, standardize data and monitoring, and create opportunities for states to promote active beneficiary engagement in their Medicaid programs. Medicaid and CHIP are the nation's largest health coverage programs. If adopted as proposed, these rules would build on Medicaid's already strong foundation as an essential program for millions of families and individuals, especially children, pregnant people, older adults, and people with disabilities.

To advance the President's long-term care priorities, President Biden's Executive Order on Increasing Access to High-Quality Care and Supporting Caregivers directs the Department of Health and Human Services (HHS) to consider issuing several regulations and guidance documents to improve the quality of home care jobs, including by leveraging Medicaid funding to ensure there are enough home care workers to provide care to seniors and people with disabilities enrolled in Medicaid. Through this proposed rule, CMS is also fulfilling the directive for HHS to consider rulemaking to improve access to HCBS under Medicaid.

Public comments are requested on the Notice of Proposed Rulemaking (NPRM), including in response to specific questions articulated throughout the publication.

A substantive component of this proposed rule focuses on improving access to, and the quality of HCBS. Over the past several decades, HCBS have become a critical component of the Medicaid program and are part of a larger framework of progress toward community integration of older adults and people of all ages with disabilities that spans efforts across the Federal government. The proposed changes in this rule are intended to strengthen necessary safeguards to ensure health and welfare, promote health equity for people receiving Medicaid-covered HCBS, and achieve a more consistent and coordinated approach to the administration of policies and procedures across Medicaid HCBS programs. Specifically, the proposed rule seeks to:

- Establish a new strategy for oversight, monitoring, quality assurance, and quality improvement for HCBS programs;
- Strengthen person-centered service planning and incident management systems in HCBS;
- Require states to establish grievance systems in FFS HCBS programs;
- Require that at least 80% of Medicaid payments for personal care, homemaker, and home health aide services be spent on compensation for the direct care workforce (as opposed to administrative overhead or profit);
- Require states to publish the average hourly rate paid to direct care workers delivering personal care, home health aide, and homemaker services;
- Require states to establish an advisory group for interested parties to advise and consult on provider payment rates and direct compensation for direct care workers;
- Require states to report on waiting lists in section 1915(c) waiver programs; service delivery timeliness for personal care, homemaker and home health aide services; and a standardized set of HCBS quality measures; and

- Promote public transparency related to the administration of Medicaid-covered HCBS through public reporting of quality, performance, and compliance measures.

Key HCBS Provisions of the "Access" Rule

If finalized, the HCBS requirements in this proposed rule, , are intended to supersede and fully replace the reporting and performance expectations described in March 2014 guidance for section 1915(c) waiver programs. To ensure consistency and alignment across HCBS authorities, CMS proposes to apply the new HCBS requirements to section 1915(c) waiver programs and to section 1915(i), (j), and (k) state plan services, except where it is noted that a proposed requirement would only apply to certain services. In addition, except where noted, the proposed requirements would apply to services delivered through both FFS and managed care delivery services. Further, we clarify in the rule that, consistent with the applicability of other HCBS regulatory requirements to section 1115 demonstration projects, the proposed requirements for section 1915(c) waiver programs and section 1915(i), (j), and (k) state plan services would apply to these same services included in demonstration projects, unless we explicitly waive or make not applicable one or more of the requirements as part of the approval of the demonstration project.

Person-Centered Planning

To ensure a more consistent application of person-centered service plan requirements across states and to protect the health and welfare of people receiving HCBS, this rule proposes to codify a minimum performance level for states to demonstrate that a reassessment of functional need, including changes in circumstances, is conducted annually for at least 90 percent of individuals continuously enrolled in the state's HCBS programs for 365 days or longer. In addition, states would be required to demonstrate that they reviewed the person-centered service plan and revised the plan as appropriate based on the results of the required reassessment of functional need every 12 months, for at least 90 percent of individuals continuously enrolled in the state's HCBS programs for 365 days or longer.

The rule proposes that States report annually on the percent of beneficiaries continuously enrolled in the State's HCBS programs for 365 days or longer for whom a reassessment of functional need was completed within the past 12 months. States would also be required to report on the percent of beneficiaries continuously enrolled in the state's HCBS programs for 365 days or longer who had a service plan updated as a result of a re-assessment of functional need within the past 12 months. For both metrics, CMS proposes allowing states to report on a statistically valid random sample of beneficiaries, rather than for all individuals continuously enrolled in the State's HCBS programs for 365 days or longer. We proposed that these new performance levels and reporting requirements, if finalized, would be effective three years after the effective date of the final rule.

HCBS Grievance System

This rule proposes to require that states establish grievance procedures for Medicaid beneficiaries receiving HCBS through an FFS delivery system. This grievance process would give beneficiaries an opportunity to file an "expression of dissatisfaction," or complaint, related to the State's or a provider's compliance with person-centered planning and service plan requirements, and the HCBS settings requirements. The rule includes proposed recordkeeping requirements related to grievances, including that the record of each grievance contains a minimum set of elements, that states maintain records of grievances and review the information as part of their ongoing monitoring procedures, and that they are maintained in a manner that would be available upon CMS request. While CMS intends to apply these requirements across HCBS programs to avoid duplication with the existing grievance requirements for managed care at part 438, subpart F, we do not propose applying these requirements to managed care delivery systems. We proposed that these new grievance system requirements would be effective two years after the effective date of the final rule.

Incident Management Systems

In the rule, CMS proposes establishing a minimum definition of "critical incident" and minimum State performance and reporting requirements for investigation and action related to critical incidents. CMS also proposes to require that states operate and maintain an incident management system that identifies, reports, triages, investigates, resolves, tracks, and trends critical incidents.

Further, through this rule, we are proposing that states' incident management systems include an electronic information system that collects, tracks, and trends data and that states identify critical incidents through required provider reporting and other data sources (e.g., claims, Medicaid Fraud Control Units, Adult Protective Services, Child Protective Services, law enforcement). If an entity other than the State investigates critical incidents, we are proposing that states must have an information-sharing agreement with the investigating entity to share the status and resolution of investigations and that states must investigate separately if the investigating entity fails to report on a resolution within state-specified timeframes. In addition, CMS proposes

to require that States report every 24 months on the results of an incident management system assessment to demonstrate that they meet the new proposed incident management system requirements. We proposed that these requirements would be effective three years after the effective date of the final rule.

HCBS Payment Adequacy and Transparency

Access to most HCBS generally requires hands-on and in-person services to be delivered by direct care workers. However, direct care worker shortages are impacting beneficiaries' access to services. In an effort to address direct care workforce shortages, CMS proposes to require that at least 80 percent of Medicaid payments in a State for homemaker, home health aide, and personal care services be spent on compensation for direct care workers. We are also proposing to require that states report annually, in the aggregate for each service, on the percent of payments for homemaker, home health aide, and personal care services that are spent on compensation for direct care workers, and separately report on payments for such services when they are self-directed. We proposed that these requirements would be effective four years after the effective date of the final rule.

To ensure that HCBS stakeholders have increased awareness of how states establish Medicaid payment rates for personal care, homemaker, and home health aide services, CMS is proposing to require states to publish, every other year, the average hourly rate paid to direct care workers delivering these services. This information would separately compare rates for individual direct care providers and direct care providers employed by an agency. In addition, this proposed rule would require the establishment of an interested parties advisory group, to advise and consult with the State on payment rates for direct care workers. This group would include, at a minimum, direct care workers, beneficiaries and their authorized representatives, and other interested parties.

HCBS Quality Measure Set

On July 21, 2022, CMS issued State Medicaid Director Letter #22-003 to release the first official version of the HCBS Quality Measure Set. The HCBS Quality Measure Set is a set of nationally standardized quality measures for Medicaid-covered HCBS. This voluntary measure set is intended to promote more common and consistent use within and across states of nationally standardized quality measures in HCBS programs, create opportunities for CMS and states to have comparative quality data on HCBS programs, drive improvement in quality of care and outcomes for people receiving HCBS, and support states' efforts to promote equity in their HCBS programs.

This rule proposes to require states to report every other year on the HCBS Quality Measure Set for their HCBS programs. We are also proposing to update the measure set at least every other year through a process in consultation with states and other interested parties. Through this process to update the measure set, CMS is proposing to include mandatory measures, measures that the Secretary of HHS will report on states' behalf, measures that states can elect to have the Secretary of HHS report on their behalf, and measures that the Secretary will provide States with additional time to report.

As part of the reporting requirements proposed in the rule, states would be required to establish performance targets, subject to CMS review and approval, for each of the mandatory measures in the HCBS Quality Measure Set, and to describe the quality improvement strategies that they will pursue to achieve the performance targets for those measures. States would also be required to stratify data for certain measures by race, ethnicity, Tribal status, sex, age, rural/urban status, disability, language, or other factors in order to enable us to measure health disparities and advance health equity. We proposed that these requirements would be effective three years after the effective date of the final rule. However, considering the level of complexity required for such state reporting, CMS proposed that reporting for certain mandatory measures and reporting for certain populations of beneficiaries proposed in the rule may be phased-in over time. Further, the requirements for states to report stratified data would be phased in over a seven-year period after the effective date of the final rule.

Access Reporting

To improve public transparency, CMS proposes to require states that have a limit on the size of their waiver program to describe annually how they maintain the list of individuals who are waiting to enroll in the waiver program, including whether the State screens individuals on the waiting list for eligibility for the waiver program, whether the State periodically re-screens individuals on the waiting list for eligibility, and the frequency of re-screening if applicable. States would also be required to report the number of people on the waiting list and the average amount of time that individuals newly enrolled in the waiver program in the past 12 months were on the waiting list.

To improve oversight efforts to ensure access to care and services, CMS proposes to require states, for section 1915(c) waiver programs and section 1915(i), (j), and (k) state plan services, to report annually on the average amount of time from when homemaker, home health aide, or personal care services are initially approved to when those services began for individuals newly approved to begin receiving services within the past 12 months. We also propose to require states to report annually on the

percent of authorized hours for homemaker, home health aide, and personal care services that are provided within the past 12 months. These reporting requirements would be effective three years after the effective date of the final rule.

Standardization of HCBS Reporting Requirements and Transparency

To promote public transparency related to the administration of Medicaid-covered HCBS, this rule proposes to add requirements for states to compile and post required reporting data referenced above to a dedicated public HCBS webpage that meets certain availability and accessibility requirements. We also propose that CMS report on its website the information reported by states. We proposed that these provisions would be effective three years after the effective date of the final rule, with the exception of the payment adequacy provision which would be effective four years after the effective date of the final rule.

There will be a 60-day comment period for the notice of proposed rulemaking, and comments must be submitted to the Federal Register no later than July 3, 2023. For more information on how to submit comments or to review the entire rule, visit the Federal Register.

###

Previous Newsroom article

Next Newsroom article

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 431, 438, 441, and 447

[CMS–2442–F]

RIN 0938–AU68

Medicaid Program; Ensuring Access to Medicaid Services

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule takes a comprehensive approach to improving access to care, quality and health outcomes, and better addressing health equity issues in the Medicaid program across fee-for-service (FFS), managed care delivery systems, and in home and community-based services (HCBS) programs. These improvements increase transparency and accountability, standardize data and monitoring, and create opportunities for States to promote active beneficiary engagement in their Medicaid programs, with the goal of improving access to care.

DATES: These regulations are effective on July 9, 2024.

FOR FURTHER INFORMATION CONTACT:

Karen LLanos, (410) 786–9071, for Medicaid Advisory Committee.

Jennifer Bowdoin, (410) 786–8551, for Home and Community-Based Services.

Jeremy Silanskis, (410) 786–1592, for Fee-for-Service Payment.

SUPPLEMENTARY INFORMATION:

I. Background

A. Overview

Title XIX of the Social Security Act (the Act) established the Medicaid program as a joint Federal and State program to provide medical assistance to eligible individuals, including many with low incomes. Under the Medicaid program, each State that chooses to participate in the program and receive Federal financial participation (FFP) for program expenditures must establish eligibility standards, benefits packages, and payment rates, and undertake program administration in accordance with Federal statutory and regulatory requirements. The provisions of each State's Medicaid program are described in the Medicaid ''State plan'' and, as applicable, related authorities, such as demonstration projects and waivers of State plan requirements. Among other responsibilities, CMS approves State plans, State plan amendments (SPAs), demonstration projects authorized under section 1115 of the Act, and waivers authorized under section 1915 of the Act; and reviews expenditures for compliance with Federal Medicaid law, including the requirements of section 1902(a)(30)(A) of the Act relating to efficiency, economy, quality of care, and access to ensure that all applicable Federal requirements are met.

The Medicaid program provides essential health coverage to tens of millions of people, covering a broad array of health benefits and services critical to underserved populations,[1] including low-income adults, children, parents, pregnant individuals, older adults, and people with disabilities. For example, Medicaid pays for approximately 41 percent of all births in the U.S.[2] and is the largest payer of long-term services and supports (LTSS),[3] the largest, single payer of services to treat substance use disorders,[4] and services to prevent and treat the Human Immunodeficiency Virus.[5]

On January 28, 2021, the President signed Executive Order (E.O.) 14009,[6] ''Strengthening Medicaid and the Affordable Care Act,'' which established the policy objective to protect and strengthen Medicaid and the Affordable Care Act and to make high-quality health care accessible and affordable for every American. The E.O. also directed executive departments and agencies to review existing regulations, orders, guidance documents, and policies to determine whether such agency actions are inconsistent with this policy. On April 5, 2022, E.O. 14070,[7] ''Continuing To Strengthen Americans' Access to Affordable, Quality Health Coverage,'' directed Federal agencies with responsibilities related to Americans' access to health coverage to review agency actions to identify ways to continue to expand the availability of affordable health coverage, to improve the quality of coverage, to strengthen benefits, and to help more Americans enroll in quality health coverage. Consistent with CMS' authorities under the Act, this final rule implements E.O.s 14009 and 14070 by helping States to strengthen Medicaid and improve access to and quality of care provided.

Ensuring that beneficiaries can access covered services is necessary to the basic operation of the Medicaid program. Depending on the State and its Medicaid program structure, beneficiaries access their health care services using a variety of care delivery systems (for example, FFS, fully-capitated managed care, partially capitated managed care, etc.), including through demonstrations and waiver programs. The volume of Medicaid beneficiaries enrolled in a managed care program in Medicaid has grown from 81 percent in 2016 to 85 percent in 2021, with 74.6 percent of Medicaid beneficiaries enrolled in comprehensive managed care organizations.[8] [9] The remaining individuals received all of their care or some services that have been carved out of managed care through FFS.

Current access regulations are neither comprehensive nor consistent across delivery systems or coverage authority (for example, State plan and demonstration authority). For example, regulations at 42 CFR 447.203 and 447.204 relating to access to care, service payment rates, and Medicaid provider participation in rate setting apply only to Medicaid FFS delivery systems and focus on ensuring that payment rates are consistent with the statutory requirements in section 1902(a)(30)(A) of the Act. The regulations do not apply to services

[1] Executive Order 13985: *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/*.

[2] National Center for Health Statistics. Key Birth Statistics. Accessed at *https://www.cdc.gov/nchs/nvss/births.htm*.

[3] Colello, Kirsten J. *Who Pays for Long-Term Services and Supports?* Congressional Research Service. Updated September 2023. Accessed at *https://crsreports.congress.gov/product/pdf/IF/IF10343*.

[4] Soni, Anita. Health Care Expenditures for Treatment of Mental Disorders: Estimates for Adults Ages 18 and Older, U.S. Civilian Noninstitutionalized Population, 2019. Statistical Brief #539, pg 12. February 2022. Agency for Healthcare Research and Quality, Rockville, MD. Accessed at *https://meps.ahrq.gov/data_files/publications/st539/stat539.pdf*.

[5] Dawson, L. and Kates, J. Insurance Coverage and Viral Suppression Among People with HIV, 2018. September 2020. Kaiser Family Foundation. Accessed at *https://www.kff.org/hivaids/issue-brief/insurance-coverage-and-viral-suppression-among-people-with-hiv-2018/*.

[6] Executive Order 14009: *https://www.federalregister.gov/documents/2021/02/02/2021-02252/strengthening-medicaid-and-the-affordable-care-act*.

[7] Executive Order 14070: *https://www.federalregister.gov/documents/2022/04/08/2022-07716/continuing-to-strengthen-americans-access-to-affordable-quality-health-coverage*.

[8] Medicaid Managed Care Enrollment Report. *https://www.medicaid.gov/medicaid/managed-care/enrollment-report/index.html*.

[9] Throughout this document, the use of the term ''managed care plan'' includes managed care organizations (MCOs), prepaid inpatient health plans (PIHPs), and prepaid ambulatory health plans (PAHPs) [as defined in 42 CFR 438.2] and is used only when the provision under discussion applies to all three arrangements. An explicit reference is used in the preamble if the provision applies to primary care case managers (PCCMs) or primary care case management entities (PCCM entities).

delivered under managed care. These regulations are also largely procedural in nature and rely heavily on States to form an analysis and reach conclusions on the sufficiency of their own payment rates.

With a program as large and complex as Medicaid, access regulations need to be multi-factorial to promote consistent access to health care for all beneficiaries across all types of care delivery systems in accordance with statutory requirements. Strategies to enhance access to health care services should reflect how people move through and interact with the health care system. We view the continuum of health care access across three dimensions of a person-centered framework: (1) enrollment in coverage; (2) maintenance of coverage; and (3) access to services and supports. Within each of these dimensions, accompanying regulatory, monitoring, and/or compliance actions may be needed to ensure access to health care is achieved and maintained.

In the spring of 2022, we released a request for information (RFI) [10] to collect feedback on a broad range of questions that examined topics such as: challenges with eligibility and enrollment; ways we can use data available to measure, monitor, and support improvement efforts related to access to services; strategies we can implement to support equitable and timely access to providers and services; and opportunities to use existing and new access standards to help ensure that Medicaid and Children's Health Insurance Program (CHIP) payments are sufficient to enlist enough providers.

Some of the most common feedback we received through the RFI related to ways that we can promote health equity through cultural competency. Commenters shared the importance that cultural competency plays in how beneficiaries access health care and in the quality of health services received by beneficiaries. The RFI respondents shared examples of actions that we could take, including collecting and analyzing health outcomes data by sociodemographic categories; establishing minimum standards for how States serve communities in ways that address cultural competency and language preferences; and reducing barriers to enrollment and retention for racial and ethnic minority groups.

In addition to the topic of cultural competency, commenters also commonly shared that they viewed reimbursement rates as a key driver of provider participation in Medicaid and CHIP programs. Further, commenters noted that aligning payment approaches and setting minimum standards for payment regulations and compliance across Medicaid and CHIP delivery systems, services, and benefits could help ensure that beneficiaries' access to services is as similar as possible across beneficiary groups, delivery systems, and programs.

As mentioned previously in this final rule, the first dimension of access focuses on ensuring that eligible people are able to enroll in the Medicaid program. Access to Medicaid enrollment requires that a potential beneficiary know if they are or may be eligible for Medicaid, be aware of Medicaid coverage options, and be able to easily apply for and enroll in coverage. The second dimension of access in this continuum relates to maintaining coverage once the beneficiary is enrolled in the Medicaid program initially. Maintaining coverage requires that eligible beneficiaries are able to stay enrolled in the program without interruption, or that they know how to and can smoothly transition to other health coverage, such as CHIP, Exchange coverage, or Medicare, when they are no longer eligible for Medicaid coverage but have become eligible for other health coverage programs. In September 2022, we published a proposed rule, *Streamlining the Medicaid, Children's Health Insurance Program, and Basic Health Program Application, Eligibility, Determination, Enrollment, and Renewal Processes* to simplify the processes for eligible individuals to enroll and retain eligibility in Medicaid, CHIP, and the Basic Health Program (BHP) (87 FR 54760). This proposed rule was finalized in two parts, the *Streamlining Medicaid; Medicare Savings Program Eligibility Determination and Enrollment Final Rule* (88 FR 65230) and the *Streamlining Eligibility & Enrollment final rule* (89 FR 22780).

The third dimension, which is the focus of this final rule, is access to services and supports. This rule addresses additional critical elements of access: (1) potential access, which refers to a beneficiary's access to providers and services, whether or not the providers or services are used; (2) beneficiary utilization, which refers to beneficiaries' actual use of the providers and services available to them; and (3) beneficiaries' perceptions and experiences with the care they did or were not able to receive. These terms and definitions build upon previous efforts to examine how best to monitor access.[11]

We completed an array of regulatory activities, including three rules: the aforementioned Streamlining Eligibility & Enrollment final rules and a final rule entitled Medicaid and Children's Health Insurance Program (CHIP) Managed Care Access, Finance, and Quality (as published elsewhere in this issue of the **Federal Register**, Managed Care final rule), on managed care including matters of access, and this final rule on access. Additionally, we are taking non-regulatory actions to improve beneficiary access to care (for example, best practices toolkits and technical assistance to States) to improve access to health care services across Medicaid delivery systems.

As noted earlier, we issued the Streamlining Eligibility & Enrollment final rules to address the first two dimensions of access to health care: (1) enrollment in coverage and (2) maintenance of coverage. Through those final rules, we streamline Medicaid, CHIP and BHP eligibility and enrollment processes, reduce administrative burden on States and applicants/enrollees toward a more seamless eligibility and enrollment process, and increase the enrollment and retention of eligible individuals.

The Managed Care final rule improves access to care and quality outcomes for Medicaid and CHIP beneficiaries enrolled in managed care by: creating standards for timely access to care and States' monitoring and enforcement efforts; reducing burden for some State directed payments and certain quality reporting requirements; adding new standards that will apply when States use in lieu of services and settings (ILOSs) to promote effective utilization, and specifying the scope and nature of ILOS; specifying medical loss ratio (MLR) requirements, and establishing a quality rating system for Medicaid and CHIP managed care plans.

Through the Managed Care final rule and this final rule (Ensuring Access to Medicaid Services), we finalize additional requirements to address the third dimension of the health care access continuum: access to services. The requirements outlined later in this section focus on improving access to services in Medicaid by utilizing tools such as FFS rate transparency,

[10] CMS Request for Information: Access to Coverage and Care in Medicaid & CHIP. February 2022. For a full list of question from the RFI, see *https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-questions.pdf.*

[11] Kenney, Genevieve M., Kathy Gifford, Jane Wishner, Vanessa Forsberg, Amanda I. Napoles, and Danielle Pavliv. ''Proposed Medicaid Access Measurement and Monitoring Plan.'' Washington, DC: The Urban Institute. August 2016. Accessed at *https://www.urban.org/sites/default/files/publication/88081/2001143-medicaid-access-measurement-and-monitoring-plan_0.pdf.*

standardized reporting for HCBS, and improving the process for interested parties, especially Medicaid beneficiaries, to provide feedback to State Medicaid agencies and for Medicaid agencies to respond to the feedback (also known as a feedback loop).

Through a combination of these four final rules, we address a range of access-related challenges that impact how beneficiaries are served by Medicaid across all of its delivery systems. FFP will be available for expenditures that are necessary to implement the activities States will need to undertake to comply with the provisions of these final rules.

Finally, we also believe it is important to acknowledge the role of health equity within this final rule. Medicaid plays a disproportionately large role in covering health care for people from underserved communities in this country.[12] Consistent with E.O. 13985 on ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (January 20, 2021),'' [13] which calls for advancing equity for underserved populations, we are working to ensure our programs consistently provide high-quality care to all beneficiaries, and thus advance health equity, consistent with the goals and objectives we have outlined in the CMS Framework for Health Equity 2022–2032 [14] and the HHS Equity Action Plan.[15] That effort includes increasing our understanding of the needs of those we serve to ensure that all individuals have access to equitable coverage and care.

We recognize that each State faces a unique set of challenges related to the resumption of its normal program activities after the end of the COVID–19 public health emergency (PHE). More specifically, the expiration of the Medicaid continuous enrollment condition authorized by the Families First Coronavirus Response Act (FFCRA) presents the single largest health coverage transition event since the first open enrollment period of the Affordable Care Act. As a condition of receiving a temporary 6.2 percentage point Federal Medical Assistance Percentage (FMAP) increase under the FFCRA, States were required to maintain enrollment of nearly all Medicaid enrollees. This continuous enrollment condition expired on March 31, 2023, after which States began completing renewals for all individuals enrolled in Medicaid, CHIP, and the BHP. Additionally, many other temporary authorities adopted by States during the COVID–19 PHE expired at the end of the PHE, and States are returning to regular operations across their programs. The resumption of normal Medicaid operations is generally referred to as ''unwinding'' and the period for States to initiate all outstanding eligibility actions that were delayed because of the FFCRA continuous enrollment condition is called the ''unwinding period.'' We considered States' unwinding responsibilities when finalizing the dates for States to begin complying with the requirements being finalized in this rule, but, as noted in the Ensuring Access to Medicaid Services proposed rule, we solicited State feedback on whether our proposals struck the correct balance.

We considered adopting an effective date of 60 days following publication of this final rule and separate compliance dates for various provisions, which we note where relevant in our discussion of specific proposals in this final rule. We solicited comment on whether an effective date of 60 days following publication would be appropriate when combined with later dates for compliance for some provisions.

We also solicited comment on the timeframe that would be most achievable and appropriate for compliance with each proposed provision and whether the compliance date should vary by provision.

B. Medical Care Advisory Committees (MCAC)

We obtained feedback during various public engagement activities conducted with States and other interested parties, which supports research findings that the beneficiary perspective and lived Medicaid experience [16] should be considered when making policy decisions related to Medicaid programs.[17] [18] A 2022 report from the HHS Assistant Secretary of Planning and Evaluation (ASPE) noted that including people with lived experience in the policy-making process can lead to a deeper understanding of the conditions affecting certain populations, facilitate identification of possible solutions, and avoid unintended consequences of potential policy or program changes that could negatively impact the people the program aims to serve.[19] We have concluded that beneficiary perspectives need to be central to operating a high-quality health coverage program that consistently meets the needs of all its beneficiaries.

However, effective community engagement is not as simple as planning a meeting and requesting feedback. To create opportunities that facilitate true engagement, it is important to understand and honor strengths and assets that exist within communities; recognize and solicit the inclusion of diverse voices; dedicate resources to ensuring that engagement is done in culturally meaningful ways; ensure timelines, planning processes, and resources that support equitable participation; and follow up with communities to let them know how their input was utilized. Ensuring optimal health outcomes for all beneficiaries served by a program through the design, implementation, and operationalization of policies and programs requires intentional and continuous effort to engage people who have historically been excluded from the process.

Section 1902(a)(4) of the Act is a longstanding statutory provision that, as implemented in part in regulations currently codified at 42 CFR 431.12,[20] requires States to have a Medical Care

[12] Guth, M and Artiga, S. Medicaid and Racial Health Equity March 2022. Accessed at *https://www.kff.org/medicaid/issue-brief/medicaid-and-racial-health-equity/*.

[13] Executive Order 13985: *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/*.

[14] CMS Framework for Health Equity 2022–2032: *https://www.cms.gov/files/document/cms-framework-health-equity.pdf*.

[15] HHS Equity Action Plan. April 2022. Accessed at *https://www.hhs.gov/sites/default/files/hhs-equity-action-plan.pdf*.

[16] Lived experience refers to ''representation and understanding of an individual's human experiences, choices, and options and how those factors influence one's perception of knowledge'' based on one's own life. In this context, we refer to people who have been enrolled in Medicaid currently or in the past. Accessed at *https://aspe.hhs.gov/lived-experience#:~:text=In%20the%20context%20of%20ASPE%E2%80%99s%20research%2C%20people%20with,programs%20that%20aim%20to%20address%20the%20issue%20%28s%29*.

[17] Zhu JM, Rowland R, Gunn R, Gollust S, Grande DT. Engaging Consumers in Medicaid Program Design: Strategies from the States. Milbank Q. 2021 Mar;99(1):99–125. doi: 10.1111/1468–0009.12492. Epub 2020 Dec 15. PMID: 33320389; PMCID: PMC7984666. Accessed at *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7984666/*.

[18] Key Findings from the Medicaid MCO Learning Hub Discussion Group Series and Roundtable—Focus on Member Engagement and the Consumer Voice. NORC at the University of Chicago. Jan 2021. Accessed at *https://www.norc.org/PDFs/Medicaid%20Managed%20Care%20Organization%20Learning%20Hub/MMCOLearningHub_MemberEngagement.pdf*.

[19] Syreeta Skelton-Wilson et al., ''Methods and Emerging Strategies to Engage People with Lived Experience,'' Office of the Assistant Secretary for Planning and Evaluation (ASPE), U.S. Department of Health and Human Services, January 4, 2022, *https://aspe.hhs.gov/reports/lived-experience-brief*.

[20] The regulatory provision was originally established in 36 FR 3793 at 3870.

Advisory Committee (MCAC) in place to advise the State Medicaid agency about health and medical care services. Under section 1903(a)(7) of the Act, expenditures made by the State agency to operate the MCAC are eligible for Federal administrative match.

The current MCAC regulations at § 431.12 require States to establish such a committee and describe high-level requirements related to the composition of the committee, the scope of topics to be discussed, and the support the Committee can receive from the State in its administration. Due to the lack of specificity in the current regulations, these regulations have not been consistently implemented across States. For example, there is no mention of how States should approach meeting periodicity or meeting structure in ways that are conducive to including a variety of Medicaid interested parties. There is also no mention in the regulations about how States can build accountability through transparency with their interested parties by publicly sharing meeting dates, membership lists, and the outcomes of these meetings. The regulations also limit the required MCAC discussions to topics about health and medical care services—which in turn limits the benefits of using the MCAC as a vehicle that can provide States with varied ideas, suggestions, and experiences on a range of issues related to the effective administration of the Medicaid program.

As such, we have determined the requirements governing MCACs need to be more robust to ensure all States are using these committees optimally to realize a more effective and efficient Medicaid program that is informed by the experiences of beneficiaries, their caretakers, and other interested parties. The current regulations have been in place without change for over 40 years.[21] Over the last four decades, we have learned that the current MCAC requirements are insufficient in ensuring that the beneficiary perspective is meaningfully represented on the MCAC. Recent research regarding soliciting input from individuals with lived experience, including our recent discussions with States about their MCAC, provide a unique opportunity to re-examine the purpose of this committee and update the policies to reflect four decades of program experience.

In 2022, we gathered feedback from various public engagement activities conducted with States, other interested parties, and directly from a subset of State Medicaid agencies that described a wide variation in how States are operating MCACs today. The feedback suggested that some MCACs operate simply to meet the broad Federal requirements. As discussed previously in this section, we have discovered that our current regulations do not further the statutory goal of meaningfully engaging Medicaid beneficiaries and other low-income people in matters related to the operation of the Medicaid program. Meaningful engagement can help develop relationships and establish trust between the communities served and the Medicaid agency to ensure States receive important information concerning how to best provide health coverage to their beneficiary populations. The current MCAC regulations establish the importance of broad feedback from interested parties, but they lack the specificity that can ensure States use MCACs in ways that facilitate that feedback.

The current regulations require that MCACs must include Medicaid beneficiaries as committee members. However, the regulations do not mention or account for the reality that other interested parties can stifle beneficiary contribution in a group setting. For example, when there are a small number of beneficiary representatives in large committees with providers, health plans, and professional advocates, it can be uncomfortable and intimidating for beneficiaries to share their perspective and experience. Based on these reasons, several States already use beneficiary-only groups that feed into larger MCACs.

Improvements to the MCACs are critical to ensuring a robust and accurate understanding of beneficiaries' challenges to health care access. The current regulations value State Medicaid agencies having a way to get feedback from interested parties on issues related to the Medicaid program. However, the current regulations lack specificity related to how MCACs can be used to benefit the Medicaid program more expressly by more fully promoting the beneficiary voice. MCACs need to provide a forum for beneficiaries and people with lived experience with the Medicaid program to share their experiences and challenges with accessing health care, and to assist States in understanding and better addressing those challenges. These committees also represent unique opportunities for States to include representation by members that reflect the demographics of their Medicaid program to ensure that the program is best serving the needs of all beneficiaries, but not all States are utilizing that opportunity.

This final rule strikes a balance that reflects how States currently use advisory committees (such as MCACs or standalone beneficiary groups). We know that some States approach these committees as a way to meet a Federal requirement while other States are using them in much more innovative ways. As a middle ground, this final rule seeks to: (1) address the gaps in the current regulations described previously in this section; and (2) establish requirements to implement more effective advisory committees. States will select members in a way that reflects a wide range of Medicaid interested parties (covering a diverse set of populations and interests relevant to the Medicaid program), place a special emphasis on the inclusion of the beneficiary perspective, and create a meeting environment where each voice is empowered to participate equally.

The changes we are making in this rule are rooted in best practices learned from States' experiences implementing the existing MCAC provisions and from other State examples of community engagement that support getting the type of feedback and experiences from beneficiaries, their caretakers, providers, and other interested parties that can then be used to positively impact care delivered through the Medicaid program.

Accordingly, this final rule includes changes that will support the implementation of the principles of bi-directional feedback, transparency, and accountability. We are making changes to the features of the new committee that can most effectively ensure member engagement, including the staff and logistical support that is required for beneficiaries and individuals representing beneficiaries to meaningfully participate in these committees. We are also making changes to expand the scope of topics to be addressed by the committee, address committee membership composition, prescribe the features of administration of the committee, establish requirements of an annual report, and underscore the importance of beneficiary engagement through the addition of a related beneficiary-only group.

C. Home and Community-Based Services (HCBS)

While Medicaid programs are required to provide medically necessary nursing facility services for most eligible individuals age 21 or older, coverage for

[21] 43 FR 45091 at 45189.

HCBS is a State option.[22] As a result of this ''institutional bias'' in the statute, Medicaid reimbursement for LTSS was primarily spent on institutional care, historically, with very little spending for HCBS.[23] However, over the past several decades, States have used several Medicaid authorities,[24] as well as CMS-funded grant programs,[25] to develop a broad range of HCBS to provide alternatives to institutionalization for eligible Medicaid beneficiaries and to advance person-centered care. Consistent with many beneficiaries' preferences for where they would like to receive their care, HCBS have become a critical component of the Medicaid program and are part of a larger framework of progress toward community integration of older adults and people with disabilities that spans efforts across the Federal government. In fact, total Medicaid HCBS expenditures surpassed the long-standing benchmark of 50 percent of LTSS expenditures in FY 2013 and has remained higher than 50 percent since then, reaching 55.4 percent in FY 2017 and 62.5 percent in FY 2020.[26] A total of 35 States spent at least 50 percent of Medicaid LTSS expenditures on HCBS in FY 2020.

Furthermore, HCBS play an important role in States' efforts to achieve compliance with Title II of the Americans with Disabilities Act (ADA) of 1990, section 504 of the Rehabilitation Act of 1973 (section 504),[27] section 1557 of the Affordable Care Act, and the Supreme Court's decision in *Olmstead* v. *L.C.,*[28] in which the Court held that unjustified segregation of persons with disabilities is a form of unlawful discrimination under the ADA [29] and States must ensure that persons with disabilities are served in the most integrated setting appropriate to their needs.[30] Section 9817 of the American Rescue Plan Act of 2021 (ARP) (Pub. L. 117–2) recently made a historic investment in Medicaid HCBS by providing qualifying States with a temporary 10 percentage point increase to the FMAP for certain Medicaid expenditures for HCBS that States must use to implement or supplement the implementation of one or more activities to enhance, expand, or strengthen HCBS under the Medicaid program.[31]

Medicaid coverage of HCBS varies by State and can include a combination of medical and non-medical services, such as case management, homemaker, personal care, adult day health, habilitation (both day and residential), and respite care services. HCBS programs serve a variety of targeted population groups, such as older adults, and children and adults with intellectual or developmental disabilities, physical disabilities, mental health/substance use disorders, and complex medical needs. HCBS programs provide opportunities for Medicaid beneficiaries to receive services in their own homes and communities rather than in institutions.

CMS and States have worked for decades to support the increased availability and provision of high-quality HCBS for Medicaid beneficiaries. While there are quality and reporting requirements for Medicaid HCBS, the requirements vary across authorities and are often inadequate to provide the necessary information for ensuring that HCBS are provided in a high-quality manner that best protects the health and welfare of beneficiaries. Consequently, quality measurement and reporting expectations are not consistent across and within services, but instead vary depending on the authorities under which States are delivering services. Additionally, States have flexibility to determine the quality measures they use in their HCBS programs. While we support State flexibility, a lack of standardization has resulted in thousands of metrics and measures currently in use across States, with different metrics and measures often used for different HCBS programs within the same State. As a result, CMS and States are limited in the ability to compare HCBS quality and outcomes within and across States or to compare the performance of HCBS programs for different populations.

In addition, although there are differences in rates of disability among demographic groups, there are very limited data currently available to assess disparities in HCBS access, utilization, quality, and outcomes. Few States have the data infrastructure to systematically or routinely report data that can be used to assess whether disparities exist in HCBS programs. This lack of available data also prevents CMS and States from implementing interventions to make improvements in HCBS programs designed to consistently meet the needs of all beneficiaries. Compounding these concerns have been notable and high-profile instances of abuse and neglect in recent years, which have been shown to result from poor quality care and inadequate oversight of HCBS in Medicaid. For example, a 2018 report, ''Ensuring Beneficiary Health and Safety in Group Homes Through State Implementation of Comprehensive Compliance Oversight,'' [32] (''Joint Report''), which was jointly developed by the U.S. Department of Health Human Services' Administration for Community Living (ACL), Office for Civil Rights (OCR), and the Office of

[22] Murray, Caitlin, Alena Tourtellotte, Debra Lipson, and Andrea Wysocki. ''Medicaid Long Term Services and Supports Annual Expenditures Report: Federal Fiscal Year 2019.'' Chicago, IL: Mathematica, December 2021. Accessed at *https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltssexpenditures2019.pdf*.

[23] Centers for Medicare and Medicaid Services. November 2020. Long-Term Services and Supports Rebalancing Toolkit. Accessed at *https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltss-rebalancing-toolkit.pdf*.

[24] These authorities include Medicaid State plan personal care services and Social Security Act (the Act) section 1915(c) waivers, section 1915(i) State plan HCBS, section 1915(j) self-directed personal assistant services, and section 1915(k) Community First Choice. See *https://www.medicaid.gov/medicaid/home-community-based-services/home-community-based-services-authorities/index.html* for more information on these authorities. Some States also use demonstration authority under section 1115(a) of the Act to cover and test home and community-based service strategies. See *https://www.medicaid.gov/medicaid/section-1115-demonstrations/index.html* for more information.

[25] Federally funded grant programs include the Money Follows the Person (MFP) demonstration program, which was initially authorized by the Deficit Reduction Act of 2005 (Pub. L. 109–171). The MFP program was recently extended under the Consolidated Appropriations Act, 2021 (Pub. L. 116–260), which allowed new States to join the demonstration and made statutory changes affecting MFP participant eligibility criteria, allowing grantees to provide community transition services under MFP earlier in an eligible individual's inpatient stay.

[26] Murray, Caitlin, Michelle Eckstein, Debra Lipson, and Andrea Wysocki. ''Medicaid Long Term Services and Supports Annual Expenditures Report: Federal Fiscal Year 2020.'' Chicago, IL: Mathematica, December 9, 2021. Accessed at *https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltssexpenditures2020.pdf*.

[27] HHS interprets section 504 and Title II of the ADA similarly regarding the integration mandate and the Department of Justice generally interprets the requirements under section 504 consistently with those under Title II of the ADA.

[28] 527 U.S. 581 (1999).

[29] Medicaid and the Olmstead Decision. Accessed at *https://www.medicaid.gov/about-us/program-history/medicaid-50th-anniversary/entry/47688*.

[30] Medicaid and the Olmstead Decision. Accessed at *https://www.medicaid.gov/about-us/program-history/medicaid-50th-anniversary/entry/47688*.

[31] Information on State activities to expand, enhance, or strengthen HCBS under ARP section 9817 can be found on *Medicaid.gov* at *https://www.medicaid.gov/medicaid/home-community-based-services/guidance/strengthening-and-investing-home-and-community-based-services-for-medicaid-beneficiaries-american-rescue-plan-act-of-2021-section-9817/index.html*.

[32] Ensuring Beneficiary Health and Safety in Group Homes Through State Implementation of Comprehensive Compliance Oversight. US Department of Health and Human Services, Office of the Inspector General, Administration for Community Living, and Office for Civil Rights. January 2018. Accessed at *https://oig.hhs.gov/reports-and-publications/featured-topics/group-homes/group-homes-joint-report.pdf*.

Inspector General (OIG), found systemic problems with health and safety policies and procedures being followed in group homes and that failure to comply with these policies and procedures left beneficiaries in group homes at risk of serious harm. In addition, while existing regulations provide safeguards for all Medicaid beneficiaries in the event of a denial of Medicaid eligibility or an adverse benefit determination by the State Medicaid agency and, where applicable, by the beneficiary's managed care plan, there are no safeguards related to other issues that HCBS beneficiaries may experience, such as the failure of a provider to comply with the HCBS settings requirements or difficulty accessing the services in the person-centered service plan unless the individual is receiving those services through a Medicaid managed care arrangement.

Finally, through our regular interactions with State Medicaid agencies, provider groups, and beneficiary advocates, we observed that all these interested parties routinely cite a shortage of direct care workers and high rates of turnover in direct care workers among the greatest challenges in ensuring access to high-quality, cost-effective HCBS for people with disabilities and older adults. Some States have also indicated that a lack of direct care workers is preventing them from transitioning individuals from institutions to home and community-based settings. While workforce shortages have existed for years, they have been exacerbated by the COVID–19 pandemic, which has resulted in higher rates of direct care worker turnover (for instance, due to higher rates of worker-reported stress), an inability of some direct care workers to return to their positions prior to the pandemic (for instance, due to difficulty accessing child care or concerns about contracting COVID–19 for people with higher risk of severe illness), workforce shortages across the health care sector, and wage increases in types of retail and other jobs that tend to draw from the same pool of workers.[33] [34] [35]

To address the list of challenges outlined in this section, we proposed Federal requirements to improve access to care, quality of care, and health and quality of life outcomes; promote health equity for people receiving Medicaid-covered HCBS; and ensure that there are safeguards in place for beneficiaries who receive HCBS through FFS delivery systems. We solicited comment on other areas for rulemaking consideration. The requirements we are finalizing in this rule are intended, individually and as a whole, to promote public transparency related to the administration of Medicaid HCBS programs.

D. Fee-For-Service (FFS) Payment

Section 1902(a)(30)(A) of the Act requires States to ''assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.'' Regulations at § 447.203 require States to develop and submit to CMS an access monitoring review plan (AMRP) for a core set of services. Currently, the regulations rely on available State data to support a determination that the State's payment rates are sufficient to ensure access to care in Medicaid FFS that is at least as great for beneficiaries as is generally available to the general population in the geographic area, as required under section 1902(a)(30)(A) of the Act.

In the May 6, 2011, **Federal Register**, we published the Medicaid Program; Methods for Assuring Access to Covered Medicaid Services proposed rule (76 FR 26341; hereinafter ''2011 proposed rule''), which outlined a data-driven process for States with Medicaid services paid through a State plan under FFS to follow in order to document their compliance with section 1902(a)(30)(A) of the Act. We finalized the 2011 proposed rule in the November 2, 2015, **Federal Register** when we published the ''Medicaid Program; Methods for Assuring Access to Covered Medicaid Services'' final rule with comment period (80 FR 67576; hereinafter ''2015 final rule with comment period''). Among other requirements, the 2015 final rule with comment period required States to develop and submit to CMS an AMRP for certain Medicaid services that is updated at least every 3 years. Additionally, the rule required that when States submit a SPA to reduce or restructure provider payment rates, they must consider the data collected through the AMRP and undertake a public process that solicits input on the potential impact of the proposed reduction or restructuring of Medicaid FFS payment rates on beneficiary access to care. We published the ''Medicaid Program; Deadline for Access Monitoring Review Plan Submissions'' final rule in the April 12, 2016 **Federal Register** (81 FR 21479; hereinafter ''2016 final rule'') with a revised deadline for States' AMRPs to be submitted to us.

Following the implementation of the AMRP process, numerous States have expressed concern regarding the administrative burden associated with the 2015 final rule with comment period requirements, especially those States with high rates of beneficiary enrollment in managed care. In an attempt to address some of the States' concerns regarding unnecessary administrative burden, we issued a State Medicaid Director letter (SMDL) on November 16, 2017 (SMDL #17–004), which clarified the circumstances in which provider payment reductions or restructurings would likely not result in diminished access to care, and therefore, would not require additional analysis and monitoring procedures described in the 2015 final rule with comment period.[36] Subsequently, in the March 23, 2018 **Federal Register**, we published the ''Medicaid Program; Methods for Assuring Access to Covered Medicaid Services-Exemptions for States With High Managed Care Penetration Rates and Rate Reduction Threshold'' proposed rule (83 FR 12696; hereinafter ''2018 proposed rule''), which would have exempted States from requirements to analyze certain data or monitor access when the vast majority of their covered beneficiaries receive services through managed care plans. That proposed rule, if it had been finalized, would have provided similar flexibility to all States when they make nominal rate reductions or restructurings to FFS payment rates. Based on the responses received during the public comment period, we decided not to finalize the proposed exemptions.

In the July 15, 2019, **Federal Register**, we published the ''Medicaid Program; Methods for Assuring Access to Covered Medicaid Services-Rescission'' proposed rule (84 FR 33722; hereinafter ''2019 proposed rule'') to rescind the regulatory access requirements at §§ 447.203(b) and 447.204, and

[33] MACPAC Issue Brief. State Efforts to Address Medicaid Home- and Community-Based Services Workforce Shortages. March 2022. Accessed at *https://www.macpac.gov/wp-content/uploads/2022/03/MACPAC-brief-on-HCBS-workforce.pdf*.

[34] Campbell, S., A. Del Rio Drake, R. Espinoza, K. Scales. 2021. Caring for the future: The power and potential of America's direct care workforce. Bronx, NY: PHI *http://phinational.org/wp-content/uploads/2021/01/Caring-for-the-Future-2021-PHI.pdf*.

[35] American Network of Community Options and Resources (ANCOR). 2021. The state of America's direct support workforce 2021. Alexandria, VA: ANCOR. Accessed at *https://www.ancor.org/sites/default/files/the_state_of_americas_direct_support_workforce_crisis_2021.pdf*.

[36] State Medicaid Director Letter #17–0004 Re: Medicaid Access to Care Implementation Guidance. Accessed at *https://www.medicaid.gov/federal-policy-guidance/downloads/smd17004.pdf* (November 2017).

concurrently issued a CMCS Informational Bulletin (CIB) [37] stating the agency's intention to establish a new access strategy. Based on the responses we received during the public comment period, we decided not to finalize the 2019 proposed rule, and instead continue our efforts and commitment to develop a data-driven strategy to understand access to care in the Medicaid program.

States have continued to question whether the AMRP process is the most effective or accurate reflection of access to care in a State's Medicaid program, and requested we provide additional clarity on the data necessary to support compliance with section 1902(a)(30)(A) of the Act. In reviewing the information that States presented through the AMRPs, we also have questioned whether the data and analysis consistently address the primary access-related question posed by section 1902(a)(30)(A) of the Act—namely, whether rates are sufficient to ensure access to care at least as great as that enjoyed by the general population in geographic areas. The unstandardized nature of the AMRPs, which largely defer to States to determine appropriate data measures to review and monitor when documenting access to care, have made it difficult to assess whether any single State's analysis demonstrates compliance with section 1902(a)(30)(A) of the Act.

While the AMRPs were intended to be a useful guide to States in the overall process to monitor beneficiary access, they are generally limited to access in FFS delivery systems and focus on targeted payment rate changes rather than the availability of care more generally or population health outcomes (which may be indicative of the population's ability to access care). Moreover, the AMRP processes are largely procedural in nature and not targeted to specific services for which access may be of particular concern, requiring States to engage in triennial reviews of access to care for certain broad categories of Medicaid services—primary care services, physician specialist services, behavioral health services, pre- and post-natal obstetric services, and home health services. Although the 2016 final rule discussed that the selected service categories were intended to be indicators for available access in the overall Medicaid FFS system, these categories do not directly translate to the services authorized under section 1905(a) of the Act, granting States deference as to how broadly or narrowly to apply the AMRP analysis to services within their programs. For example, the category ''primary care services'' could encompass several of the Medicaid service categories described within section 1905(a) of the Act and, without clear guidance on which section 1905(a) services categories, qualified providers, or procedures we intended States to include within the AMRP analyses, States were left to make their own interpretations in analyzing access to care under the 2016 final rule.

Similarly, a number of the AMRP data elements, both required and suggested within the 2016 final rule, may be overly broad, subject to interpretation, or difficult to obtain. Specifically, under the 2016 final rule provisions, States are required to review: the extent to which beneficiary needs are fully met; the availability of care through enrolled providers to beneficiaries in each geographic area, by provider type and site of service; changes in beneficiary utilization of covered services in each geographic area; the characteristics of the beneficiary population (including considerations for care, service and payment variations for pediatric and adult populations and for individuals with disabilities); and actual or estimated levels of provider payment available from other payers, including other public and private payers, by provider type and site of service. Although service utilization and provider participation are relatively easy measures to source and track using existing Medicaid program data, an analysis of whether beneficiary needs are fully met is at least somewhat subjective and could require States to engage in a survey process to complete. Additionally, while most Medicaid services have some level of equivalent payment data that can be compared to other available public payer data, such as Medicare, private payer information may be proprietary and difficult to obtain. Therefore, many States struggled to meet the regulatory requirement to compare Medicaid program rates to private payer rates because of their inability to obtain private payer data.

Due to these issues, States produced varied AMRPs through the triennial process that were, as a whole, difficult to interpret or to use in assessing compliance with section 1902(a)(30)(A) of the Act. In isolation, a State's specific AMRP most often presented data that could be meaningful as a benchmark against changes within a State's Medicaid program, but did not present a case for Medicaid access consistent with the general population in geographic areas. Frequently, the data and information within the AMRPs were presented without a formal determination or attestation from the State that the information presented established compliance with section 1902(a)(30)(A) of the Act. Because the States' AMRPs generally varied to such a great degree, there was also little to glean in making State-to-State comparisons of performance on access measures, even for States with geographic and demographic similarities.

Based on results of the triennial AMRPs, we were uncertain of how to make use of the information presented within them other than to make them publicly available. We published the AMRPs on Medicaid.gov but had little engagement with States on the content or results of the AMRPs since much of the information within the plans could not meaningfully answer whether access in Medicaid programs satisfied the requirements of section 1902(a)(30)(A) of the Act. Additionally, we received little feedback from providers, beneficiaries, or advocates on whether or how interested parties made use of the triennial AMRPs. However, portions of the 2016 final rule related to public awareness and feedback on changes to Medicaid payment rates and the analysis that we received from individual States proposing to make rate changes was of great benefit in determining approvals of State payment change proposals. Specifically, the portion of the AMRP process where States update their plans to describe data and measures to serve as a baseline against which they monitor after reducing or restructuring Medicaid payments allows States to document consistency with section 1902(a)(30)(A) of the Act at the time of SPA submission, usually as an assessment of how closely rates align with Medicare rates, and to understand the impact of reductions through data monitoring after SPA approval.

Under this final rule, we balance elimination of unnecessary Federal and State administrative burden with robust implementation of the Federal and State shared obligation to ensure that Medicaid payment rates are set at levels sufficient to ensure access to care for beneficiaries consistent with section 1902(a)(30)(A) of the Act. The provisions of this final rule, as discussed in more detail later, will better achieve this balance through improved transparency of Medicaid FFS payment rates, through publication of a comparative payment rate analysis to Medicare and payment rate disclosures,

[37] CMCS Informational Bulletin: Comprehensive Strategy for Monitoring Access in Medicaid, Accessed at *https://www.medicaid.gov/federal-policy-guidance/downloads/CIB071119.pdf* (July 2019).

and through a more targeted and defined approach to evaluating data and information when States propose to reduce or restructure their Medicaid payment rates. Payment rate transparency is a critical component of assessing compliance with section 1902(a)(30)(A) of the Act. In addition, payment rate transparency helps to ensure that interested parties have basic information available to them to understand Medicaid payment levels and the associated effects of payment rates on access to care so that they may raise concerns to State Medicaid agencies via the various forms of public processes discussed within this final rule. Along with improved payment rate transparency and disclosures as well as comparative payment rate analyses, we are finalizing a more efficient process for States to undertake when submitting rate reduction or restructuring SPAs to CMS for review. As we move toward aligning our Medicaid access to care strategy across FFS and managed care delivery systems, we will consider additional rulemaking to help ensure that Medicaid payment rate information is appropriately transparent and rates are fully consistent with broad access to care across delivery systems, so that interested parties have a more complete understanding of Medicaid payment rate levels and resulting access to care for beneficiaries.

II. Summary of the Proposed Provisions and Analysis of and Responses to the Public Comments

We received 2,123 public comments from individuals and organizations, including, but not limited to, individuals, State government agencies, non-profit health care organizations, advocacy groups, associations, law firms, managed care plans, academic groups, and tribal organizations. We thank and appreciate the commenters for their consideration of the proposed requirements for ensuring access to care, quality and health outcomes, and better addressing health equity issues in the Medicaid program across FFS and managed care delivery systems, and in HCBS programs. In general, commenters supported the proposed rule. In this section, arranged by subject area, we summarize the proposed provisions, the public comments received, and our responses. For a complete and full description of the proposed requirements, see the 2023 proposed rule, ''Medicaid Program; Ensuring Access to Medicaid Services'' (88 FR 27960, May 5, 2023) hereafter referred to as the ''proposed rule.''

We also received a number of out-of-scope comments that are not addressed in this final rule. In addition, we received some comments which were s solely applicable to the Managed Care proposed rule. Please see the Managed Care final rule for a for a summary of the comments CMS received pertaining to that proposed rule.

We are clarifying and emphasizing our intent that if any provision of this final rule is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further action, it shall be severable from this final rule, and from rules and regulations currently in effect, and not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances. If any provision is held to be invalid or unenforceable, the remaining provisions which could function independently, should take effect and be given the maximum effect permitted by law. Through this rule, we adopt provisions that are intended to and will operate independently of each other, even if each serves the same general purpose or policy goal. Where a provision is necessarily dependent on another, the context generally makes that clear.

Finally, we note that we are finalizing with modification several of the dates for when we expect States to begin complying with the requirements being finalized in this rule, instead of what we proposed. Generally, we are finalizing that this rule, including the proposals being finalized herein, will be effective 60 days after publication of this final rule. However, we are finalizing that States are not required to begin compliance with most requirements being finalized in this rule until a specified applicability date, which we have specified for each such individual proposal being finalized. We discuss in detail the applicability date we are finalizing for each proposal being finalized in this rule in the respective section of this preamble. We encourage States, providers, and interested parties to confirm the applicability dates indicated in this final rule for any changes from the proposed. To assist, we are including Table 1 with the provisions and relevant timing information and dates.

BILLING CODE 4120–01–P

TABLE 1: Provisions and Relevant Timing Information and Dates*

Regulation Section(s) in Title 42 of the CFR	Applicability Dates**
Medicaid Advisory Committee (MAC) & Beneficiary Advisory Council (BAC) § 431.12	*Establishment of MAC and BAC*: 1 year after the effective date of the final rule.
	BAC crossover on MAC: For the period from the effective date of the final rule through 1 year after the effective date, 10 percent; for the period from year 1 plus one day through year 2 after the effective date of the final rule, 20 percent; and thereafter, 25 percent of committee members must be from the BAC
	Annual report: States have 2 years from the effective date of the final rule to finalize the first annual report. After the report has been finalized, States will have 30 days to post the annual report.
Person-Centered Service Plans §§ 441.301(c)(1) and (3), 441.450(c), 441.540(c), and 441.725(c)	Beginning 3 years after the effective date of the final rule***
Grievance Systems §§ 441.301(c)(7), 441.464(d)(5), 441.555(e), and 441.745(a)(1)(iii)	Beginning 2 years after the effective date of the final rule
Incident Management System §§ 441.302(a)(6), 441.464(e), 441.570(e), 441.745(a)(1)(v), and (b)(1)(i)	Beginning 3 years after the effective date of the final rule***; except for the requirement at § 441.302(a)(6)(i)(B) (electronic incident management system), which begins 5 years after the effective date of the final rule***
HCBS Payment Adequacy §§ 441.302(k), 441.464(f), 441.570(f), and 441.745(a)(1)(vi)	Beginning 6 years after the effective date of the final rule***
Reporting Requirements §§ 441.311, 441.474(c), 441.580(i), and 441.745(a)(1)(vii)	Beginning 3 years after the effective date of the final rule*** for § 441.311(b) (compliance reporting) and § 441.311(d) (access reporting) Beginning 4 years after the effective date of the final rule*** for § 441.311(c) (reporting on the HCBS Quality Measure Set) and (e) (HCBS payment adequacy reporting)
HCBS Quality Measure Set §§ 441.312, 441.474(c), 441.585(d), and 441.745(b)(1)(v)	HHS Secretary begins identifying quality measures no later than December 31, 2026, and no more frequently than every other year. HHS Secretary shall make technical updates and corrections to the HCBS Quality Measure Set annually as appropriate.
Website Transparency §§ 441.313, 441.486, 441.595, and 441.750	Beginning 3 years after the effective date of the final rule***
Payment Rate Transparency Publication § 447.203(b)(1)	July 1, 2026, then updated within 30 days of a payment rate change.
Comparative Payment Rate Analysis Publication § 447.203(b)(2) to (4)	July 1, 2026, then every 2 years
Payment Rate Disclosure § 447.203(b)(2) to (4)	July 1, 2026, then every 2 years
Interested Parties Advisory Group § 447.203(b)(6)	The first meeting must be held within 2 years after effective date of the final rule (then at least every 2 years).
Rate Reduction and Restructuring SPA procedures § 447.203(c)(1) and (2)	Effective date of the final rule

* Regulatory provisions in this table are applicable at the time this rule becomes effective.

** In this final rule, including the regulations being finalized herein, we use the term "applicability date" to indicate when a new regulatory requirement will be applicable and when States must begin compliance with the requirements as specified in that regulation.

*** In the case of the State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes HCBS in the managed care organization's (MCO), prepaid inpatient health plan's (PIHP), or prepaid ambulatory health plan's (PAHP) contract, the applicability date is the first rating period for contracts with the MCO, PIHP or PAHP beginning on or after the applicability date specified in the chart.

BILLING CODE 4120–01–C

A. Medicaid Advisory Committee and Beneficiary Advisory Council (§ 431.12)

The current regulations at § 431.12 require States to have a Medical Care Advisory Committee (MCAC) to advise the State Medicaid agency about health and medical care services. The regulations are intended to ensure that State Medicaid agencies had a way to receive feedback regarding health and medical care services from interested parties. However, these regulations lacked specificity related to how these committees can be used to ensure the proper and efficient administration of the Medicaid program more expressly by more fully promoting beneficiary perspectives.

Under the authority of section 1902(a)(4) of the Act, section 1902(a)(19) of the Act, and our general rulemaking authority in section 1102 of the Act, we are finalizing proposals to § 431.12 to replace the current MCAC requirements with a committee framework designed to ensure the proper and efficient administration of the Medicaid program and to better ensure that services under the Medicaid program will be provided in a manner consistent with the best interests of the beneficiaries. States will be required to establish and operate the newly named Medicaid Advisory Committee (MAC) and a Beneficiary Advisory Council (BAC). Please note that in the proposed rule, the BAC was referred to as the Beneficiary Advisory Group, or BAG. The MAC and its corresponding BAC will serve as vehicles for bi-directional feedback between interested parties and the State on matters related to the effective administration of the Medicaid program as determined by the State and MAC. With the changes in this final rule FFP, or Federal match, for Medicaid administrative activities will remain available to States for expenditures related to MAC and BAC activities in the same manner as the former MCAC.

The proposed and finalized requirements of the MAC amend previous and add new Federal requirements to: (1) expand the scope and use of States' MACs; (2) rename the Medicaid Advisory Committee, which will advise the State on a range of issues including medical and non-medical services; (3) require States to establish a BAC; (4) establish minimum requirements for Medicaid beneficiary representation on the MAC, membership, meetings materials, and attendance; and (5) promote transparency and accountability between the State and interested parties by making information on the MAC and BAC activities publicly available. The finalized requirements aimed at promoting transparency and accountability also include a requirement for States to create and publicly post an annual report summarizing the MAC and BAC activities.

We note that some commenters expressed general support for all of the provisions in section II.A. of this rule, as well as for this rule in its entirety. In response to commenters who supported some, but not all, of the policies and regulations we proposed in the proposed rule, we are clarifying and emphasizing our intent that each final policy and regulation is distinct and severable to the extent it does not rely on another final policy or regulation that we proposed.

While the provisions in section II.A. of this final rule are intended to present a comprehensive approach to implementing Medicaid Advisory Committees and Beneficiary Advisory Councils, and these provisions complement the goals expressed and policies and regulations being finalized in sections II.B. (Home and Community-Based Services) and II.C.(Documentation of Access to Care and Service Payment Rates) of this final rule, we intend that each of them is a distinct, severable provision, as finalized. Unless otherwise noted in this rule, each policy and regulation being finalized under this section II.A is distinct and severable from other final policies and regulations being finalized in this section or in sections II.B. or II.C of this final rule, as well as from rules and regulations currently in effect.

Consistent with our previous discussion earlier in section II. of this final rule regarding severability, we are clarifying and emphasizing our intent that if any provision of this final rule is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further State action, it shall be severable from this final rule, and from rules and regulations currently in effect, and not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances. For example, we intend that the policies and regulations we are finalizing related to the State Plan requirement (section II.A.2 of this final rule) are distinct and severable from the policies and regulations we are finalizing related to the MAC Membership and Composition requirement and the Annual Report requirement (sections II.A.4 and II.A.9 of this final rule, which we further intend are severable from each other).

1. Basis and Purpose (§ 431.12(a))

Under § 431.12 of the current regulation, paragraph (a) Basis and Purpose, sets forth a State plan requirement for the establishment of a committee (Medical Care Advisory Committee) to advise the Medicaid agency about health and medical care services. In the proposed rule, we proposed to amend the title of § 431.12 and paragraph (a) to update the name of the existing MCAC to the Medicaid Advisory Committee (MAC), and to add the requirement for States to establish and operate a dedicated advisory council comprised of Medicaid beneficiaries, the Beneficiary Advisory Group. In this final rule, we are changing the name from the Beneficiary Advisory Group to the Beneficiary Advisory Committee (BAC).

In the proposed rule, we stated that our goal was for the committee and its corresponding advisory council to serve in an advisory role to the State on issues related to health and medical services, as the MCAC did, as well as on other matters related to policy development and to the effective administration of the Medicaid program consistent with the language of section 1902(a)(4)(B) of the Act, which requires a State plan to meaningfully engage Medicaid beneficiaries and other low-income people in the administration of the plan.[38] The Medicaid program covers medical services and is increasingly also covering services designed to address beneficiaries' social determinants of health and their health-related social needs more generally. Therefore, we believe that the MAC should discuss topics directly related to covered services as well as the potential need for the coverage of additional services that may be necessary to ensure that beneficiaries are able to meaningfully access these services. Expanding the scope of the current committee is necessary in order to align with the expanding scope of the Medicaid program. These changes are consistent with section 1902(a)(4)(B) of the Act because the MAC creates a formalized way for interested parties and beneficiary representatives to provide feedback to the State about issues related to the Medicaid program and the services it covers. The feedback from the MAC and BAC will be used by the State to ensure that the program operates efficiently and as it was designed to operate.

We received public comments on these proposals. The following is a

[38] Medicaid Program; Ensuring Access to Medicaid Services,'' (88 FR 27967).

summary of the comments we received and our responses.

Comment: We received a large number of comments in support of the proposed changes to the MCAC regulation and structure as proposed in § 431.12(a). The commenters expressed broad support for creation of the dual structure of the MAC and BAC. They noted that the creation of the BAC was a positive and welcome step to better capturing the lived experiences of people enrolled in Medicaid. Commenters also noted that having the BAC advise the MAC on policy development was a way to prioritize beneficiaries' perspectives. Commenters noted that the improvements proposed to the existing MCAC structure had the potential to be transformative and make the State more attuned to the needs and priorities of Medicaid beneficiaries.

Response: We thank commenters for their support of our overhaul of the MCAC. We are finalizing as proposed, with minor technical changes, the creation of the MAC and BAC.

Comment: We also received comments in opposition to the creation of a BAC. Generally, opposing commenters wanted CMS to be less prescriptive and allow States to engage Medicaid beneficiaries in other ways (for example, using existing State committees to serve as the BAC, conducting focus groups, and fielding surveys). Other commenters noted that States would need resources to implement the BAC, citing the additional administrative burden and layering of meetings for certain members.

Response: We encourage States to engage with their Medicaid beneficiaries in a variety of ways, and we understand that many States may already operate groups or committees comprised of Medicaid beneficiaries. However, having a formalized structure to work directly with Medicaid beneficiaries will help to ensure a level and manner of engagement across all State programs. For the commenters concerned with the BAC adding administrative burden, we acknowledge that implementing these changes will create administrative burden. We discuss administrative burden to States in the Regulatory Impact Analysis section of this rule. However, in an effort to minimize administrative burden for States, we note that existing committees can be used to fulfill the BAC requirement as long as the committees meet the membership requirements specified in § 431.12(e). Later in this section, we also note that States do not have to use the same BAC members to join all MAC meetings. While it may not be an ideal way to create long-term consistency of the MAC membership, States could, in an effort to lessen the time commitment of BAC members, choose to rotate which members attend the quarterly MAC meetings.

Comment: We received several comments asking for the BAG name to be changed. The commenters cited potentially negative connotations that could be associated with the acronym BAG. Additionally, a few commenters requested that States with existing beneficiary groups be able to maintain their names.

Response: We have changed the name of the BAG to the BAC, as noted earlier in this final rule. For commenters concerned with duplicative efforts, we noted in the proposed rule that States with existing BAC-like committees can use those committees to fulfil the BAC requirement as long as they meet the membership requirements specified § 431.12(e). States are not required to change their existing group names to match the BAC name as long as interested parties understand what existing group or committee is being used to fulfill regulatory requirement of the BAC. To clarify this for interested parties, States must note in their publicly posted by-laws (§ 431.12 (f)(1)) that the group is being used to fulfill the regulatory requirements of § 431.12.

Comment: Several commenters asked CMS to clarify the role of the MAC and BAC, citing that in the proposals, the language varies from ''advisory'' to ''providing feedback.'' Other commenters expressed that they do not want the MAC and BACs to be approval bodies that lack the ability to make decisions.

Response: The primary role of the MAC and BAC is to advise the State Medicaid agency on policy development and on matters related to the effective administration of the Medicaid program. It is our intention that the MAC and BAC serve in an advisory capacity to the State. However, serving in an advisory capacity does not preclude the MAC and BAC members from sharing experiential feedback. We did not propose to give the MAC or BAC a decision-making role because we want to allow States the freedom to administer their Medicaid programs in the manner they see fit, but be guided by these two entities' recommendations and experiences with the Medicaid program.

Comment: We received a comment asking CMS to require that the MAC and BAC not be used to take the place of a State's tribal consultation requirements.

Response: We do not anticipate that the MAC or BAC could be used to fulfill tribal consultation requirements under section 1902(a)(73) of the Act. For States with one or more Indian Health Programs or Urban Indian Organizations that furnish health care services, the State must consult with such Programs and Organizations on a regular, ongoing basis. While the statute specifically permits representatives of such Programs and Organizations to be included on the MCAC [now known as the MAC], this alone would not meet the requirement to consult on any State plan amendments (SPAs), waiver requests, and proposals for demonstration projects likely to have a direct effect on Indians, Indian Health Programs, or Urban Indian Organizations prior to submission.

Comment: We received a few comments requesting that CMS conduct a study to assess which States already have MCACs or BACs to ensure they are no duplicative efforts. Another commenter asked CMS to solicit feedback from existing MCAC members to see how it can be improved before making beneficiary groups a requirement.

Response: We clarify that MCACs are currently required of all States so conducting an assessment to see which States already have MCACs would not necessarily result in a lot of new information. However, we agree that understanding which States already have BAC-like committees in place would be helpful. In fact, when developing the proposed rule, we engaged with interested parties, both from State Medicaid agencies and the wider Medicaid community, to determine what improvements were needed to the MCACs to allow States and beneficiaries to obtain the most benefit from their work. For commenters concerned with duplicative BAC activities, we note again that States with an existing beneficiary group or beneficiary committee that meets the requirement of the BAC, as finalized in this rule at § 431.12(e), do not need to set up a second beneficiary committee.

Comment: We received a few comments asking CMS to require the MAC and BAC to coordinate with other State advisory committees.

Response: States will vary in how they run their advisory committees. Some States may choose to coordinate across their different advisory committees, while other States may have reasons for keeping their advisory committees and their processes separate. We do not want to add more administrative burden by adding a requirement to § 431.12 for States to coordinate across State advisory committees. However, if coordinating

across these committees in some manner would be advantageous for the Medicaid program, then we encourage the State to do so.

After consideration of public comments, we are finalizing § 431.12(a) as proposed with the following change:

Language modifications to reflect the new name of the ''Beneficiary Advisory Council (BAC).''

2. State Plan Requirement (§ 431.12(b))

Under § 431.12 of the current regulation, paragraph (b) State Plan Requirement, calls for a State plan to provide for a MCAC to advise the Medicaid agency director about health and medical care services.

We proposed conforming updates to paragraph (b) regarding the State plan requirements, to reflect the addition of the BAC and the expanded scope.

The Interested Parties Advisory Group, described in a later section of this final rule (Interested Parties Advisory Group § 447.203(b)(6)), is designed to advise States on rate setting and other matters for certain HCBS and is not related to the MAC or BAC specified here. In section II.C.2.c. of this final rule, under § 447.203(b)(6), we explain that States will have the option to use its MAC and BAC to provide recommendations for payment rates, thereby satisfying the requirements of § 447.203(b)(6). However, the MAC and BAC requirements finalized here are wholly separate from the Interested Parties Advisory Group.

We did not receive public comments on § 431.12(b). However, we are making one conforming edit to this paragraph based on a language change identified in § 431.12(c) to replace the term State Medicaid Director. We are finalizing as proposed with the following changes:

- Language modifications to reflect the new name of the ''Beneficiary Advisory Council (BAC).''
- Replacing the term Medicaid Agency Director with the term, ''director of the single State Agency for the Medicaid program.''

3. Selection of Members (§ 431.12(c))

Under § 431.12 of the current regulation, paragraph (c) Appointment of members, the agency director, or a higher State authority, must appoint members to the advisory committee on a rotating and continuous basis.

We proposed to revise paragraph (c) to specify that the members of the MAC and BAC must be appointed by the agency director or a higher State authority on a rotating and continuous basis. We also proposed to require the State to create a process for the recruitment and appointment of members of the MAC and BAC. Additionally, we proposed to require the State to post this information on the State's website. As discussed in the proposed rule,[39] the website page where this information is located would be required to be easily accessible by the public. These proposed updates align with how some States' existing MCACs are already run, which will facilitate the transition of these MCACs into MAC/BACs. Additionally, the proposed changes are designed to provide additional details to support States' operation of the MAC and BAC. Further, we believe these proposed updates will facilitate transparency, improving the current regulations, which did not mention nor promote transparency of information related to the MCAC with the public. We also believe that transparency of information can lead to enhanced accountability on the part of the State in making its MAC and BAC as effective as possible.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received several comments regarding the terms used to describe who should be given the authority to appoint members to the MAC and BAC. Many commenters supported the proposal of having the State Medicaid Director appoint the members. A few commenters suggested that we make clarifications to the proposed regulation language so that only the State Medicaid Director and not ''a higher State authority'' is referenced, since the work of the MAC and BAC is to advise the State Medicaid Director. Others noted that the correct term to use in the regulation when referring to the State Medicaid Director is the director of the single State agency for the Medicaid program. There was another category of commenters that did not believe the authority to select MAC and BAC members should sit with either the State Medicaid Director or a higher State Authority. These commenters instead stated it would be more equitable if prospective MAC and BAC members were selected by an outside company, a computer, at random, or by a lottery system. They noted that in their experiences sometimes parents or family members are excluded from selection processes. Finally, other commenters noted that the term ''appointed'' implied that the State did not use any kind of a ''selection process'' to choose its MAC and BAC members. These commenters may have felt that the term ''appoint'' means that the State can simply pick whomever it wants to serve as a member rather than ''selecting'' members from a pool of people who submitted applications to serve as MAC or BAC members.

Response: We appreciate the comments provided on this section and acknowledge the complicated work that comes with selecting MAC and BAC members. Since the MAC and BAC serve in an advisory role to the Medicaid program, we believe strongly that the authority to select should lie with the director of the State Medicaid agency. We know that Medicaid agencies' names may vary from State to State, and thus, agree that language in the regulation can be changed to more clearly reflect a more commonly used term for the Medicaid agency (that is, the single State Agency for the Medicaid Program). For commenters that expressed concern that parents or family members are excluded from the selection processes, we note that the BAC regulations require both Medicaid beneficiaries and individuals with direct experience supporting Medicaid beneficiaries, such as family members to be selected. Finally, we agree that the word ''appoint'' in the proposed rule does not accurately reflect the intention of the regulation and could be misinterpreted to mean that the State did not use a selection process where interested parties submit an application and then the State reviews those applications before selecting its MAC and BAC members. Based on the comments we received, we now understand that the term ''appoint'' can be taken to mean that a selection process did not occur. We want to avoid any confusion that the requirements are asking the State to appoint members without using a selection process, which was not our intention. For clarity, we are also amending the regulatory language in § 431.12(c) to now state that the ''director of the single State Agency for the Medicaid program,'' must ''select'' members for the MAC and BAC.

Comment: We received comments on the proposed changes to § 431.12(c) related to term limits of the MAC and BAC members. The commenters were generally divided across wanting CMS to require States to have set term limits for members, not wanting any term limits, and not wanting short term limits. Commenters who expressed support for set term limits noted that setting term limits ensured that new perspectives would be added on a regular basis while others noted that setting term limits allowed members to

[39] Medicaid Program; Ensuring Access to Medicaid Services,'' (88 FR 27960, 27968).

share recommendations or constructive criticism without fear of retaliation. The commenters who opposed term limits noted that finding people with Medicaid expertise may be difficult in some geographic areas and, as a result, the State would benefit from having the same members serve without term limits. Other commenters noted that it takes time for members to build their expertise and understanding of the Medicaid program and setting short term limits may not take into account the time needed to accumulate enough knowledge to contribute fully to the MAC and BAC. These commenters suggested term limits with lengths ranging from 2 to 6 years.

Response: States have the ability to determine the tenure of members, as States are best situated to assess their members' ability to participate in and meaningfully contribute to the MAC and BAC and for what length of time. In the proposed rule, we described the requirement for States to determine the length of terms for committee and council members. For clarity, we are amending the regulatory language in § 431.12(c) to reflect this information as well, to now state ''. . . members to the MAC and BAC for a term of a length determined by the State, which may not be followed immediately by a consecutive term for the same member, on a rotating and continuous basis.'' We proposed this type of term because we believe there is value in ensuring new voices and perspectives are introduced to the committee and council. We further clarify that once a MAC or BAC member's term has been completed, the State will select a new member, thus ensuring that MAC and BAC memberships rotate continuously. Setting memberships as continuously rotating means that the State must seek to recruit members to fill open seats on the MAC and BAC on an ongoing basis. States can also select members to serve multiple non-consecutive terms.

After consideration of public comments, we are finalizing § 431.12(c) with the following changes:

- Language modifications to reflect the new name of the BAC.
- Replacing the term agency director or higher authority with the term, ''director of the single State Agency for the Medicaid program.''
- Replacing the word ''appoint'' with ''select'' in various places.
- Adding language to the regulation to reflect that ''the term of length for MAC and BAC members will be term of a length determined by the State, which may not be followed immediately by a consecutive term for the same member, on a rotating and continuous basis.''

4. MAC Membership and Composition (§ 431.12(d))

Under § 431.12 of the current regulation, paragraph (d), Committee Membership, States are required to select three types of committee members: (1) Board-certified physicians and other representatives of the health professions who are familiar with the medical needs of low-income population groups and with the resources available and required for their care; (2) Members of consumers' groups, including Medicaid beneficiaries, and consumer organizations such as labor unions, cooperatives, consumer-sponsored prepaid group practice plans, and others; and (3) the director of the public welfare department or the public health department, whichever does not head the Medicaid agency.

In the proposed rule, paragraph (d) of § 431.12, MAC membership and composition, we proposed in (d)(1) to require that a minimum of 25 percent of the MAC must be individuals with lived Medicaid beneficiary experience from the BAC. The BAC, which is defined later in § 431.12(e), is comprised of people who: (1) are currently or have been Medicaid beneficiaries, and (2) individuals with direct experience supporting Medicaid beneficiaries (family members or caregivers of those enrolled in Medicaid).

We proposed 25 percent as the minimum threshold requirement for (d)(1) to reflect the importance of including the beneficiary perspective in the administration of the Medicaid program and to ensure that the beneficiary perspective has meaningful representation in the feedback provided by the MAC. We did not propose a higher percentage because we acknowledge that States will benefit from a MAC that includes representation from a diverse set of interested parties who work in areas related to Medicaid but are not beneficiaries, their family members, or their caregivers.

In terms of the required representation from the remaining MAC members, as specified in the proposed rule, paragraph (d)(2), we proposed that a State must include at least one from each category: (A) State or local consumer advocacy groups or other community-based organizations that represent the interests of, or provide direct service, to Medicaid beneficiaries; (B) clinical providers or administrators who are familiar with the health and social needs of Medicaid beneficiaries and with the resources available and required for their care; (C) participating Medicaid managed care organizations or the State health plan association representing such organizations, as applicable; and (D) other State agencies serving Medicaid beneficiaries, as ex-officio members.

We believe that advisory committees and councils can be most effective when they represent a wide range of perspectives and experiences. Since we know that each State environment is different, we aimed to provide the State with discretion on how large the MAC and BAC should be. In the proposed changes we did, however, specify the types of categories of Committee members that can best reflect the needs of a Medicaid program. We believe that diversely populated MACs and BACs can provide States with access to a broad range of perspectives, and importantly, beneficiaries' perspective, which can positively impact the administration of the Medicaid program. This approach is consistent with the language of section 1902(a)(4)(B) of the Act, which requires a State plan to meaningfully engage Medicaid beneficiaries and other low-income people in the administration of the plan. The changes in membership we proposed and are finalizing will support States to set up MACs that align with section 1902(a)(4)(B) since States will now have to select the membership composition to reflect the community members who represent the interests of Medicaid beneficiaries. The State also benefits from having a way to hear how the Medicaid program can be responsive to its beneficiaries' and the wider Medicaid community's needs.

We also noted in the proposed rule that we encourage States to take into consideration, as part of their member selection process, the demographics of the Medicaid population in their State. Keeping diverse representation in mind as a goal for the MAC membership can be a way for States to help ensure that specific populations and those receiving critically important services are appropriately represented on the MAC. For example, in making MAC membership selections, the State may want to balance the representation of the MAC according to geographic areas of the State with the demographics and health care needs of the Medicaid program of the State. The State will want to consider geographical diversity (for example, urban and rural areas) when making its membership selections. We noted in the proposed rule, that a State could also consider demographic representation of its membership by including members representing or serving Medicaid beneficiaries who receive services in the

following categories: (1) pediatric health care; (2) behavioral health services; (3) preventive care and reproductive health services; (4) health or service issues pertaining specifically to people over age 65; and (5) health or service issues pertaining specifically to people with disabilities. By offering these considerations, we seek to support States in their efforts to eliminate differences in health care access and outcomes experienced by diverse populations enrolled in Medicaid. We intend that the MAC and the BAC can support several of the priorities for operationalizing health equity across CMS programs as outlined in the CMS Framework for Health Equity (2022–2032) and the HHS Equity Action Plan which is consistent with E.O. 13985, which calls for advancing equity for underserved communities.

Rather than prescribing specific percentages for the other (non-BAC) categories in the proposed rule, we only required representation from each category as part of the MAC. The specific percentage of each of category (other than the BAC members) relative to the whole committee can be determined by each State. This approach will provide States with the flexibility to determine how to best represent the unique landscape of each State's Medicaid program. We solicited comment on what should be the minimum percentage requirement that MAC members be current/past Medicaid beneficiaries or individuals with direct experience supporting Medicaid beneficiaries (such as family members or caregivers of those enrolled in Medicaid). In addition to hearing directly from beneficiaries, the State can gain insights into how to effectively administer its program from other members of the Medicaid community.

States will determine which types of providers to include under the clinical providers or administrators category, and we recommend they consider a wide range of providers or administrators that are experienced with the Medicaid program including, but not limited to: (1) primary care providers (internal or family medicine physicians or nurse practitioners or physician assistants that practice primary care); (2) behavioral health providers (that is, mental health and substance use disorder providers); (3) reproductive health service providers, including maternal health providers; (4) pediatric providers; (5) dental and oral health providers; (6) community health, rural health clinic or Federally Qualified Health Center (FQHC) administrators; (7) individuals providing long-term care services and supports; and (8) direct care workers [40] who can be individuals with direct experience supporting Medicaid beneficiaries (such as family members or caregivers).

We have also identified managed care plans, including Primary Care Case Management (PCCM) entities and Primary Care Case Managers (PCCMs),[41] as an important contributor to the MAC, but we acknowledge that not all States have managed care delivery systems. We know many Medicaid managed care plans administer similar committees and thus allow for States to tailor managed care plan representation based on its delivery system and the experience and expertise of managed care plans in the State. For example, States, if applicable, can fulfill this category with only one or with multiple managed care plans operating in the State. In addition, we also give States the flexibility to meet the managed care plan representation requirements with either participating Medicaid managed care plans or a health plan association representing more than one such organization.

The language in paragraph (d)(2)(D) broadens the previous MCAC requirement to allow for additional types of representatives from other State agencies to be on the committee. Specifically, the previous MCAC regulation requires membership by ''the director of the public welfare department or the public health department, whichever does not head the Medicaid agency.'' In the proposed rule, we expanded the requirement for external agency representation to be broader than the welfare or public health department, which would give States more flexibility in representing the Medicaid program's interests based on States' unique circumstances and organizational structure. States can work with sister State agencies to determine who should participate in the MAC (for example, foster care agency, mental health agency, department of public health). We also proposed that these representatives be part of the committee as ex-officio members, meaning that they hold the position because they work for the relevant State agency. In finalizing the proposals, we reviewed this requirement closer. While we believe it will be essential to have these State-interested parties present for program coordination and information-sharing, we intended to reflect in the proposed rule that the formal representation of the MAC should be comprised of beneficiaries, advocates, community organizations, and providers that serve Medicaid beneficiaries. Therefore, we clarify in this final rule that while these ex-officio members will sit on the MAC, they will not be voting members of the MAC. Therefore, on matters that the MAC decides by vote, including but not necessarily limited to finalizing the MAC's recommendations to the State, the ex-officio members will not participate in voting.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received many comments about the proposed requirement of having some BAC members serving on the MAC. Commenters either agreed with the importance of having a subset of Medicaid beneficiaries serve on both the BAC and the MAC, or they noted that having a subset of BAC members on both committees could lead to undue burden for these members based on the number of meetings they would have to attend. One commenter suggested a phased-in approach where the BAC members meet only as the BAC for a time (for example, a year) and then transition to serving on the MAC only.

Response: We understand the concerns raised by the commenters about putting undue burden on a subset of BAC members. We believe it is vital for the success of both the BAC and MAC that there is a point of integration via the crossover membership requirement since this is the way to ensure that the Medicaid beneficiary perspective is included in both groups.

[40] As finalized in § 441.302(k) of this final rule, CMS defines as Direct care worker as any of the following individuals who may be employed by a Medicaid provider, State agency, or third party; contracted with a Medicaid provider, State agency, or third party; or delivering services under a self-directed service model: (A) A registered nurse, licensed practical nurse, nurse practitioner, or clinical nurse specialist who provides nursing services to Medicaid beneficiaries receiving home and community-based services available under this subpart; (B) A licensed or certified nursing assistant who provides such services under the supervision of a registered nurse, licensed practical nurse, nurse practitioner, or clinical nurse specialist; (C) A direct support professional; (D) A personal care attendant; (E) A home health aide; or (F) Other individuals who are paid to provide services to address activities of daily living or instrumental activities of daily living, behavioral supports, employment supports, or other services to promote community integration directly to Medicaid beneficiaries receiving home and community-based services available under this subpart, including nurses and other staff providing clinical supervision.

[41] Throughout this document, the use of the term ''managed care plan'' includes managed care organizations (MCOs), prepaid inpatient health plans (PIHPs), and prepaid ambulatory health plans (PAHPs) [as defined in 42 CFR 438.2] and is used only when the provision under discussion applies to all three arrangements. An explicit reference is used in the preamble if the provision applies to primary care case managers (PCCMs) or primary care case management entities (PCCM entities).

We created this crossover requirement to reflect the importance of including the beneficiary perspective in the administration of the Medicaid program and to ensure that the beneficiary perspective has meaningful representation in the feedback provided by the MAC. For commenters that are concerned with undue burden of having a subset of BAC members also attend MAC meetings, in § 431.12(f)(3), we note that MACs and BACs are only required to meet once per quarter. While the regulation does not state that the subset of BAC members that join each MAC meeting has to be the same, we recognize that it would be more effective to have consistency in the BAC members that attend the MAC meetings in many cases. However, if States or the BAC are concerned with overburdening its BAC members, a potentially less efficient but workable alternative could be to rotate which BAC members attend the MAC in an effort to further reduce the number of meetings attended for a given BAC member. Nevertheless, the suggestion of having a member transition from solely being on the BAC to solely being on the MAC might not always promote the crossover concept we are seeking with the requirement that the MAC membership consist of 10 to 25 percent members from the BAC, since we are striving for inclusion of the Medicaid beneficiary perspective in both groups via the BAC members.

Comment: In response to our solicitation about having 25 percent as the minimum threshold of BAC membership crossover on the MAC, the majority of the commenters stated that a minimum 25 percent was the appropriate amount of crossover members. They noted that 25 percent crossover membership would help to center and amplify beneficiary voices on the MAC. A few commenters stated that the percentage should be lower (for example 10 or 15 percent). These commenters cited several reasons why having a lower threshold number would be better. Some commenters noted that having a smaller number of BAC members would allow States to better support or train their members so they could fully participate in the MAC. Other commenters stated that having a smaller number of BAC members could lessen the burden on States of finding and recruiting members to participate. Another group of commenters wanted the percentage of BAC crossover to be higher than 25 percent (for example 33, 50, 51, or 75 percent). These commenters sought a higher BAC crossover in order to: safeguard against marginalization of beneficiary members on the MAC; amplify diverse voices through a higher crossover number; and rectify any power imbalances that may exist. There were also a few commenters who noted that States should have the ability to determine their own percentages for the BAC crossover. Finally, we received comments asking CMS to consider allowing States to use a graduated approach to reach the 25 percent minimum requirement of BAC crossover on the MAC.

Response: We thank the commenters who agreed with our proposed threshold of the requirement for a minimum of 25 percent BAC crossover on the MAC. For commenters who thought the percentage should be lower, we understand States may face challenges with finding, recruiting, and training beneficiary members to serve on the BAC. To account for these challenges, we are extending the timeframe for implementation of this requirement in this final rule so that States have 2 years to achieve the 25 percent minimum threshold requirement of MAC members that come from the BAC. Instead of the 25 percent minimum threshold coming into effect right away, we are revising this final rule to provide in § 431.12(d)(1) that, for the period from July 9, 2024 through July 9, 2025, 10 percent of the MAC members must come from the BAC; for the period from July 10, 2025 through July 9, 2026 20 percent of MAC members must come from the BAC; and thereafter, 25 percent of MAC members must come from the BAC.

For commenters who expressed the need for a percentage higher than 25 for the BAC member crossover, we note that the policy we proposed and are finalizing establishes a minimum percentage threshold for States to meet. If a State so chooses, it can select a percentage higher than the minimum of 25 percent, provided the MAC membership also satisfies the requirements of § 431.12(d)(2) of this final rule. For commenters who raised the issue of providing training for BAC members, we have a comment/response on this topic under § 431.12(h)(3).

Comment: The majority of comments received on § 431.12(d) were about § 431.12(d)(2), MAC composition categories. We received comments that fell into four groups. The first group of commenters shared their broad support for the MAC committee member categories that we proposed and also urged CMS to ensure that States select members that represented the Medicaid community and who were geographically as well as racially/ethnically diverse. The second group of commenters asked for the MAC to include representation from members who would qualify for the BAC (for example, Medicaid beneficiaries, their families, and caregivers). It is unclear from the comments if these commenters were asking for an additional group of Medicaid beneficiaries be added to the MAC (in addition to the 25 percent of MAC we proposed to require be from the BAC) or if they did not understand that the MAC composition already includes a category which accounts for this category of members. The third group of commenters asked that specific types of interested parties be required to be represented on the MAC categories (for example, specific provider types, unions, HCBS provider agencies, hospitals, protection and advocacy programs, legal professionals, and medical billing professionals). The fourth group of commenters suggested ideas for types of MAC members that States could use to meet categories specified in the proposed rule (for example add a State Ombudsman to the ex-officio category). We also received a few suggestions to add specific member categories (for example, a member category for FFS members, a member category for people with behavioral health conditions, and a youth member category).

Response: We appreciate the wide range of comments that were submitted about the MAC membership composition. We developed the MAC composition framework in the proposed rule by creating broad membership categories that captured a range of interested parties who are members of the Medicaid community while giving States as much flexibility as possible to build their MACs in ways that account for the unique features of the State's environment. All of the membership categories, as currently written, are broad enough to accommodate the types of members described by the commenters. For example, a State Ombudsman can be used to fulfil the State agency category; a State with both managed care and FFS could chose to select two members (one for each type of delivery system) for the MAC; a person with behavioral health condition(s) could be suitable for multiple categories depending on whether they are a Medicaid beneficiary (current or former) or represent a consumer advocacy or community-based organization. Finally, for the commenter asking for a specific youth member category, we will note that there are no Federal requirements or limitations concerning youth participation on the MAC or BAC, and this is in the State's discretion. The

State could select a youth member to fulfill a MAC or BAC member category as long as that person meets the requirements of that membership category.

We also want to clarify for commenters that Medicaid beneficiaries, their families, and caregivers have their own MAC category in the regulation, because the BAC is listed in the final regulation as one of the categories of MAC members at § 431.12(d)(1).

After consideration of public comments, for § 431.12(d), we are finalizing as proposed with:

- Language modifications to reflect the new name of the BAC;
- Replacing the language at § 431.12 (d)(1) to clarify the timeframe for States to reach 25 percent of MAC members coming from the BAC. The new sentence will now read, ''For the period from July 9, 2024 through July 9, 2025, 10 percent of the MAC members must come from the BAC; for the period from July 10, 2025 through July 10, 2026 20 percent of MAC members must come from the BAC; and thereafter, 25 percent of MAC members must come from the BAC.''
- Language modifications to § 431.12 (d)(2)(C) to replace ''managed care plan'' with ''MCOs, PIHPs, PAHPs, PCCM entities or PCCMs as defined in § 438.2''; and
- Adding the word ''non-voting'' to ex-officio members at the end of § 431.12 (d)(2)(D).

5. Beneficiary Advisory Council (§ 431.12(e))

The current requirements governing MCACs require the presence of beneficiaries in committee membership but do little else to ensure their contributions are considered or their voices heard. For example, in the current regulations of § 431.12, paragraph (e) Committee participation, only briefly mentions the participation of beneficiary members. The current requirement provides little guidance about how to approach the participation of beneficiary members on the committee.

We proposed to add new paragraph § 431.12(e). The proposed rule noted that in the new paragraph, (e) Beneficiary Advisory Council, States would be required to create a BAC, a dedicated Beneficiary Advisory Council, that will meet separately from the MAC on a regular basis and in advance of each MAC meeting.

Specifically, at new paragraph (e)(1), we proposed to require that the MAC members described in paragraph (d)(1) must also be members of the BAC. This requirement will facilitate the bi-directional communication essential to effective beneficiary engagement and allow for meaningful representation of diverse voices across the MAC and BAC. In paragraph (e)(2), we proposed to require that the BAC meetings occur in advance of each MAC meeting to ensure BAC member preparation for each MAC discussion. BAC meetings will also be subject to requirements in paragraph (f)(5), described later in this section, that the BAC meetings must occur virtually, in-person, or through a hybrid option to maximize member attendance. We plan to expound on best practices for engaging beneficiary participation in committees like the MAC in a future toolkit.

We proposed the addition of the BAC because we believe that it will result in providing States with increased access to beneficiary perspectives. The creation of a separate beneficiary-only advisory council also aligns with what we have learned from multiple interviews with State Medicaid agencies and other Medicaid interested parties (for example, Medicaid researchers, former Medicaid officials) conducted over the course of 2022 on the operation of the existing MCACs. These interested parties described the importance of having a comfortable, supportive, and trusting environment that facilitates beneficiaries' ability to speak freely on matters most important to them. Further, we believe that the crossover structure for the MAC and BAC proposed in § 431.12(d) allows for the beneficiary-only group to meet separately while still having a formal connection to the broader, over-arching MAC. It is important the MAC members can directly engage with the beneficiaries and hear from their experience. We noted earlier that some States may already have highly effective BAC-type councils operating as part of their Medicaid program. These existing councils may represent specific constituencies such as children with complex medical needs or older adults or may be participants receiving services under a specific waiver. In these instances, States may use these councils to satisfy the requirements of this rule, as long as the pre-existing BAC-type council membership includes the type of members required in the proposed paragraph of § 431.12(e).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received many comments in support of the BAC as specified in the newly proposed § 431.12(e). Commenters noted that the BAC would provide a necessary and less-intimidating venue where Medicaid beneficiaries along with their families and caregivers can share first-person experiences and feedback to the State. While many commenters stated the BAC was needed and a welcomed improvement, a few commenters cautioned that States would need more than just to set up a BAC; they will also need to invest in creating opportunities for meaningful engagement.

Response: We agree that the BAC must be supported and used by the State in ways that create opportunities for BAC members to be actively involved and have their contributions considered.

Comment: A few commenters asked CMS to clarify how existing community groups or advisory councils could be used to satisfy the requirements of the BAC. One commenter asked if the BAC would meet a State's inclusive Community First Choice (CFC) requirements.

Response: The proposed new paragraph (e) requires that States form a BAC, but notes that the State can use an existing beneficiary group. Prior to rulemaking, CMS spoke to several States and researchers to understand how States were implementing the MCAC requirements. From the information gathered, we know that many States already have active Medicaid beneficiary groups that could fill these requirements and can function as their BACs. In these instances, it is not our intention to ask a State to create a second Medicaid beneficiary group to meet the BAC requirements. If a State wants to use an existing group to satisfy the BAC requirements, they will need to ensure that the existing committee's membership meets the membership requirements of the BAC and that the existing committee's bylaws are developed or updated, and published, to explain that the committee functions to meet the BAC requirements.

Regarding the ability to use the BAC to meet CFC requirements of the State, CMS notes in the ''Medicaid Program; State Plan Home and Community-Based Services, 5-Year Period for Waivers, Provider Payment Reassignment, and Home and Community-Based Setting Requirements for Community FirstChoice and Home and Community Based Services (HCBS) Waivers'' final rule,[42] that States may utilize existing

[42] ''Medicaid Program; State Plan Home and Community-Based Services, 5-Year Period for Waivers, Provider Payment Reassignment, and Home and Community-Based Setting Requirements for Community FirstChoice and Home and Community Based Services (HCBS) Waivers *https://www.medicaid.gov/sites/default/files/2019-12/cfc-final-settings.pdf*,'' (79 FR 2948, 2982).

advisory bodies in the implementation of CFC, as long as the statutory requirements as specified in § 441.715 for the Development and Implementation Council are met. We acknowledge the benefits of the Implementation Council coordinating with related interested parties councils and commissions and encourage States to do so. States may also choose to leverage these councils and/or include members from these councils to meet the requirements for CFC.

Comment: The majority of the comments received related to the newly proposed § 431.12(e) were commenters providing recommendations on which groups of people should also be required to be included as BAC members. We received a range of suggestions such as: HCBS beneficiaries, individuals with specific chronic diseases and disabilities, individuals using long term care services and supports (LTSS), individuals who are receiving perinatal health services, individuals who have lived experience with behavioral health conditions, and Medicaid beneficiaries who are deaf, hard of hearing, or deaf blind. Commenters also requested that the BAC members represent a cross-section of Medicaid beneficiaries that can also be regarded as demographically and geographically diverse.

Response: We agree with commenters that the States should select the types of BAC members that can provide them with representative views of the experience of Medicaid beneficiaries in their State. The regulatory language provides States with the flexibility to make those determinations based on the characteristics of their individual State Medicaid program. It can be challenging to find beneficiaries available to serve on a council, particularly if the requirements of membership are very specific. By keeping our regulations broad for what types of beneficiaries should be selected for the BAC, we seek to ensure States are able to recruit members with fewer challenges.

Comment: A few commenters asked for CMS to clarify or further define a few terms used in newly proposed § 431.12(e). Specifically, a couple of commenters asked CMS to clarify the phrase ''individuals with direct care experience supporting Medicaid beneficiaries.'' Another commenter asked if CMS could define whether the term ''caregivers'' included paid caregivers.

Response: In the proposed and in this final rule, we have described individuals with direct experience supporting Medicaid beneficiaries as ''family members or caregivers of those enrolled in Medicaid.'' In the proposed rule's preamble,[43] we state that caregivers can be paid or unpaid caregivers. To better clarify these definitions, we are adding the words ''paid or unpaid'' before the word caregiver to the proposed regulatory language at new paragraph § 431.12(e) so that the phrase reads, ''. . . individuals who are currently or have been Medicaid beneficiaries and individuals with direct experience supporting Medicaid beneficiaries (family members and paid or unpaid caregivers of those enrolled in Medicaid), to advise the State. . . .''

Comment: As noted in an earlier section, several commenters asked CMS to clarify the role of the BAC, citing that in the proposals, the language varies from ''advisory'' to ''providing feedback.''

Response: The primary role of the BAC is to advise the State Medicaid agency on policy development and on matters related to the effective administration of the Medicaid program. To better clarify the BAC's advisory role, we are removing from the proposed regulatory language at new paragraph § 431.12(e) the words and to ''provide input to.'' The phrase now reads ''. . . to advise the State regarding their experience with the Medicaid program, on matters of concern related to policy development and matters related to the effective administration of the Medicaid program.''

Comment: A few commenters shared suggestions related to the BAC meetings described in new paragraph § 431.12(e)(2). One commenter asked CMS to encourage States to hold BAC and MAC meetings on the same day, with the BAC meeting occurring first in an effort to minimize travel. Other commenters asked CMS for additional meetings for the BAC to be required to attend (for example, meetings with the State Medicaid Director and meetings with CMS regional administrators).

Response: The meeting structure specified in the BAC proposal is focused on the interplay between the BAC and MAC meetings. In new paragraph § 431.12(e)(2), we are requiring that the BAC meetings be held separate from the MAC and in advance of the MAC, so that the BAC members have the opportunity to prepare and hold an internal discussion among themselves. Holding MAC and BAC meetings in the same day could be in line with the meeting requirements. States may wish to hold additional BAC meetings with other parties, as needed.

Comment: Some commenters asked CMS to create a Federal-level BAC to ensure consistency across States.

Response: A Federal-level BAC would not further the goal of providing States with beneficiary input into their programs because it would not focus on the particular features of each individual State's Medicaid program or beneficiary and provider communities. Such a group is beyond the scope of this rulemaking.

After consideration of public comments, we are finalizing new § 431.12(e) as proposed, with changes to:

- Language modifications to reflect the new name of the BAC;
- Adding language that caregivers on the BAC can be ''paid or unpaid.'' Section 431.12 (e) will now state, ''. . . individuals who are currently or have been Medicaid beneficiaries and individuals with direct experience supporting Medicaid beneficiaries (family members and paid or unpaid caregivers of those enrolled in Medicaid) . . . .''
- Deleting the phrase ''. . . and provide input to . . . .'' Section 431.12(e) will now state ''. . . to advise the State regarding their experience with the Medicaid program, on matters of concern related to policy development and matters related to the effective administration of the Medicaid program.''

6. MAC and BAC Administration (§ 431.12(f))

We proposed to add new paragraph § 431.12(f), MAC and BAC administration, to provide an administrative framework for the MAC and BAC that ensures transparency and a meaningful feedback loop to the public and among the members of the committee and council.[44]

Specifically, in new paragraph (f)(1), we proposed that State agencies would be required to develop and post publicly on their website bylaws for governance of the MAC and BAC, current lists of MAC and BAC memberships, and past meeting minutes for both the committee and council. In paragraph (f)(2), we proposed that State agencies would be required to develop and post publicly a process for MAC and BAC member recruitment and selection along with a process for the selection of MAC and BAC leadership. In paragraph (f)(3), we proposed that State agencies would be required to develop, publicly post, and implement a regular meeting schedule for the MAC and BAC. The proposed

[43] ''Medicaid Program; Ensuring Access to Medicaid Services,'' (88 FR 27960, 27968).

[44] ''Medicaid Program; Ensuring Access to Medicaid Services,'' (88 FR 27960, 27920).

requirement specified that the MAC and BAC must each meet at least once per quarter and hold off-cycle meetings as needed. In paragraph (f)(4), we proposed requiring that that at least two MAC meetings per year must be opened to the public. For the MAC meetings that are open to the public, the meeting agenda would be required to include a dedicated time for public comment to be heard by the MAC. None of the BAC meetings were required to be open to the public unless the State's BAC members decided otherwise. We also proposed that the State ensure that the public is provided adequate notice of the date, location, and time of each public MAC meeting and any public BAC meeting at least 30 calendar days in advance. We solicited comment on this approach. In paragraph (f)(5), we proposed that States would be required to offer in-person, virtual, and hybrid attendance options including, at a minimum telephone dial-in options at the MAC and BAC meetings for its members to maximize member participation at MAC and BAC meetings. If the MAC or BAC meeting was deemed open to the public, then the State must offer at a minimum a telephone dial-in option for members of the public.

With respect to in-person meetings, we proposed in paragraph (f)(6) that States would be required to ensure that meeting times and locations for MAC and BAC meetings were selected to maximize participant attendance, which may vary by meeting. For example, States may determine, by consulting with their MAC and BAC members, that holding meetings in various locations throughout the State may result in better attendance. In addition, States may ask the committee and council members about which times and days may be more favorable than others and hold meetings at those times accordingly. We also proposed that States use the publicly posted meeting minutes, which lists attendance by members, as a way to gauge which meeting times and locations garner maximum participate attendance.

Finally, in paragraph (f)(7), we proposed that State agencies were required to facilitate participation of beneficiaries by ensuring that meetings are accessible to people with disabilities, that reasonable modifications are provided when necessary to ensure access and enable meaningful participation, that communication with individuals with disabilities is as effective as with others, that reasonable steps are taken to provide meaningful access to individuals with Limited English Proficiency, and that meetings comply with the requirements at § 435.905(b) and applicable regulations implementing the ADA, section 504 of the Rehabilitation Act, and section 1557 of the Affordable Care Act at 28 CFR part 35 and 45 CFR parts 84 and 92.

Interested parties' feedback and recent reports [45] [46] published on meaningful beneficiary engagement illuminate the need for more transparent and standardized processes across States to drive participation from key interested parties and to facilitate the opportunity for participation from a diverse set of members and the community. Further, we believe that in order for the State to comply with the language of section 1902(a)(4)(B) of the Act, which requires a State plan to meaningfully engage Medicaid beneficiaries and other low-income people in the administration of the plan, it needs to be responsive to the needs of its beneficiaries. To be responsive to the needs of its beneficiaries, the State needs to be able to gather feedback from a variety of people that touch the Medicaid program, and the MAC and BAC will serve as a vehicle through which States can obtain this feedback.

We acknowledge that interested parties may face a range of technological and internet accessibility limitations, and proposed requiring that, at a minimum, States provide a telephone dial-in option for MAC and BAC meetings. While we understand that in-person interaction can sometimes assist in building trusted relationships, we also recognize that accommodations for members and the public to participate virtually is important, particularly since the beginning of the COVID–19 pandemic. We solicited comment on ways to best strike this balance.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received many comments expressing broad support of § 431.12(f)(1) proposals requiring States to post publicly information on the MAC and BAC (bylaws, meeting minutes). The commenters noted that transparency plays an important role in promoting multi-directional accountability and could also help ensure the success of the MAC and BAC. While commenters were supportive, they also recommended that States consider their Medicaid communities' communication access needs, including cultural competency and linguistic needs, when posting these materials to their websites.

Response: We agree with commenters that States should take steps to ensure that any publicly posted materials are accessible to the various interested parties that comprise their Medicaid community.

Comment: We received a few comments asking us to reconsider the requirement of having States to post their BAC membership list on their websites. Several commenters suggested that States should give BAC members the choice of being publicly identified.

Response: We thank commenters for raising this issue, as we want to avoid any situation where a Medicaid beneficiary, family member or caregiver, does not want to be publicly identified. In response to these comments, we are updating and finalizing the proposed regulations to permit BAC members to choose whether to be publicly identified in materials such as membership lists and meeting minutes. If BAC members choose not to be identified in public materials, they can be referred to as BAC member 1, BAC member 2 and so on. Specifically, we are updating and finalizing the proposed language under new paragraph § 431.12(f)(1) to state, ''Develop and publish by posting publicly on its website, bylaws for governance of the MAC and BAC along with a current list of members . . . States will give BAC members the option to include their names on the membership list and meeting minutes that will be posted publicly.''

Comment: We received comments supporting the § 431.12(f)(2) requirement of having States publicly post their process for recruitment and selection. Commenters emphasized that these processes must be inclusive and reflect the diversity of their State's Medicaid community and beneficiaries. Other commenters asked for CMS to provide guidance or best practices on how to recruit members, as well as marketing best practices and the preferred format for print and audio materials.

Response: We agree that States should develop recruitment strategies that will result in identifying members that are

[45] Resources for Integrated Care and Community Catalyst, ''Listening to the Voices of Dually Eligible Beneficiaries: Successful Member Advisory Councils'', 2019. Retrieved from *https://www.resourcesforintegratedcare.com/listening_to_voices_of_dually_eligible_beneficiaries/.*

[46] Centers for Medicare & Medicaid Services, Person & Family Engagement Strategy: Sharing with Our Partners. Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/Person-and-Family-Engagement-Strategic-Plan-12-12-16.pdf#:~:text=person%E2%80%99s%20priorities%2C%20goals%2C%20needs%20and%20values.%E2%80%9D%20Using%20these,to%20guide%20all%20clinical%20decisions%20and%20drives%20genuine.*

representative of a State's Medicaid community and beneficiaries. However, we have kept the requirements flexible to be cognizant of the fact that States can experience challenges in recruiting Medicaid beneficiaries to serve on the BAC. We also encourage States to examine best practices from entities that specialize in marketing, recruitment, and the accessibility of published materials as outlined on *Digital.gov*.[47]

Comment: We received some comments asking that States have a process for identifying conflicts of interest when making member selections.

Response: We agree that avoiding conflicts of interest is important, and we encourage States to establish conflict of interest policies, to be documented in the MAC/BAC bylaws or other organizing documents that govern the membership and operations of the MAC/BAC, and to ensure these policies are respected when selecting MAC/BAC members. Since MAC and BAC membership represent a variety of backgrounds and interest relevant to Medicaid, we also believe that building in a time for conflict-of-interest disclosure into each meeting's agenda is important. Specifically, under new § 431.12(f)(3) we are now adding that each MAC and BAC meeting agenda should have time set aside for members to disclose any matters that are not incompatible with their participation on the MAC and/or BAC under the State's conflict of interest policy, but which nevertheless could give rise to a perceived or actual conflict of interest and therefore should be disclosed. We also believe our requirements for MAC and BAC meetings, including the posting of meeting minutes and membership lists, will provide the public and States with the transparency needed to know if a conflict of interest (perceived, apparent, or actual) occurred during a meeting.

Comment: We received comments regarding the requirement in § 431.12(f)(3) for both the MAC and BAC to each meet at a minimum of once quarterly. Commenters noted the number of meetings could pose a burden to the States and members. Several commenters suggested that CMS allow Medicaid agencies to hold meetings in a way that matches their administrative resources and goals.

Response: We selected a quarterly meeting versus a monthly meeting schedule for the MAC and BAC because we believe it will provide States with more flexibility in determining when to meet. For example, rather than having the MAC and BAC members meeting every month (12 times annually), we reduce the time commitment for members by having the State select which month per quarter works best for the MAC and BAC members (4 times annually). Further, the goal of the MAC and BAC is to advise the State on matters related to policy development and to the effective administration of the Medicaid program. We believe that holding a quarterly meeting, as a minimum, allows States to integrate their Medicaid community's voice into the effective administration of the Medicaid program in a way that is timely and meaningful. Further, we believe that holding quarterly meetings would result in the least amount of burden for States. Holding more meetings per year would likely result in additional strain of time and resources for the State and its members. Holding meetings less frequently than quarterly would not assist the timely integration of the community voice into the administration of the Medicaid program. We also strive to further reduce the burden to MAC and BAC members by structuring the meeting requirements in a way that allows States to select non-traditional meeting times and to use different telecommunications options (for example, online meetings) for its meetings which would eliminate members' commuting times to meetings.

Comment: We received several comments about new § 431.12(f)(4) in support of the requirement that each MAC meeting must have a public comment period, citing the importance of all interested parties to be able to share feedback. Additionally, a few commenters asked that States also have a process to accept input from interested parties while developing MAC agendas.

Response: States will have the flexibility to develop the MAC agendas in accordance with their own processes and procedures. We encourage commenters to work with their State regarding those processes.

Comment: A couple of commenters suggested that all MAC and BAC meetings be open to the public.

Response: We place great importance on meeting transparency, but we also believe that States may need the flexibility to keep closed some of their meetings each year. The proposed requirement in § 431.12(f)(4) related to BAC meetings notes that BAC meetings are not required to be open to the public unless the State and the BAC members decide otherwise. It is important for States to create a dedicated space for this group of Medicaid beneficiaries and people with lived Medicaid experience to share their interactions with and perceptions of the Medicaid program. Having a comfortable, supportive, and trusting environment will encourage members to speak freely on matters most important to them. We note that in order to support overall transparency, we proposed that the meeting minutes of the BAC meetings be required to be posted online and MAC members who are also on the BAC will share input from the BAC with the broader MAC.

Comment: We received comments in response to our request for comments about in-person and virtual attendance options for the MAC and BAC meetings. The comments emphasized the need for States to offer both in-person and virtual attendance options. One commenter questioned if the proposed requirement meant that offering an in-person attendance option was a requirement for each meeting.

Response: We thank commenters for responding to our request for comments. In response to those comments, we are updating new § 431.12(f)(5) to list the different types of meeting options. Specifically, § 431.12(f)(5) states, ''Offer a rotating, variety of meeting attendance options. These meeting options are: all in-person attendance, all virtual attendance, and hybrid (in-person and virtual) attendance options. Regardless of which attendance type of meeting it is, States are required to always have, a minimum, telephone dial-in option at the MAC and BAC meetings for its members.'' For the commenter who questioned if States had to always provide in-person attendance options, we are clarifying that if the meeting is designated as a virtual-only meeting, States do not need to have in-person attendance.

Comment: One commenter suggested we add a requirement for meetings to be held both during and after work hours.

Response: In new § 431.12(f)(6), we require that States ensure that the meeting times selected for MAC and BAC meetings maximize member attendance. We encourage States to consider working hours and the impact on their MAC and BAC membership, as appropriate.

Comment: Several commenters expressed broad support for the proposal to ensure that MAC and BAC meetings are accessible by people with disabilities and Limited English Proficiency (LEP). Commenters also provided suggestions to better ensure meaningful participation, such as making sure States have available: interpreter services, American Sign Language translation services, closed captioning for virtual meeting, and

[47] *https://digital.gov/resources/an-introduction-to-accessibility/?dg.*

making materials available in plain language.

Response: As reflected in § 431.12(f)(7), we agree that MAC and BAC members with disabilities and LEP should have access to the types of supports needed to meaningfully engage in meetings. We have updated the relevant Federal requirements for States to meet in this final rule.

Comment: One commenter requested that CMS clarify what is meant by the phrase, ''that reasonable steps are taken to provide meaningful access to individuals with Limited English Proficiency . . . .''

Response: Title VI of the Civil Rights Act requires recipients of Federal financial assistance, including State Medicaid programs, to take reasonable steps to provide meaningful access to their programs or activities for individuals with Limited English Proficiency.[48] Section 1557 of the Affordable Care Act similarly requires recipients of Federal financial assistance to take reasonable steps to provide meaningful access to their health programs or activities for individuals with Limited English Proficiency, and the implementing regulation requires the provision of interpreting services and translations when it is a reasonable step to provide meaningful access.[49]

After consideration of public comments, we are finalizing § 431.12(f) as proposed with:

- Language modifications to reflect the new name of the BAC.
- Updates to § 431.12(f)(1) to now state, ''States will also post publicly the past meeting minutes of the MAC and BAC meetings, including a list of meeting attendees. States will give BAC members the option to include their names in the membership list and meeting minutes that will be posted publicly.''
- Updates to § 431.12(f)(3) to state, ''Each MAC and BAC meeting agenda must include a time for members and the public (if applicable) to disclose conflicts of interest.''
- Updates to § 431.12(f)(4) to move one sentence up to be the new second sentence and the deletion of a repetitive sentence so that third sentence now reads as, ''The public must be adequately notified of the date, location, and time of each public MAC meeting and any public BAC meeting at least 30 calendar days in advance of the date of the meeting.''
- Updates to § 431.12(f)(5) to state, ''Offer a rotating, variety of meeting attendance options. These meeting options are: all in-person attendance, all virtual attendance, and hybrid (in-person and virtual) attendance options. Regardless of which attendance type of meeting it is, States are required to always have at a minimum, telephone dial-in option at the MAC and BAC meetings for its members.''
- Updates to paragraph (f)(7) to reflect additional Federal requirements (adding reference to the Title VI of the Civil Rights Act of 1964). The sentence will now state, ''. . . that reasonable steps are taken to provide meaningful access to individuals with Limited English Proficiency, and that meetings comply with the requirements at § 435.905(b) of this chapter and applicable regulations implementing the ADA, Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act, and section 1557 of the Affordable Care Act at 28 CFR part 35 and 45 CFR parts 80, 84 and 92, respectively.''

7. MAC and BAC Participation and Scope (§ 431.12(g))

We proposed to replace former paragraph (e) Committee participation, with new paragraph (g) MAC and BAC Participation and Scope. The original paragraph (e), Committee participation, required that the MCAC must have opportunity for participation in policy development and program administration, including furthering the participation of beneficiary members in the agency program.

In new paragraph § 431.12(g), we proposed and are finalizing the expansion of the types of topics which provide the MAC and BAC should advise to the State. The list of topics we proposed included at a minimum topics related to: (1) addition and changes to services; (2) coordination of care; (3) quality of services; (4) eligibility, enrollment, and renewal processes; (5) beneficiary and provider communications by State Medicaid agency and Medicaid managed care plans; (6) cultural competency, language access, health equity and disparities and biases in the Medicaid program; or (7) other issues that impact the provision or outcomes of health and medical services in the Medicaid program as identified by the MAC, BAC or State.

In researching States' MCACs, we know that some already use the MCACs advice on a variety of topics relating to the effective and efficient administration of the Medicaid program. With these changes, we aim to strike a balance that reflects some States' current practices without putting strict limitations on specific topics for discussion in a manner that would constrict flexibility for all States. Broadening the scope of the topics that the MAC and BAC discuss will benefit the State by giving greater insight into how it is currently delivering coverage and care for its beneficiaries and thereby assist in identifying ways to improve the way the Medicaid program is administered.

The State will use this engagement with the MAC and BAC to ensure that beneficiaries' and other interested parties' voices are considered and to allow the opportunity to adjust course based on the advice provided by the committee and council members. The State will base topics of discussion on State need and will determine the topics in collaboration with the MAC and BAC to address matters related to policy development and matters related to the effective administration of the Medicaid program. In finalizing the proposals, we reviewed the wording for this requirement closer. When listing the types of topics on which the MAC and BAC should advise to the State, we used the term ''or''. However, using the term ''or'' does not represent the intention behind the regulation. The MAC or BAC should not be limited to advising the State on one topic at a time. Our intent is that the MAC and BAC, in collaboration with the State, should be able to provide recommendations on all or any of the subset of the topics listed. We clarify this intention in this final rule by making a technical change to replace the word ''and'' with the word ''or'' in the list of the types of topics on which the MAC and BAC should advise the State.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: As noted in other sections, we received a few comments asking CMS to clarify the advisory authority of the MAC and BAC, noting that language fluctuated between advisory and experiential feedback.

Response: As discussed earlier with respect to § 431.12(a), the role of the MAC and BAC is to advise the State Medicaid agency. In reviewing the language proposed in § 431.12(g), we see similar opportunities where CMS can refine its wording to make clear the advisory roles that the MAC and BAC hold. The primary role of the MAC and BAC is to advise the State Medicaid agency on policy development and on

[48] *Lau* v. *Nichols,* 414 U.S. 563, 566 (1974) (interpreting Title VI and its implementing regulations to require a school district with students of Chinese origin with limited English proficiency to take affirmative steps to provide the students with a meaningful opportunity to participate in federally funded educational programs).

[49] 45 CFR 92.101; *see alsohttps://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/guidance-federal-financial-assistance-title-vi/index.html.*

matters related to the effective administration of the Medicaid program. By replacing the wording in § 431.12(g) from ''provide recommendations'' to ''advise'' we are being consistent with the wording used in similar updates made in this final rule and also making clear that our intention is for the MAC and BAC to serve in an advisory capacity to the State.

Comment: All commenters who addressed § 431.12(g) supported the change in the MAC and BAC scope. The majority of those commenters also suggested additional topics for which the MAC and BAC should advise the State. These topics include getting feedback on Secret Shopper studies, external quality organization reports, consumer facing materials, enrollment materials, implementation of integrated programs for dually eligible individuals, rate reviews, and annual medical loss ratio report. We also received a comment noting the importance of access to services with a request that it be added it to the list of topics.

Response: We appreciate the support to the proposed changes. We clarify that the categories of topics we named in this section were selected as examples because they represented far-reaching parameters related to the effective administration of the Medicaid program. We believe that the proposal we are finalizing in this final rule allows for a broad interpretation of the topics that are within scope while leaving the ultimate decision on which topics the MAC and BAC will advise on to the MAC, BAC, and State. We encourage commenters to work with their States to define the topics that will be discussed at the MAC and BAC. Finally, we agree that specifically mentioning access to services is important, as it represents a key topic area of this regulation. Therefore, we are redesignating the proposed § 431.12(g)(7) as (g)(8) and adding a new § 431.12(g)(7), access to services.

After consideration of public comments, we are finalizing § 431.12(g) as proposed with:

- Language modifications to reflect the new name of the BAC.
- Replacing the wording at § 431.12(g) ''to participate in and provide recommendations'' with ''advise'' so as to clarify the advisory role of the MAC and BAC.
- Conforming edits to replacing the term State Medicaid Director at § 431.12(g) with the term, ''director of the single State Agency for the Medicaid program.''

Language modifications to § 431.12(g)(5) to replace ''managed care plan'' with ''MCOs, PIHPs, PAHPs, PCCM entities or PCCMs as defined in § 438.2.''

- Redesignating and finalizing proposed § 431.12(g)(7) as (g)(8) and adding a new § 431.12(g)(7), ''access to services.''
- Replacing the word ''or'' with the word ''and'' after 431.12(g)(7), access to services.

8. State Agency Staff Assistance, Participation, and Financial Help (§ 431.12(h))

Under § 431.12 of the current regulation, paragraph (f) Committee staff assistance and financial help, the State was required to provide the committee with—(1) Staff assistance from the agency and independent technical assistance as needed to enable it to make effective recommendations; and (2) Financial arrangements, if necessary, to make possible the participation of beneficiary members.

In the proposed rule, we proposed to redesignate previous paragraph § 431.12(f) to new paragraph (h) and expand upon existing State responsibilities for managing the MAC and BAC regarding staff assistance, participation, and financial support. The changes we proposed and are finalizing to new paragraph (h) are for the State to provide staff to support planning and execution of the MAC and the BAC to include: (1) Recruitment of MAC and BAC members; (2) Planning and execution of all MAC and BAC meetings; and (3) The provision of appropriate support and preparation (providing research or other information needed) to the MAC and BAC members who are Medicaid beneficiaries to ensure meaningful participation. These tasks include: (i) Providing staff whose responsibilities are to facilitate MAC and BAC member engagement; (ii) Providing financial support, if necessary, to facilitate Medicaid beneficiary engagement in the MAC and the BAC; and (iii) Attendance by at least one staff member from the State agency's executive staff at all MAC and BAC meetings.

The overlap of the current regulation with our proposed changes will mean much of the work to implement is already occurring. We are not changing the existing financial support requirements. We understand from States and other interested parties that many States already provide staffing and financial support to their MCACs in ways that meet or go beyond what we require through our updated requirements. We believe that expanding upon the current standards regarding State responsibility for planning and executing the functions of the MAC and BAC will ensure consistent and ongoing standards to further beneficiaries' and other interested parties' engagement. For example, we know that when any kind of interested parties council meets, all members of that council need to fully understand the topics being discussed in order to meaningfully engage in that discussion. This is particularly relevant when the topics of discussion are complex or based in specific terminology as Medicaid related issues often can be.

We believe that when States provide their MACs and BACs with additional staffing support that can explain, provide background materials, and meet with the members in preparation for the larger discussions, the members have a greater chance to provide more meaningful feedback and be adequately prepared to engage in these discussions. The proposed changes to the existing requirements seek to create environments that support meaningful engagement by the members of the MAC and the BAC, whose feedback can then be used by States to support the efficient administration of their Medicaid program. We anticipate providing additional guidance on model practices, recruitment strategies, and ways to facilitate beneficiary participation, and we solicited comments on effective strategies to ensure meaningful interested parties' engagement that in turn can facilitate full beneficiary participation.

Further, the proposed changes to the requirement for beneficiary support, including financial support, are similar to the original MCAC requirements. For example, using dedicated staff to support beneficiary attendance at both the MAC and BAC meetings and providing financial assistance to facilitate meeting attendance by beneficiary members are similar to the current regulations. Staff may support beneficiary attendance through outreach to the Medicaid beneficiary MAC and BAC members throughout the membership period to provide information and answer questions; identify barriers and supports needed to facilitate attendance at MAC and BAC meetings; and facilitate access to those supports.

In the proposed rule, we proposed to add a new requirement that at least one member of the State agency's executive staff attend all MAC and BAC meetings to provide an opportunity for beneficiaries and representatives of the State's leadership to interact directly.

We received public comments on these proposals. The following is a

summary of the comments we received and our responses.

Comment: Many commenters supported the modifications proposed at § 431.12(h), but they emphasized the importance of requiring States to appropriately compensate members that are beneficiaries for their participation. The comments noted that there should be financial compensation to beneficiary members for the time spent on BAC activities, as well as financial reimbursement for any travel, lodging, meals, and childcare associated with their participation in the BAC and/or MAC. Commenters also asked CMS to exclude the value of any financial compensation paid to members for their participation in the MAC and/or BAC from consideration in determining eligibility for Medicaid. A few commenters expressed that the term ''if necessary'' should be dropped from the regulatory language, noting that States should offer reimbursement to all participating Medicaid beneficiaries.

Response: Under the policies we are finalizing at § 431.12(h)(3)(ii), States will have the ability to reimburse all beneficiaries to facilitate Medicaid beneficiary engagement in the MAC and the BAC. This can include, at the State's discretion, reimbursement for travel, lodging, meals, and childcare. We did not remove the words ''if necessary'' to account for Medicaid beneficiaries who may not need financial support to engage in the MAC and BAC activities.

We are also clarifying the circumstances in which compensation provided to beneficiary members would be considered income for Medicaid eligibility purposes. For both MAGI and non-MAGI methodologies, reimbursements (such as for meals eaten away from home, mileage, and lodging) do not count as income, but other compensation (such as a daily stipend) for participating in an advisory council is countable income under applicable financial methodologies. For non-MAGI methodologies, the State could submit a SPA to CMS to disregard such stipends or other countable income under section 1902(r)(2) of the Act. Other means tested programs may have other rules for counting income, and we encourage States to assess those rules and advise Medicaid beneficiary members of the MAC and BAC accordingly.

Comment: Many commenters in support of the proposed requirements in § 431.12(h)(3) noted how critical it will be for States to provide appropriate technical support and preparation to MAC and BAC members who are also Medicaid beneficiaries in order to ensure their full and active participation in discussions. Commenters shared a variety of suggestions for the type of support that can help prepare these members to feel comfortable fully and meaningfully engaging in the process. The suggestions made by the commenters included specific areas to be addressed in the trainings and materials that the State agency staff provides, such as providing background materials in plain language, implementing techniques to empower members to participate successfully and equally in MAC and BAC discussions, supporting health literacy needs, and training members on digital access to meetings/technology. Additionally, some commenters suggested that States be required to provide MAC and BAC members with a mentor and training on the Medicaid program throughout the length of their membership term. Several commenters suggested that States be required to select an independent (outside of the Medicaid agency) policy advisor or technical expert to provide BAC members with support in understanding Medicaid topics and policy.

Response: We appreciate the support for our proposals and understand the interest in ensuring support for beneficiary members of the MAC and BAC. The underpinning of meaningful member engagement is that members have a substantial understanding of the topics to be discussed. We agree with commenters' suggestions in general, but given the differences in States' structures and resources, we believe there is a benefit in leaving the decision of how best to provide training and support to the MAC and BAC members to the States. As we noted earlier in the preamble, CMS will post publicly a MAC best practices toolkit.

Comment: We received a couple of comments asking CMS to clarify the role of the State Medicaid agency staff attending the MAC and BAC meetings.

Response: The purpose of requiring a member from the State Medicaid agency's executive staff to attend MAC and BAC meetings is to provide an opportunity for beneficiaries and representatives of the State's Medicaid agency leadership to interact directly. The role of the executive staff person is not to be a MAC/BAC co-chair, nor to facilitate these meetings. The executive staff person's role is to hear directly from and interact with Medicaid beneficiaries and with the wider Medicaid community in that State. The person attending generally will be expected to share take-aways from these meetings with State's Medicaid agency leadership.

After consideration of public comments, we are finalizing § 431.12(h) as proposed with:

- Language modifications to reflect the new name of the BAC.
- Conforming edits to replace the word ''State Agency'' with the ''single State agency for the Medicaid program'' in several places across § 431.12(h).

Language modifications to § 431.12(h)(3) to state, ''. . . MAC and BAC members who are Medicaid beneficiaries . . .''

9. Annual Report (§ 431.12(i)).

In the spirit of transparency and to ensure compliance with the updated regulations, we added in the proposed rule [50] and are finalizing new paragraph § 431.12(i) to require that the MAC, with support from the State and in accordance with the requirements updated at this section, must submit an annual report to the State. The State must review the report and include responses to the recommended actions. The State must also: (1) provide MAC members with final review of the report; (2) ensure that the annual report of the MAC includes a section describing the activities, topics discussed, and recommendations of the BAC, as well as the State's responses to the recommendations; and (3) post the report to the State's website. In the proposed rule, we noted that States had one year to implement the annual report requirement and we sought comment on that timeline. In finalizing the proposals, we reviewed these requirements closer. It is our intention that the MAC is required to submit an annual report to the State. We clarify this intention in this final rule by making a technical change to add the word ''must'' which was unintentionally omitted in the proposed rule.

The proposed requirements of this paragraph seek to ensure transparency while also facilitating a feedback loop and view into the impact of the MAC and BAC's recommendations. We solicited comment on additional ways to ensure that the State can create a feedback loop with the MAC and BAC.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposed requirements in new § 431.12(i), of having States submit an annual report that describes activities of the MAC and BAC, including the topics discussed and their

[50] ''Medicaid Program; Ensuring Access to Medicaid Services,'' (88 FR 27960, 27971).

recommendations. Commenters noted that requiring these reports is critical to building trust as well as ensuring transparency and accountability among the State, MAC, and BAC members. In addition, several commenters agreed with the annual report requirement, but they also wanted CMS to stipulate the contents of the annual report. One commenter suggested that States' annual reports include results from anonymous surveys of MAC and BAC members indicating whether these members felt they have been listened to and if they felt the State used members' feedback.

Response: We appreciate the support for the proposed regulations. We carefully considered the benefits of national uniformity of the contents of an annual report. However, due to the differences in how States may approach setting priorities, creating their MAC and BACs, and the varying level of resources, we believe that States should have the flexibility to adopt an approach to the content of the annual report that works best within their State.

Comment: A few commenters asked CMS to either further require that the BAC issue its own set of reports and recommendations independently or as part of the MAC report.

Response: While we fully understand and agree with the importance of the BAC and ensuring that their voices are heard, we believe that requiring States to create a second BAC-only annual report would add administrative burden. The proposed regulatory language requires that States create an annual report that reflects the activities of both the MAC and BAC. Since the annual report is required to contain the priorities and activities of both the MAC and BAC, there is no need for a separate BAC-only report.

Comment: There were a handful of commenters that wanted CMS to reconsider the report requirement because they thought the resource burden was too great to develop an annual report, the reporting requirement lacked meaning, or they wanted CMS to allow Medicaid agencies to set their own cadence to the reports.

Response: We understand the concerns of the commenters, but we have written the annual report requirement broadly to ensure maximal flexibility for States to meet this requirement. It is critical that States document the work and key outcomes of the MAC and BAC. Further, we believe the annual report requirement supports the implementation of the principles of bi-directional feedback, transparency, and accountability on the part of the State, MAC, and BAC. In response to comments about burden to States, we have adjusted the proposed applicability date for this requirement of 1 year and are now finalizing it as, States have 2 years from July 9, 2024 to finalize the first annual MAC report. After the report has been finalized, States will have 30 days to post the annual report.

Comment: A few commenters asked CMS to require States to conduct additional activities related to monitoring the MAC and BAC, in addition to the annual report. The commenters' suggestions included: implementing a corrective action plan for States that failed to meet the MAC requirements; requiring process evaluations on the experiences of the MAC and BAC members be conducted and the findings be made public; and requiring States to engage in program improvement activities in response to the recommendations made by the MAC that appear in the annual report.

Response: We carefully considered the benefits of requiring additional studies and activities to be captured by States and included in the annual report. However, we want to keep the parameters of our expectations on the content of a State's annual report to be as broad as possible to give each State the ability to create a report that will help them best document the interested parties' engagement with the MAC and the BAC and serve as a tool for helping advance programmatic goals over time.

Comment: A couple of commenters requested CMS publish the annual reports on its website.

Response: We thank the commenters for this suggestion. Currently, we believe each respective State Medicaid agency's website to be the most appropriate place for the annual reports to be published. However, we will consider whether the needs of interested parties would be better served with CMS collecting and publishing annual reports as well.

Comment: A few commenters inquired about how CMS would provide oversight on compliance with activities such as the annual report and number of meetings requirements.

Response: We thank commenters for these questions. We are currently assessing the most effective strategies with which to provide oversight. As these requirements implement State plan requirements in section 1902(a)(4) and (a)(19) of the Act, noncompliance with the provisions of this final rule could result in a State plan compliance action in accordance with § 430.35.

After consideration of public comments, we are finalizing § 431.12(i) as proposed with:

- Language modifications to reflect the new name of the BAC.
- Additional sentences at the end of § 431.12(i)(3), ''States have 2 years from July 9, 2024 to finalize the first annual MAC report. After the report has been finalized, States will have 30 days to post the annual report.''

10. Federal Financial Participation (§ 431.12(j))

In the current regulation, paragraph (g) Federal financial participation, noted that FFP is available at 50 percent in expenditures for the committee's activities. As noted in the proposed rule, we are not making changes to, and thus are maintaining, the current regulatory language on FFP from previous paragraph (g) to support committee activities, to appear in new paragraph (j) with conforming edits for the new MAC and BAC names.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received a few comments about the newly proposed § 431.12(j), encouraging CMS to offer a higher FFP than 50 percent. One commenter suggested that 90 percent FFP would be ideal.

Response: For Medicaid, all States receive a statutory 50 percent Federal matching rate for general administrative activities. States may also receive higher Federal matching rates for certain administrative activities, such as design, development, installation, and operation of certain qualifying systems. Federal matching rates are established by Congress, and CMS does not have the authority to change or increase them.

After consideration of public comments, we are finalizing new paragraph § 431.12(j) as proposed with:

- Language modifications to reflect the new name of the BAC.

11. Applicability Dates § 431.12(k)

For this final rule, we are adding new paragraph § 431.12 (k) *Applicability dates.* In the proposed rule, we noted that the requirements of § 431.12 would be effective 60 days after the publication date of the final rule, although we established different applicability dates by which States must implement certain provisions. We then solicited comment on whether 1 year was too much or not enough time for States to implement the updates in this regulation in an effective manner. We understand that States may need to modify their existing MCACs to reflect the finalized requirements for MACs and may also need to create the BAC and recruit members to participate

if they do not already have a similar entity already in place.

We received public comments on proposed implementation timeline. The following is a summary of the comments we received and our responses.

Comment: We received several comments related to the implementation timeframes specified in the MAC and BAC provisions of the proposed rule. The majority of comments fell into two categories: commenters who noted that 1 year should be sufficient to implement the required changes; and commenters who suggested that CMS provide at least 2 years for implementation. Other commenters suggested that CMS consider a graduated approach that would allow States to demonstrate compliance with the minimum 25 percent BAC crossover requirement over a period of time. The commenters who requested additional time shared concerns about States' many other ongoing priorities, workforce shortages, the amount of time and resources it would take to set up the MAC and BAC, and having enough time to submit budget requests to their legislature so they can get the resources to support the required activities.

Response: We have carefully considered the comments received and acknowledge that additional time for implementation of the requirements could be beneficial for States given competing priorities, budgeting and other challenges States may encounter. Additionally, we weighed the request for a graduated approach to demonstrate compliance with a 25 percent BAC crossover requirement, and we agree that a graduated approach will allow States a longer ramp-up time to modify their current MCACs, as well as to set up the BAC and recruit members to participate.

In the proposed rule, we proposed that States have 1 year from the effective date of the final rule to recruit members, set up their MAC and BAC, hold meetings, and submit their first annual report. Based on public comment, we understand that 1 year is not enough time to complete all of these activities. As a result, we are adding and finalizing in this final rule a second implementation year. Based on these changes, States would now recruit members and set up their MACs and BACs during the first year implementation year. In the second implementation year, States would hold the required MAC and BAC meetings. At the end of that second implementation year, States would summarize the information from the MAC and BAC activities and use that information to complete an annual report. States would then fulfill the annual report requirement by finalizing the report and posting the annual report to their websites. This annual report would need to be posted by States within 30 days of the report being completed.

Additionally, as noted in section II.A.4., and in response to public comment asking for States to have a more graduated approach to reach the requirement of having 25 percent of MAC members be from the BAC, we are finalizing in this rule an extended implementation timeline for this requirement. The finalized provision at § 431.12(d)(1) will require that, for the period from July 9, 2024 through July 9, 2025, 10 percent of the MAC members must come from the BAC; for the period from July 10, 2025 through July 9, 2026, 20 percent of MAC members must come from the BAC; and thereafter, 25 percent of MAC members must come from the BAC. We developed this approach based on the comments we received about competing State priorities and the time and resources that a State would need to meet the new requirements. Additionally, we understand States may face challenges with finding, recruiting, and training beneficiary members to serve on the BAC.

Based on the comments received, we are changing two applicability dates. We note in this new paragraph *Applicability dates* § 431.12(k), that except as noted in paragraphs (d)(1) and (i)(3) of this section, the requirements in paragraphs (a) through (j) are applicable July 9, 2025.

B. Home and Community-Based Services (HCBS)

To address several challenges that we described in the proposed rule (88 FR 27964 and 27965), we proposed both to amend and add new Federal HCBS requirements to improve access to care, quality of care, and beneficiary health and quality of life outcomes, while consistently meeting the needs of all beneficiaries receiving Medicaid-covered HCBS. The preamble of the proposed rule (88 FR 27971 through 27996) outlined our proposed changes in the context of current law.

As we noted in the proposed rule (88 FR 27971), we have previously received questions from States about the applicability of HCBS regulatory requirements to demonstration projects approved under section 1115 of the Act that include HCBS. As a result, we proposed that, consistent with the applicability of other HCBS regulatory requirements to such demonstration projects, the requirements for section 1915(c) waiver programs and section 1915(i), (j), and (k) State plan services included in the proposed rule would apply to such services included in approved section 1115 demonstration projects, unless we explicitly waive one or more of the requirements as part of the approval of the demonstration project.

We proposed not to apply the requirements for section 1915(c) waiver programs and section 1915(i), (j), and (k) State plan services that we proposed in the proposed rule to the Program of All-Inclusive Care of the Elderly (PACE) authorized under sections 1894 and 1934 of the Act, as the existing requirements for PACE either already address or exceed the requirements outlined in the proposed rule, or are substantially different from those for section 1915(c) waiver programs and section 1915(i), (j), and (k) State plan services.

We received public comments on these proposals for HCBS under the Medicaid program. The following is a summary of the comments we received and our responses. We discuss the comments we received related to specific proposals, and our responses, in further detail throughout the sections in this portion of the final rule (section II.B.).

Comment: Many commenters expressed general support for our efforts to increase transparency and accountability in HCBS programs, and ultimately improve access to Medicaid services. Commenters in particular noted general support for our proposed provisions in this section that are designed to support HCBS delivery systems through improvements in data collection around waiting lists and service delivery, enhancements to person-centered planning, standardization of critical incident investigation and grievance process requirements, and establishment of defined quality measures. While overall reaction to the payment adequacy minimum performance level (discussed in section II.B.5. of the proposed rule and this final rule) was mixed, many commenters agreed that HCBS programs are facing shortages of direct care workers that pose obstacles to beneficiaries' access to high-quality HCBS.

Commenters also shared several ideas for ways we could improve beneficiaries' access to, or the overall quality of, HCBS beyond the provisions presented in the proposed rule.

Some commenters expressed concerns that the HCBS provisions we proposed, when taken together, could present significant administrative costs to States and, in some cases, to providers.

Response: We thank commenters for their support. Comments on specific provisions that we proposed are summarized below, along with our responses. We also appreciate the many thoughtful suggestions made by commenters for other ways they believe HCBS could be improved beyond what we proposed in the proposed rule. While comments that are outside the scope of what we proposed in the proposed rule and not relevant are not summarized in this final rule, we will take these recommendations under consideration for potential future rulemaking.

We recognize that we must balance our desire to stimulate ongoing improvements in HCBS programs with the need to give States, managed care plans, and providers sufficient time to make adjustments and allocate resources in support of these changes. After consideration of comments we received, we are finalizing many of our proposals, some with modifications. These modifications are discussed in this section (section II.B.) of the final rule.

We also note that some commenters expressed general support for all of the provisions in section II.B. of this rule, as well as for this rule in its entirety. In response to commenters who supported some, but not all, of the policies and regulations we proposed in the proposed rule (particularly in section II.B related to HCBS), we are clarifying and emphasizing our intent that each final policy and regulation is distinct and severable to the extent it does not rely on another final policy or regulation that we proposed.

While the provisions in section II.B. of this final rule are intended to present a comprehensive approach to improving HCBS and complement the goals expressed and policies and regulations being finalized in sections II.A. (Medicaid Advisory Committee and Beneficiary Advisory Group) and II.C. (Documentation of Access to Care and Service Payment Rates) of this final rule, we intend that each of them is a distinct, severable provision, as finalized. Unless otherwise noted in this rule, each policy and regulation being finalized under this section II.B is distinct and severable from other final policies and regulations being finalized in this section or in sections II.A. or II.C of this final rule, as well as from rules and regulations currently in effect.

Consistent with our previous discussion earlier in section II. of this final rule regarding severability, we are clarifying and emphasizing our intent that if any provision of this final rule is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further action, it shall be severable from this final rule, and from rules and regulations currently in effect, and not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances. For example, we intend that the policies and regulations we are finalizing related to person-centered planning and related reporting requirements (sections II.B.1 and II.B.7. of this final rule) are distinct and severable from the policies and regulations we are finalizing related to grievance system (section II.B.2. of this final rule), and incident management system and related reporting requirements (sections II.B.3 and II.B.7. of this final rule). The standalone nature of the finalized provisions is further discussed in their respective sections in this rule.

Comment: Several commenters addressed the relationship between the proposed HCBS requirements and HCBS authorized under a section 1115 demonstration project. A few commenters requested clarification about the application of the proposed HCBS requirements in this section to services delivered under section 1115 authority. A few commenters expressed concern about what they perceived was the exclusion of services provided through a managed care delivery system under section 1115 demonstration authority. One commenter recommended only applying the finalized rules to new section 1115 demonstration programs; in the alternative, if applying the finalized requirements to current section 1115 demonstration programs, the commenter recommended that States develop transition plans and be given a reasonable timeframe for bringing their programs into compliance. A few commenters recommended that we add a specific reference to section 1115 demonstration authority of the Act in our proposed HCBS requirements (if finalized), including at § 438.72(b) (applying various finalized requirements to managed care programs) and § 441.302(k) (applying new payment adequacy requirements to section 1915(c) waiver programs).

Response: We are confirming that, consistent with the applicability of other HCBS regulatory requirements to such demonstration projects, the requirements for section 1915(c) waiver programs and section 1915(i), (j), and (k) State plan services included in this final rule, apply to such services included in approved section 1115 demonstration projects, unless we explicitly waive one or more of the requirements as part of the approval of the demonstration project. Further, we have not identified a compelling reason to treat States operating section 1115 demonstration projects differently from States operating other HCBS programs in terms of implementation, such as by requiring States with section 1115 demonstration programs to develop transition plans (as was recommended by one commenter). We also believe that the timeframes that are finalized in this rule are reasonable and sufficient to allow all States operating programs under all relevant authorities to come into compliance. If States have specific questions or concerns regarding compliance with the finalized requirements, we will provide assistance as needed.

We note that we have already included references to managed care delivery systems implemented under section 1115(a) of the Act in the implementation requirements at §§ 441.301(c)(3)(iii) (implementing the person-centered planning process minimum performance requirements), 441.302(a)(6)(iii) (implementing the critical incident management system minimum performance requirements), 441.302(k)(8) (implementing the payment adequacy minimum performance requirement), 441.311(f) (implementing reporting requirements), and 441.313(c) (implementing the website transparency provision). We decline commenters' recommendations that we include additional references to section 1115 of the Act, as we believe doing so would be duplicative. We will ensure that the approved standard terms and conditions of States' section 1115 demonstration projects are clear that the States must comply with all applicable HCBS requirements that we are finalizing in this rule.

We did not receive any comments on our proposal not to extend HCBS requirements that we are finalizing in this rule to PACE. We are finalizing our proposal to not apply the requirements we are finalizing in this rule for section 1915(c) waiver programs and section 1915(i), (j), and (k) State plan services to PACE authorized under sections 1894 and 1934 of the Act.

1. Person-Centered Service Plans (§§ 441.301(c), 441.450(c), 441.540(c), and 441.725(c))

Section 1915(c)(1) of the Act requires that services provided through section 1915(c) waiver programs be provided under a written plan of care (hereinafter referred to as person-centered service plans or service plans). Existing Federal regulations at § 441.301(c) address the person-centered planning process and

include a requirement at § 441.301(c)(3) that the person-centered service plan be reviewed and revised, upon reassessment of functional need, at least every 12 months, when the individual's circumstances or needs change significantly, or at the request of the individual.

In 2014, we released guidance for section 1915(c) waiver programs [51] (hereinafter the 2014 guidance) that included expectations for State reporting of State-developed performance measures to demonstrate compliance with section 1915(c) of the Act and the implementing regulations in 42 CFR part 441, subpart G through six assurances, including assurances related to person-centered service plans. The 2014 guidance indicated that States should conduct systemic remediation and implement a Quality Improvement Project when they score below an 86 percent threshold on any of their performance measures. We refer readers to section II.B.1. of the proposed rule (88 FR 27972) for a detailed discussion of the six assurances identified in the 2014 guidance.

In the proposed rule (88 FR 27972 through 27975), we proposed a different approach for States to demonstrate that they meet the statutory requirements in section 1915(c) of the Act and the regulatory requirements in 42 CFR part 441, subpart G, including the requirements regarding assurances around service plans. We proposed this approach based on feedback CMS obtained during various public engagement activities conducted with States and other interested parties over the past several years about the reporting discussed in the 2014 guidance, as well as feedback received through a request for information (RFI) [52] we released in the spring of 2022. Through this feedback, many States and interested parties expressed, and we identified, that there is a need to standardize reporting and set minimum standards for HCBS. We proposed HCBS requirements to establish a new strategy for oversight, monitoring, quality assurance, and quality improvement for section 1915(c) waiver programs, including minimum performance requirements and reporting requirements for section 1915(c) waiver programs. Further, as is discussed later in this section (section II.B.1. of the rule), to ensure consistency and alignment across HCBS authorities, we proposed to apply the proposed requirements for section 1915(c) waiver programs to section 1915(i), (j), and (k) State plan services, as appropriate.

As support for our proposals, we noted that under section 1902(a)(19) of the Act, States must provide safeguards to assure that eligibility for Medicaid-covered care and services are determined and provided in a manner that is consistent with simplicity of administration and that is in the best interest of Medicaid beneficiaries. While the needs of some individuals who receive HCBS may be relatively stable over some time periods, individuals who receive HCBS experience changes in their functional needs and individual circumstances, such as the availability of natural supports or a desire to choose a different provider, that necessitate revisions to the person-centered service plan to remain as independent as possible or to prevent adverse outcomes. Thus, the requirements to reassess functional need and to update the person-centered service plan based on the results of the reassessment, when circumstances or needs change significantly or at the request of the individual, are important safeguards that are in the best interest of beneficiaries because they ensure that an individual's section 1915(c) waiver program services change to meet the beneficiary's needs most appropriately as those needs change.

We also noted that effective State implementation of the person-centered planning process is integral to ensuring compliance with section 2402 of the of the Patient Protection and Affordable Care Act (Affordable Care Act) (Pub. L. 111–148, March 23, 2010). Section 2402 of the Affordable Care Act requires the Secretary of HHS to ensure that all States receiving Federal funds for HCBS, including Medicaid, develop HCBS systems that are responsive to the needs and choices of beneficiaries receiving HCBS, maximize independence and self-direction, provide support and coordination to facilitate the participant's full engagement in community life, and achieve a more consistent and coordinated approach to the administration of policies and procedures across public programs providing HCBS.[53]

Finally, we noted that since the release of the 2014 guidance, we have received feedback from States, the HHS Office of Inspector General (OIG), Administration for Community Living (ACL), and Office for Civil Rights (OCR), and other interested parties on how crucial person-centered planning is in the delivery of care and the significance of the person-centered service plan for the assurance of health and welfare for section 1915(c) waiver program participants that underscored the need for the proposals.[54]

To ensure a more consistent application of person-centered service plan requirements across States and to protect the health and welfare of section 1915(c) waiver participants, under our authority at sections 1915(c)(1) and 1902(a)(19) of the Act and section 2402(a)(1) and (2) of the Affordable Care Act, we proposed several changes to our person-centered service plan requirements in section II.B.1 of the proposed rule (88 FR 27972 through 27975), as discussed in more detail in this section of the final rule. First, we proposed revisions to § 401.301(c)(3)(i) to clarify that: (1) States are required to ensure person-centered service plans are reviewed and revised in compliance with requirements set forth therein; and (2) changes to the person-centered service plans are not required if the reassessment does not indicate a need for changes. Second, we proposed to establish a minimum performance level for States to demonstrate they meet the requirements at § 441.301(c)(3). Specifically, at § 441.301(c)(3)(ii)(A), we proposed to require that States demonstrate that a reassessment of functional need was conducted at least annually for at least 90 percent of individuals continuously enrolled in the waiver for at least 365 days. At § 441.301(c)(3)(ii)(B) we proposed to require that States demonstrate that they reviewed the person-centered service plan, and revised the plan as appropriate, based on the results of the required reassessment of functional need at least every 12 months for at least 90 percent of individuals continuously enrolled in the waiver for at least 365 days. Finally, we proposed to apply the requirements at § 441.301(c)(3) to section 1915(j), (k), and (i) State plan

[51] Modifications to Quality Measures and Reporting in § 1915(c) Home and Community-Based Waivers. March 2014. Accessed at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/3-cmcs-quality-memo-narrative_0_2.pdf.*

[52] CMS Request for Information: Access to Coverage and Care in Medicaid & CHIP. February 2022. For a full list of question from the RFI, see *https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-questions.pdf.*

[53] Section 2402(a) of the Affordable Care Act—Guidance for Implementing Standards for Person-Centered Planning and Self-Direction in Home and Community-Based Services Programs. Accessed at *https://acl.gov/sites/default/files/news%202016-10/2402-a-Guidance.pdf.*

[54] Ensuring Beneficiary Health and Safety in Group Homes Through State Implementation of Comprehensive Compliance Oversight. U.S. Department of Health and Human Services, Office of the Inspector General, Administration for Community Living, and Office for Civil Rights. January 2018. Accessed at *https://oig.hhs.gov/reports-and-publications/featured-topics/group-homes/group-homes-joint-report.pdf.*

services at §§ 441.450(c), 441.540(c), and 441.725(c), respectively.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: One commenter questioned whether States would continue to be required to demonstrate compliance with the six assurances and the related subassurances, including those related to person-centered service plans described in the 2014 guidance, or whether the minimum performance requirements and reporting requirements that we proposed in the proposed rule for the section 1915(c) waiver program, if finalized in the final rule, supersede these six assurances and related subassurances.

Response: We noted in the proposed rule (88 FR 27972), and reiterate here, that States must demonstrate that they meet the statutory requirements in section 1915(c) of the Act and the regulatory requirements in part 441, subpart G, including the requirements regarding assurances around person-centered service plans.

We proposed new minimum performance requirements and new reporting requirements for section 1915(c) waiver programs that are intended to supersede and fully replace the reporting requirements and the 86 percent performance level threshold for performance measures described in the 2014 guidance. Further, to ensure consistency and alignment across HCBS authorities, we proposed to apply the proposed requirements for section 1915(c) waiver programs to section 1915(i), (j), and (k) State plan services as appropriate.

We confirm that the section 1915(c) six assurances and the related subassurances,[55] including those related to person-centered service plans, continue to apply. The requirements proposed at § 441.301(c)(3)(ii)(A) and (B) (discussed in the next section, II.B.1.b. of this rule) assess State performance with the requirements at § 441.301(c)(3) and we did not intend to suggest that they would fully supersede the section 1915(c) six assurances and the related subassurances in the 2014 guidance. Further, as finalized later in this rule, States will be required to report on the minimum performance levels at § 441.301(c)(3)(ii)(A) and (B). To reduce unnecessary burden and to avoid duplicative or conflicting reporting requirements, we plan to work with States to phase-out the reporting requirements and the 86 percent performance level threshold for performance measures described in the 2014 guidance as they implement these requirements in the final rule.

Comment: A commenter requested we clarify what the impacts would be to the existing section 1915(c) waiver reporting tools as defined in the Version 3.6 HCBS Waiver Application if we finalize our proposals.

Response: We expect to implement new reporting forms for the new reporting requirements that we are finalizing in this final rule. However, some components of the existing reporting forms may remain in effect to the extent that they cover other requirements that remain unchanged by the requirements that we are finalizing in this final rule. States and interested parties will have an opportunity to comment on the new reporting forms and the revised forms through the Paperwork Reduction Act notice and comment process.

a. Finalization of Amended Requirement for Review of the Person-Centered Service Plan (§ 441.301(c)(3)(i))

At § 441.301(c)(3), we proposed to revise the regulatory text so that it is clearer that the State is the required actor under § 441.301(c)(3), and that changes to the person-centered service plan are not required if the reassessment does not indicate a need for changes. In the proposed rule (88 FR 27973), we noted that, with this revision to the regulatory text, the State could, for instance, meet the requirement that the person-centered service plan was reviewed, and revised as appropriate, based on the results of the required reassessment of functional need by documenting that there were no changes in functional needs or the individual's circumstances upon reassessment that necessitated changes to the service plan. However, the State would still be expected to review the service plan to confirm that no revisions are needed, even if the reassessment identified no changes in functional needs or the individual's circumstances.

Specifically, we proposed to move the sentence at § 441.301(c)(3) beginning with ''The person-centered service plan must be reviewed. . .'' to a new paragraph at § 441.301(c)(3)(i) and reposition the regulatory text under the proposed title, *Requirement.* In addition, we proposed to revise the regulatory text at the renumbered paragraph to clarify that the person-centered service plan must be reviewed, and revised as appropriate, based on the reassessment of functional need as required by § 441.365(e), at least every 12 months, when the individual's circumstances or needs change significantly, or at the request of the individual.

We received public comment on this proposal. Below is the summary of the comment and our response.

Comment: Commenters did not raise specific concerns about the proposal at § 441.301(c)(3)(i). However, one commenter raised concerns about the impact the minimum performance requirement proposed at § 441.301(c)(3)(ii) (discussed in greater detail in the next section) would have on the requirement at § 441.301(c)(3)(i). The commenter expressed concern that States may interpret the 90 percent minimum performance levels proposed at § 441.301(c)(3)(ii)(A) and (B) as meaning they are only required to conduct the reassessments and updates to person-centered service plans as required by § 441.301(c)(3)(i) for 90 percent of beneficiaries, not for 100 percent of beneficiaries receiving HCBS. This commenter also suggested that CMS clarify that States should conduct functional assessments and person-centered plan updates for every individual to make sure that the requirement at § 441.301(c)(3)(i) is not open to interpretation.

Response: We intend that the 90 percent minimum performance requirements proposed at § 441.301(c)(3)(ii) would assess States' minimum performance of the requirements at § 441.301(c)(3)(i); we do not suggest that reassessments of functional need and reviews, and revisions as appropriate, of the person-centered service plan, based on the results of the required reassessment of functional need, are required for only 90 percent of individuals enrolled in the waiver program. The minimum performance requirements at § 441.301(c)(3)(ii) (and the associated reporting requirements at § 441.311(b)(3), discussed in section II.B.7. of this final rule), while important for aiding in our oversight and States' accountability for complying with § 441.301(c)(3)(i), are distinct and severable requirements from § 441.301(c)(3)(i). In other words, States would be expected to comply fully with § 441.301(c)(3)(i) even had we not also proposed the specific minimum performance requirement at § 441.301(c)(3)(ii). Thus, the minimum performance of 90 percent proposed in § 441.301(c)(3)(ii) notwithstanding, it is our intent to require at § 441.301(c)(3)(i) that States ensure that the person-

[55] Modifications to Quality Measures and Reporting in § 1915(c) Home and Community-Based Waivers. March 2014. Accessed at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/3-cmcs-quality-memo-narrative_0_2.pdf.*

centered service plan for every individual is reviewed, and revised as appropriate, at least every 12 months, when the individual's circumstances or needs change significantly, or at the request of the individual. To ensure that this expectation is clear in the requirement, we are finalizing § 441.301(c)(3)(i) with a modification to specify that the requirement at § 441.301(c)(3)(i) applies to every individual.

Upon further review, we also determined that retaining the reference to § 441.301(c)(3) in § 441.365(e), governing the frequency of functional assessments for section 1915(d) waiver programs, at the redesignated § 441.301(c)(3)(i), is both obsolete and unnecessary. Section 441.365(e) was a standard used by section 1915(d) waiver programs, which were time-limited programs that are no longer in effect, to establish the frequency of functional assessments. The requirements at § 441.301(c)(3) establish the frequency of functional assessments for section 1915(c) programs, thus referencing § 441.365(e), which is obsolete, is unnecessary.

Accordingly, we are finalizing § 441.301(c)(3)(i) with the previously noted modifications to specify that the requirement applies to every individual and removing reference to § 441.365(e), as well as a minor technical modification to remove an extraneous comma after the word ''revised.'' As finalized, § 441.301(c)(3)(i) specifies that the State must ensure that the person-centered service plan for every individual is reviewed, and revised as appropriate, based upon the reassessment of functional need at least every 12 months, when the individual's circumstances or needs change significantly, or at the request of the individual.

b. Minimum Performance Level (§ 441.301(c)(3)(ii))

To ensure a more consistent application of person-centered service plan requirements across States and to protect the health and welfare of section 1915(c) waiver participants, under our authority at sections 1915(c)(1) and 1902(a)(19) of the Act and section 2402(a)(1) and (2) of the Affordable Care Act, we proposed to codify a minimum performance level to demonstrate that States meet the requirements at § 441.301(c)(3) (88 FR 27973).

Specifically, at new § 441.301(c)(3)(ii)(A), we proposed to require that States demonstrate that a reassessment of functional need was conducted at least annually for at least 90 percent of individuals continuously enrolled in the waiver for at least 365 days. We also proposed, at new § 441.301(c)(3)(ii)(B), to require that States demonstrate that they reviewed the person-centered service plan and revised the plan as appropriate based on the results of the required reassessment of functional need at least every 12 months for at least 90 percent of individuals continuously enrolled in the waiver for at least 365 days.

We intended that these proposed minimum performance levels would strengthen person-centered planning reporting requirements while taking into account that there may be legitimate reasons why assessment and care planning processes occasionally are not completed timely in all instances. We also considered whether to propose allowing good cause exceptions to the minimum performance level in the event of a natural disaster, public health emergency, or other event that would negatively impact a State's ability to achieve a minimum 90 percent performance level. In the end, we decided not to propose good cause exceptions because the minimum 90 percent performance level is intended to account for various scenarios that might impact a State's ability to achieve these minimum performance levels. Further, we noted that there are existing disaster authorities that States could utilize to request a waiver of these requirements in the event of a public health emergency or a disaster (88 FR 27973).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported our proposals to codify at § 441.301(c)(3)(ii)(A) and (B) minimum performance levels for States to demonstrate that they meet the requirements at § 441.301(c)(3)(i). These commenters noted that, by CMS establishing minimum performance levels for the person-centered planning requirements, beneficiaries who receive HCBS may be more empowered to actively participate in decision-making processes related to their care and services.

Response: We appreciate the support for our proposals.

Comment: One commenter suggested we specify that a beneficiary's services should not be reduced, suspended, or terminated because the reassessment of functional need or person-centered service plan update did not occur within the specified timeframe.

Response: The proposed requirements to reassess functional need and to update the person-centered service plan based on the results of the reassessment, when circumstances or needs change significantly, or at the request of the individual, are important safeguards that are in the best interest of beneficiaries because they ensure that an individual's section 1915(c) waiver program services are reassessed to ensure they continue meeting the beneficiary's needs most appropriately as those needs change. Any changes in the services and supports included in the person-centered service plan for beneficiaries should be based on changes in circumstances or needs or preferences of the individual; they should not result from a failure by the State or managed care plan to conduct required assessment and service planning processes timely. Further, States should not reduce, suspend, or terminate a beneficiary's services solely to reach the minimum performance level required at § 441.301(c)(3)(ii)(A) and (B).

Comment: A couple of commenters suggested we clarify whether States would be required to implement corrective action for noncompliance with the 90 percent performance level if the same beneficiaries do not receive timely reassessments or updated person-centered plans repeatedly. One commenter questioned whether a 90 percent performance level provides an acceptable margin of error (10 percent) and requested clarification on whether States will be expected to remediate through corrective action if this threshold is not met.

Response: Corrective actions or other enforcement actions will be determined on a case-by-case basis, using our standard enforcement authority, for States that are determined to not be compliant with the requirements at § 441.301(c)(3)(ii)(A) and (B). We will take this feedback into account as we plan technical assistance and develop guidance for States.

Comment: One commenter stated that the person-centered planning requirements are essential to ensure choice and access to appropriate service and suggested that, although the proposed approach meets compliance oversight and monitoring objectives, a quality improvement strategy to address improving outcomes with the person-centered planning requirements is needed.

Response: We note that the proposed requirements at § 441.301(c)(3)(ii)(A) and (B) were intended to strengthen person-centered planning reporting requirements by codifying a minimum performance level to demonstrate that States meet the requirements at § 441.301(c)(3). We encourage States to consider implementing quality

improvement processes to strengthen and improve person-centered planning in their HCBS programs. Further, as discussed in section II.B.8. of this final rule, we are finalizing the HCBS Quality Measure Set reporting requirements to include requirements for States to implement quality improvement strategies in their HCBS programs; while the HCBS Quality Measure Set is distinct from the person-centered planning requirements being finalized at § 441.301(c)(3), we believe the HCBS Quality Measure Set requirements support the quality improvement objectives described by this commenter.

Comment: A few commenters suggested CMS include a good cause exception for States that do not meet the minimum performance level to take into account certain instances that fall outside of the specified performance standards for appropriate reasons, such as for resource challenges in rural areas, or for beneficiary-related events that could delay the ability to complete the assessment, such as medical emergencies/hospitalizations. Alternatively, a few commenters supported our proposal to not allow good cause exceptions to the performance level, observing that the 90 percent minimum performance level already gives States leeway for unexpected occurrences.

Response: We believe that the 90 percent minimum performance level proposed at § 441.301(c)(3)(ii)(A) and (B) sets a realistic and achievable threshold.

As we noted in the proposed rule (88 FR 27973), we decided to not propose any good cause exceptions because the minimum 90 percent performance level accounts for various scenarios that might impact the State's ability to achieve these performance levels, and there are existing disaster authorities, such as the waiver authority under section 1135 of the Act, that States could utilize to request a waiver of these requirements in the event of a public health emergency or a disaster. We decline to include good cause exceptions in the minimum performance level in this final rule.

After consideration of public comments, we are finalizing our proposals at § 441.301(c)(3)(ii) with minor modifications to clarify that the State must ensure that the minimum performance levels specified at § 441.301(c)(3)(ii)(A) and (B) are met (since States typically have person-centered planning requirements carried out by entities such as case managers or providers, rather than directly by the State). We are also finalizing § 441.301(c)(3)(ii)(B) with minor technical modifications to make the same punctuation correction as the modification finalized in § 441.301(c)(3)(i).

c. Application to Managed Care and Fee-for-Service (§ 441.301(c)(3))

To ensure consistency in person-centered service plan requirements between FFS and managed care delivery systems, we proposed to add the requirements for services delivered under FFS at § 441.301(c)(3) to services delivered under managed care delivery systems. Section 2402(a)(3)(A) of the Affordable Care Act requires States to improve coordination among, and the regulation of, all providers of Federally and State-funded HCBS programs to achieve a more consistent administration of policies and procedures across HCBS programs. In the context of Medicaid coverage of HCBS, it should not matter whether the services are covered directly on a FFS basis or by a managed care plan to its enrollees. Therefore, we proposed that a State must ensure compliance with the requirements in § 441.301(c)(3) with respect to HCBS delivered both under FFS and managed care delivery systems.

We note that in the proposed rule at 88 FR 27974, we made the statement that to ensure consistency in person-centered service plan requirements between FFS and managed care delivery systems, we propose to add the requirements at § 441.301(c)(3) to 42 CFR 438.208(c). This statement was published in error, and we did not intend to propose this specific regulation text include reference to § 438.208(c). We note that § 438.208(c)(3)(v) already requires that managed care plans comply with § 441.301(c)(3), generally, so we believe that referencing § 438.208(c) is not necessary. We also note that § 438.208(c)(3)(ii) requires compliance with the other person-centered planning requirements at § 441.301(c)(1) and (2). Thus, also referring to § 438.208(c) would be unnecessary.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Commenters expressed support for the proposed requirements at § 441.301(c)(3) to be applied to managed care delivery systems as well, noting that States must ensure compliance with respect to HCBS delivered both in FFS and managed care delivery systems. Commenters also noted that the process of conducting reassessments and making updates to a person-centered service plan is agnostic to whether a provider is paid by a managed care plan or through a FFS delivery system.

Response: We appreciate the support for our proposal.

After consideration of public comments received, we are finalizing our proposed policy to require that the person-centered planning requirements at § 441.301(c)(3) finalized in this section are applied to HCBS delivered under both managed care and FFS delivery systems. As noted above, we are not finalizing a new reference to § 441.301(c)(3) at § 438.208(c), as § 438.208(c) already requires that managed care plans comply with § 441.301(c)(1) through (c)(3), which includes the requirements being finalized in this rule at § 441.301(c)(3)(i) and (ii). Additionally, as is discussed in section II.B.11. of this rule, we are finalizing our proposal at § 438.72(b) to direct States to comply with the requirements finalized in this final rule, including the revised person-centered centered planning requirements at § 441.301(c)(1) through (c)(3), for services authorized under HCBS authorities and provided under managed care delivery systems.

d. Person-Centered Planning—Definition of Individual (§ 441.301(c)(1))

We also proposed updates to existing language describing the person-centered planning process specific to section 1915(c) waivers. Current language describes the role of an individual's authorized representative as if every waiver participant will require an authorized representative, which is not the case. This language has been a source of confusion for States and providers. We proposed to amend the regulation text at § 441.301(c)(1) to better reflect that the individual, or if applicable, the individual and the individual's authorized representative, will lead the person-centered planning process. When the term individual is used throughout this section, it includes the individual's authorized representative will lead the person-centered planning process if applicable. We note that, in the proposed rule, we described our proposal as removing extraneous language and not as an amendment of § 441.301(c)(1) (88 FR 27974). Upon further consideration, we believe characterizing this proposal as an amendment is more accurate. We intend that this proposed language as finalized will bring the section 1915(c) waiver regulatory text in line with person-centered planning process language in both the section 1915(j) and (k) State plan options.

We did not receive public comments on this proposal. However, after further

consideration of the proposed requirement, we are finalizing § 441.301(c)(1) with a technical modification to clarify that the language contained in § 441.301(c)(1), as finalized, applies to the person-centered planning requirements **throughout § 441.301(c)(1) through (3)**. (New language identified in bold.) This modification expresses our intent that § 441.301(c)(1) applies to the person-centered planning requirements in § 441.301(c)(1) through (3), rather than § 441.301(c) in its entirety.

e. Applicability Date (§ 441.301(c)(3)(iii))

We proposed at § 441.301(c)(3)(iii) to make the performance levels under § 441.301(c)(3)(ii) effective 3 years after the effective date of § 441.301(c)(3) (in other words, 3 years after the effective date of the final rule) in FFS delivery systems. For States that implement a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and include HCBS in the managed care organization's (MCO's), prepaid inpatient health plan's (PIHP's), or prepaid ambulatory health plan's (PAHP's) contract, we proposed to provide States until the first rating period with the MCO, PIHP, or PAHP, beginning on or after 3 years after the effective date of the final rule to implement these requirements. We solicited comment on whether the timeframe to implement the proposed regulations is sufficient, whether we should require a shorter timeframe or longer timeframe to implement these provisions, and, if an alternate timeframe is recommended, the rationale for that alternate timeframe.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Most commenters supported the 3-year timeframe for the effective date as defined at § 441.301(c)(3)(iii). A few commenters expressed concerns about the overall burden they believe will be associated with the final rule, due to competing priorities, and the effect it may have on States' ability to implement the proposed person-centered planning provisions at § 441.301(c)(3)(ii) within 3 years following the effective date of the final rule. A few commenters expressed that the performance levels under § 441.301(c)(3)(ii) may require States to have a longer runway to implement and operationalize State regulation changes and processes, revise policies, and hire critical staff. A few commenters also requested we consider alternative effective dates for the person-centered planning minimum performance requirements, ranging from 18 months to 4 years.

Response: We noted, in the proposed rule (88 FR 27974), that we recognize many States may need time to implement the proposed HCBS requirements we are finalizing in the final rule. We acknowledge that States will have to expend resources in addressing the person-centered planning minimum performance requirements, including needing time to amend provider agreements, make State regulatory or policy changes, implement process or procedural changes, update information systems for data collection and reporting, or conduct other activities to implement these person-centered planning requirements.

We believe that 3 years for States to ensure compliance with the person-centered planning minimum performance requirements being finalized at § 441.301(c)(3)(ii) is realistic and achievable for States. We also note that the minimum performance requirements measure performance of the requirements at § 441.301(c)(3)(i), which substantively reflect activities States are currently expected to perform under existing § 441.301(c)(3). For States implementing a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and include HCBS in the in the MCO's, PIHP's, or PAHP's contract, we similarly believe it is realistic and achievable to provide States with a date to comply that is until the first rating period with the MCO, PIHP, or PAHP, beginning on or after 3 years after the effective date of this final rule to implement these requirements. We will provide technical assistance to States as needed with meeting the timeframe for compliance.

After consideration of the comments received, we are finalizing the substance of §§ 441.301(c)(3)(iii) as proposed, but with minor modifications to correct erroneous uses of the word ''effective'' and to make technical modifications to the language pertaining to managed care delivery systems to improve accuracy and alignment with common phrasing in managed care contracting policy. We are retitling the requirement at § 441.301(c)(3)(iii) as Applicability date (rather than Effective date). We are also modifying the language at § 441.301(c)(3)(iii) to specify that **States must comply with** the requirements at § 441.301(c)(3)(ii) **beginning** 3 years from the effective date of this final rule (rather than stating that the performance levels described in § 441.301(c)(3)(ii) are effective 3 years after the date of enactment of the final rule); and in the case of the State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes HCBS in the MCO's, PIHP's, or PAHP's contract, the first **rating period *for contracts with the MCO, PIHP, or PAHP beginning*** on or after **the date that is** 3 years after the effective date of this **final rule**. (New language identified in bold.).

f. Application to Other Authorities

Section 2402(a)(3)(A) of the Affordable Care Act requires States to improve coordination among, and the regulation of, all providers of Federally and State-funded HCBS programs to achieve a more consistent administration of policies and procedures across HCBS programs. In accordance with the requirement of section 2402(a)(3)(A) of the Affordable Care Act and because HCBS State plan options have similar person-centered planning and service plan requirements, we proposed to include the proposed requirements at § 441.301(c)(3) in section 1915(j), (k), and (i) State plan services, at §§ 441.450(c), 441.540(c), and 441.725(c), respectively. Consistent with our proposal for section 1915(c) waivers, we proposed these requirements under section 1902(a)(19) of the Act, which authorizes safeguards necessary to assure that eligibility for care and services under the Medicaid program will be determined, and such care and services will be provided, in a manner consistent with the best interest of beneficiaries. We believe these same reasons for proposing these requirements for section 1915(c) waivers are equally applicable for these other HCBS authorities.

We considered whether to apply the proposed person-centered plan requirements at § 441.301(c)(3) to section 1905(a) ''medical assistance'' State plan personal care services, home health services, and case management services. However, we did not propose that these requirements apply to any section 1905(a) State plan services at this time. First, States do not have the same data collection and reporting capabilities for these services as they do for other HCBS at section 1915(c), (i), (j), and (k). Second, person-centered planning and service plan requirements are not required by Medicaid for section 1905(a) services, although we recommend that States implement person-centered planning processes for all HCBS. We note that the vast majority of HCBS is delivered under section 1915(c), (i), (j), and (k) authorities, while only a small percentage of HCBS

nationally is delivered under section 1905(a) State plan authorities. However, the small overall percentage includes large numbers of people with mental health needs who receive case management.

We solicited comment on whether we should establish similar person-centered planning and service plan requirements for section 1905(a) State plan personal care services, home health services and case management services.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters expressed support for applying the proposed person-centered planning and person-centered plan requirements at § 441.301(c)(3) to section 1915(j), (k), and (i) State plan services.

Response: We appreciate the support for our proposal. As noted earlier, we are finalizing modifications to § 441.301(c)(3)(i) to specify that the requirement applies to every individual and to make a technical correction to remove an extraneous comma. We are finalizing corresponding edits for section 1915(k) in § 441.540(c) and section 1915(i) in § 441.725(c). The revised language for both § 441.540(c) and § 441.725(c) will specify that the State must ensure that the person-centered service plan for every individual is reviewed, and revised as appropriate, based upon the reassessment of functional need, at least every 12 months, when the individual's circumstances or needs change significantly, and at the request of the individual. States must adhere to the requirements of § 441.301(c)(3).

Comment: A few commenters responded to our request for comment on whether we should establish similar health and welfare requirements for section 1905(a) State plan personal care services, home health services, and case management services. Several commenters supported that we decided not to propose to extend the person-centered plan requirements at § 441.301(c)(3) to section 1905(a) services. These commenters expressed concern that applying these requirements to these State plan benefits could pose critical challenges for State Medicaid and other operating agencies, due to varying levels of HCBS provided and different data reporting infrastructure States have for section 1905(a) services. A few commenters recommended that CMS apply the person-centered planning requirements to mental health rehabilitative services delivered under section 1905(a) State plan authority. A couple of other commenters suggested that mental health rehabilitative services are considered HCBS under the broader definition enacted by Congress in the American Rescue Plan Act of 2021 (Pub. L. 117–2, March 11, 2021), suggesting that CMS should consider including these services in the person-centered plan requirements at § 441.301(c)(3).

Response: At this time and as noted in the proposed rule (88 FR 27974 and 27975), we are not applying the person-centered service plan requirements at § 441.301(c)(3) to section 1905(a) services, due to the statutory and regulatory differences between services authorized under sections 1905(a) and 1915 of the Act. For example, there are no statutory provisions in section 1905(a) of the Act that attach State-level reporting requirements to any section 1905(a) service. Relatedly, States do not have the same data collection and reporting capabilities for these services as they do for HCBS at section 1915(c), (i), (j), and (k).

Additionally, we note that section 1905(a) services do not have the same person-centered planning requirements at § 441.301(c)(1) through (6). Formal person-centered service planning requirements are established for section 1915(j) services in § 441.468, for section 1915(k) services in § 441.540, and for section 1915(i) services at § 441.725. While service planning might be part of some specific 1905(a) services, it is not a required component of all section 1905(a) services.

We acknowledge that many beneficiaries, particularly those receiving mental health services, are served by section 1905(a) services, and encourage States to implement effective person-centered planning processes that are based on individual preferences and personal goals and support full engagement in community for Medicaid beneficiaries receiving section 1905(a) State plan personal care services, home health services, case management services, and rehabilitative services. We thank commenters for their feedback on this request for comment, which we may consider in future rulemaking.

After consideration of public comments, we are finalizing the application of § 441.301(c)(3), as finalized in this rule, to section 1915(j), (k), and (i) State plan services by finalizing relevant requirements at §§ 441.450(c), 441.540(c), and 441.725(c), respectively. We are finalizing §§ 441.450(c), 441.540(c), and 441.725(c), with a technical modification to clarify that service plans must meet the requirements of § 441.301(c)(3), but that references therein to section 1915(c) of the Act are instead references to section 1915(j), 1915(k), and 1915(i) of the Act, respectively. We are finalizing the requirements at §§ 441.540(c) and 441.725(c) with minor modifications. To maintain consistency with modifications finalized in § 441.301(c)(3)(i), we are finalizing §§ 441.540(c) and 441.725(c) with modifications to specify that the requirements apply to every individual and to remove an extraneous comma.

g. Summary of Finalized Requirements

After consideration of the public comments, we are finalizing the proposals at §§ 441.301(c)(1), 441.301(c)(3), 441.450(c), 441.540(c), and 441.725(c) as follows:

- We are finalizing the requirement at § 441.301(c)(1) with a technical modification to clarify that § 441.301(c)(1) applies to paragraphs (c)(1) through (3) of this section.
- We are finalizing § 441.301(c)(3)(i) with modifications to specify that the requirement applies to every individual and to remove the reference to § 441.365(e), as well as finalizing a minor technical change to remove an extraneous comma.
- We are finalizing our proposals at § 441.301(c)(3)(ii) with minor modifications to clarify that the State must ensure that the minimum performance levels specified at § 441.301(c)(3)(ii)(A) and (B) are met. We are also finalizing § 441.301(c)(3)(ii)(B) with minor technical modifications to correct the punctuation (consistent with the change finalized in § 441.301(c)(3)(i)).
- We are finalizing the applicability date requirement at § 441.301(c)(3)(iii), with a technical modification to the language to improve accuracy and alignment with common phrasing in managed care contracting policy. We also are finalizing § 441.301(c)(3)(iii) to specify that States must comply with the performance levels described in paragraph (c)(3)(ii) of this section beginning 3 years after July 9, 2024; and in the case of the State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes HCBS in the MCO's, PIHP's, or PAHP's contract, the first rating period for contracts with the MCO, PIHP, or PAHP beginning on or after the date that is 3 years after July 9, 2024.
- We are finalizing §§ 441.450(c), 441.540(c), and 441.725(c), with a technical modification to clarify that service plans must meet the requirements of § 441.301(c)(3), but that references therein to section 1915(c) of

the Act are instead references to section 1915(j), 1915(k), and 1915(i) of the Act, respectively.

- We are finalizing §§ 441.540(c) and 441.725(c), consistent with modifications finalized in § 441.301(c)(3)(i), with a modification to specify that the requirements apply to every individual, and with technical modification to correct the punctuation.

2. Grievance System (§ 441.301(c)(7); Proposed at § 441.464(d)(2)(v), Being Finalized at § 441.464(d)(5); Proposed at § 441.555(b)(2)(iv), Being Finalized at § 441.555(e); and § 441.745(a)(1)(iii))

a. Scope of Grievance System and Definitions (§ 441.301(c)(7)(i) and § 441.301(c)(7)(ii))

Section 2402(a) of the Affordable Care Act requires the Secretary of HHS to ensure that all States receiving Federal funds for HCBS, including Medicaid HCBS, develop HCBS systems that are responsive to the needs and choices of beneficiaries receiving HCBS, maximize independence and self-direction, provide support and coordination to assist with a community-supported life, and achieve a more consistent and coordinated approach to the administration of policies and procedures across public programs providing HCBS.[56] Among other things, section 2402(a)(3)(B)(ii) of the Affordable Care Act requires development and monitoring of an HCBS complaint system. Further, section 1902(a)(19) of the Act requires States to provide safeguards to assure that eligibility for Medicaid-covered care and services will be determined and provided in a manner that is consistent with simplicity of administration and the best interest of Medicaid beneficiaries.

Federal regulations at 42 CFR part 431, subpart E, require States to provide Medicaid applicants and beneficiaries with an opportunity for a fair hearing before the State Medicaid agency in certain circumstances, including for a denial, termination, suspension, or reduction of Medicaid eligibility, or for a denial, termination, suspension, or reduction in benefits or services. These fair hearing rights apply to all Medicaid applicants and beneficiaries, including those receiving HCBS regardless of the delivery system. Under 42 CFR part 438, subpart F, Medicaid managed care plans must have in place an appeal system that allows a Medicaid managed care enrollee to request an appeal, which is a review by the Medicaid managed care plan of an adverse benefit determination issued by the plan; and a grievance system, which allows a Medicaid managed care enrollee to file an expression of dissatisfaction with the plan about any matter other than an adverse benefit determination. Currently, our regulations do not provide for a venue to raise concerns about issues that HCBS beneficiaries in an FFS delivery system may experience which are not subject to the fair hearing process, such as the failure of a provider to comply with the HCBS settings requirements at § 441.301(c)(4) (which are issues that a managed care enrollee could file a grievance with their plan).

Under our authority at section 1902(a)(19) of the Act and section 2402(a)(3)(B)(ii) of the Affordable Care Act, we proposed to require that States establish grievance procedures for Medicaid beneficiaries receiving services under section 1915(c), (i), (j) and (k) authorities through a FFS delivery system. Specifically, for section 1915(c) HCBS waivers, we proposed at § 441.301(c)(7) that States must establish a procedure under which a beneficiary can file a grievance related to the State's or a provider's compliance with the person-centered planning and service plan requirements at §§ 441.301(c)(1) through (3) and the HCBS settings requirements at §§ 441.301(c)(4) through (6). This proposal was based on feedback obtained during various public engagement activities conducted with interested parties over the past several years about the need for beneficiary grievance processes in section 1915(c) waiver programs related to these requirements. We also proposed to apply this requirement to section 1915(i), (j) and (k) authorities, which are discussed below in section II.B.2.h. of this final rule.

To avoid duplication with the grievance requirements at part 438, subpart F, we proposed not to apply this requirement to establish a grievance procedure to managed care delivery systems. We note, though, that the requirements in this section are similar to requirements for managed care grievance requirements found at part 438, subpart F, with any differences reflecting changes appropriate for FFS delivery systems. The proposed requirements included at § 441.301(c)(7) in the proposed rule (88 FR 27975) were focused specifically on grievance systems and did not establish new fair hearing system requirements, as appeals of adverse eligibility, benefit, or service determinations are addressed by existing fair hearing requirements at 42 CFR part 431, subpart E. We solicited comments on any additional changes we should consider in this section with respect to a grievance system.

As discussed earlier in this section II.B.2. of this final rule, section 2402(a)(3)(B)(ii) of the Affordable Care Act requires development and monitoring of an HCBS complaint system. In addition, section 2402(a)(3)(A) of the Affordable Care Act requires the Secretary of HHS to ensure that all States receiving Federal funds for HCBS, including Medicaid HCBS, develop HCBS systems that achieve a more consistent and coordinated approach to the administration of policies and procedures across public programs providing HCBS. As such, we believe the proposed requirement for States to establish grievance procedures for Medicaid beneficiaries receiving HCBS through a FFS delivery system is necessary to comply with the HCBS complaint system requirements at section 2402(a)(3)(B)(ii) of the Affordable Care Act and to ensure consistency in the administration of HCBS between managed care and FFS delivery systems. Further, in the absence of a grievance system requirement for FFS HCBS programs, States may not have established processes and systems for people receiving HCBS through FFS delivery systems to express dissatisfaction with or voice concerns related to States' compliance with the person-centered planning and service plan requirements at § 441.301(c)(1) through (3) and the HCBS settings requirements at § 441.301(c)(4) through (6), as such concerns are not subject to the existing fair hearing process at 42 CFR part 431 subpart E. As a result, we believe the proposal for a grievance system for FFS HCBS programs is necessary to assure that care and services will be provided in a manner that is in the best interests of the beneficiaries, as required by section 1902(a)(19) of the Act.

We specifically focused our proposed grievance system requirement on States' and providers' compliance with the person-centered service plan requirements at § 441.301(c)(1) through (3) and the HCBS settings requirements at § 441.301(c)(4) through (6) because of the critical role that person-centered planning and service plans play in appropriate care delivery for people receiving HCBS. Additionally, we focused the grievance system requirements on the HCBS settings requirements because of the importance of the HCBS settings requirements to ensuring that HCBS beneficiaries have full access to the benefits of community

[56] Section 2402(a) of the Affordable Care Act—Guidance for Implementing Standards for Person-Centered Planning and Self-Direction in Home and Community-Based Services Programs. Accessed at *https://acl.gov/sites/default/files/news%202016-10/2402-a-Guidance.pdf*.

living and are able to receive services in the most integrated setting appropriate to their needs. Beneficiary advocates and other interested parties indicated to us that these are especially important areas for which to ensure that grievance processes are in place for all Medicaid beneficiaries receiving HCBS. Further, focusing the grievance systems requirements on the person-centered service plan requirements at § 441.301(c)(1) through (3) and the HCBS settings requirements at § 441.301(c)(4) through (6) helps to ensure that the proposed grievance requirements do not duplicate or conflict with existing fair hearing requirements at part 431, subpart E, as HCBS settings requirements and person-centered planning requirements are outside the scope of the fair hearing requirements.

At § 441.301(c)(7)(ii), we proposed to define a grievance as an expression of dissatisfaction or complaint related to the State's or a provider's compliance with the person-centered service plan requirements at § 441.301(c)(1) through (3) and the HCBS settings requirements at § 441.301(c)(4) through (6), regardless of whether the beneficiary requests that remedial action be taken to address the area of dissatisfaction or complaint. Also, at § 441.301(a)(7)(ii), we proposed to define the grievance system as the processes the State implements to handle grievances, as well as the processes to collect and track information about them.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters expressed support for our proposal to require that States establish a procedure under which a beneficiary can file a grievance related to the State's or a provider's compliance with the person-centered service plan requirements at §§ 441.301(c)(1) through (3) and the HCBS settings requirements at §§ 441.301(c)(4) through (6). In general, commenters believed that clear, transparent, and accessible grievance processes are critical to ensuring that beneficiaries can address violations of their rights, provide feedback on their experiences in HCBS, and more fully participate in HCBS programs. One commenter noted that a Federal requirement will help establish national best practices.

Some commenters connected a strong grievance process with improved safety and service quality in HCBS programs. For instance, one commenter noted that a grievance process can complement other quality mechanisms (such as performance measures) because a grievance system can address problems as they happen, thus preventing harm before it can occur. Another commenter suggested that preventing or remediating poor service delivery has the potential of improving the HCBS workforce by promoting professionalism and improving the public perception of HCBS providers, which could aid providers' worker recruitment and retention efforts; this commenter noted that a strong workforce would promote quality in HCBS.

Other commenters noted that a grievance system would allow beneficiaries to state their rights and provide a fair and unbiased review of beneficiaries' concerns. Several commenters were specifically supportive of the proposal's potential to collect and track standardized information about service system issues, including obstacles to informed choice and person-centered planning.

A few commenters also described frustrations with current State or provider grievance processes that they have found difficult to access, unresponsive, ineffective, or opaque. One commenter described our proposal as ''overdue,'' but also expressed concerns about whether providers will comply with requirements moving forward. In this vein, a few commenters suggested that CMS involvement and oversight may be critical to ensuring that existing or newly created grievance processes are effective. One commenter expressed the hope that beneficiaries would be able to contact CMS if they believe the State is not complying with grievance process obligations.

Response: We thank commenters for their support. We believe the personal experiences with grievance systems that commenters shared underscore the need for national standards. Additionally, while States will have a great deal of responsibility for developing and monitoring their own systems, having Federal requirements for grievance systems will facilitate our ability to engage in oversight. We note that members of the public are able to share concerns with us about their State's Medicaid activities, which would include the grievance system, once implemented.[57] We also note that in addition to the grievance process finalized under this rule, individuals who believe they have been discriminated against in HCBS programs, including the right to be served in the most integrated setting, may file a civil rights complaint with the HHS Office for Civil Rights at *https://www.hhs.gov/civil-rights/filing-a-complaint/index.html.*

Comment: Several commenters expressed opposition to the proposal, suggesting that it was too prescriptive and would result in unnecessary information technology (IT) systems changes in States that already have grievance systems in place. Several commenters also noted concerns that the proposal would place administrative burdens on providers. Additionally, several commenters noted that this requirement could be administratively burdensome for States with a small percentage of their population enrolled in FFS. One commenter suggested that we provide an exceptions process in these circumstances.

Response: We address specific concerns from commenters—including concerns about potential duplication, burden, and provider involvement—in more detail in subsequent responses. As described below, we are seeking to balance State flexibility with the need for accountability and consistency among State systems. We also do not believe that this proposal should place excessive burdens on providers, as we are requiring that States, and not providers, bear the primary responsibility of managing the grievance system. Finally, as part of our goal of establishing national standards, we do not intend to exempt States from these requirements based on the size of their FFS populations.

Comment: One commenter requested clarification on whether the State or CMS is ''in charge'' of the grievance process.

Response: We have proposed and, as discussed further below, we are finalizing Federal requirements that States operate and maintain a grievance system. The State is responsible for this system. However, we will monitor the States' compliance with these requirements.

Comment: A few commenters raised concerns or expressed confusion about how the proposed grievance system requirement will affect dually eligible beneficiaries who are enrolled in managed care plans that already have grievance processes. One commenter raised concerns about the possibility of multiple investigations being conducted parallel to one another. Other commenters inquired if Medicare Advantage care navigators could be required to help beneficiaries file grievances, or if the proposed grievance system requirements can be made part of dual eligible special needs plan (D–

[57] Specific questions or concerns regarding the application or implementation of the regulations finalized in section II.B. of this rule may be directed to *HCBS_Access_Rule@cms.hhs.gov*.

SNP) contracts. One commenter noted that it is critical for dually eligible beneficiaries to have one place to file grievances about both Medicare and Medicaid services. Another commenter requested clarification on how the grievance systems should work for dually eligible beneficiaries who have, as described by the commenter, ''multiple, perhaps conflicting plans of care.''

Response: We plan to provide States with technical assistance to help address issues specific to dually eligible beneficiaries. We note that we proposed that the grievance system requirements at § 441.301(c)(7), and as finalized in this rule, apply only to beneficiaries receiving services under section 1915(c), (i), (j), and (k) authorities through FFS delivery systems, and to issues arising with these services. The new grievance system requirement would not affect, for instance, dually eligible beneficiaries who receive services under section 1915(c), (i), (j), or (k) authorities through fully integrated dual eligible special needs plans (FIDE SNP), highly integrated dual eligible special needs plans (HIDE SNP), or D–SNPs otherwise affiliated with MLTSS plans, as those beneficiaries receive their HCBS through managed care and not through FFS. We also note that some dually eligible beneficiaries may be enrolled in managed care plans known as applicable integrated plans (AIP), which are subject to the integrated grievance requirements at § 422.630. AIPs must resolve and notify enrollees within required timeframes for integrated grievances filed for Medicare and Medicaid services. We will provide technical assistance as needed regarding the application of the requirements finalized at § 441.301(c)(7) to beneficiaries in different categories of dual eligibility.

Comment: One commenter recommended continuity across grievance systems in FFS and managed care delivery systems to ensure consistent and equitable processes for addressing enrollee concerns.

Response: We agree that such continuity is important. In drafting the proposed requirements at § 441.301(c)(7) for FFS grievance systems, which we are finalizing as described in this section II.B.2 of the final rule, we attempted to mirror the requirements for managed care grievance processes in part 438, subpart F, as much as possible in order to promote consistency between the two systems.

Comment: A few commenters requested that we allow States to arrange for the operations of the grievance procedures to be performed by a vendor, local agencies, or other contracted entity. Conversely, a few other commenters raised concerns about the possibility of the grievance process being administered by providers. Some of these commenters expressed concerns that the requirement might be burdensome for local and regional entities to administer, and one commenter raised concerns that administration of the grievance process by local agencies might cause problems in terms of oversight and conflict of interest.

A few commenters also noted that, unlike in managed care where care is managed under one plan, some FFS delivery systems involve multiple State agencies or agency divisions operating different programs. The commenters requested more clarification about which agency or department is responsible for oversight of the system and coordination in these circumstances.

Response: The requirements proposed, and being finalized, in § 441.301(c)(7) are applied to the State, by which we refer (as we do in many of our regulations) to the single State agency as described in § 431.10(b). However, we believe that some States may find it more efficient or effective to have the operations of the grievance system performed by other government agencies or contractors, depending on how a State's systems are organized. Allowing such contracting may also help preserve existing State grievance processes; we address additional comments about preservation of existing grievance systems later in this section II.B.2. of the final rule. However, the single State agency must retain ultimate responsibility for ensuring compliance with the requirements set forth in § 441.301(c)(7). We expect that States are familiar with their local resources (including the capacity of local agencies) and would only have the operations of the grievance system performed by an entity that had the necessary infrastructure and resources to operate a system that would comply with the requirements in § 441.301(c)(7). To ensure that the responsibility of the single State agency is clear, we are finalizing § 441.301(c)(7)(i) with a modification to specify that the State may contract with contractors or other government entities to perform activities described in § 441.301(c)(7) provided however that the State retains responsibility for ensuring performance of and compliance with these provisions.

We also note that we intend that the proposed requirements at § 441.301(c)(7)(iii)(C)(3), which we are finalizing as discussed in detail later in this section II.B.2. of the final rule, promote an unbiased review of grievances because they prohibit someone who has previously made decisions related to the grievance from reviewing the grievance. While we do not intend to specify any additional restrictions on the entities operating the grievance system in this final rule, we believe that it would be difficult to envision scenarios in which it would be appropriate for the State to contract with a provider (or local agencies that act as providers) to operate the grievance system. For example, an employee of a provider who signed off on the provider's actions that gave rise to the grievance would be someone who was involved with making a decision about the grievance and thus neither that employee (nor their subordinates) would be appropriate decisionmakers in the grievance process. If a State believed it necessary to arrange for the operations of the grievance system to be performed by a local agency that also provided services, firewalls would have to be put in place to ensure that grievances were reviewed by a neutral decisionmaker within that agency.

Comment: Several commenters supported the definition of grievance we proposed at § 441.301(c)(7)(ii). Overall, these commenters supported the focus on compliance with the person-centered planning process and the HCBS settings rule. One of these commenters observed that issues with these requirements are often at the core of challenges experienced by beneficiaries. One commenter, however, questioned the inclusion of concerns about the HCBS settings requirements, noting that if a setting violates the HCBS settings requirements, the individual has the choice of moving to a different setting.

Response: We appreciate commenters' support for the definition of grievances. We specifically included noncompliance with the HCBS settings requirements as one of the bases for grievances so that beneficiaries do not have the burden of addressing violations of their rights by having to change providers, which could result in some circumstances in having to move out of their home. We do not believe that beneficiaries should have to choose between their rights or their homes. As a practical matter, switching residences can be disruptive, emotionally and physically demanding, costly, and time-intensive, not to mention particularly difficult in areas that lack plentiful affordable and accessible housing options. We also believe that requiring States to address these issues related to

compliance with HCBS settings requirements in the context of a grievance system may encourage States and providers to prevent similar issues from occurring with other beneficiaries.

Comment: One commenter stated that the definition of grievance was too broad and requested that CMS narrow the scope of allowable grievances. The commenter stated that although the proposed requirements limit the grievance system to person-centered planning, service plan requirements, and HCBS settings requirements, they would still allow a beneficiary to file a grievance on nearly every aspect of their HCBS experience, which would in turn create the potential for an unreasonably high volume of grievances to which States would be required to respond.

A few commenters stated that the definition of grievance was subjective, and asked for general clarification on what is meant by an ''expression of dissatisfaction.'' Conversely, a few commenters stated the definition of grievance was not broad enough. One commenter stated that the reference to §§ 441.301(c)(1) through (3) would only allow for the filing of grievances in relation to the person-centered planning process but would not allow for grievances in relation to beneficiaries' dissatisfaction with the delivery of the services in the plan. The commenter provided examples, such as a care provider handling an HCBS beneficiary roughly, failing to assist the beneficiary with certain activities of daily living or perform other services in the care plan, being slow to respond to the beneficiary's requests for assistance in residential settings, improper administration of chemical restraints, or general poor care that leads to injuries such as bed sores. The commenter recommended that the regulatory language be revised to include the right to file a grievance to protect beneficiary health and welfare.

One commenter suggested that we specify that grievances may include issues regarding timeliness, quality, and effectiveness of services, in addition to the HCBS setting, person-centered planning, and service plan requirements. The commenter noted that, in the commenter's State, beneficiaries have had to wait for long periods of time for the initiation of services after being approved for the services.

Finally, another commenter noted that they believed that the managed care regulations' grievance definition includes an expression of dissatisfaction about any matter other than an adverse benefit determination and recommended adding clarifying language to the definition of a grievance to ensure that beneficiaries do not mistakenly file grievances about issues that are adverse benefit decisions and that entitle them to a fair hearing.

Response: We disagree with commenters that the proposed definition is overly broad. The definition of grievance proposed at § 441.301(c)(7)(ii) was crafted to strike a balance between providing beneficiaries with broad, but not unlimited, bases for filing a grievance. We believe that the requirements in §§ 441.301(c)(1) through (6) provide a clear list of activities that the States and providers must perform to ensure that HCBS beneficiaries receive appropriate person-centered planning, receive the services described in the person-centered service plan to support the individual in the community, and have full access to the benefits of community living and are able to receive services in the most integrated setting appropriate to their needs.[58] We note that some specific examples of when a beneficiary may express dissatisfaction by filing a grievance are discussed further in this section.

We also disagree that the scope of the definition is too narrow. We proposed that the definition of grievance include an expression of dissatisfaction or complaint related to the State's or provider's compliance with the person-centered service planning process, required in §§ 441.301(c)(1) through (3). We note that some issues regarding the timeliness, quality, or effectiveness of services may need to be addressed as part of the person-centered service planning process itself. For instance, if a beneficiary believes the service is not effective, the beneficiary may request revision to the person-centered service plan, as required at § 441.301(c)(3), to identify either a more effective service or a more effective provider; non-responsiveness on the part of the entity responsible for updating the service plan could be a reason to file a grievance.

Additionally, § 441.301(c)(4) requires that home and community-based settings must meet certain requirements enumerated therein, including (but not limited to): being integrated in and supporting full access of individuals to community life; ensuring that an individual has rights to privacy, dignity and respect, and freedom from coercion and restraint; optimizing an individual's initiative, autonomy, and independence in daily activities and the physical environment; and facilitating an individual's choice in services and supports, as well as who provides them. If, for instance, a beneficiary believes that a worker has not treated the beneficiary with respect, or the worker is chronically late, and the provider has failed to address the worker's behavior or provide a different worker at the beneficiary's request, it would be reasonable for a beneficiary to file a grievance, as the provider is not ensuring that all of the qualities of a home and community-based setting (as described by § 441.301(c)(4)) are being met. Accordingly, we believe that the activities set forth in §§ 441.301(c)(1) through (6) (both currently and as are being amended in this final rule) generally describe the actions of both providers and States that are necessary to uphold and promote high-quality service delivery that promotes respect for beneficiaries' rights.

While we believe the scope of grievances that may be considered under the grievance system that we proposed, and are finalizing, appropriately captures activities that promote delivery of quality HCBS and respect for beneficiaries' rights, we do believe further clarity is warranted. We believe it is more appropriate and precise to say grievances may be filed regarding the State's or a provider's performance of (rather than compliance with) the requirements described in §§ 441.301(c)(1) through (6). We note that the activities described in § 441.301(c)(1) through (6) must, as required at § 441.301(c), be included in a State's waiver application; we want to make it clear that grievances may be filed when a State or provider fails to perform these activities (not solely if the State fails to include these items in a waiver application). To clarify this point, we are finalizing the scope of grievances that may be filed under the grievance system we proposed to set forth at § 441.301(c)(7) with modification, by revising the language in § 441.301(c)(7)(i) to specify that beneficiaries may file grievances regarding a State's or provider's performance of (rather than compliance with) the activities described in §§ 441.301(c)(1) through (6). We are finalizing a conforming modification to the definition of grievance at § 441.301(c)(7)(ii).

We observe that most of the examples provided by commenters, as described above, included instances in which a beneficiary experienced abuse or harm during the performance (or lack thereof) of services in the person-centered service plan. These types of complaints

[58] We note that compliance with CMS regulations and reporting requirements does not imply that a State has complied with the integration mandate of Title II of the ADA, as interpreted by the Supreme Court in the Olmstead Decision.

may be more appropriately addressed under the critical incident system being finalized at § 441.302(a)(6). As discussed in II.B.3. of this rule, we believe the critical incident system proposed at § 441.302(a)(6) is the appropriate mechanism for investigating harms to beneficiaries' health and safety. As we discuss in II.B.3 of this rule, we proposed additional performance measures and reporting requirements for the critical incident system (beyond what is proposed for the grievance system) to ensure more formal oversight of the investigations and resolutions of threats to beneficiary health and safety. We do not believe a grievance system is an appropriate mechanism for investigating threats to the beneficiary's health and welfare. Therefore, we decline to broaden the definition of grievances that may be addressed under the grievance system we are finalizing at § 441.301(c)(7) in such a way that would suggest that the grievance system is intended for complaints regarding health and safety. We believe doing so would create duplicative system requirements for the grievance process and critical incident system and potentially cause States to resolve threats to health and safety in the grievance system that should have been investigated and addressed within the critical incident system.

We also disagree with the commenter that suggested we align the definition of grievance we proposed at § 441.301(c)(7)(ii) with the definition of grievance for managed care grievance processes at § 438.400(b). We believe that, for the purposes of a FFS grievance system intended to address specific concerns with HCBS, using the same or similar definition of grievance for managed care grievance processes would be overly broad and will not diminish confusion about whether an issue is appropriate to be filed as a grievance, a critical incident, or a fair hearing. We plan to provide technical assistance to States as needed on this topic.

We refer readers to section II.B.2.b. of this final rule where we also address more specific concerns related to ensuring matters are filed with the correct system in our discussion of § 441.301(c)(7)(iii).

Comment: One commenter suggested that we broaden the definition of grievance to specify that beneficiaries can file grievances when their rights are violated, and suggested that the following be included in the definition of rights:

- Right to work and fair pay;
- Right to control one's own money;
- Right of possessions and ownership;
- Right to privacy, dignity, and respect;
- Freedom of choice and decision-making;
- Right to leisure activities;
- Freedom to marry and have children;
- Right to food, shelter, and clothing;
- Freedom of movement;
- Freedom of religion;
- Freedom of speech and expression;
- Free association and assembly;
- Freedom from harm;
- Access to health care;
- Right to citizenship and right to vote;
- Right to equal education;
- Right to equal access; and
- Due process.

Response: We believe that some of the consumer rights listed by the commenter are addressed in or mirrored by components of the existing HCBS settings rule requirements at § 441.301(c)(4), such as: ensuring that the individuals have access to the greater community, including engagement in community life, opportunities for employment in competitive integrated settings, and control over personal resources (§ 441.301(c)(4)(i)); the right to privacy, dignity and respect, and freedom from coercion and restraint (§ 441.301(c)(4)(ii)); allowing for individuals to choose their activities and set their own schedules (§ 441.301(c)(4)(iv) and (vi)(C)); the ability to determine with whom the individual will interact, as well as to have visitors of the individual's choosing at any time (§ 441.301(c)(4)(iv) and (vi)(D)); and control over the individual's own physical environment, living and sleeping space, and access to food (§ 441.301(c)(4)(iv), (v)(B), and (vi)(C)).

We note that many of the other rights suggested by the commenter are either addressed by other systems (such as access to health care which, if related to an adverse benefit determination made by the State Medicaid agency, may be subject to the fair hearings process or are out of scope of the State Medicaid agency's authority) or by other authorities (such as fair wages, equal access to education, or violations of constitutional rights).

Comment: Several commenters requested that the grievance process include issues such as authorization disputes and the provision of services.

Response: We are not certain if the commenters are referring to using the grievance system to allow beneficiaries or providers to challenge denials of services. We are also uncertain if disputes over ''provision of services'' refers to the quantity or quality of services. We note that the fair hearings process at 42 CFR part 431, subpart E, sets out the parameters that allow beneficiaries to challenge an adverse action by the State Medicaid agency. For the purposes of a fair hearing, an ''action'' is defined at § 431.201 in part, as the termination, suspension of, or reduction in covered benefits or services, or a termination, suspension of, or reduction in Medicaid eligibility. A State must provide an individual the opportunity for a fair hearing in the circumstances described in § 431.220(a), which include when the Medicaid agency has denied eligibility, services, or benefits, and when the claim for medical assistance has not been acted on with reasonable promptness. In most circumstances, a refusal of a State Medicaid agency to authorize a particular service for a beneficiary, or to authorize the quantity of services the beneficiary believes is necessary, would be addressed in the fair hearings process. In contrast, the grievance process we have proposed is intended to allow beneficiaries to raise concerns about specific aspects of their services that have been authorized.

Comment: Several commenters who supported this proposal did so because they agreed that, currently, concerns regarding person-centered planning and HCBS settings requirements are not subject to the existing fair hearings process at 42 CFR part 431 subpart E. One commenter, however, suggested that, rather than create a grievance process to hear complaints about person-centered service plans and the HCBS settings requirements, we should require that concerns about person-centered service plans or the HCBS settings requirements be added to fair hearings processes. The commenter stated the belief that fair hearings permit an unbiased third-party Administrative Law Judge (ALJ) to consider the facts and render an objective decision. By contrast, the commenter believed that, in their State, the current State grievance process did not permit unbiased or effective review.

Response: We agree that it is important to provide beneficiaries with the opportunity to raise concerns about the person-centered service plans and planning process and the HCBS settings requirements. We do not, however, believe that these are necessarily appropriate matters for the fair hearings process. The authority for the fair hearings process comes from section 1902(a)(3) of the Act, which requires that States provide beneficiaries and

applicants an opportunity for a fair hearing before the State agency to any individual whose claim for medical assistance is denied or is not acted upon with reasonable promptness.

While beneficiaries can request a fair hearing to address concerns about service denials (including partial denials) and other concerns described under § 431.220(a), we believe that an individual's concerns about person-centered service plans, the planning process, and HCBS settings are outside the scope of issues for which the statute requires that a fair hearing be provided, and therefore we cannot require States to provide an opportunity for a fair hearing to address such issues. We note, however, that States have discretion to decide whether integrating their grievance processes with other State systems, including their fair hearings systems, is feasible and appropriate, and that the requirements for both systems may still be met.

Separate from the fair hearing requirement at section 1902(a)(3) of the Act, section 2402(a)(3)(B)(ii) of the Affordable Care Act requires the development and monitoring of an HCBS complaint system. To address this statutory requirement, we proposed that the grievance system address matters that do not arise from a denial of Medicaid eligibility or denial of services, or failure to act upon the individual's claim for medical assistance with reasonable promptness, which are addressed separately under the required fair hearing process. We expect the grievance system will help beneficiaries resolve concerns about the quality of the services they are receiving. We also note that the purpose of our proposals in this section II.B.2. is to require that States create, implement, and maintain grievance systems that, while not necessarily as formal as a fair hearings process in all cases, will nevertheless result in unbiased and effective reviews of grievances.

We note that, while States may choose to use ALJs as hearing officers to conduct a Medicaid fair hearing, hearing officers are not required to be ALJs. Medicaid regulations at § 431.240(a)(3) require that all fair hearings be conducted by one or more impartial officials or other individuals who were not directly involved in the initial determination in question. We also note that the proposed requirements at § 441.301(c)(7)(iii)(C)(3), which we are finalizing as discussed in detail later in this section II.B.2. of the final rule, are intended to promote an unbiased review of grievances because they prohibit someone who has previously made decisions related to the grievance from reviewing the grievance.

Comment: A few commenters expressed concerns that, in States that already have grievance systems, the proposed requirements could result in duplication of processes and confusion for beneficiaries about where and how to report grievances. Several of these commenters requested we allow States to use existing grievance systems to meet the Federal requirement. One commenter also suggested that if the State's existing system meets our proposed criteria, the State should be considered in compliance with the requirements. Another commenter suggested that providers or States with existing grievance systems should not have to modify their systems.

Commenters were especially concerned about the impact on States that already had multiple grievance systems for different programs, administered by different operating agencies. These commenters requested that we allow States flexibility to design grievance systems and processes to fit their unique program and systems structures and implement multiple grievance systems or processes tailored to their programs. One commenter raised specific concerns about having to consolidate current grievance systems into a single electronic system.

One commenter, however, requested that we require States to have a single grievance system; the commenter stated that having multiple grievance processes can be confusing and burdensome for beneficiaries.

Response: We acknowledge that many States already have grievance processes in place for HCBS, and it is not our intent for States to abandon these systems or create additional systems. We agree with the suggestion that, if a State already has a grievance process in place that meets the requirements that we are finalizing in this rule, that State will be considered in compliance with these requirements. However, we disagree that States with existing grievance systems should be allowed to maintain the system without modification where their systems do not meet Federal requirements. While we encourage States to economize by maintaining current systems as much as possible, we do expect that States will make any needed adjustments to bring their systems into compliance with the requirements we are finalizing in this rule. We believe that having Federal requirements for grievance systems will promote consistency and accountability across the country.

Additionally, we note that the definition of grievance system that we proposed referred to ''processes,'' suggesting that a grievance system may be made up of one or more processes (88 FR 28080). If a State wishes to maintain multiple grievance processes, and each of these processes comply with the Federal requirements we are finalizing in this rule, the State will be considered in compliance.

We did not propose a requirement for a State to maintain a single electronic system for their grievance system and, as discussed above, believe it would be acceptable to maintain multiple grievance processes. However, we also emphasize that part of the definition of grievance system we proposed, and are finalizing, in § 441.307(c)(7)(ii) is that the system allows States to collect and track information about grievances. If States choose to maintain separate systems, including separate electronic systems, they must develop ways to ensure that they are able to track trends across systems in meaningful ways. We refer readers to section II.B.2.f of this final rule, where we discuss our proposals related to recordkeeping requirements for the required grievance system.

Although not required, we encourage States to implement a single integrated system across their HCBS programs, as we echo one commenter's concerns that a single integrated system would likely reduce confusion for beneficiaries and facilitate their ability to access the system. We also believe that a single system would best permit States to track trends across their HCBS programs and use the data and information generated by the grievance system to address systemic issues in their HCBS programs. Additionally, a single integrated system may be more cost-effective for States to operate once implemented.

Comment: One commenter requested clarification on whether there is a difference between a complaint and a grievance, as well as what would elevate a complaint to the level of a grievance.

One commenter asked for clarification on the role of conflict-free case managers in the grievance system.

Response: While section 2402(a)(3)(B)(ii) requires that we promulgate regulations to ensure that all States develop service systems that include development and monitoring of a complaint system, the Affordable Care Act does not define the terms complaint or complaint system. In developing our proposal to implement this requirement from the Affordable Care Act, we have chosen to use the term grievance, instead of complaint, and proposed to define grievance and grievance system at § 441.301(c)(7)(ii). If a State has implemented a system it calls a

complaint system that meets the requirements we proposed, and are finalizing, at § 441.301(c)(7), it is possible that this system could satisfy the requirement for a State to have a grievance system.

We do not understand the specific nature of the comment regarding conflict-free case managers. We note, in general, that we will provide technical assistance to States to assist in adapting their HCBS programs and any associated existing grievance processes to comply with the requirements finalized at § 441.301(c)(7).

Comment: Several commenters observed that some States currently require providers to have policies and procedures in place related to service-delivery complaints. One commenter requested that we provide clarification, either in the final rule or subregulatory guidance, regarding the inclusion of the proposed grievance system requirements in existing provider-level complaint and grievance processes. Commenters stated that additional guidance is needed to help all interested parties understand when beneficiaries should file a grievance with their provider and when they should file with the State. One commenter recommended that beneficiaries be required to exhaust these processes at the provider level before a complaint is submitted to the State agency for investigation or intervention.

Response: Our goal for proposing uniform requirements for grievance systems applicable to all States providing HCBS under section 1915(c) waiver program authority, and other HCBS authorities as discussed in section II.B.2.h of this final rule, is to ensure consistent processes are available for Medicaid beneficiaries receiving such services. We decline to require in this final rule that beneficiaries exhaust their provider-level complaint process prior to accessing the State grievance system. We believe that such a Federal requirement would be inapplicable or confusing in States that do not have provider-level complaint process requirements, do not require all providers to have them, or do not require that providers have uniform complaint processes. We have attempted to provide States with as much flexibility as possible in the design of their grievance system. Additionally, we have concerns that such an exhaustion requirement would be a barrier, or would cause unnecessary delay, for beneficiaries where the relationship between the beneficiary and the provider is contentious, or where the provider does not have an effective or efficient complaint process.

Comment: Commenters requested that grievance processes be developed with input from providers, beneficiaries, families, and advocacy groups to create a grievance system that is accessible, practical, and sets realistic expectations for its users.

Response: We have attempted to provide States with as much flexibility as possible in the design of their grievance system and decline to add a specific requirement on this point in this final rule. We encourage States to include input from interested parties when developing their grievance system policies and procedures to comply with the requirements we are finalizing in this rule.

Comment: Several commenters suggested that the grievance system be integrated with the critical incident system. One commenter stated that States should be required to enter the grievance information and data into a State database with standardized fields that is either part of, or integrated with an incident management system, so that grievance data can be compared to data on relevant individuals, providers, and incidents (both reported and unreported). Similarly, a few commenters suggested that the grievance system should be integrated with the fair hearings system in States.

Response: While we agree that States may find it useful to have a single, integrated system for grievances, critical incidents, and fair hearings, we are not requiring in this final rule that States do so. We believe it is important for States to have flexibility in how they design their grievance systems so that they may expand on infrastructures and processes they already have in place and tailor the grievance systems to meet their programmatic and operational needs, even as they are held to standardized Federal grievance system requirements.

After consideration of the comments received, we are finalizing the language at § 441.301(c)(7)(i) and (ii) with modifications. For the reasons discussed above, we are modifying § 441.301(c)(7)(i) to include language specifying the State may have activities described in paragraph (c)(7) of this section performed by contractors or other government entities, provided, however, that the State retains responsibility for ensuring performance of and compliance with these provisions. Additionally, we are finalizing § 441.301(c)(7)(i) and the definition of grievance in § 441.301(c)(7)(ii) with the modification that States must establish a procedure under which a beneficiary can file a grievance related to the State's or a provider's *performance of* (rather than compliance with) the person-centered planning and service plan requirements at §§ 441.301(c)(1) through (3) and the HCBS settings requirements at §§ 441.301(c)(4) through (6). We are otherwise finalizing the definition of grievance system at § 441.301(c)(7)(ii) as proposed.

b. Grievance Process Requirements (§ 441.301(c)(7)(iii))

At § 441.301(c)(7)(iii)(A) through (C), we proposed new general requirements for States' grievance procedures for section 1915(c) HCBS waiver programs and other HCBS authorities as discussed in section II.B.2.h of this final rule. Specifically, at § 441.301(c)(7)(iii)(A), we proposed to require that a beneficiary or authorized representative be permitted to file a grievance under the section 1915(c) HCBS waiver program. As discussed below in section II.B.2.h. of this final rule, we also proposed to apply these same requirements to section 1915(i), (j) and (k) HCBS programs. Under the proposal, another individual or entity may file a grievance on a beneficiary's behalf, so long as the beneficiary or authorized representative provides written consent. We noted that our proposal would not permit a provider to file a grievance that would violate conflict of interest guidelines, which States are required to have in place under § 441.540(a)(5). At § 441.301(c)(7)(iii)(A), we also proposed to specify that all references to beneficiary in the regulatory text of this section includes the beneficiary's representative, if applicable.

At § 441.301(c)(7)(iii)(B)(1) through (7), we proposed to require States to:

- Have written policies and procedures for their grievance processes that at a minimum meet the requirements of this proposed section and serve as the basis for the State's grievance process;
- Provide beneficiaries with reasonable assistance in completing the forms and procedural steps related to grievances and to ensure that the grievance system is consistent with the availability and accessibility requirements at § 435.905(b);
- Ensure that punitive action is not threatened or taken against an individual filing a grievance;
- Accept grievances, requests for expedited resolution of grievances, and requests for extensions of timeframes from beneficiaries;
- Provide beneficiaries with notices and other information related to the grievance system, including information on their rights under the grievance

system and on how to file grievance, and ensure that such information is accessible for individuals with disabilities and individuals who are limited English proficient in accordance with § 435.905(b);

- Review grievance resolutions with which beneficiaries are dissatisfied; and
- Provide information on the grievance system to providers and subcontractors approved to deliver services under section 1915(c) of the Act.

At § 441.301(c)(7)(iii)(C)(1) through (6),[59] we proposed to require that the processes for handling grievances must:

- Allow beneficiaries to file a grievance either orally or in writing;
- Acknowledge receipt of each grievance;
- Ensure that decisions on grievances are not made by anyone previously involved in review or decision-making related to the problem or issue for which the beneficiary has filed a grievance or a subordinate of such an individual, are made by individuals with appropriate expertise, and are made by individuals who consider all of the information submitted by the beneficiary related to the grievance;
- Provide beneficiaries with a reasonable opportunity, face-to-face (including through the use of audio or video technology) and in writing, to present evidence and testimony and make legal and factual arguments related to their grievance;
- Provide beneficiaries, free of charge and in advance of resolution timeframes, with their own case files and any new or additional evidence used or generated by the State related to the grievance; and
- Provide beneficiaries, free of charge, with language services, including written translation and interpreter services in accordance with § 435.905(b), to support their participation in grievance processes and their use of the grievance system.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposal at § 441.301(c)(7)(iii)(A) to require that a beneficiary or the beneficiary's authorized representative be permitted to file a grievance, including allowing another individual or entity to file a grievance on a beneficiary's behalf, with written consent from the beneficiary or the beneficiary's authorized representative.

However, several commenters raised concerns about the proposed requirement that beneficiaries or their authorized representatives must provide written consent to another individual or entity to file a grievance on the beneficiary's behalf. A few commenters noted that some beneficiaries may not be able to give written consent, or that waiting for written consent to be obtained could create unnecessary delays in grievance filings and investigations. One commenter suggested that we either remove the word ''written'' or specify that consent may be verbal or written. Another commenter, using their State as an example, suggested that a grievance could be filed with verbal consent from the beneficiary or authorized representative, with written consent obtained later. One commenter suggested an agency could obtain a beneficiary or authorized representative's consent over the phone to allow another individual or entity to file a grievance on the beneficiary's behalf.

Response: As discussed further herein, we are finalizing the requirement that consent must be written as proposed. We modelled the proposed requirement and language at § 441.301(c)(7)(iii)(A) on requirements for the managed care grievance process at § 438.402(c)(1)(ii), which provides that, if State law permits and with the written consent of the enrollee, a provider or an authorized representative may request an appeal or file a grievance, or request a State fair hearing, on behalf of a managed care enrollee. Our general intent is to align the FFS grievance system and managed care grievance process to the greatest extent possible. We also believe it is important to ensure that there is some documentation demonstrating that beneficiaries or their authorized representatives have provided consent for a grievance to be filed on the beneficiary's behalf, especially as the investigation of a grievance may involve reviewing records pertaining to the beneficiary's care.

We note that written consent may be broadly interpreted to include electronic signatures, voice signatures, or other methods that provide reasonable accommodations to individuals who might face challenges providing traditional written signatures. States will have flexibility in determining how written consent is obtained and verified, so long as the system States develop ensures that the process presents as few administrative barriers as possible for a beneficiary or authorized representative to provide the necessary consent.

Comment: Several commenters recommended that we clarify that beneficiaries be able to choose who represents them throughout the grievance process. One commenter recommended that the grievance process should provide the beneficiary with the opportunity to indicate who they want to assist them in the process, and this should serve as a type of release.

Response: It was our intent that beneficiaries and their authorized representatives be able to involve other individuals or entities of their choosing to assist them throughout the grievance process, in addition to filing a grievance. We believe that it is logical to assume that if a beneficiary or their authorized representative needs assistance filing a grievance, they may also need assistance with other parts of the process (such as requesting and reviewing their case file, or presenting information to support their concerns at a hearing). We also note that while States are required at § 441.301(c)(7)(iii)(B)(*2*) to provide beneficiaries with reasonable assistance in completing forms and taking other procedural steps related to a grievance, beneficiaries may prefer to get this assistance from an individual or entity of their own choosing, particularly in situations where the beneficiary has filed a grievance against the State. To clarify this intent, we are finalizing § 441.301(c)(7)(iii)(A)(*1*) with a modification to specify that another individual or entity may file a grievance on behalf of the beneficiary, or provide the beneficiary with assistance or representation throughout the grievance process, with the written consent of the beneficiary or authorized representative. We note that we expect that, as part of ensuring the process is person-centered, beneficiaries or their authorized representatives will be able to withdraw consent for this third-party representation at any time, and that beneficiaries can generally terminate the grievance process at any time.

We are finalizing § 441.301(c)(7)(iii)(B)*(1)* with a modification to correct an erroneous reference to subchapter in the regulatory language and replace subchapter with paragraph (c)(7).

Comment: Several commenters requested clarifications or made suggestions regarding our proposal at § 441.301(c)(7)(iii)(B)(2) to require that States provide beneficiaries reasonable assistance in completing forms and taking other procedural steps related to a grievance. One commenter

[59] At 88 FR 27976, we incorrectly stated that we were proposing these requirements at § 441.301(c)(7)(iii)(C)(*1*) through (*5*), rather than (*1*) through (*6*). This typo has been corrected.

recommended that we set minimum criteria for reasonable assistance in filing a grievance, including but not limited to the State making someone available to meet with the beneficiary in person. Another commenter observed that many individuals who receive section 1915(c) waiver services, for example, have significant intellectual and developmental disabilities and as a result may need substantially more assistance than other beneficiaries to complete forms and procedural steps. The commenter requested clarification as to whether, in these circumstances, the reasonable threshold is determined by the needs of the beneficiary or the burden is on the State to determine how to provide reasonable assistance.

Response: We disagree that the term reasonable assistance that we proposed at § 441.301(c)(7)(iii)(B)(*2*) is unclear. We intentionally proposed language that would require States to determine, on a case-by-case basis, what constitutes reasonable assistance for beneficiaries utilizing the grievance system. Reasonable assistance may vary among beneficiaries and thus we intended to provide States with flexibility in determining what assistance is reasonable to provide. We decline to include additional formal definitions or criteria for the term reasonable assistance in this final rule lest we inadvertently set rigid standards that would, counterproductively, inhibit States from modifying processes for beneficiaries. For instance, if we were to require that States make someone available to meet with the beneficiary in person, we would not want this misinterpreted as a requirement that grievances may only be filed in person, which could pose significant barriers to individuals who lack transportation or live far from the physical locations in which grievances could be filed, even though we recognize that some beneficiaries may prefer to file a grievance in person.

We agree with the commenter that some beneficiaries may need more assistance, or different types of assistance, than other beneficiaries. We decline, however, to weigh in on what would be the threshold for determining reasonableness, as this appears to be a request for an opinion on hypothetical situations. We note that the concept of reasonableness is central to many areas of law and bodies of guidance regarding reasonableness are well-developed. We also note that the grievance system in general, by virtue of being administered by State Medicaid programs, will be subject to Title II of the Americans with Disabilities Act (ADA) of 1990, and section 504 of the Rehabilitation Act of 1973 (section 504), which may provide some specific guidance for what may be considered a reasonable modification in a government service.

Comment: A number of commenters advocated for the creation of a requirement for an HCBS Ombudsman program, similar to those required by the Older Americans Act. Many commenters noted an independent ombuds program could provide more effective assistance to individuals in filing grievances, helping them navigate the process, and representing them during the proceedings, rather than relying on assistance provided by the State.

Response: We thank commenters for their interest in this issue. As commenters noted, Title VII of the Older American Act authorizes and provides Federal funding for the national Long-Term Care Ombudsman Program, which is administered at the State level. These programs provide advocacy on behalf of residents of long-term care facilities. While there is no similar Federal statutory requirement for States to create an HCBS ombuds program, States may create such a program or similar programs at their own discretion to assist during grievance processes or to provide other advocacy supports.

Comment: Several commenters expressed concerns that it will be challenging for beneficiaries to understand when and how to file grievances. Several commenters noted the possibility that beneficiaries will be confused by the grievance and fair hearings processes and will file grievances or appeals with the wrong entities. One commenter suggested that beneficiaries enrolled in managed care for some medical services but receive FFS HCBS may be confused when presented with multiple grievance processes.

A number of commenters recommended that the grievance system should be set up with a ''no wrong door'' process so that, for example, a managed care plan receiving a grievance related to a FFS service would be responsible for forwarding the grievance to the appropriate entity. Similarly, another commenter suggested that if an enrollee mistakenly files a grievance about an adverse benefit determination, we require that this submission be treated as a fair hearing request unless the beneficiary objects. One commenter cautioned that, based on the commenter's experience, creating a ''no wrong door'' approach to grievances can be complicated and resource intensive. Another commenter requested that, if setting up a ''no wrong door'' approach, we ensure that the burden does not fall entirely on local entities, such as local Area Agencies on Aging.

One commenter requested clarification on whether appropriate referral of a grievance to the critical incident management process will count as a successful resolution of the grievance.

Response: We take very seriously the concerns raised by commenters regarding potential confusion among beneficiaries about which matters should be filed with which system. Our understanding of the commenters' suggestions is that such system should be coordinated for accepting grievances, fair hearing requests, and reports of critical incidents, among other engagements with beneficiaries, and ensure that each grievance, fair hearing request, or report of a critical incident is appropriately and seamlessly processed once it has been received by that system. However, we are not adding a formal ''no wrong door'' requirement in this final rule. Rather, we are finalizing the grievance system requirements we proposed with modifications as described below. We understand that, despite efforts to provide beneficiaries and interested parties with information and to make systems as user-friendly as possible, there will be instances in which beneficiaries attempt to access the ''wrong'' system. Additionally, there may be some matters where it is not immediately clear to the beneficiary if the problem, for instance, is a matter for the grievance system, critical incident investigation, or the fair hearings process. We also note that the beneficiary (or someone on their behalf) may report a critical incident (as defined at § 441.302(a)(6) of this final rule), or file an appeal under the fair hearings process that may not, as a whole, meet the definition of a grievance, but may contain elements that are more appropriate for consideration under the grievance system, while the remaining elements should still proceed as a critical incident investigation or in the fair hearing process. (We note that additional concerns about perceived overlap between grievances and critical incidents are addressed more fully later in this section.) Further, we agree that something akin to a ''no wrong door'' approach may be a good solution, to ensure that matters that are brought to the grievance system are not rejected because they are really a matter for a fair hearing or critical incident investigation. We encourage States to create a ''no wrong door'' policy and system or integrate grievance filings with existing ''no wrong door'' systems,

if feasible. We believe that such a system would help ensure that matters are filed correctly, which could reduce administrative burden on the grievance system.

However, we did not propose, nor are we requiring, that States create a ''no wrong door'' system. We note that some States may already have ''no wrong door'' systems that could be used to support beneficiary filings in the grievance system. While we encourage States that do not have such ''no wrong door'' systems to consider developing them, we recognize that there is variety among State systems and we do not wish to create a potentially rigid requirement that misaligns with States' existing infrastructures. We also want to ensure that the grievance process requirements finalized in this section focus on standardizing the grievance process itself, and are concerned that an attempt to further standardize ancillary processes would distract from this intention. We will take commenters' suggestions regarding ''no wrong door'' systems under consideration for potential future policy development or rulemaking.

While we are not requiring States develop a ''no wrong door'' system, we do take seriously commenters' concerns that beneficiaries may attempt to file grievances with other systems operated by the State. We proposed a requirement at § 441.301(c)(7)(iii)(B)(*2*) that States must provide reasonable assistance to beneficiaries both with filing grievances and completing other procedural steps; we believe it is logical to expect that if a beneficiary needs reasonable assistance from the State for the procedural steps, then they may need assistance with determining where to file their grievance in the first place. To better address the concern about potential beneficiary confusion about the grievance, incident management, fair hearings, and managed care grievance and appeal systems, we are modifying the language in § 441.301(c)(7)(iii)(B)(*2*) to indicate more clearly that States must provide reasonable assistance to ensure that grievances are appropriately filed with the grievance system (in other words, that States help beneficiaries identify whether their concern should be filed in the grievance system and, to the greatest extent possible, redirect grievances filed with other State systems to the grievance system).

Additionally, we note that the disposition of matters that are not grievances is outside the scope of the grievance process requirements at § 441.301(c)(7) finalized in this section regarding the grievance system; however, we strongly encourage States to ensure that grievances filed with the grievance system that contain matters that are appropriate for other systems, including the critical incident system (as finalized in section II.B.3. of this rule), the fair hearings system (as described in part 431, subpart E), or the managed care grievance or appeal system (as described in part 438, subpart F) are also considered filings with the appropriate system or systems in accordance with the requirements and timeframes for those systems.

We also remind States that States have the option under current regulations to assist beneficiaries with filing fair hearing requests (as described in part 431, subpart E). Section 431.221(c) provides that State Medicaid agencies may assist applicants or beneficiaries in submitting fair hearings requests and section 2901.3 of the State Medicaid Manual instructs States to make every effort to assist applicants and beneficiaries to exercise their appeal rights. Additionally, section 2902.1 of the State Medicaid Manual states that oral inquiries about the opportunity to appeal should be treated as an appeal for purposes of establishing the earliest possible date for an appeal. Thus, if a beneficiary submits a matter to the grievance system which the State recognizes as a matter more appropriate for a fair hearing, the State should treat this matter in accordance with the requirements of § 431.221(c) and the State Medicaid Manual by assisting the beneficiary with filing a fair hearing request and using the grievance submission date to establish the earliest possible submission date for the fair hearing requests. States also have the option to establish procedures that treat the request made to the grievance system as a submission of a fair hearing request described at § 431.221(a) when the matter raised in the grievance filing is more appropriate for a fair hearing.

Finally, we clarify that matters that are mistakenly filed with the grievance system but are appropriately referred to another system may be considered ''resolved grievances'' unless the State determines that the matter also contains separate grounds for a grievance review. We note that should a matter be resolved through referral to another system, this matter would still be subject to the requirements at § 441.301(c)(7)(v) and (vi) (notifying the beneficiary of the resolution of a grievance) and § 441.301(c)(7)(iii)(B)(*6*) (review of grievance resolutions with which the beneficiary is dissatisfied), which are being finalized in this section II.B.2. of the final rule.

Comment: A few commenters provided support for our proposal at § 441.301(c)(7)(iii)(B)(2) that the reasonable assistance provided by the State includes, but is not limited to, ensuring the grievance system is accessible to individuals with disabilities and individuals with Limited English Proficiency. These commenters noted the importance of providing accessible information to beneficiaries, to ensure beneficiaries have full participation in the process.

Some commenters suggested modifications or additions to the accessibility requirements, including:

- Replacing the term, interpreter services, with the term, linguistic accommodations, noting this would better capture the need for trans creative supports that addresses differences in cultural norms and understandings;
- Requiring plain language explanations of the grievance procedures; and
- Adding mention of the regulations implementing section 1557 of the Affordable Care Act, particularly to reflect §§ 92.201–92.205 of the 2022 Nondiscrimination in Health Programs and Activities proposed rule (87 FR 47824).

Response: As discussed further herein, we are not making modifications to § 441.301(c)(7)(iii)(B)(2) in response to these comments. While it may be a term of art used in some fields, there is no Federal guidance or definition of the term, linguistic accommodations. We retain the term, interpreter services, as defined at § 441.301(c)(7)(iii)(B)(*2*), in this final rule to remain consistent with other Federal requirements. We thank the commenter for bringing the term linguistic accommodations to our attention, and we will take it into consideration for future technical assistance related to this provision.

We note that the proposed requirement at § 441.301(c)(7)(iii)(B)(2) already included a mention of existing accessibility requirements at § 435.905(b). Section 435.905(b) includes a requirement that communications be provided in plain language. We believe it would be duplicative to add a specific requirement that information be provided in plain language.

We also decline to add specific reference to section 1557 of the Affordable Care Act or its implementing regulations, as we find such an addition to be unnecessary. State Medicaid agencies must comply with all relevant requirements in section 1557 in all aspects of their programs, including the grievance process.

Upon review, we are finalizing § 441.307(c)(7)(iii)(B)(*2*) with some modifications to better align the provision with other regulations. We are finalizing a modification to revise the term ''individuals who are limited English proficient'' to ''individuals with Limited English Proficiency.'' This modification conforms with the language being finalized in § 431.12(f)(7) (discussed in section II.A. of this final rule). We are finalizing a modification to clarify that auxiliary aids and services are to be available where necessary to ensure effective communication (instead of upon request as originally proposed), which we believe better conforms to access standards such as those set forth in the ADA and section 504.

Comment: One commenter noted that the repeated references to the regulation at § 435.905(b) (in the proposed requirements at § 441.301(c)(7)(iii)(B)(*2*), (c)(7)(iii)(C)(*6*), and (c)(7)(vi)(A)) may suggest that these accessibility services are not necessary outside of the specific provisions for which they are listed. The commenter suggested we create a separate provision related to language and disability access under the general requirements for the grievance system and specify that it applies to all components of the grievance system.

Response: We disagree that a separate, standalone accessibility requirement would add clarity to States' accessibility requirements. We also do not believe that we have overlooked a part of the process that must be accessible and note that the entire grievance system is subject to other accessibility requirements, including the ADA and section 504, by virtue of being administered by government agencies. As discussed further herein, we are finalizing the references to § 435.905(b) included in the provisions in § 441.301(c)(7) as proposed, as we believe that it is helpful to reiterate the importance of compliance with § 435.905(b) in the various steps of the grievance process.

Comment: One commenter recommended that we mandate that States accept electronic grievances with fill-in forms that could be completed by someone using a smart phone. Another commenter also requested that we require that the grievance system be web-based. One commenter, however, expressed concerns about a grievance system that is only accessible electronically, noting that some people may not have access to or be able to use computers.

Another commenter suggested that we specify that States must maintain a toll-free number, a regularly monitored email address for receiving grievances from Medicaid HCBS beneficiaries, and multiple modes of submitting a grievance, including a request for assistance with articulating and submitting a grievance as a reasonable accommodation.

Response: We appreciate commenters' many thoughtful suggestions on how to ensure that the grievance process system is accessible and user-friendly. At this time, we are not making changes in this final rule at § 441.301(c)(7) to include specific regulatory requirements for exactly how States should implement an electronic system for filing grievances. We believe that the diversity of comments on this issue demonstrates that beneficiaries will likely need the ability to access the grievance filing process through multiple modalities. We encourage States to consider user access (in addition to legally required accessibility considerations) and engage the interested parties within the HCBS community regarding the construction of a user-friendly grievance filing process that accommodates beneficiaries' different communication and technology needs.

Comment: A few commenters expressed support for our proposal to prohibit punitive actions against individuals who file grievances. One commenter noted that, in their State, beneficiaries are reluctant to complain about care due to fear of retaliation. Another commenter requested that CMS clarify that the requirement applies to punitive actions taken by either the State or a provider. The commenter also requested that CMS clarify that States must investigate punitive actions from providers. One commenter requested that CMS clarify that punitive action includes implying that an individual or family might lose services if they access the grievance process. Another commenter stated that the State should provide operational definitions of punitive actions and provide easily understood guidance to providers and State entities as to what types of actions would be considered punitive.

Several commenters offered specific suggestions for revising the proposed requirement at § 441.301(c)(7)(iii)(B)(*3*). One commenter suggested we revise the language to read ''retaliatory action'' or ''retaliatory or punitive action.'' Another commenter suggested that we amend the proposed regulatory text to define such action as ''any negative action following a grievance, complaint, and appeal or reporting of any issue to any regulatory body.''

Response: We clarify that this requirement is intended to prohibit punitive actions from either the State or providers. We do expect that, as part of ensuring that beneficiaries (as well as authorized representatives or other individuals who have filed a grievance on the beneficiary's behalf) are protected from punitive action, States will have a system for both identifying and investigating allegations of punitive action. We agree with the commenter that verbal threats from a provider directed at the beneficiary, or the beneficiary's family, would be the type of punitive action contemplated by this provision that would merit investigation. We also agree that providing additional definitions and examples of punitive actions will be an important part of States' grievance system policies.

To better clarify who is protected from punitive actions (both beneficiaries and those filing grievances on their behalf), we are finalizing a modification to § 441.301(c)(7)(iii)(B)(*3*) to clarify that prohibited actions are neither threatened nor taken against an individual filing a grievance *or who has had a grievance filed on their behalf.* As discussed in this section (section II.B.2.b.), we are finalizing our proposal at § 441.301(c)(7)(iii)(A)(*1*) to allow beneficiaries to have another individual or entity file a grievance on their behalf with written consent. We intend to make it clear that punitive action may not be taken against a beneficiary, whether the beneficiary personally filed the grievance or received assistance filing the grievance. We also want to ensure that authorized representatives or other individuals (including family members or other beneficiaries) are protected from punitive action when helping beneficiaries file grievances.

We agree that amending the regulatory language to ''punitive or retaliatory actions'' would further clarify the intent of the requirement, as ''retaliation'' is a common term associated with prohibited behavior in other types of complaints systems. While there is overlap in the connotations of ''punitive'' and ''retaliatory'' actions, we also believe that some actions that could be taken against individuals in response to the filing of a grievance could be perceived as ''retaliatory'' rather than ''punitive.'' We believe that the word ''retaliatory'' may particularly capture threats or actions that could negatively affect a beneficiary's access to services, whether or not the threat or negative outcome actually materializes. For instance, if a provider noted negative things to other providers about a beneficiary or the beneficiary's authorized representative and discouraged other providers from accepting that beneficiary as client after a grievance was filed against the

provider, this action could be perceived as ''retaliatory'' rather than ''punitive,'' particularly if this did not ultimately result in a reduction or alteration of the beneficiary's services. Therefore, we are finalizing § 441.301(c)(7)(iii)(B)(*3*) with modification in this final rule to specify that States must ensure that punitive or retaliatory action is neither threatened nor taken against an individual filing a grievance or who has had a grievance filed on their behalf.

We decline to make the other modifications that commenters suggested. We believe the requirement we proposed at § 441.301(c)(7)(iii)(B)(*3*), as modified herein, is sufficiently broad and clear to address the essential concerns raised by commenters. We believe including language prohibiting ''any negative action'' may be ambiguous and overly broad. Additionally, we do not believe the grievance system regulations should be used to prohibit punitive or retaliatory actions in response to actions performed outside of the grievance process. However, we note that, if a beneficiary believes they are experiencing poor treatment from a provider because the beneficiary has filed a complaint about the provider in a system other than the grievance system, the beneficiary may have grounds to file a grievance on the basis of the poor treatment.

Comment: Several commenters recommended the addition of more specific provisions to protect against punitive or retaliatory action, including a post-grievance follow-up with the beneficiary and assessing fines or other penalties against a provider who has taken retaliatory action. One commenter also requested that CMS require States to make the results of investigations into allegations of punitive behavior available to the public.

Response: We decline to make modifications to § 441.301(c)(7)(iii)(B)(*3*) based on these commenters' suggestions because we believe that the proposed regulation text at § 441.301(c)(7)(iii)(B)(*3*), which we are finalizing with modification as discussed herein, is sufficient. To comply with the requirement that States ensure that punitive or retaliatory actions are neither threatened nor taken against individuals who have filed a grievance or have had a grievance filed on their behalf, we expect that States will develop a system for identifying, investigating, and deterring punitive or retaliatory actions. We believe creating more regulatory requirements as commenters suggested would not provide States with flexibility in how they comply with this requirement. Instead, States may develop processes in accordance with their grievance system's structure and other relevant considerations, such as provider agreements and State laws.

Comment: We received a few comments on the requirement we proposed at § 441.301(c)(7)(iii)(B)(*4*) that States must accept grievances, requests for expedited resolution of grievances, and requests for extensions of timeframes from beneficiaries. One commenter recommended that § 441.301(c)(7)(iii)(B)(*4*) be revised to specify that no ''magic language'' is needed to initiate the grievance process. The commenter noted that a ''demonstrated intent'' to obtain assistance with an HCBS-related problem should be accepted as a grievance.

Response: We are concerned that the language proposed by the commenter is overly broad. We agree that States should make filing a grievance as simple and accessible as possible for beneficiaries, their authorized representatives, and other individuals or entities filing on a beneficiary's behalf. For example, we believe that it would be inappropriate for a State to create a complex grievance filing form and then refuse to review a grievance because the form was not filled out completely or properly. We note that this scenario would also be a plausible illustration of a State's failure to provide reasonable assistance and accessibility as required at § 441.301(c)(7)(iii)(B)(*2*). We also believe it is critical that States make every effort to ensure that beneficiaries and their advocates know that a grievance system exists and how to access it. We do not, however, expect that every expression of dissatisfaction, in any context, must be treated as a presumptive grievance filing. We believe it is acceptable for States to develop a grievance filing process that requires a clear intent to file a grievance. Further, we do not want to encourage situations in which grievances are pursued on the beneficiary's behalf without the beneficiaries' knowledge or consent.

Comment: We received a number of comments regarding the requirement we proposed at § 441.301(c)(7)(iii)(B)(5) that States provide beneficiaries with notices and other information related to the grievance system, including information on their rights under the grievance system and on how to file grievances. One commenter expressed particular support for this requirement. Other commenters provided several suggestions for additional requirements to ensure that beneficiaries receive information regarding the grievance process, including:

- Requiring that States add an explanation of grievance rights in any HCBS-related communication from the State to the beneficiary;
- Requiring that providers include an explanation of grievance rights in the person-centered service planning process;
- Requiring that information on grievance procedures be posted in each group home or other provider owned or controlled residential setting, along with a toll-free number and email address for filing grievances; and
- Including common examples of grievances in the information given to beneficiaries, so that beneficiaries are better able to understand the potential utility of the process.

A few commenters noted that, regardless of where or how the information was shared, the information should be in accessible plain language and large print formats.

Response: We do not intend to add additional requirements in this final rule regarding how States must inform beneficiaries about the grievance system, as we believe it is important for States to retain flexibility in how they communicate with beneficiaries. We believe the ideas shared by commenters are great examples of what could be done. We note that there is a lot of diversity among beneficiaries receiving HCBS, States' existing communication pathways, and HCBS program design—all factors that will affect the methods of informing beneficiaries about the grievance process. Therefore, we believe it may be necessary for the information about the grievance system to be presented in multiple ways and through multiple modalities. We encourage States to engage with interested parties to determine the most effective ways to inform beneficiaries. We will also work with States to identify effective ways to inform beneficiaries about the State's grievance system.

We also highlight that our proposed text at § 441.301(c)(7)(iii)(B)(*5*) requires that information provided to beneficiaries must comply with § 435.905(b), which does require that materials use plain language. In addition, States generally must comply with the ADA and section 504, and their implementing regulations. We are finalizing § 441.301(c)(7)(iii)(B)(*5*) largely as proposed, although with a modification to change mention of individuals who are limited English proficient to individuals with Limited English Proficiency, consistent with the change to § 441.301(c)(7)(iii)(B)(*2*) discussed previously in this section.

Comment: One commenter requested clarification whether States have an

ongoing obligation to provide this notice and information to beneficiaries, including to people who begin HCBS after the effective date of the grievance system requirements that we proposed at § 441.301(c)(7).

Response: We agree and clarify that States will have an ongoing responsibility to ensure that both new and current beneficiaries receive information about the grievance system to comply with § 441.301(c)(7)(iii)(B)(*5*), which we are finalizing as described in this section (section II.B.2. of the final rule).

Comment: One commenter noted that our proposal at § 441.301(c)(7)(iii)(B)(*6*), requiring the State to review any grievance resolution with which the beneficiary is dissatisfied, is too vague. This commenter suggested that the regulations should specify that the reviewer be someone not involved in the original determination, and the beneficiary should have a process to submit information as to why the original resolution was insufficient. The commenter also suggested that we specify that the beneficiary must request review, believing that otherwise the expectation appears to be that the State must decide whether the beneficiary is dissatisfied. Finally, the commenter suggested that the notice of the original resolution should inform the beneficiary of this review process and how to initiate it.

One commenter also requested clarification on how beneficiaries should express dissatisfaction with a resolution for the purpose of seeking review of a resolution under § 441.301(c)(7)(iii)(B)(6).

Response: We believe that the requirements at § 441.301(c)(7)(iii)(C)(3), which we are finalizing as described in this section II.B.2, address several of the commenter's concerns. We clarify that the requirements at § 441.301(c)(7)(ii)(C)(*3*) apply to initially filed grievances and review of grievances under § 441.301(c)(7)(iii)(B)(*6*). We note that § 441.301(c)(7)(iii)(C)(*3*)(*i*) requires that the individual making a decision on a grievance is an individual who was neither involved in any previous level of review or decision-making related to the grievance nor a subordinate of any such individual. Section 441.301(c)(7)(iii)(C)(*3*)(*iii*) specifies that the individual must consider all comments, documents, records, and other information submitted by the beneficiary without regard to whether such information was submitted to or considered previously by the State.

We expect that beneficiaries would express dissatisfaction by affirmatively requesting review of a grievance resolution. We agree that beneficiaries have the responsibility of requesting the review, and expect that States will include, as part of their written policies, the method for how beneficiaries may request review and how beneficiaries will be notified of this right.

Comment: We did not receive comments on the requirement we proposed at § 441.301(c)(7)(iii)(B)(*7*) that States must provide information on the grievance system to providers and subcontractors. However, one commenter requested that we require States to give providers 14 days' notice if the provider is a party to the grievance.

Response: We believe that whether, and how, a State chooses to involve providers in individual grievances filed pursuant to § 441.301(c)(7) will vary on a case-by-case basis and, thus, a standardized notification requirement may not be appropriate. For instance, some grievances may be resolvable without the provider's involvement, and in some cases, the beneficiary may not want the provider to know the beneficiary's identity. If the beneficiary and the State believe it is necessary to have the provider involved in the investigation, including appearing at the resolution meeting, we expect that States will give the provider reasonable notice and ensure that the provider is able to participate in the process. Therefore, we intend to provide States with flexibility in determining their grievance system policies in this respect.

Comment: One commenter supported the requirement we proposed at § 441.301(c)(7)(iii)(C)(*1*) to allow beneficiaries to file grievances orally but recommended that we revise the requirement to specify that States must follow up with a written summary of the oral grievance so the beneficiary can ensure accuracy. Another commenter suggested that we revise the requirement at § 441.301(c)(7)(iii)(C)(*2*) to specify that acknowledgement of the receipt of a grievance must be in writing.

Response: We appreciate the comments and believe it is a best practice for States to provide a summary of the grievance to the beneficiary for accuracy. However, we decline to mandate that States provide a written summary, as we intend to allow flexibility for States to decide their own policies to operationalize this requirement. We believe that part of acknowledging the grievance, as required at § 441.301(c)(7)(iii)(C)(*2*), involves developing an appropriate system for providing beneficiaries with confirmation of their grievance.

Comment: One commenter requested that we specify whether all grievances filed must receive a full resolution or whether there are instances in which the acknowledgement of the grievance is sufficient. The commenter anticipated that because of the current direct care workforce crisis, many grievances may be filed related to provider shortages. While acknowledging that understaffing is a serious problem, the commenter believed that the grievance process is unlikely to be able to address the problem to the beneficiary's satisfaction.

Response: We note that the definition of grievance that we are finalizing at § 441.301(c)(7)(ii) indicates that a beneficiary may file a grievance regardless of whether remedial action is requested. We agree that, in instances in which the beneficiary does not wish to pursue remedial action and indicates they are not interested in presenting and debating their grievance as we proposed at § 441.301(c)(7)(iii)(C)(*4*), acknowledging the grievance may be considered resolving the complaint (rather than conducting additional inquiry). We note that should a matter be resolved with an acknowledgment, this matter would still be subject to the requirements at § 441.301(c)(7)(v) and (vi) (notifying the beneficiary of the resolution of a grievance) and § 441.301(c)(7)(iii)(B)(*6*) (review of grievance resolutions with which the beneficiary is dissatisfied).

Comment: A few commenters commented on our proposal at § 441.301(c)(7)(iii)(C)(*3*), establishing requirements for decisionmakers reviewing grievances considered under the grievance system. Several of these commenters supported our efforts to require a system that would provide a fair and unbiased review of beneficiaries' concerns. However, one commenter noted that the requirement at § 441.301(c)(7)(iii)(C)(*3*) would require a separate set of personnel to respond to and investigate grievances than the staff that is currently allocated for program management, administration, and support, and expressed concern that this would require additional resources.

Response: We note that the requirement we proposed at § 441.301(c)(7)(iii)(C)(*3*) requires that individuals reviewing and making decisions about grievances are not the same individuals, nor subordinates of individuals, who made the original decision or action that has given rise to the grievance. This would require that the provider that made the decision or performed the action giving rise to the

grievance would not be able to be the decisionmaker for the grievance. However, this would not preclude State Medicaid agency personnel from reviewing a grievance filed against a provider. Additionally, even for grievances filed about the State's performance, the requirement does not necessarily require review from separate departments or entities. With firewalls as needed, reviewers may be from the same department (or a different department) so long as the necessary expertise and independence standards are met, and the reviewer takes into account the information described in § 441.301(c)(7)(iii)(C)(*3*)(*ii*). We are not making modifications to § 441.301(c)(7)(iii)(C)(*3*) based on these comments.

Comment: One commenter questioned if the intent of the requirement we proposed at § 441.301(c)(7)(iii)(C)(*3*)(*iii*) is to require a ''de novo'' review of the grievances.

Response: De novo review typically refers to a standard of review of a matter on appeal after a trial court or administrative body has reached a determination. If a matter is being reviewed *de novo,* the reviewer is reviewing the whole matter as if it is freshly presented to them, without regard for what the prior decisionmaker determined, or their rationale supporting that determination. We did not specify in the regulation text (either proposed or finalized) whether this process is intended as a *de novo* review of grievances, as reference to *de novo* review would have been inapplicable. The general intent of the grievance system we proposed at § 441.301(c)(7) is not to address specific determinations that are being appealed, as would be the case in the fair hearing process. The grievance system is intended to address a beneficiary's dissatisfaction or complaint related to the State's or provider's performance of person-centered planning or HCBS settings requirements. We expect that the grievance system will typically represent the first opportunity a beneficiary has had to present their concerns directly to the State. Because there likely has not been an initial determination to consider and possibly affirm or reverse, we do not believe *de novo* review is applicable.

For example, consider two scenarios in which a provider fails to send a personal care assistant to two beneficiary's homes. For Beneficiary A, the failure was because the provider forgot to ensure a worker was scheduled to deliver the services. For Beneficiary B, the provider decided, unilaterally, that Beneficiary B had been authorized more personal care services than the provider believed was necessary and thus refused to send a personal care assistant to Beneficiary B's home. In both scenarios, Beneficiary A and Beneficiary B could file grievances about the provider's failure to provide services as outlined in the person-centered care plan or attempt to change the service plan without going through the process required in § 441.301(c)(1) through (3). The proper focus in both cases would be on whether the provider provided services in accordance with the current person-centered care plan. We would not expect in Beneficiary B's situation that the State would treat the provider's actions as a formal determination requiring *de novo* review (such as reviewing whether the provider's objections to the number of service hours in the service plan were valid, or making the beneficiary prove that the service hours were needed). Further, even if there has been an initial decision by a provider or State that the beneficiary disputes, we did not intend the grievance system to operate like a formal legal proceeding (that is, an administrative hearing or trial) and, again therefore, we do not believe the concept of *de novo* review is applicable.

Comment: One commenter suggested that we amend the definition of ''skilled professional medical personnel'' to allow the designation to apply to staff administering the grievance process, which would make the activity eligible for a 75 percent Federal matching rate.

Response: We are not amending the definition of skilled professional medical personnel in this final rule. The term ''skilled professional medical personnel'' is defined at § 432.2 as physicians, dentists, nurses, and other specialized personnel who have professional education and training in the field of medical care or appropriate medical practice and who are in an employer-employee relationship with the Medicaid agency. The term explicitly does not include other, nonmedical health professionals such as public administrators, medical analysts, lobbyists, senior managers, or administrators of public assistance programs of the Medicaid program. Per § 432.50, the FFP rate for skilled professional medical personnel and directly supporting staff of the Medicaid agency is 75 percent. We do not intend to require that the administrative activities required for grievance process must be administered by personnel with specialized medical education and training. Even for those who meet the criteria to be considered skilled professional medical personnel, only the portion of their activities that require their advanced skills and expertise would be eligible for the enhanced matching rate. If similar functions are performed by non-skilled professional medical personnel, then the activities themselves would not qualify for the higher matching rate.

Comment: One commenter requested clarification as to whether a telephonic communication would satisfy the proposed requirement at § 441.301(c)(7)(iii)(C)(*4*) that the State provide a beneficiary with a reasonable opportunity face-to-face, including through the use of audio or video technology.

Response: We believe that audio-only telephone calls, when requested by the beneficiary and with the inclusion of any necessary accommodations, satisfy this requirement.

Comment: One commenter recommended that we revise proposed § 441.301(c)(7)(iii)(C)(*4*) by removing the word ''limited'' from before ''time available,'' as the commenter believed the inclusion of the word ''limited'' was unnecessary.

Response: We disagree with the commenter's statement that the word ''limited'' is unnecessary. The language in this requirement was intended to mirror similar language in the managed care grievance process requirements at § 438.406(b)(4). Further, we believe it is important that beneficiaries understand the timeframes associated with the grievance resolutions and understand that it is intended, for their benefit, to be a time-limited process.

Comment: One commenter recommended that we mandate a minimum number of days afforded to a beneficiary to review their record and submit additional germane evidence and testimony to the State agency before resolution. The commenter noted that the proposed regulation merely requires that the State agency provide the beneficiary with ''a reasonable opportunity.'' The commenter regarded this as a vague standard and was concerned that States would not grant beneficiaries sufficient time. The commenter noted that beneficiaries with disabilities or complex medical issues may need additional time and supports to prepare evidence and testimony. The commenter suggested that granting beneficiaries a minimum of 21 days to prepare their evidence and testimony after receipt of the agency record would ensure that the State provided the record well in advance of the resolution deadline and would protect beneficiaries from the imposition of unreasonable timeframes to prepare.

Response: We note that § 441.301(c)(7)(iii)(C)(*4*) requires that

the State provide the beneficiary a reasonable opportunity to present evidence and testimony and make legal and factual arguments related to their grievance, while § 441.301(c)(7)(iii)(C)(*5*) requires the State to provide the beneficiary with their case file and other records sufficiently in advance of the resolution timeframe for grievances. We are unclear on which provision the commenter is recommending we modify. We decline to modify either provision by prescribing specific deadlines within the overall resolution timeframe, to allow States to develop flexible processes to accommodate beneficiaries. We expect that States will develop appropriate processes to allow beneficiaries to request postponements or rescheduling of any face-to-face hearings that they have requested if they find they need more time to prepare, or other situations arise that would prevent a beneficiary from being able to participate in the hearing.

We also note that we are finalizing a requirement at § 441.301(c)(7)(v)(C) to allow beneficiaries to have the option of requesting 14-day extensions if (for any reason) a beneficiary requires additional time beyond the 90-day resolution timeframe we are finalizing at § 441.301(c)(7)(v)(B).

Comment: Several commenters expressed concern about legal representation during the process. One commenter stated that beneficiaries should get access to State-provided legal assistance. Another commenter requested that, if a beneficiary is unable to afford an attorney, the opposing party not be allowed an attorney.

Response: As discussed in a prior response, beneficiaries have flexibility in determining who will assist them throughout the grievance process—which could, if the beneficiary chose, include assistance from a legal professional. We believe that the grievance system should be easy to navigate and largely non-adversarial, such that beneficiaries would not be required, nor feel pressured, to have legal representation. We also believe that at least some portion of grievances filed will be for minor issues that do not require a formal inquiry. We agree with commenters that it is preferable that hearings neither be, nor have the appearance of being, imbalanced in terms of support for the beneficiary. We encourage States, as they develop their policies, to consider what level of assistance beneficiaries will need during face-to-face meetings and ensure that reasonable assistance is provided.

Comment: One commenter stated that § 441.301(c)(7)(iii)(C)(*5*) should be revised to expand the documents beyond the beneficiary's ''case file.'' The commenter recommended that the regulations require that the State obtain relevant files and other information held by the provider and then provide that information to the beneficiary. The commenter stated that, particularly in cases involving residential providers, provider-maintained information will be relevant and often pivotal.

Response: We disagree and believe adding this language is unnecessary. We believe that the term, case file, could have several meanings, depending on the circumstances, and could include the records related to the beneficiary's services maintained by the provider that would be obtained by the State as part of review of the grievance. We also note that proposed § 441.301(c)(7)(iii)(C)(*5*) already requires beneficiaries to receive other documents and records, as well as new and current evidence considered or relied upon by the State related to the grievance. We believe relevant records from providers could fall into these categories, depending on the record and the circumstances by which the State obtained it. We do not intend our requirement at § 441.301(c)(7)(iii)(C)(*5*), as proposed and being finalized in this rule, to amend any existing obligations for confidentiality of certain records and we expect States to comply with applicable Federal and State laws and regulations governing confidentiality of those records in determining what records to provide to the beneficiary related to their grievance in compliance with § 441.301(c)(7)(iii)(C)(*5*). We decline to make modifications to § 441.301(c)(7)(iii)(C)(*5*) as requested by the commenter.

Comment: One commenter suggested that we require that the grievance system be compliant with the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Response: We had proposed at § 441.301(c)(7)(iii)(C)(*5*) that medical records being used as part of a grievance be handled in compliance with 45 CFR 164.510(b) (a provision of the HIPAA Privacy Rule), to ensure that protected health information (PHI) used during the grievance review are obtained and used with beneficiaries' authorization. In general, whenever a beneficiary's PHI may be obtained, maintained, or disclosed by a State agency that is a covered entity as defined in 45 CFR 160.103 (such as a State Medicaid agency), States are responsible for ensuring compliance with the requirements of HIPAA and its implementing regulations, as well as any other applicable Federal or State privacy laws governing confidentiality of a beneficiary's records. We also note that 45 CFR 164.510(b) is just one provision of the HIPAA Privacy Rule that permits the disclosure of PHI, and other provisions may also permit the disclosure of PHI (such as disclosure of PHI to personal representatives under 45 CFR 164.502(g)); other permissions may also apply in addition to what is cited here and included in the regulatory text of this final rule. Upon further review, we have determined that, given that a number of requirements of the HIPAA Privacy Rule may apply to the obtaining and sharing of beneficiaries' information, we are finalizing § 441.301(c)(7)(iii)(C)(5) with a modification to change the citation of 45 CFR 164.510(b) to a broader reference to the HIPAA Privacy Rule (45 CFR part 160 and part 164 subparts A and E).

Finally, we also note that individuals who believe their health information privacy has been violated may file a complaint with the HHS Office for Civil Rights at *https://www.hhs.gov/hipaa/filing-a-complaint/index.html.*

After consideration of public comments, we are finalizing § 441.301(c)(7)(iii)(A) as proposed, with the following modification. We are finalizing § 441.301(c)(7)(iii)(A)(1) with modification to specify that another individual or entity may file a grievance on behalf of the beneficiary or provide the beneficiary with assistance or representation throughout the grievance process with the written consent of the beneficiary or authorized representative. We are finalizing § 441.301(c)(7)(iii)(A)(2) as proposed.

We are finalizing requirements at § 441.301(c)(7)(iii)(B) as proposed, with the following modifications. We are finalizing § 441.301(c)(7)(iii)(B)(*1*) with a modification to correct an erroneous reference to subchapter by replacing subchapter with paragraph (c)(7). We are finalizing § 441.301(c)(7)(iii)(B)(*2*) with modifications by: (1) adding to States' obligation the requirement that States must provide beneficiaries reasonable assistance in ensuring grievances are appropriately filed with the grievance system; (2) modifying language to refer to individuals with Limited English Proficiency; and (3) clarifying that auxiliary aids and services must be made available where necessary to ensure effective communication. We are finalizing § 441.301(c)(7)(iii)(B)(*3*) with modifications to require that States ensure that punitive or retaliatory actions (rather than just punitive actions) are neither threatened nor taken. We are also adding language to specify that the punitive or retaliatory actions cannot be threatened or taken

against an individual filing a grievance **or who has had a grievance filed on their behalf**. (New language identified in bold.)

For reasons we discuss in greater detail in the next section (section II.B.2.c. of this rule) we are finalizing § 441.301(c)(7)(iii)(B)(*4*) with a modification to remove the reference to expedited grievances. We are finalizing § 441.301(c)(7)(iii)(B)(*5*) with a modification to change the language to refer to individuals with Limited English Proficiency. We are finalizing § 441.301(c)(7)(iii)(B)(6) and (7) as proposed.

We are finalizing § 441.301(c)(7)(iii)(C)(*1*) through (*5*) with minor technical modifications. We are replacing the periods at the end of each paragraph with semi-colons and adding the word and at the end of § 441.301(c)(7)(iii)(C)(*5*) to accurately reflect that § 441.301(c)(7)(iii)(C)(*1*) through (*6*) are elements of a list, not separate declarative statements. Additionally, for reasons we discuss in greater detail in a later section (section II.B.2.d.) because we are not finalizing the expedited resolution timeframe at § 441.301(c)(7)(v)(B)(2), we are finalizing § 441.301(c)(7)(iii)(C)(*5*) with modifications to remove references to § 441.301(c)(7)(v)(B)(1) and (2) and add a reference to § 441.301(c)(7)(v). We are also finalizing § 441.301(c)(7)(iii)(C)(5) with a modification to change the citation of 45 CFR 164.510(b) to a broader reference to the HIPAA Privacy Rule (45 CFR part 160 and part 164 subparts A and E).

c. Filing Timeframe (§ 441.301(c)(7)(iv))

At § 441.301(c)(7)(iv)(A), we proposed to require that the beneficiary be able to file a grievance at any time. At § 441.301(c)(7)(iv)(B), we proposed to require that beneficiaries be permitted to request expedited resolution of a grievance, whenever there is a substantial risk that resolution within standard timeframes will adversely affect the beneficiary's health, safety, or welfare, such as if, for example, a beneficiary cannot access personal care services authorized in the person-centered service plan.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters made suggestions or submitted clarifying questions about our proposal at § 441.301(c)(7)(iv)(A) that beneficiaries be able to file a grievance at any time. One commenter requested clarification on whether our intent was to prohibit limits on the timeframe between the occurrence of the subject of the grievance and the date when the individual files a grievance. Another commenter noted that there should be a 90-day time limit on when beneficiaries can file grievances.

Response: We do not intend for beneficiaries' ability to file grievances to be time-limited. We appreciate commenters' concerns regarding this issue; however, we defer to the rationale we used when declining to add a timeframe cap in the managed care grievance filing process (81 FR 27511). In the managed care grievance process, § 438.402(c)(2)(i) specifies that enrollees may file a grievance with their managed care plan at any time. As we previously noted, grievances do not progress to the level of a State fair hearing, which is a time-sensitive process; therefore, we found it unnecessary to include filing limits because grievances are resolved without having to consider the time limits of other processes (81 FR 27511).

We understand that States may be concerned about revisiting grievance issues that occurred in the past, but we believe this is a normal part of providing services and that beneficiaries should be permitted to file a grievance at any time. We also note, that, as discussed in more detail below, States believe that educating beneficiaries about the grievance process will take time; therefore, we do not want to prevent beneficiaries from filing grievances in cases where the delay in filing was because the beneficiary was not initially aware of their ability to file a grievance.

Comment: A few commenters supported the proposal at § 441.301(c)(7)(iv)(B) to create a pathway for expedited resolutions when there is a substantial risk that resolution within standard timeframes will adversely affect the beneficiary's health, safety, or welfare.

Several commenters, however, believed that the proposal at § 441.301(c)(7)(iv)(B) to create a pathway for an expedited resolution was unclear or overly broad and requested additional clarification as to what would constitute a grievance warranting expedited resolution. Some of these commenters stated that technical assistance would be needed to help States identify the criteria for determining whether a resolution should be expedited, and how to proceed if a beneficiary disagrees with the State's determination that a grievance request should be expedited or resolved in the standard timeframe. One commenter raised the concern that if a beneficiary's request for an expedited resolution was denied, they may follow up with submitting another grievance or file a fair hearing request. Another commenter suggested that expedited resolutions should be defined as being contingent on the timely receipt of information from the beneficiary.

Some commenters noted that the expedited resolution process's focus on health, safety, and welfare could lead to duplication with other systems, including the critical incident system. They expressed the belief that there are separate channels to address health and safety concerns. For this reason, a few commenters suggested that there should only be one standard grievance resolution and notice timeline of 90 calendar days. A few commenters also suggested that we should not have an expedited resolution process in the FFS grievance system because there is not such a process in the managed care grievance system (as described in 42 CFR part 438, subpart F).

One commenter stated that, in their experience, few grievances were about issues affecting beneficiaries' health and safety, and thus it would not be appropriate to create a requirement for an expedited process as it was defined in proposed § 441.301(c)(7)(iv)(B). The commenter offered examples of typical grievances, based on the commenter's experience with operating a State grievance system. The commenter noted that many grievances involve education about the HCBS program (for example, additional services and limitations), information about available providers in their area as an alternative to their current provider, dissatisfaction with their paid caregiver, and frustrations with provider workforce shortages.

Response: We are persuaded by commenters' feedback summarized here, as well as comments summarized later in this section regarding the expedited resolution timeframe. After consideration of public comments, as discussed here in section II.B.2, we are not finalizing § 441.301(c)(7)(iv)(B) and are removing other references to the expedited resolution process where it appears in § 441.301(c)(7) in this final rule.

In particular, we are persuaded by the concern that the expedited resolution process as proposed could create overlap with the critical incident system, which is described in section II.B.3 of this final rule. We believe that the critical incident system is the most appropriate mechanism for investigating situations when a beneficiary has experienced actual harm or substantial risks to their health and safety. We do not want there to be a delay in the investigation of a critical incident

because it was incorrectly filed as a grievance, nor do we want matters that should be investigated as critical incidents resolved only in the grievance process.

In addition, as some commenters correctly noted, the managed care requirements at 42 CFR part 438, subpart F, do not include an expedited grievance resolution process. We have not identified a compelling reason why beneficiaries receiving HCBS through FFS systems should need an expedited resolution process for grievances when no similar process has, as yet, been deemed necessary in the managed care system. After reexamining these requirements in light of comments received, we do not wish to create misalignment between managed care and FFS systems' grievance resolution processes.

In general, we agree with the commenter that it is likely that many grievances filed would not meet the standard we proposed for expedited resolution (and, as noted above, if they did meet the standard, they are likely candidates for the critical incident or fair hearings systems). However, we envision that there remains the potential for some grievances to require immediate attention and intervention, even if they do not rise to the level of a critical incident (as defined in § 441.302(a)(6)(i)(A)) or do not qualify for a fair hearing (as set out in part 431, subpart E). Therefore, we encourage States to include in their grievance system a system for identifying, triaging, and expediting resolution of grievances that require, according to the State's criteria, prioritization and prompt resolution.

After consideration of the comments received about § 441.301(c)(7)(iv), we are finalizing our proposal at § 441.301(c)(7)(iv) with modification by removing the expedited resolution requirement at § 441.301(c)(7)(iv)(B) and redesignating § 441.301(c)(7)(iv)(A) as § 441.301(c)(7)(iv). Additionally, we are removing references to the expedited resolution process in § 441.301(c)(7)(iii)(B)(*4*). We are also removing requirements related to the expedited resolution process in § 441.301(c)(7)(v). These changes are discussed in their respective sections below.

d. Resolution and Notification (§ 441.301(c)(7)(v))

At § 441.301(c)(7)(v), we proposed resolution and notification requirements for grievances. Specifically, at § 441.301(c)(7)(v)(A), we proposed to require that States resolve and provide notice of resolution related to each grievance as quickly as the beneficiary's health, safety, and welfare requires and within State-established timeframes that do not exceed the standard and expedited timeframes proposed in § 441.301(c)(7)(v)(B). At § 441.301(c)(7)(v)(B)(1), we proposed to require that standard resolution of a grievance and notice to affected parties must occur within 90 calendar days of receipt of the grievance. At § 441.301(c)(7)(v)(B)(2), we proposed to require that expedited resolution of a grievance and notice must occur within 14 calendar days of receipt of the grievance.

At § 441.301(c)(7)(v)(C), we proposed that States be permitted to extend the timeframes for the standard resolution and expedited resolution of grievances by up to 14 calendar days if the beneficiary requests the extension, or the State documents that there is need for additional information and how the delay is in the beneficiary's interest. At § 441.301(c)(7)(v)(D), we proposed to require that States make reasonable efforts to give the beneficiary prompt oral notice of the delay, give the beneficiary written notice, within 2 calendar days of determining a need for a delay but no later than the timeframes in paragraph (c)(7)(v)(B), of the reason for the decision to extend the timeframe, and resolve the grievance as expeditiously as the beneficiary's health condition requires and no later than the date the extension expires, if the State extends the timeframe for a standard resolution or an expedited resolution.

We also proposed at § 441.301(c)(7)(iv)(B) and (c)(7)(v)(B)(*2*) that beneficiaries be permitted to request, and the State provide for, expedited resolution of a grievance. However, we noted that these proposed requirements differ from the current grievance system requirements for Medicaid managed care plans at part 438, subpart F, which do not include specific requirements for an expedited resolution of a grievance. We solicited comment on whether part 438, subpart F should be amended to include the proposed requirements for expedited resolution of a grievance at § 441.301(c)(7)(iv)(B) and (v)(B)(2).

We received public comments on these proposals. The following is a summary of the comments we received and our responses. We note that, as discussed in the previous section, we are not finalizing the expedited resolution process at § 441.301(c)(7)(iv)(B). We will discuss the impact of this change to the requirements in § 441.301(c)(7)(v) in our response to the comments below.

Comment: A few commenters requested that we provide additional information to clarify what is expected for a grievance to be considered resolved.

Response: We believe that the resolutions of grievances can take many forms and may vary on a case-by-case basis, and thus we decline to revise the requirements at § 441.301(c)(7)(v) to provide a more specific definition. We proposed and are finalizing as discussed in this section II.B.2 that a beneficiary may file a grievance even if the beneficiary does not request remedial action. We expect that grievances will vary not only in severity and urgency but will also vary according to the formality of the response. Some grievances, as noted in a response above, may require only a simple acknowledgment of the concern. Others may require immediate action(s), including intervention(s) with or action(s) taken against the provider. Still others may involve the State setting up a long-term corrective action plan or monitoring, consistent with applicable State laws governing such. We believe that a critical part of the grievance process involves collecting input from the beneficiary filing the grievance on the resolution or outcome they hope to achieve through the grievance process. This may include instances in which the beneficiary wishes to bring a concern to the State's attention but is not necessarily pursuing a specific resolution.

Comment: A few commenters raised concerns or questions about how States should ensure compliance with resolutions. One commenter noted the importance of ensuring corrective actions are taken in response to grievances so that policy and systems transformation can take place in a timely manner. One commenter requested that we provide States with more tools to ensure provider compliance, including appropriate monetary and nonmonetary penalties. Another commenter stated that the grievance resolution process should include an order for the creation of a corrective action plan and subsequent monitoring.

Response: We appreciate the commenters' suggestions, but we decline to add specific actions to the requirements at § 441.301(c)(7)(v). As noted above, we believe that there will be variety in both grievances and resolutions. It would be difficult, and perhaps detrimental, to establish a set of Federal penalties that may be over- or under-responsive to the range of matters heard in the grievance process. Thus, we want to retain flexibility in the

regulatory requirements to allow State grievance systems to respond appropriately to each situation. We expect that States will apply a reasonable interpretation to the requirement that the States ''resolve'' the grievance. For instance, if resolution reasonably requires a corrective action plan for a provider (for grievances resolved against providers) or a corrective action plan for the State (for grievances resolved against the State), we expect that a corrective action plan would be executed and monitored as part of the resolution in accordance with applicable State laws. Through State law and regulations, States can create penalties, whether monetary or non-monetary, for providers that have violated their obligations as set forth by the State Medicaid program.

Comment: Several commenters suggested that the grievance resolution process should include formal follow-up requirements. To ensure proper follow-up, one commenter recommended that the regulations specify that grievances and their resolutions be reviewed at the subsequent person-centered planning process. One commenter recommended that the State should perform a follow up at 30 and 90 days after the resolution.

Response: We decline to add specific follow-up requirements to § 441.301(c)(7)(v). As discussed in prior responses, we believe that grievances are likely to take many forms. We agree that, in some instances, follow-up or ongoing monitoring may be a critical element of a particular resolution and, thus, should be included. In other cases, the grievance may not require follow-up and, thus, a formal follow-up requirement would impose an unnecessary administrative burden. There may also be instances in which a beneficiary may not wish to be repeatedly contacted after they believe the matter has been resolved. We believe that determining the appropriateness of when, and how, to monitor outcomes of grievances should be part of policies States develop for their grievance system.

Comment: One commenter recommended that we revise the requirement at § 441.301(c)(7)(v)(A) to require that the State solicit more information from beneficiaries on how a delayed resolution could hurt the beneficiary. One commenter suggested that we include the language from this provision in the timeframe requirement for expedited grievances at § 441.301(c)(7)(v)(B)(2) so that the requirement reads, ''as expeditiously as the beneficiary's health condition requires and no longer than 14 calendar days after the State receives the grievance.''

Response: We decline to make the suggested modifications to the requirement at § 441.301(c)(7)(v)(A). We clarify that this requirement at § 441.301(c)(7)(v)(A) sets a general expectation for expeditious resolutions for all grievances. We encourage States to ensure that beneficiaries provide, in their grievances, detailed information about their concerns (including negative impacts they are experiencing or believe they will experience). However, we have specifically not set requirements for the amount or type of information beneficiaries must submit when filing a grievance, as we do not wish to inadvertently mandate a process that is administratively burdensome for beneficiaries. We believe that commenters may have interpreted this requirement as a means of identifying grievances being filed for expedited resolution, which was not the intent. Additionally, as discussed above, we are not finalizing the requirement for an expedited resolution at § 441.301(c)(iv)(B)(*2*).

We also note that, consistent with our discussion above related to concerns about confusion between the purpose of the grievance system and the critical incident system described in § 441.302(a)(6), we are revising the language in this provision. Specifically, we are finalizing our proposal at § 441.301(c)(7)(v)(A) with modification to require that the State resolve each grievance and provide notice as expeditiously as the beneficiary's health condition requires, instead of our proposal, which would have required that such notice be provided as expeditiously as the beneficiary's health, safety, and welfare requires. We believe this avoids confusion with the critical incident system and aligns the language with a parallel requirement in the managed care grievance requirements at § 438.408(a), as well as our language in §§ 441.301(c)(7)(v)(D)(*3*) (pertaining to expeditious resolution during extensions). We believe that ''health condition'' may be broadly interpreted to refer both to physical and mental health and well-being of the beneficiary.

Comment: A few commenters supported our proposal at § 441.301(c)(7)(v)(B)(*1*) that standard resolution of a grievance and notice to affected parties must occur within 90 calendar days of receipt of the grievance. However, some commenters, while not specifically opposing the 90-day timeframe, expressed concerns that the timeframe proposed for resolving grievances may not always allow for a thorough investigation. One commenter noted that, while this timeframe might allow for investigation and resolution of some grievances, other grievances might require more extensive investigation (such as interviews, on-site visits, legal review and consultation, and request for additional documentation) and could take longer. The commenter also worried about the time involved in allowing the beneficiary a reasonable opportunity to present evidence face-to-face and in writing, as well as access to their case file to review in advance.

Conversely, a number of commenters recommended that the standard resolution timeframe be shortened to 45 days. Many of these commenters stated that 90 days is too long for an individual to wait for resolution if they are experiencing a serious violation of their rights or access to services.

Response: We agree with commenters that some grievances may take longer than 90 days to resolve properly and note that these extenuating circumstances can be addressed through the use of the 14-day extension we are finalizing at § 441.301(c)(7)(v)(C) if the conditions set forth in that requirement are met. We also agree with commenters that grievances should be resolved as expeditiously as possible, but we do not agree that cutting the proposed timeframe in half (to 45 days) would be a sufficient timeframe. We based our proposal of 90 calendar days on the current timeframe for resolution in the managed care grievance system at § 438.408(b), and we do not find reason to believe that FFS grievances would require less time to resolve than grievances in the managed care system. We do not wish to set a timeframe that encourages hasty investigations, nor the overuse of the 14-day extensions. We also note that 90 calendar days is the maximum allowed timeframe and that States may choose to set a shorter timeframe, or several timeframes for different types of grievances, so long as none of the timeframes exceed 90 calendar days. We are finalizing the 90-calendar day timeframe for resolutions as proposed.

Comment: One commenter noted that the proposed timeframe of 14 days for expedited resolution was too long and suggested that it be reduced to 7 days. On the other hand, many commenters expressed concerns about staff capacity necessary to respond to expedited grievances within 14 calendar days, as well as the feasibility of completing investigations within the proposed 14-day timeframe. Commenters believed that, given the potential seriousness of grievance inquiries, it may be difficult

for all necessary information to be gathered in 14 days and to grant the beneficiary a reasonable opportunity to present evidence in a face-to-face meeting. Several commenters recommended that, if finalizing an expedited resolution timeframe, we extend the timeframe to 30 calendar days, and one commenter recommended 30 business days.

Response: As discussed above, we are not finalizing the requirement for an expedited resolution process. In addition to the comments summarized above about the process itself, we agree with commenters that if a beneficiary has filed a grievance and wishes to present evidence and participate in a face-to-face meeting with the decisionmaker, 7 calendar days, or even 14 calendar days, may not be sufficient time for all relevant materials to be gathered and reviewed by the beneficiary and decisionmaker, nor to arrange for a resolution meeting. As discussed above, we are encouraging States to create their own processes for expediting resolution of certain grievances. We believe that there will be some grievances filed that may (and should) be resolved almost immediately, including by a referral to the critical incident system or fair hearings process. We note that several commenters suggested that 30 days is a reasonable timeframe for expediting resolutions, and States may want to take that recommendation under consideration when developing their own processes.

Consistent with our decision not to finalize the expedited resolution process at § 441.301(c)(7)(iv)(B), we are not finalizing § 441.301(c)(7)(v)(B)(*2*).

Comment: One commenter noted that imposing any timelines for resolving grievances could detract from staff resources needed to investigate critical incidents, particularly if the grievance and critical incident systems use the same staff.

Response: We recognize that States will have to supply staff and resources for both the grievance and critical incident systems that we are finalizing in this rule. We will provide technical assistance to States as needed to help identify ways to manage both systems, including setting priorities and managing the critical incident investigation and grievance resolution timeframes.

Comment: A number of commenters responded to our invitation to comment on whether part 438, subpart F should be amended to include the proposed expedited resolution requirements at § 441.301(c)(7)(iv)(B) and (v)(B)(*2*). Several commenters recommended that expedited procedures be extended to the managed care grievance procedures at part 438 subpart F. However, several commenters opposed adding expedited resolution timeframes to part 438 subpart F. Similar to the opposition presented to including expedited resolutions in the FFS grievance system, these commenters believed that very few expressions of dissatisfaction require expedited resolution and that other mechanisms exist to address health and safety concerns in a timely manner. A few commenters also provided suggestions on possible changes to the managed care grievance requirements, such as adding a prohibition of punitive action against beneficiaries who file grievances.

Response: We will take these comments under consideration. We note that we are not, at this time, finalizing an expedited resolution process in the FFS grievance system and are not finalizing the requirements we proposed at § 441.301(c)(7)(iv)(B) and at § 441.301(c)(7)(v)(B)(*2*) for such a process. We also note that, while outside the scope of this proposal, we will take other recommendations regarding potential changes to the managed care grievance process under consideration as well.

Comment: A few commenters noted support for the proposal at § 441.301(c)(7)(v)(C) that States be permitted to extend the timeframes for the resolution of grievances by up to 14 calendar days.

Response: We thank the commenters for their support.

We did not receive comments on the requirements we proposed at § 441.301(c)(7)(v)(D).

After consideration of public comments, we are finalizing our proposal at § 441.301(c)(7)(v)(A) with modification to require that the State resolve each grievance, and provide notice, as expeditiously as the beneficiary's health condition (instead of health, safety, and welfare) requires. Additionally, consistent with our decision not to finalize the expedited resolution process at § 441.301(c)(7)(iv)(B), we are not finalizing the expedited resolution timeframe at § 441.301(c)(7)(v)(B)(2), redesignating § 441.301(c)(7)(v)(B)(1) as § 441.301(c)(7)(v)(B), and retitling § 441.301(c)(7)(v)(B) as ''Resolution timeframes.'' We are also removing the word ''standard'' in § 441.301(c)(7)(v)(B)(1) (which we are finalizing at § 441.301(c)(7)(v)(B)) since the finalized requirements do not distinguish between ''standard resolution'' and other types of resolutions.

We are finalizing § 441.301(c)(7)(v)(C), with a technical correction to redesignate paragraphs (C)(*1)*(i) and (C)(*1*)(ii) as (C)(*1*) and (C)(*2*), respectively. We are finalizing § 441.301(c)(7)(v)(D) as proposed, with minor technical corrections. Specifically, we are changing the periods at the end of § 441.301(c)(7)(v)(D)(*1*) and (*2*) to semi-colons and adding ''and'' at the end of § 441.301(c)(7)(v)(D)(*2*).

e. Notice of Resolution (§ 441.301(c)(7)(vi))

We proposed at § 441.301(c)(7)(vi) requirements related to the notice of resolution for beneficiaries. Specifically, at § 441.301(c)(7)(vi)(A), we proposed to require that States establish a method for written notice to beneficiaries and that the method meet the availability and accessibility requirements at § 435.905(b). At § 441.301(c)(7)(vi)(B), we proposed to require that States make reasonable efforts to provide oral notice of resolution for expedited resolutions.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters recommended that we expand the requirements proposed at § 441.301(c)(7)(vi) pertaining to the information beneficiaries receive at the resolution of their grievance. The commenters requested we include a requirement that the notice explain what the grievance is, the information considered, the necessary remedial actions (if any) for resolution, and the ability to request further review.

Response: We encourage States to include this information in resolution notices as appropriate, but we decline to make changes to this requirement in our final rule. We note that this requirement, as written, is consistent with the parallel requirement in § 438.408(d), which provides States with flexibility in developing a method by which managed care plans will notify enrollees of resolutions. We intend to provide States with this same flexibility in the FFS system, as we see no compelling reason to impose more rigid requirements on one system than the other.

We also note that, consistent with the discussion above not to finalize the expedited resolution process, we are not finalizing § 441.301(c)(7)(vi)(B), which requires oral notice for expedited resolutions. We expect that States, should they decide to include an expedited resolution process in their grievance system, would develop an

appropriate system for notifying beneficiaries of these resolutions.

After consideration of the comments received, we are finalizing § 441.301(c)(7)(vi)(A) without substantive changes. However, consistent with our decision (discussed above) not to finalize the expedited resolution process at § 441.301(c)(7)(iv)(B), we are not finalizing the requirement we proposed relating to the expedited resolution process at § 441.301(c)(7)(vi)(B) and redesignating § 441.301(c)(7)(vi)(A) as § 441.301(c)(7)(vi).

f. Recordkeeping (§ 441.301(c)(7)(vii))

We proposed at § 441.301(c)(7)(vii) recordkeeping requirements related to grievances. Specifically, at § 441.301(c)(7)(vii)(A), we proposed to require that States maintain records of grievances and review the information as part of their ongoing monitoring procedures. At § 441.301(c)(7)(vii)(B), we proposed to require that the record of each grievance must contain at a minimum the following information: a general description of the reason for the grievance, the date received, the date of each review or review meeting (if applicable), resolution and date of the resolution of the grievance (if applicable), and the name of the beneficiary for whom the grievance was filed. Further, at § 441.301(c)(7)(vii)(C), we proposed to require that grievance records be accurately maintained and in a manner that would be available upon our request.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposal at § 441.301(c)(7)(vii)(A) to require that States maintain records of grievances and review the information as part of their ongoing monitoring procedures, and for the proposal at § 441.301(c)(7)(vii)(C) that grievance records would be available upon CMS's request. A few commenters were also specifically supportive of what they regarded as the proposal's potential to collect and track standardized information about service system issues, including obstacles to informed choice and person-centered planning.

One commenter observed that there will be important lessons and conclusions that may be drawn from the data that should help the State to take steps to deter future service provider actions that lead to grievances. The commenter also hoped that such data could lead to educational opportunities to refine State and service provider knowledge of HCBS settings and person-centered service plan rules, and data should be collected on the efficacy of such educational interventions. One commenter suggested that we require qualitative, as well as quantitative, reporting.

Response: We decline to make any additional changes to our proposal at § 441.301(c)(7)(vii) in this final rule, but we agree with the commenters that the data and records that States collect as part of the grievance process may be critical in helping States improve their HCBS programs. While we are not finalizing specific requirements for how States must use this data, promising practices related to data collection and analysis, including methods of capturing qualitative data from the records, will likely be included in the technical assistance that will be available to States during the implementation period.

Comment: A few commenters recommended requiring States to make information on grievances publicly available, such as by releasing an annual report on the anonymized grievances received in the previous 12 months, categorized by issue, severity, and resolution or lack of resolution. One commenter suggested that such a report would enhance transparency and could assist with quality improvement by providing States, providers, and consumer advocates with insight into grievance patterns and trends. Another commenter recommended that we require public online disclosure of grievance details and resolutions. The commenter noted this would help individuals make informed choices about providers and would encourage compliance with person-centered planning and settings requirements. One commenter, presuming that the State's recordkeeping system would be made publicly available, suggested that we include the name of the decision maker in the records so that CMS, researchers, and advocacy groups can ensure that decision makers are making unbiased decisions.

Response: We did not propose that States publicly report information about grievance resolutions in this final rule; we note, for instance, that we did not include reporting on the grievance system as part of the reporting requirement being finalized at § 441.311, nor are we requiring that States report information about grievances as part of the website posting requirement being finalized at § 441.313. We decline to make any changes in this final rule to require such public reporting.

We believe that some public disclosures may not be suitable or appropriate in every instance, and it would be difficult to tailor a meaningful requirement to anticipate all of these circumstances. We are concerned that, for example, in States with smaller HCBS populations, it may be difficult to truly anonymize information about grievances. Relatedly, some beneficiaries may not want grievances published about specific providers, as some commenters suggest, as this would further complicate anonymity when some providers only serve a few clients. We are concerned also that public disclosure could have a chilling effect if beneficiaries believed their grievance could be made part of a public report. While we agree that, over time, data about trends in grievances could be useful to both the States and external interested parties in promoting systemic improvements of HCBS, we defer to States to determine when and how to make this information public and for what purpose. We also note that the specific recommendation to add the name of the decision maker to the record is addressed in another response later in this section.

Comment: One commenter recommended that we establish a process for an annual or regular review of the States' summary of issues and the States' resolution of the issues. Another commenter recommended requiring an independent evaluator periodically review States' grievance processes to identify common barriers, trends, participation rates, and effectiveness of resolutions.

Response: When developing the proposed requirements at § 441.301(c)(7), we did not intend to create a formal system in which we would routinely review individual resolutions made by States' grievance systems and are not persuaded otherwise after review of public comments received. As discussed further in this section II.B., we proposed, and are finalizing, the requirement at § 441.301(c)(7)(vii)(C) that States must make records available to us upon request. This provides CMS with authority to review records should we need to review the functioning of a State's grievance system on a case-by-case basis.

We believe that the grievance system's designated decision makers are generally in the best position to determine appropriate resolutions to beneficiaries' concerns and that the need to review individual records should be decided on a case-by-case basis. We do agree regular review of the States' grievance systems is a good

suggestion, and we will take it under consideration for future guidance and rulemaking. Similarly, we are not requiring that States have their grievance system reviewed by an independent evaluator in this final rule—in part because we believe many States will likely do this anyway, as part of their standard audit processes. However, we agree that having the system regularly reviewed by an independent entity is a good practice that States may consider.

Comment: A few commenters suggested specific categories of information to be added to the record of each grievance proposed at § 441.301(c)(7)(vii)(B). One commenter suggested that all information considered should be included as a category in the record of each grievance. A few commenters recommended we add that the name of the decisionmaker be included in the record to ensure that conflict of interest requirements at § 441.301(c)(7)(iii)(C)(*3*) are preserved.

Response: We thank commenters for their suggestions, but we decline to add new record requirements for States at § 441.301(c)(7)(vii)(B). We believe capturing the names of staff and individuals who decided the outcome of each grievance is an operational and internal matter for States. States can record whatever information about a grievance resolution that they deem appropriate in addition to what is required. We believe § 441.301(c)(7)(vii)(B) as finalized reflects an appropriate minimum level of detail. We note that § 441.301(c)(7)(vii)(B) aligns with the managed care grievance system recordkeeping requirement at § 438.416.

After consideration of public comments received, we are finalizing § 441.301(c)(7)(vii) without substantive modifications. However, we are finalizing § 441.301(c)(7)(viii)(B)(*1*) through (*5*) with minor technical modifications. We are replacing the periods at the end of each paragraph with semi-colons, to accurately reflect that § 441.301(c)(7)(vii)(B)(*1*) through (*6*) are elements of a nonexhaustive list, not separate declarative statements. We are also adding the word ''and'' to the end of § 441.301(c)(7)(vii)(B)(*5*).

g. Applicability Date (§ 441.301(c)(7)(viii))

In the proposed rule (88 FR 27977), we recognized that many States may need time to implement the proposed grievance system requirements, including needing time to amend provider agreements, make State regulatory or policy changes, implement process or procedural changes, update information systems for data collection and reporting, or conduct other activities to implement these requirements. However, we noted that the absence of a grievance system in FFS HCBS systems poses a substantial risk of harm to beneficiaries. We proposed at § 441.301(c)(7)(viii) that the requirements at § 441.301(c)(7) be effective 2 years after the effective date of the final rule. A 2-year time period after the effective date of the final rule for States to implement these requirements reflected our attempt to balance two competing challenges: (1) the fact that there is a gap in existing regulations for FFS HCBS grievance processes related to important HCBS beneficiary protection issues involving person-centered planning and HCBS settings requirements; and (2) feedback from States and other interested parties that it could take 1 to 2 years to amend State regulations and work with their State legislatures, if needed, as well as to revise policies, operational processes, information systems, and contracts to support implementation of the proposals outlined in this section. We also considered all of the HCBS proposals outlined in the proposed rule (88 FR 27971 through 27995) as whole. We solicited comments on overall burden for States to meet the requirements of this section, whether this timeframe is sufficient, whether we should require a shorter timeframe (1 year to 18 months) or longer timeframe (3 to 4 years) to implement these provisions, and if an alternate timeframe is recommended, the rationale for that alternate timeframe.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: One commenter supported our proposal at § 441.301(c)(7)(viii) that the requirement at § 441.301(c)(7) be effective 2 years after the effective date of the final rule. However, one commenter, stating that these grievance protections will be vital to HCBS beneficiaries, recommended that States be required to come into compliance within 18 months after the effective date of the regulations.

A few commenters expressed concerns about the burden they believe will be associated with developing a grievance system, particularly in States that do not already have grievance processes in place. Commenters believed that it would take significant resources to help beneficiaries understand what rights they can claim under the grievance system. Commenters also described costs or activities such as: funding and statutory change requests to State legislatures; administrative rulemaking; IT and administrative system design and development, which may include vendor procurement; collaboration with other State agencies or agency divisions; partnering with providers for implementation; hiring and training new staff; and approval of implementation advance planning documents by CMS. These commenters suggested alternative effective dates ranging from 3 to 5 years. One commenter also suggested an effective date of 4 years after CMS releases relevant subregulatory guidance.

Response: We appreciate the fact that States will have to expend resources in developing the grievance system, particularly States that do not currently have grievance systems for Medicaid beneficiaries receiving services under section 1915(c), (i), (j) and (k) authorities through a FFS delivery system. Because of the activities that some States will have to perform to develop the grievance system shared by commenters, we agree that requiring an earlier timeframe of 18 months is not realistic. We also appreciate, and agree with, the sense of urgency expressed by commenters. We believe it is important to prioritize giving beneficiaries the opportunity to have their concerns heard. In this final rule, we have provided States with as much flexibility as possible to build on or retain existing grievance systems and have kept specific information systems requirements to a minimum. We have also reduced some potential initial administrative challenges by not finalizing a formal expedited resolution requirement and by allowing States to decide whether, and how, to implement such a policy. After consideration of public comments received as discussed herein, we are finalizing the substance of § 441.301(c)(7)(viii) as proposed, but with minor modifications to correct erroneous uses of the word ''effective'' and retitle the requirement as Applicability date (rather than Effective date). We are also modifying the language at § 441.301(c)(7)(viii) to specify that **States must comply with** the requirements at § 441.301(c)(7) **beginning** 2 years from the effective date of this final rule, rather than stating that this requirement is effective 2 years after the date of enactment of the final rule. (New text in bolded font). We are finalizing § 441.301(c)(7)(viii) with a technical modification to specify that the applicability date applies to the requirements at § 441.301(c)(7).

Comment: A few commenters requested enhanced FMAP to support implementation and operationalization

of the grievance process. Two commenters recommended that, in addition to providing 90 percent FFP for information systems improvements, we should offer 75 percent FFP for all quality-related activities, including operational costs associated with a grievance system. The commenters suggested this would create parity between the States whose service delivery systems are largely FFS and the States with managed care services that can receive 75 percent FFP for External Quality Review (EQR) activities.

Response: We note that enhanced FMAP is available for certain activities related to administering the Medicaid program and designing, developing, implementing, and operating certain IT systems.[60] However, Federal matching rates are established by Congress and CMS does not have the authority to change or increase them, nor do we have the authority to add additional activities not specified in statute into the scope of an existing enhanced FMAP. We also do not agree that providing broader enhanced match for the FFS grievance system would create parity with managed care, as we believe this is an inaccurate characterization of payments related to the managed care grievance systems. While commenters are correct that States can receive 75 percent enhanced match for EQR activities, which are listed at § 438.358, these activities are primarily validation and review of data on performance measures; the operation of a grievance system is not listed as an EQR activity. We also note that the associated administrative costs for MCOs, PIHPs, and PAHPs are variable and negotiated with the State as part of their contracts.

After consideration of public comments received, we are finalizing the substance of § 441.301(c)(7)(viii) as proposed, but with minor modifications to correct erroneous uses of the word ''effective'' and retitle the requirement as Applicability date (rather than Effective date). We are also modifying the language at § 441.301(c)(7)(viii) to specify that States must comply with the requirements at § 441.301(c)(7) beginning 2 years from the effective date of this final rule, rather than stating that this requirement is effective 2 years after the date of enactment of the final rule. (New text in bolded font.) We are finalizing § 441.301(c)(7)(viii) with a technical modification to specify that the applicability date applies to the requirements at § 441.301(c)(7).

h. Application to Other Authorities

As discussed earlier in section II.B.1. of this preamble, section 2402(a)(3)(A) of the Affordable Care Act requires States to improve coordination among, and the regulation of, all providers of Federally and State-funded HCBS programs to achieve a more consistent administration of policies and procedures across HCBS programs. In accordance with the requirement of section 2402(a)(3)(A) of the Affordable Care Act for States to achieve a more consistent administration of policies and procedures across HCBS programs and because HCBS State plan options also must comply with the HCBS Settings Rule and with similar person-centered planning and service plan requirements, we proposed to include these grievance requirements within the applicable regulatory sections. Specifically, we proposed to apply these proposed requirements in § 441.301(c)(7) to sections 1915(j), (k), and (i) State plan services at §§ 441.464(d)(2)(v), 441.555(b)(2)(iv), and 441.745(a)(1)(iii), respectively.

Also, consistent with our proposal for section 1915(c) waivers, we proposed to apply the proposed grievance requirements in § 441.301(c)(7) to sections 1915(j), (k), and (i) State plan services based on our authority under section 1902(a)(19) of the Act to assure that there are safeguards for beneficiaries and our authority at section 2402(a)(3)(B)(ii) of the Affordable Care Act to require a complaint system for beneficiaries. We stated that the same arguments for applying these requirements for section 1915(c) waivers are equally applicable to these other HCBS authorities. We requested comment on the application of the grievance system provisions to section 1915(i), (j), and (k) authorities. We also noted that, in the language added to § 441.464(d)(2)(v), the proposed grievance requirements apply when self-directed personal assistance services authorized under section 1915(j) include services under a section 1915(c) waiver program.

As described in the proposed rule (88 FR 27978), we did not propose to apply these requirements to section 1905(a) services. Specifically, we considered whether to also apply the proposed requirements to section 1905(a) ''medical assistance'' in the form of State plan personal care services, home health services, and case management services, but did not propose these requirements apply to any section 1905(a) State plan services because section 1905(a) services are not required to comply with HCBS settings requirements and because the person-centered planning and service plan requirements for most section 1905(a) services are substantially different from those for section 1915(c), (i), (j), and (k) services. Further, the vast majority of HCBS is delivered under section 1915(c), (i), (j), and (k) authorities, while only a small percentage of HCBS nationally is delivered under section 1905(a) State plan authorities. We solicited comment, seeing the value in discussing and seeking public input, on whether we should establish grievance requirements for section 1905(a) State plan personal care services, home health services and case management services.

We received public comments on these proposals. The following is a summary of the comments and our responses.

Comment: A few commenters supported the proposal to apply the grievance system provisions proposed for section 1915(c) at § 441.301(c)(7) to sections 1915(i), (j) and (k) authorities. They agreed with the goal of aligning the different HCBS program authorities and promoted consistency with managed care.

Response: We thank commenters for their support.

Comment: One commenter supported the application of the grievance requirements to self-directed personal assistance services under section 1915(j) of the Act as well. This commenter noted that, during the pandemic, there was no clear way to file a grievance with Medicaid concerning a lack of access to direct care workers, for example.

One commenter, on the other hand, questioned the operationalization of the grievance process for self-directed personal care service models under sections 1915(j) and (k), where the beneficiary acts as the employer for purposes of hiring, training, supervising, and firing, their provider, if necessary. This commenter was concerned that allowing beneficiaries to file grievances against their provider would erode a beneficiary's responsibilities as the employer. Another commenter, while supporting application of the grievance process to section 1915(j) self-directed services, did suggest that implementing this requirement in self-directed models may require additional time and guidance.

Response: We believe it would be inappropriate to exclude beneficiaries enrolled in self-directed services delivery models from the grievance system and decline to do so in this final rule. As noted by other commenters, beneficiaries enrolled in self-directed

[60] For a current list of activities eligible for this enhanced FMAP, refer to: MACPAC, ''Federal Match Rates for Medicaid Administrative Activities,'' last access: October 22, 2023. *https://www.macpac.gov/federal-match-rates-for-medicaid-administrative-activities/.*

services may experience systemic challenges with their services; they may also interact with other providers in addition to their self-directed service provider (such as the entity providing financial management services). We also note that the grievance system is a venue for expressing concerns about violations of the HCBS settings requirements, which may be relevant to some beneficiaries in self-directed programs. We do not believe that additional time needs to be granted specifically for inclusion of beneficiaries using self-directed services.

Comment: Several commenters responded to our request for comment on whether we should establish grievance requirements for section 1905(a) State plan personal care services, home health services and case management services. A few commenters supported the proposal not to extend the requirements to section 1905(a) services on the basis that these services are not subject to the same person-centered planning and HCBS settings rules. Additionally, several commenters also believed the expansion of these requirements to section 1905(a) State plan services would pose additional challenges to State Medicaid and operating agencies. One commenter noted that, in States that deliver section 1905(a) State plan services and section 1915(c) services through different agencies or agency divisions, implementation could prove challenging and costly. A few commenters stated that States should be encouraged (but not required) to implement the proposed provisions to their section 1905(a) State plan services.

However, a few commenters supported extending the grievance system requirements to section 1905(a) services. Among these commenters, a few commenters recommended that CMS apply the grievance system requirements specifically to mental health rehabilitative services delivered under section 1905(a) services. These services, some commenters stated, are delivered to large numbers of Medicaid beneficiaries, particularly those with mental health needs. These commenters elaborated on concerns that, otherwise, there would be disparities between individuals receiving similar services from the same State Medicaid agency under different authorities, and that many Medicaid recipients with mental health disabilities receiving services under the section 1905(a) authority would not have recourse if their rights were violated. One commenter also suggested that mental health rehabilitative services are considered ''home- and community-based services'' under the broader definition enacted by Congress in the American Rescue Plan Act of 2021.

Response: At this time, we are not requiring inclusion of section 1905(a) services in the State grievance system. That said, we are not convinced by the argument that including section 1905(a) services would simply be too much work, as we do believe it is critical that beneficiaries have access to mechanisms to claim their rights and have their concerns heard. Rather, we note that there are statutory and regulatory differences between services authorized under sections 1905(a) and 1915 of the Act. We would need to consider how to define the nature of the grievances that would be filed for section 1905(a) services, given that they do not have the same person-centered planning and HCBS settings rule requirements at § 441.301(c)(1) through (6). As we discussed extensively in this section, the bases for a grievance are providers' and States' performance of the requirements at § 441.301(c)(1) through (6). We believe this definition of grievance provides clear parameters for matters that would be the subject of grievances. We note that person-centered service planning requirements are established for section 1915(j) services in § 441.468, for section 1915(k) services in § 441.540, and for section 1915(i) services at § 441.725. While person-centered service planning might be part of some specific 1905(a) services, it is not a required component of all section 1905(a) services.

Similarly, the HCBS settings requirements a § 441.301(c)(3) through (6) that apply to section 1915(c) services have counterparts for section 1915(k) services at § 441.530 and for 1915(i) services at § 441.710. (For more discussion of the application of the HCBS settings rule's application to section 1915(c), (i), and (k) services, we refer readers to the final rule published in 2014 at 79 FR 2948.) Section 1915(j) services offered through a section 1915(c) waiver (as specified, for instance, at § 441.452(a)) would also be subject to the HCBS settings requirements at § 441.301(c)(3) through (6). There is not a similar application of the HCBS settings rule to section 1905(a) services.

If we are to apply a grievance process to 1905(a) services, it is likely we would weigh proposing a grievance process for all section 1905(a) services versus for only specific section 1905(a) services. These services are diverse, are offered in diverse settings, and lack the clear regulatory framework that we were able to use in constructing the bases for grievances in section 1915 services. We believe this requires additional consideration and discussion with the public beyond what could be finalized in this current rule.

Though we are not finalizing inclusion of section 1905(a) services in the State grievance system in this rule, we acknowledge that many beneficiaries, including those receiving mental health services, are served by section 1905(a) services and encourage States to consider development of grievance processes to address these beneficiaries' concerns. We appreciate the commenters' suggestions. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

After consideration of public comments, we are finalizing the application of the grievance system requirements for section 1915(c) waivers, as finalized in this rule at § 441.301(c)(7), to the other HCBS authorities under sections 1915(j), 1915(k), and 1915(i). However, after further review, we determined it is necessary to make modifications to our regulations for these other HCBS authorities to clarify this intention. Our proposed regulation text for these HCBS authorities did not accurately reflect or effectuate our proposal to require States to implement and maintain a grievance system, in accordance with § 441.301(c)(7), for these HCBS authorities as well. We are finalizing the regulation text we proposed at §§ 441.464 (for section 1915(j)), 441.555 (for section 1915(k)), and 441.745 (for section 1915(i)) with modification to more clearly specify that a State must implement and maintain a grievance system in accordance with the requirements we are finalizing at § 441.301(c)(7) for HCBS programs they administer under these authorities.

For application to section 1915(j) services, we are not finalizing the amendment we proposed at § 441.464(d)(2)(v), but rather finalizing this new requirement for a grievance system at § 441.464(d)(5). We will retain the current language at § 441.464(d)(2)(v), which indicates that States must include grievance processes, generally, among the support activities about which States provide information, counseling, training, and assistance. At § 441.464(d)(5), we are finalizing with modification for clarity and precision that the State must implement and maintain a grievance process in accordance with § 441.301(c)(7), rather

than the language we proposed at § 441.464(d)(2)(v) (Grievance process, as defined in § 441.301(c)(7) when self-directed PAS include services under a section 1915(c) waiver program). We are also finalizing § 441.464(d)(5) with a technical modification to clarify that the grievance system must meet the requirements of § 441.301(c)(7), but that references therein to section 1915(c) of the Act are instead references to section 1915(j) of the Act.

For application to section 1915(k) services, we are not finalizing the amendment we proposed at § 441.555(b)(2)(iv), but rather finalizing this new requirement for a grievance system at § 441.555(e). We will retain the current language at § 441.555(b)(2)(iv), which indicates that States must include grievances processes, generally, among the support activities about which States provide information, counseling, training, and assistance. At § 441.555(e), we are finalizing with modification for clarity and precision that the State must implement and maintain a grievance process in accordance with § 441.301(c)(7), rather than the language we proposed at § 441.555(b)(2)(iv) (Grievance process, as defined in § 441.301(c)(7)). We are also finalizing § 441.555(e) with a technical modification to clarify that the grievance system must meet the requirements of § 441.301(c)(7), but that references therein to section 1915(c) of the Act are instead references to section 1915(k) of the Act.

For application to section 1915(i) services, we are finalizing the amendment we proposed at § 441.745(a)(1)(iii) with modifications. As proposed, § 441.745(a)(1)(iii) had indicated that a State must provide beneficiaries receiving section 1915(i) services with the opportunity to file a grievance. To clarify that the State must maintain a grievance process in accordance with § 441.301(c)(7) for beneficiaries receiving HCBS under section 1915(i), we are finalizing § 441.745(a)(1)(iii) to specify that the State must implement and maintain a grievance process in accordance with § 441.301(c)(7). We note that several requirements being finalized at § 441.301(c)(7) (such as § 441.301(c)(7)(iii)(A), (B)(*2*), and (C)(*1*), discussed in section II.B.2.b. of this final rule) require States to provide the beneficiary with the opportunity to file grievances in the grievance system. We are also finalizing § 441.745(a)(1)(iii) with a technical modification to clarify that the grievance system must meet the requirements of § 441.301(c)(7), but that references therein to section 1915(c) of the Act are instead references to section 1915(i) of the Act. Additionally, as we are finalizing a new § 441.745(a)(1)(iii) in this rule, we are redesignating the current § 441.745(a)(1)(iii) as § 441.745(a)(1)(iv).

We also note that while we are finalizing these amendments to regulations under section 1915(j), (k) and (i) authorities, we are not suggesting that States that provide HCBS through multiple authorities must operate a separate grievance process for each program. As discussed earlier in II.B.2. of this preamble, while States are allowed to maintain multiple grievance processes (so long as each process complies with § 441.301(c)(7)), we strongly encourage States to maintain a single, integrated grievance system for all HCBS beneficiaries.

i. Summary of Finalized Requirements

After consideration of the public comments, we are finalizing the proposals at §§ 441.301(c)(7) as follows:

- We are finalizing the requirement describing the grievance system purpose at § 441.301(c)(7)(i) with technical modifications to specify that States must establish a procedure under which a beneficiary can file a grievance related to the State's or a provider's **performance of** (rather than **compliance with**) the activities described in paragraphs (c)(1) through (6) of § 441.301(c)(7). (New language identified in bold.) We are also adding language to § 441.301(c)(7)(i) stating that the State may contract with other entities to perform activities described in § 441.301(c)(7) but retains responsibility for ensuring performance of and compliance with these provisions. The finalized requirement at § 441.301(c)(7)(i) will read: *Purpose.* The State must establish a procedure under which a beneficiary may file a grievance related to the State's or a provider's performance of the activities described in paragraphs (c)(1) through (6) of this section. This requirement does not apply to a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act. The State may have activities described in paragraph (c)(7) of this section performed by contractors or other government entities, provided, however, that the State retains responsibility for ensuring performance of and compliance with these provisions.
- We are finalizing the definition of grievance at § 441.301(c)(7)(ii) with a technical modification, conforming with the modification at § 441.301(c)(7)(i), to specify that a grievance will mean an expression of dissatisfaction or complaint related to the State's or a provider's performance of (rather than **compliance with**) the activities described in paragraphs (c)(1) through (6), regardless of whether remedial action is requested. (New language identified in bold.) We are finalizing the definition of grievance system at § 441.301(c)(7)(ii) as proposed.
- We are finalizing the process requirement at § 441.301(c)(7)(iii)(A) as proposed, with the following exceptions. We are finalizing § 441.301(c)(7)(iii)(A)(*1*) with modification to specify that another individual or entity may file a grievance on behalf of the beneficiary, or provide the beneficiary with assistance or representation throughout the grievance process, with the written consent of the beneficiary or authorized representative. The finalized requirement at § 441.301(c)(7)(ii)(A)(*1*) will read: Another individual or entity may file a grievance on behalf of the beneficiary, or provide the beneficiary with assistance or representation throughout the grievance process, with the written consent of the beneficiary or authorized representative. We are finalizing § 441.301(c)(7)(iii)(A)(*2*) as proposed.
- We are finalizing the process requirement at § 441.301(c)(7)(iii)(B) as proposed.
- We are finalizing § 441.301(c)(7)(iii)(B)(*1*) with a modification to correct an erroneous reference to subchapter by replacing subchapter with paragraph (c)(7).
- We are finalizing the process requirements at § 441.301(c)(7)(iii)(B)(*2*) with a modification to specify that States must provide beneficiaries with reasonable assistance in ensuring grievances are appropriately filed with the grievance system. We are also finalizing § 441.307(c)(7)(iii)(B)(2) with modifications to change the term ''individuals who are limited English proficient'' to ''individuals with Limited English Proficiency.'' We are also finalizing with modification to clarify that auxiliary aids and services are to be available where necessary to ensure effective communication. As finalized, § 441.301(c)(7)(iii)(B)(2) specifies that States must provide beneficiaries reasonable assistance in ensuring grievances are appropriately filed with the grievance system, completing forms, and taking other procedural steps related to a grievance. This includes, but is not limited to, ensuring the grievance system is accessible to individuals with disabilities and to provide meaningful access to individuals with Limited English Proficiency, consistent with § 435.905(b) of this chapter, and includes auxiliary aids and services

where necessary to ensure effective communication, such as providing interpreter services and toll-free numbers that have adequate TTY/TTD and interpreter capability.

- We are finalizing the process requirement at § 441.301(c)(7)(iii)(B)(3) with modifications to require that States ensure that punitive or retaliatory action (rather than just punitive actions) is neither threatened nor taken against an individual filing a grievance or who has had a grievance filed on their behalf. The finalized requirement at § 441.301(c)(7)(iii)(B)(3) will read: Ensure that punitive or retaliatory action is neither threatened nor taken against an individual filing a grievance **or who has had a grievance filed on their behalf**. (New language identified in bold.)
- We are finalizing the process requirement § 441.301(c)(7)(iii)(B)(4) with a modification to remove the reference to expedited grievances. The finalized requirements at § 441.301(c)(7)(iii)(B)(4) will read: Accept grievances and requests for extension of timeframes from the beneficiary.
- We are finalizing the process requirements at § 441.301(c)(7)(iii)(B)(5) with a modification to change mention of individuals who are limited English proficient to individuals with Limited English Proficiency.
- We are finalizing the process requirements at § 441.301(c)(7)(iii)(B)(6) and (7) as proposed.
- We are finalizing the requirements at § 441.301(c)(7)(iii)(C)(*4*) and (*5*) with a modification to replace the reference to § 441.301(c)(7)(v)(B)(1) and (2) and adding a reference to § 441.301(c)(7)(v). We are also finalizing § 441.301(c)(7)(iii)(C)(5) with a modification to change the reference to 45 CFR 164.510(b) to a broader reference to the HIPAA Privacy Rule (45 CFR part 160 and part 164 subparts A and E).
- Aside from the modifications noted previously to § 441.301(c)(7)(iii)(C)(*4*) and (5), we are finalizing § 441.301(c)(7)(iii)(C) as proposed, with minor formatting changes.
- We are finalizing the filing timeframe requirement at § 441.301(c)(7)(iv) with modifications by removing the expedited resolution requirement at § 441.301(c)(7)(iv)(B) and redesignating § 441.301(c)(7)(iv)(A) as § 441.301(c)(7)(iv). The finalized requirement at 441.301(c)(7)(iv) will read: *Filing timeframes.* A beneficiary may file a grievance at any time.
- We are finalizing the resolution and notification requirement at § 441.301(c)(7)(v)(A) with a modification to require that the State resolve each grievance, and provide notice, as expeditiously as the beneficiary's health condition (instead of health, safety, and welfare) requires. The finalized requirement at § 441.301(c)(7)(v)(A) will read: *Basic rule.* The State must resolve each grievance, and provide notice, as expeditiously as the beneficiary's health condition requires, within State-established timeframes that may not exceed the timeframes specified in this section.
- We are not finalizing the expedited resolution timeframe at § 441.301(c)(7)(v)(B)(*2*). Instead, we are redesignating § 441.301(c)(7)(v)(B)(*1*) as § 441.301(c)(7)(v)(B) and retitling § 441.301(c)(7)(v)(B) as ''Resolution timeframes.'' We are also removing the word ''standard'' from § 441.301(c)(7)(v)(B). The finalized requirement at § 441.301(c)(7)(v)(B) will read: *Resolution timeframes.* For resolution of a grievance and notice to the affected parties, the timeframe may not exceed 90 calendar days from the day the State receives the grievance. This timeframe may be extended under paragraph (c)(7)(v)(C) of this section.
- We are finalizing the timeframe extension requirement at § 441.301(c)(7)(v)(C) and (D) without substantive changes. We are finalizing § 441.301(c)(7)(v)(C) with a technical modification to redesignate paragraphs (C)(*1*)(i) and (C)(*1*)(ii) as (C)(*1*) and (C)(*2*), respectively. We are finalizing § 441.301(c)(7)(v)(D) as proposed, but with a technical modification to change the periods at the end of § 441.301(c)(7)(v)(D)(*1*) and (*2*) to semi-colons, and adding ''and'' at the end of § 441.301(c)(7)(v)(D)(*2*).
- We are finalizing the notice format requirement at § 441.301(c)(7)(vi)(A) without substantive modification. However, we are not finalizing the proposal relating to the expedited resolution process at § 441.301(c)(7)(vi)(B). Therefore, we are redesignating § 441.301(c)(7)(vi)(A) as § 441.301(c)(7)(vi).
- We are finalizing the recordkeeping requirements at § 441.301(c)(7)(vii) without substantive modifications. However, we are finalizing § 441.301(c)(7)(viii)(B)(*1*) through (*5*) with semi-colons rather than periods at the end of each paragraph, and with the word ''and'' at the end of § 441.301(c)(7)(vii)(B)(*5*).
- We are finalizing the applicability date requirements at § 441.301(c)(7)(viii) to specify that States must comply with the requirement at paragraph (c)(7) beginning 2 years from the effective date of this final rule.

Additionally, we are finalizing the application of the grievance process requirements at § 441.301(c)(7) to section 1915(j), (k) and (i) authorities as follows:

- For application to section 1915(j) services, we are not finalizing a reference at § 441.464(d)(2)(v), as we had proposed, but rather finalizing a new requirement at § 441.464(d)(5) that specifies that States must implement and maintain a grievance process in accordance with § 441.301(c)(7), except that the references to section 1915(c) of the Act are instead references to section 1915(j) of the Act.
- For application to section 1915(k) services, we are not finalizing a reference at § 441.555(b)(2)(iv), as we had proposed, but rather finalizing a new requirement at § 441.555(e) that specifies that States must implement and maintain a grievance process in accordance with § 441.301(c)(7), except that the references to section 1915(c) of the Act are instead references to section 1915(k) of the Act.
- For application to section 1915(i) services, we are finalizing a new § 441.745(a)(1)(iii) with modification to clarify that the State must maintain a grievance process in accordance with § 441.301(c)(7), except that the references to section 1915(c) of the Act are instead references to section 1915(i) of the Act. We are redesignating the existing § 441.745(a)(1)(iii) as § 441.745(a)(1)(iv).

3. Incident Management System (§§ 441.302(a)(6), 441.464(e), 441.570(e), 441.745(a)(1)(v) and 441.745(b)(1)(i))

Section 1902(a)(19) of the Act requires States to provide safeguards as may be necessary to assure that eligibility for care and services will be determined, and that such care and services will be provided, in a manner consistent with simplicity of administration and the best interests of the recipients. Section 1915(c)(2)(A) of the Act and current Federal regulations at § 441.302(a) require that States have in place necessary safeguards to protect the health and welfare of individuals receiving section 1915(c) waiver program services. Further, as discussed previously in section II.B.1. of this rule, section 2402(a) of the Affordable Care Act requires the Secretary of HHS to ensure that all States receiving Federal funds for HCBS, including Medicaid, develop HCBS systems that are responsive to the needs and choices of beneficiaries receiving HCBS, maximize independence and self-direction, provide support and coordination to assist with a community-supported life, and achieve a more a more consistent

and coordinated approach to the administration of policies and procedures across public programs providing HCBS.[61] Among other things, section 2402(a)(3)(B)(ii) of the Affordable Care Act requires development and oversight of a system to qualify and monitor providers.

As noted earlier in section II.B.1. of this rule, we released guidance for section 1915(c) waiver programs included in the 2014 guidance,[62] which noted that States should report on State-developed performance measures to demonstrate that they meet six assurances, including a Health and Welfare assurance for States to demonstrate that they have designed and implemented an effective system for assuring waiver participant health and welfare. Specifically, the 2014 guidance highlighted, related to the Health and Welfare assurance, the following:

- The State demonstrates on an ongoing basis that it identifies, addresses, and seeks to prevent instances of abuse, neglect, exploitation, and unexplained death;
- The State demonstrates that an incident management system is in place that effectively resolves incidents and prevents further similar incidents to the extent possible;
- The State's policies and procedures for the use or prohibition of restrictive interventions (including restraints and seclusion) are followed; and
- The State establishes overall health care standards and monitors those standards based on the responsibility of the service provider as stated in the approved waiver.

Consistent with the expectations for other performance measures, the 2014 guidance noted that States should conduct systemic remediation and implement a Quality Improvement Project when they score below 86 percent on any of their Health and Welfare performance measures.

Despite States implementing these statutory and regulatory requirements to protect the health and welfare of individuals receiving section 1915(c) waiver program services, and States' adherence to related subregulatory guidance, there have been notable and high-profile instances of abuse and neglect in recent years that highlight the risks associated with poor quality care and with inadequate oversight of HCBS in Medicaid. For example, a 2018 report, ''Ensuring Beneficiary Health and Safety in Group Homes Through State Implementation of Comprehensive Compliance Oversight,'' [63] (referred to as the Joint Report, developed by ACL, OCR, and the OIG), found systemic problems with health and safety policies and procedures being followed in group homes and that failure to comply with these policies and procedures left beneficiaries in group homes at risk of serious harm.

In addition, in 2016 and 2017, OIG released several reports on their review of States' compliance with Federal and State requirements regarding critical incident reporting and monitoring.[64] [65] [66] OIG found that several States did not comply with Federal waiver and State requirements for reporting and monitoring critical incidents involving individuals receiving HCBS through waivers. In particular, the reports indicated that:

- Critical incidents were not reported correctly;
- Adequate training to identify appropriate action steps for reported critical incidents or reports of abuse or neglect was not provided to State staff;
- Appropriate data sets to trend and track critical incidents were not accessible to State staff; and
- Critical incidents were not clearly defined, making it difficult to identify potential abuse or neglect.

In 2016, we conducted three State audits based at least in part on concerns regarding health and welfare and media coverage on abuse, neglect, or exploitation issues.[67] We found that these three States had not been meeting their section 1915(c) waiver assurances, similar to findings reported by the OIG. In two cases, for the incidents of concern, tracking and trending of critical incidents were not present. Further, in at least two of the States, staffing at appropriate levels was identified as an issue.

In January 2018, the United States Government Accountability Office (GAO) released a report on a study of 48 States that covered assisted living services.[68] The GAO found large inconsistencies between States in their definition of a critical incident and their system's ability to report, track, and collect information on critical incidents that have occurred. States also varied in their oversight methods, as well as the type of information they were reviewing as part of this oversight. The GAO recommended that requiring States to report information on incidents (such as the type and severity of incidents and the number of incidents) would strengthen the effectiveness of State and Federal oversight.

In July 2019, we issued a survey to States that operate section 1915(c) waivers, requesting information on their approach to administering incident management systems. The goal of the survey was to obtain a comprehensive understanding of how States organize their incident management system to best respond to, resolve, monitor, and prevent critical incidents in their waiver programs. The survey found that:

- Definitions of critical incidents vary across States and, in some cases, within States for different HCBS programs or populations;
- Some States do not use standardized forms for reporting incidents, thereby impeding the consistent collection of information on critical incidents;
- Some States do not have electronic incident management systems, and, among those that do, many use systems with outdated electronic platforms that are not linked with other State systems, leading to the systems operating in silos and the need to consolidate information across disparate systems; and
- Many States cited the lack of communication within and across State agencies, including with investigative agencies, as a barrier to incident resolution.

[61] Section 2402(a) of the Affordable Care Act—Guidance for Implementing Standards for Person-Centered Planning and Self-Direction in Home and Community-Based Services Programs. Accessed at *https://acl.gov/sites/default/files/news%202016-10/2402-a-Guidance.pdf*.

[62] Modifications to Quality Measures and Reporting in § 1915(c) Home and Community-Based Waivers. March 2014. Accessed at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/3-cmcs-quality-memo-narrative_0_2.pdf*.

[63] Ensuring Beneficiary Health and Safety in Group Homes Through State Implementation of Comprehensive Compliance Oversight. US Department of Health and Human Services, Office of the Inspector General, Administration for Community Living, and Office for Civil Rights. January 2018. Accessed at *https://oig.hhs.gov/reports-and-publications/featured-topics/group-homes/group-homes-joint-report.pdf*.

[64] HHS OIG. ''Connecticut did not comply with Federal and State requirements for critical incidents involving developmentally disabled Medicaid beneficiaries.'' May 2016. Accessed at *https://oig.hhs.gov/oas/reports/region1/11400002.pdf*.

[65] HHS OIG. ''Massachusetts did not comply with Federal and State requirements for critical incidents involving developmentally disabled Medicaid beneficiaries.'' July 2016. Accessed at *https://oig.hhs.gov/oas/reports/region1/11400008.pdf*.

[66] HHS OIG. ''Maine did not comply with Federal and State requirements for critical incidents involving Medicaid beneficiaries with developmental disabilities.'' August 2017. Accessed at *https://oig.hhs.gov/oas/reports/region1/11600001.pdf*.

[67] Presentation by CMS for Advancing States: Quality in the HCBS Waiver—Health and Welfare. See: *http://www.nasuad.org/sites/nasuad/files/Final%20Quality%20201.pdf*.

[68] Government Accountability Office. ''Medicaid assisted living services—improved Federal oversight of beneficiary health and welfare is needed.'' January 2018. Accessed at *https://www.gao.gov/assets/690/689302.pdf*.

Additionally, during various public engagement activities conducted with interested parties over the past several years, we have heard that ensuring access to HCBS requires that we must first ensure health and safety systems are in place across all States, a theme underscored by the Joint Report.

a. Incident Management System Requirements (§ 441.302(a)(6))

Based on these findings and reports, under the authorities at sections 1902(a)(19) and 1915(c)(2)(A) of the Act and section 2402(a)(3)(B)(ii) of the Affordable Care Act, we proposed a new requirement at § 441.302(a)(6) to require that States provide an assurance that they operate and maintain an incident management system that identifies, reports, triages, investigates, resolves, tracks, and trends critical incidents. This proposal is intended to ensure standardized requirements for States regarding incidents that harm or place a beneficiary at risk of harm and is based on our experience working with States as part of the section 1915(c) waiver program and informed by the incident management survey described previously in this section of the final rule. In the absence of an incident management system, people receiving section 1915(c) waiver program services are at risk of preventable or intentional harm. As such, we believe that such a system to identify and address incidents of abuse, neglect, exploitation, or other harm during the course of service delivery is in the best interest of and necessary for protecting the health and welfare of individuals receiving section 1915(c) waiver program services. We proposed similar requirements for section 1915(i), (j) and (k) HCBS programs at §§ 441.464(e), 441.570(e), 441.745(a)(1)(v), and 441.745(b)(1)(i); these are discussed further in section II.B.3.i of this final rule.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal at § 441.302(a)(6) to require States to provide an assurance that they operate and maintain an incident management system that identifies, reports, triages, investigates, resolves, tracks, and trends critical incidents. Additionally, these commenters noted that the proposed requirements for this incident management system can ensure States standardize data and processes for critical incident monitoring, identify trends, and influence timely oversight of responses to incidents to minimize health and safety risks for beneficiaries receiving HCBS.

Several commenters stated that establishing an incident management system, including requirements for data-driven analytics and trend reporting, would help to better inform States and providers by creating new collaborative models to measure improvements to better ensure quality of life for HCBS beneficiaries. In the same vein, one commenter noted that States should use the data and information collected on critical incidents to develop strategies to reduce or eliminate the risk of abuse, neglect, or exploitation; to enable discovery of root cause for occurrence of critical incidents; and to identify actions to influence critical incidents proactively, instead of reactively.

Response: We appreciate the support for our proposal and agree that requiring States to provide an assurance that they operate and maintain an incident management system that identifies, reports, triages, investigates, resolves, tracks, and trends critical incidents will ensure that States are better informed and more able to identify root causes for the occurrence of critical incidents, enabling them to act more proactively to influence and prevent the occurrence of such incidents.

Comment: A few commenters requested we clarify how States can fully address critical incidents for dually eligible beneficiaries who are enrolled in managed care plans, when the managed care plan does not have access to Medicare claims data. In the same vein, they were also concerned that States would require extensive resources to utilize the Medicare claims data.

These commenters also requested clarification on the feasibility of reporting across Medicare and Medicaid in dual eligible special needs plan (D–SNP) contracts.

Response: Since 2011, we have provided States access to Medicare data for dually-eligible beneficiaries, including for beneficiaries in different categories of dual eligibility, free-of-charge via the Medicare-Medicaid Data Sharing Program.[69] Information on the Medicare-Medicaid Data Sharing Program, including how to request data and the standard data sharing agreements, is available through the State Data Resource Center.[70]

We proposed that the incident management system requirements, as specified at § 441.302(a)(6) and as finalized in this rule, will apply to section 1915(c)(i), (j), and (k) services delivered through managed care plans. We also note that dually eligible beneficiaries enrolled in managed care plans known as fully integrated dual eligible special needs plans (FIDE SNP) and highly integrated dual eligible special needs plans (HIDE SNP), are subject to the incident management requirements at § 441.302(a)(6) as finalized. We will provide technical assistance regarding the application of these requirements to beneficiaries in different categories of dual eligibility.

Comment: A few commenters expressed concern that the requirements we proposed for this incident management system generally seemed to be more focused on documentation of critical incidents, rather than impacting quality and outcomes for HCBS participants to ensure optimal health and welfare. One commenter recommended that States should assure that resolution of critical incidents focuses on preventing harm to the HCBS participant(s) involved in the critical incident. This commenter also suggested that States should take actions to not only prevent further harm to HCBS participant(s) involved in a critical incident, but actions based on the critical incident should be taken to prevent further harm to all HCBS participants.

Response: We believe the requirements we proposed at § 441.302(a)(6), and as finalized in this rule, give States the flexibility to decide how to design and implement their incident management system. We encourage States to consider implementing quality improvement processes as part of their incident management systems, as quality improvement processes can help States to promote the health and welfare of beneficiaries by addressing systemic issues in their HCBS programs. We also note that the purpose of tracking and trending critical incidents is to assist States in understanding patterns that require interventions to promote improvement and prevent the recurrence of harm to beneficiaries.

We also refer readers to the requirements currently set forth at § 438.330(b)(5)(ii) that MCOs, PHIPs, and PAHPs participate in efforts by the State to prevent, detect, and remediate critical incidents, consistent with assuring beneficiary health and welfare as required in § 441.302 and § 441.703(a). Further, as noted herein, the six assurances and related

[69] See Medicare-Medicaid Data Sharing Program at *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/StateAccesstoMedicareData.*

[70] See State Data Resource Center at *https://www.statedataresourcecenter.com/home/contact-us.*

subassurances for section 1915(c) waiver programs, including the Health and Welfare assurance, as set forth in the 2014 guidance, continue to apply. In addition, as discussed in section II.B.8. of this final rule, the HCBS Quality Measure Set reporting requirements include requirements for States to implement quality improvement strategies in their HCBS programs; while the HCBS Quality Measure Set requirements being finalized in this rule are distinct and severable from the incident management requirements being finalized at § 441.302(a)(6), we believe the HCBS Quality Measure Set requirements support the quality improvement objectives described by this commenter.

After consideration of these public comments, we are finalizing our proposal to require at § 441.302(a)(6) that States must provide an assurance that the State operates and maintains an incident management system that identifies, reports, triages, investigates, resolves, tracks, and trends critical incidents as proposed.

b. Critical Incident Definition (§ 441.302(a)(6)(i)(A))

At § 441.302(a)(6)(i)(A) through (G), we proposed new requirements for States' incident management systems. Specifically, at § 441.302(a)(6)(i)(A), we proposed to establish a standard definition of a critical incident to include, at a minimum, verbal, physical, sexual, psychological, or emotional abuse; neglect; exploitation including financial exploitation; misuse or unauthorized use of restrictive interventions or seclusion; a medication error resulting in a telephone call to or a consultation with a poison control center, an emergency department visit, an urgent care visit, a hospitalization, or death; or an unexplained or unanticipated death, including but not limited to a death caused by abuse or neglect.

We proposed the Federal minimum standard definition of a critical incident at § 441.302(a)(6)(i)(A) to address the lack of a standardized Federal definition for the type of events or instances that States should consider a critical incident that must be reported by a provider to the State and considered for an investigation by the State to assess whether the incident was the result of abuse, neglect, or exploitation, and whether it could have been prevented. The definition we proposed at § 441.302(a)(6)(i)(A) is based on internal analyses of data and information obtained through a CMS survey of States' incident management systems, commonalities across definitions, and common gaps in States' definitions of critical incidents (for instance, that many States do not consider sexual assault to be a critical incident).

We also requested comment on whether there are specific types of events or instances of serious harm to section 1915(c) waiver participants, such as identity theft or fraud, that would not be captured by the proposed definition and that should be included, and whether the inclusion of any specific types of events or instances of harm in the proposed definition would lead to the overidentification of critical incidents.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposed minimum standard definition of a critical incident. Commenters expressed that the proposed requirements at § 441.302(a)(6)(i)(A) establish a minimum Federal definition of a critical incident which would help to standardize practices across States and HCBS programs to better serve and prevent harm or risk of harm for beneficiaries. A few commenters noted the standardized Federal minimum definition of a critical incident will increase consistency across States, section 1915(c) waivers, and HCBS programs. A few commenters suggested CMS further explain the critical incident definition to minimize misinterpretation, stating that explanations of definitions for each type of critical incident could ensure reporting is uniform and consistent across all State programs and services. These commenters stated that without a uniform understanding of each type of critical incident, critical incidents could be over or under reported. Similarly, several other commenters suggested that the definition of critical incident we proposed is overly broad, expressing it could impede the State's coordination with other agencies and interested parties. These commenters indicated that more explanation of the definitions of critical incident at § 441.302(a)(6)(i)(A) could help to address varying interpretations in implementation of the proposed requirements, noting that each State Medicaid agency or interested parties could independently establish meaning.

Response: We disagree with commenters that the proposed definition of critical incident is overly broad. We believe that the proposed requirements at § 441.302(a)(6)(i)(A) provide States with a comprehensive minimum standard definition of a critical incident. We recommend that States view the definition as a minimum Federal standard. States may consider expanding the definition to include other health and safety concerns based on the unique needs of their HCBS populations and the specific characteristics of their HCBS programs. We plan to provide technical assistance, as needed, to States if they have questions about the types of incidents that should be included in the standardized definition, and how this definition relates to existing critical incident definitions already in use.

Comment: Commenters responded to our request for comment on whether there were specific types of events or instances of serious harm that would not be captured by the proposed critical incident definition and should be included. A few commenters suggested that we broaden the definition of critical incident and suggested that the following types of incidents be included in the proposed definition of critical incident at § 441.302(a)(6)(i)(A): abuse between HCBS waiver housemates; expression of racism, sexism, homophobia, or transphobia by a provider toward a beneficiary; lack of direct care workers; physical or emotional harm suffered by participant; falls with severe or moderate injury/illness; missed or delayed provision of services identified in the person-centered plan; refusal of service; self-neglect; and a range of harmful things beneficiaries may experience.

Alternatively, a few commenters recommended that CMS not expand the minimum definition of critical incident further, indicating the critical incident definition offers flexibility to States to expand their critical incident definition to fit the HCBS program and population served by the State. Commenters expressed that CMS should provide technical assistance, for all States, including for States that already have an incident management system with critical incident definitions and policies and programs in place.

Response: We appreciate commenters sharing these suggestions. We note that many of these types of events would be captured by the minimum standard definition. For instance, we would consider abuse between HCBS waiver housemates to fall under verbal, physical, sexual, psychological, or emotional abuse. Similarly, expressions of racism, sexism, homophobia, or transphobia by a provider toward a beneficiary may be considered a critical incident. If a lack of direct care workers, a refusal of service, or missed or delayed provision of services identified in the person-centered service plan results in

harm or risk of risk from the failure of a provider to deliver needed services, we would expect a State to consider those events as instances of neglect. Physical or emotional harm suffered by a participant as a result of one or more types of events included in our definition of critical incidents or that results in death would also be captured as a critical incident. Falls with severe or moderate injury/illness may be considered critical incidents depending on whether they occur as a result of an event included in our definition of critical incidents. They would also be considered critical incidents if they result in death. Some of these events, such as missed or delayed provision of services identified in the person-centered service plan, could also meet the definition of a grievance and be appropriate for consideration under the grievance system, which we are finalizing as part of a separate provision in § 441.301(c)(7) (discussed in section II.B.2 of this rule.)

We decline to include refusing a service or self-neglect in the minimum standard definition because we intend this definition to focus on incidents that occur during the course of service delivery. However, States may include these events in their own definitions.

We are unsure what the commenter intended by ''range of harmful things beneficiaries may experience'' and are unable to respond directly to that recommendation.

We appreciate these comments and will take this feedback into consideration when developing resources for States on the incident management system's requirements.

Comment: One commenter stated that we should consider whether what constitutes a critical incident might differ between adult and child beneficiaries and recommended that pediatricians could assist States in development and implementation of incident management requirements, including critical incident requirements. This commenter also stated that data and information for children receiving HCBS and housed in pediatric health systems should be linked with the State electronic critical incident system proposed at § 441.302(a)(6)(i)(B).

Response: As previously discussed, our proposal is to establish a minimum Federal definition, and States may consider expanding the definition to include other health and safety concerns based on the unique needs of their HCBS populations. We also encourage States to include input from interested parties, including experts in children receiving HCBS, when developing and implementing their incident management systems and policies and procedures to meet the proposed requirements. We discuss requirements for data and information sharing and electronic systems in more detail below in this section II.B.3. of the rule.

Comment: Several commenters provided feedback about the inclusion of medication errors resulting in a telephone call to or a consultation with a poison control center in the proposed critical incident definition at § 441.302(a)(6)(i)(A)(*5*). One commenter expressed support for the reporting of a medication error resulting in a telephone call to or a consultation with a poison control center, and agreed they should be reported by the provider to the State. Another commenter expressed that beneficiaries receiving HCBS are encouraged to be independent and have the right to self-determination, and completing investigations on medication errors could be infringing upon HCBS beneficiaries' self-determination. One commenter requested we consider that managed care plans do not typically receive member data from poison control centers unless they are contracted with the managed care plan to provide this notification, making it difficult to track incidents that result in a consultation with the poison control center unless this data is captured elsewhere in member claims data. One commenter expressed concern that including a medication error in the definition of critical incidents could be problematic since not all providers who serve HCBS beneficiaries are clinical staff who can render a professional clinical determination of medication error, which could result in medication errors being over or under reported and skew data reports.

Response: We plan to provide States with technical assistance to help address issues raised by providers in reporting any critical incidents that occur during the delivery of services as specified in a beneficiary's person-centered service plan, or any critical incidents that are a result of the failure to deliver authorized services, including medication errors resulting in a telephone call to or a consultation with a poison control center. Because we also are finalizing § 441.302(a)(6)(i)(C) as described in II.B.3.d. of this rule, we confirm that States must require providers to report to them any critical incidents that occur during the delivery of services as specified in a beneficiary's person-centered service plan, or any critical incidents that are a result of the failure to deliver authorized services. As such, a provider would be expected to report a medication error resulting in a contact with a poison control center if the medication error occurred during the delivery of services or a result of the failure to deliver services. We believe that such a system to identify and address incidents of abuse, neglect, exploitation, or other harm during the course of service delivery is in the best interest of and necessary for protecting the health and welfare of individuals receiving HCBS.

Comment: One commenter requested that CMS clarify that in addition to audio-only telephone, that the use of audio or video technology be made acceptable to satisfy the requirement proposed at § 441.302(a)(6)(i)(A)(*5*) that the State adopt the minimum standard definition for critical incident for a medication error resulting in contact with a poison control center.

Response: We do not have the authority to define additional communication types or consultation methods for poison control centers. We decline to add ''use of audio or video technology'' to the requirement proposed at § 441.302(a)(6)(i)(A)(*5*). We encourage States to collaborate with their State and local poison control centers to understand the types of consultation that are acceptable and make requests for additional communication types or consultation methods for poison control centers.

Comment: Several commenters responded to our solicitation to comment on whether the proposed critical incident definition at § 441.302(a)(6)(i)(A) should include other specific types of events or instances of serious harm to beneficiaries receiving HCBS, such as identity theft or fraud. Most commenters responding to the request for comment recommended that CMS not expand the critical incident definition to include identity theft or fraud, noting it could create duplication of existing investigative and reporting processes. Alternatively, a few commenters supported the inclusion of identity theft and fraud in the critical incident definition. One commenter recommended that CMS provide additional guidance on identity theft or fraud in the context of exploitation, including financial exploitation if added to the minimum critical incident definition. One commenter expressed concern with including identity theft or fraud in the proposed critical incident definition, except when the individual has been formally and legally judged incompetent to make relevant decisions.

Response: We agree with commenters that expanding the critical incident definition at § 441.302(a)(6)(i)(A) to include identity theft or fraud could

create duplication of existing Federal investigative agencies and reporting processes. Therefore, we have not identified a compelling reason to add other types of incidents, such as identity theft or fraud, to the standardized minimum definition of critical incidents we proposed and are finalizing in this rule.

Comment: One commenter specifically responded to the request for comment soliciting whether the proposed critical incident definition at § 441.302(a)(6)(i)(A) includes any specific types of events or instances of harm that would lead to the overidentification of critical incidents. The commenter supported the proposed definition, noting it would not result in overidentification of critical incidents. This commenter noted that, although the events included in the critical incident definition they use are not the same as those in the proposed critical incident definition at § 441.302(a)(6)(i)(A), they believed that the proposed definition would not cause overidentification of critical incidents because their policies require any incident, not solely those that are defined, to be reported.

Response: We appreciate the support for our proposal.

After consideration of these public comments, we are finalizing § 441.302(a)(6)(i)(A) as proposed with the following minor modifications: a minor formatting modification at § 441.302(a)(6)(i)(A)(3) to correct an improper italicization; a minor technical modification at § 441.302(a)(6)(i)(A)(5) to correct missing punctuation; and a minor formatting modification to conclude § 441.302(a)(6)(i)(A)(6) with a semi-colon.

c. Electronic Critical Incident Systems (§ 441.302(a)(6)(i)(B))

At § 441.302(a)(6)(i)(B), we proposed that States must have electronic critical incident systems that, at a minimum, enable electronic collection, tracking (including of the status and resolution of investigations), and trending of data on critical incidents. We also solicited comment on the burden associated with requiring States to have electronic critical incident systems and whether there is specific functionality, such as unique identifiers, that should be required or encouraged for such systems. As part of our proposal, we also encouraged, but did not propose to require, States to advance the interoperable exchange of HCBS data and support quality improvement activities by adopting standards in 45 CFR part 170 and other relevant standards identified in the Interoperability Standards Advisory (ISA).[71]

We received public comments on these proposals. Below is a summary of the public comments we received and our responses.

Comment: Several commenters supported the proposed requirements at § 441.302(a)(6)(i)(B), that a State have an electronic critical incident system that, at a minimum, enables electronic collection, tracking (including of the status and resolution of investigations), and trending of data on critical incidents. A few commenters expressed concern about the impact of the proposed requirements on States that already have multiple incident management systems, including electronic systems, for different programs, administered by different operating agencies. Commenters requested that we allow States flexibility to design the electronic critical incident systems, which we proposed to require at § 441.302(a)(6)(i)(B), by taking into account existing State incident management systems and processes which fit their unique program and systems structures. A few commenters were especially concerned about the impact on States that already enable electronic collection of critical incidents and questioned whether a single incident management system is required to be implemented across all waivers and authorities, or whether a separate system can be implemented for each waiver or program. Commenters expressed concern about having to consolidate current incident management systems, designed based on State infrastructure, into a single electronic system.

Response: We acknowledge that some States currently have electronic incident management systems in place for HCBS, and it is not our intent for States to abandon these systems. We encourage States to build upon existing incident management system infrastructure and protocols to meet the electronic critical incident systems requirements we proposed at § 441.302(a)(6)(i)(B) and are finalizing in this rule.

We believe that a single electronic critical incident system may best enable the State to prevent the occurrence of critical incidents and protect the health and safety of beneficiaries across their lifespan. For example, in the absence of a single electronic critical incident system, States may have more difficulty developing and implementing a comprehensive plan to address and resolve critical incidents across HCBS programs and authorities. A single electronic incident management system could also better enable the State to track critical incidents for providers that deliver services in multiple HCBS programs or under different HCBS authorities, identify systemic causes of critical incidents, or detect patterns of preventable critical incidents and, in turn, implement strategies to more effectively prevent critical incidents.

We assume that some States may need to make at least some changes to their existing systems to fully comply with the requirements at § 441.302(a)(6)(i)(B). We have attempted to provide the State with as much flexibility as possible in the design of their incident management system. As such, the State may opt to maintain multiple systems that comply with the requirements at § 441.302(a)(6).

We encourage each State to consider developing a single electronic critical incident system for all of their HCBS programs under section 1915(c), (i), (j), and (k) authorities.

However, if a State chooses to implement multiple systems, we strongly encourage the State to share data among those systems to enable the development and implementation of a comprehensive plan to address and resolve critical incidents for HCBS beneficiaries and track and trend incidents for specific providers. We note that the State is responsible for ensuring compliance with the requirements of applicable Federal or State laws and regulations governing confidentiality, privacy, and security of certain information and records.

Comment: Several commenters recommended that CMS consider providing additional funding opportunities to assist States in the development and implementation of electronic critical incident systems we proposed to require at § 441.302(a)(6)(i)(B).

Response: As noted in the proposed rule (88 FR 27979), in Medicaid, enhanced Federal financial participation (FFP) is available at a 90 percent Federal Medical Assistance Percentage (FMAP) for the design, development, or installation of improvements of mechanized claims processing and information retrieval systems, in accordance with applicable

[71] Relevant standards adopted by HHS and identified in the ISA include the USCDI (*https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi*), eLTSS (*https://www.healthit.gov/isa/documenting-care-plans-person-centered-services*), *and Functional Assessment Standardized Items* (*https://www.healthit.gov/isa/representing-patient-functional-status-andor-disability*).

Federal requirements.[72] Enhanced FFP at a 75 percent FMAP is also available for operations of such systems, in accordance with applicable Federal requirements.[73] However, we reiterate that receipt of these enhanced funds is conditioned upon States meeting a series of standards and conditions to ensure investments are efficient and effective.[74]

Comment: A few commenters supported CMS encouraging States to advance the interoperable exchange of HCBS data by adopting standards in the Interoperability Standards Advisory (ISA), and requested we further promote, support, and incentivize the development of better interoperability infrastructure to facilitate more seamless data sharing between States, providers, and managed care plans.

Response: While we did not propose any specific requirements related to interoperability for the electronic incident management system, States should ensure the advancement of the interoperable exchange of HCBS data, to further improve the identification and reporting on the prevalence of critical incidents for HCBS beneficiaries to support quality improvement activities that can help promote the health and safety of HCBS beneficiaries. We clarify that, to receive enhanced FMAP funds, the State Medicaid agency is required at § 433.112(b)(12) to ensure the alignment with, and incorporation of, standards and implementation specifications for health information technology adopted by the Office of the National Coordinator for Health IT in 45 CFR part 170, subpart B, among other requirements set forth in § 433.112(b)(12). States should also consider adopting relevant standards identified in the Interoperability Standards Advisory (ISA) [75] to bolster improvements in the identification and reporting on the prevalence of critical incidents for HCBS beneficiaries and present opportunities for the State to develop improved information systems that can support quality improvement activities that can help promote the health and safety of HCBS beneficiaries.

Comment: A few commenters recommended CMS not require States to include additional specific functionalities, including unique identifiers.

Response: We agree with commenters to not require or encourage a specific functionality, such as unique identifiers.

After consideration of public comments received, we are finalizing our proposal to require at § 441.302(a)(6)(i)(B) that States use an information system, meeting certain requirements, for electronic data collection, tracking, and trending of critical incident data, as proposed, with minor modifications. We are finalizing § 441.302(a)(6)(i)(B) with the addition of the word ''enables'' and striking ''enables'' from § 441.302(a)(6)(i)(B)(*1*) so that it applies to all paragraphs in § 441.302(a)(6)(i)(B). We are finalizing minor formatting changes to conclude paragraphs (a)(6)(i)(B)(*2*) and (3) with semi-colons.

d. Provider Critical Incident Reporting—During Delivery of or Failure To Deliver Services (§ 441.302(a)(6)(i)(C))

At § 441.302(a)(6)(i)(C), we proposed that States must require providers to report to the State any critical incidents that occur during the delivery of section 1915(c) waiver program services as specified in a waiver participant's person-centered service plan, or any critical incidents that are a result of the failure to deliver authorized services. We believe that this proposed requirement will help to specify provider expectations for reporting critical incidents and to ensure that harm that occurs because of the failure to deliver services will be appropriately identified as a critical incident.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the requirement we proposed at § 441.302(a)(6)(i)(C) that a State must require providers to report to the State any critical incidents that occur during the delivery of services as specified in a beneficiary's person-centered service plan, or any critical incidents that are a result of the failure to deliver authorized services. One commenter expressed that requiring providers to report on any critical incidents that occur during service delivery, or as a result of the failure to deliver authorized services, encourages better, more transparent reporting and provides a more accurate reflection of the prevalence and types of critical incidents occurring in HCBS delivery. Another commenter noted missed or delayed services, especially a pattern of missed or delayed service appointments, can lead to poor health outcomes for beneficiaries.

Response: We appreciate the expressions of support for our proposal.

Comment: A few commenters raised concerns with the requirement we proposed at § 441.302(a)(6)(i)(C) that States require providers to report to them any critical incidents that occur during the delivery of section 1915(c) waiver program services as specified in a waiver participant's person-centered service plan, or as a result of the failure to deliver services authorized under a section 1915(c) waiver program and as specified in the waiver participant's person-centered service plan. One commenter expressed that this requirement would require reviewers of critical incidents to draw conclusions about the service provider's role, without taking into account a beneficiary's right to privacy, decision making, personal preferences, and autonomy, especially for beneficiaries who live in their own home and/or receive care from different providers. Another commenter expressed concern that, even after a thorough investigation, it is often impossible to definitively substantiate certain allegations of abuse or neglect or determine whether a negative outcome, such as a hospitalization, was the direct result of a critical incident that occurred during the delivery of services or as a result of the failure to deliver services as authorized. A commenter expressed concern that the requirement for providers to report to States any critical incidents that are a result of the failure to deliver authorized services is too broad and could cause critical incident reporting to be ineffective and inconsistent.

Response: We proposed requirements for States regarding the reporting of critical incidents by providers that we believe are important for identifying and addressing incidents of abuse, neglect, exploitation, or other harms that occur during the course of service delivery or as a result of the failure to deliver services. We note that the reporting of a critical incident does not necessarily mean that an action should be taken by the State in response to the critical incident. Further, even if no action is warranted or it is not possible to substantiate an allegation of abuse or neglect, it is still important to have the critical incident reported, and investigation conducted if appropriate, in case, for instance, a pattern later

[72] See section 1903(a)(3)(A)(i) and § 433.15(b)(3), 80 FR 75817–75843; *https://www.medicaid.gov/state-resourcecenter/faq-medicaid-and-chip-affordable-care-act-implementation/downloads/affordable-care-act-faq-enhancedfunding-for-medicaid.pdf; https://www.medicaid.gov/federal-policy-guidance/downloads/SMD16004.pdf.*

[73] See section 1903(a)(3)(B) and § 433.15(b)(4).

[74] See § 433.112 (b, 80 FR 75841; *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-433/subpart-C.*

[75] Relevant standards adopted by HHS and identified in the ISA include the USCDI (*https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi*), eLTSS (*https://www.healthit.gov/isa/documenting-care-plans-person-centered-services*), and Functional Assessment Standardized Items (*https://www.healthit.gov/isa/representing-patient-functional-status-andor-disability*).

emerges that indicates systemic causes of critical incidents or that warrants action by the State.

Comment: A few commenters suggested we modify § 441.302(a)(6) to specify that critical incident records be collected in accordance with applicable privacy laws, such as HIPAA and its implementing regulations.

Response: In consideration of public comments received, we have not identified a compelling reason, and therefore decline, to add a reference to specific privacy laws to the requirements at § 441.302(a)(6). We note that States have existing obligations to comply with applicable Federal and State laws and regulations governing confidentiality, privacy, and security of information, records, and data obtained and maintained in a critical incident system. We note that this regulatory requirement does not modify these obligations to comply with applicable laws.

Comment: One commenter suggested we require States to accept critical incident reports, and acknowledge receipt of the report, directly from beneficiaries or other interested parties, establish a process to accept such reports, and allow reports to be made orally or in writing. The commenter recommended that we should require that punitive action is neither threatened nor taken against any individual who makes a report in good faith.

Response: We decline to modify our proposal to broaden the requirements related to critical incidents we proposed at § 441.302(a)(6)(i)(C) in this final rule. Although we proposed to only require providers to report critical incidents at § 441.301(a)(6)(i)(C), the State is not precluded from accepting the reporting of critical incidents from others, who are not providers, including beneficiaries or other interested parties. We believe that our proposal that the State assure a system to identify and address incidents of abuse, neglect, exploitation, or other harm during the course of service delivery, or as a result of the failure to deliver services, is in the best interest of, and necessary for, protecting the health and welfare of beneficiaries receiving HCBS in section 1915(c) waiver programs and under section 1915(i), (j) and (k) State plan services.

We encourage States to include in their policies and procedures that beneficiaries would not be prohibited from reporting critical incidents and, in doing so, would be free from any punitive action when reporting a critical incident to the State. We have provided States with flexibility to establish their own policies and procedures related to addressing punitive actions against beneficiaries involved in the critical incident process.

After consideration of these public comments, we are finalizing our proposal at § 441.302(a)(6)(i)(C) with a modification to require providers to report to the State, within State-established timeframes and procedures, any critical incident that occurs during the delivery of services authorized under section 1915(c) of the Act and as specified in the **beneficiary's** (instead of waiver participant's) person-centered service plan, or occurs as a result of the failure to deliver services authorized under section 1915(c) of the Act and as specified in the **beneficiary's** (instead of waiver participant's) person-centered service plan. (New language identified in bold.) We are also finalizing § 441.302(a)(6)(i)(C) with minor formatting changes to conclude § 441.302(a)(6)(i)(C) with a semi-colon.

e. Data Sources To Identify Unreported Critical Incidents (§ 441.302(a)(6)(i)(D))

At § 441.302(a)(6)(i)(D), we proposed to require that States use claims data, Medicaid Fraud Control Unit data, and data from other State agencies such as Adult Protective Services or Child Protective Services to the extent permissible under applicable State law to identify critical incidents that are unreported by providers and occur during the delivery of section 1915(c) waiver program services, or as a result of the failure to deliver authorized services. We believe that such data can play an important role in identifying serious instances of harm to waiver program participants, which may be unreported by a provider, such as a death that occurs as a result of choking of an individual with a developmental disability residing in a group home, or a burn that occurs because a provider failed to appropriately supervise someone with dementia and that results in an emergency department visit.

We solicited comment on whether States should be required to use these data sources to identify unreported critical incidents, and whether there are other specific data sources that States should be required to use to identify unreported critical incidents.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed support for our proposal at § 441.302(a)(6)(i)(D). One commenter noted that these data sources could help establish pathways at the beneficiary and systems levels for reporting, tracking, and addressing issues with person-centered planning and provider noncompliance, and they will also advance efforts to ensure States' ongoing compliance with the HCBS Settings Rule. Another commenter approved of the requirement that States use data sources to identify unreported critical incidents, including claims data, Medicaid Fraud Control Unit data, and data from other State agencies such as Adult Protective Services or Child Protective Services to the extent permissible under applicable State law, expressing that implementation of this requirement could result in a more accurate reflection of the prevalence and types of critical incidents occurring in HCBS delivery, in working with managed care plans and providers.

Response: We appreciate the support for our proposal.

Comment: Two commenters requested that collaboration with police and law enforcement be included in the data sources under § 441.302(a)(6)(i)(D). One commenter noted CMS should require providers to report to law enforcement in a timely manner any reasonable suspicion of a crime committed against a beneficiary receiving HCBS. Another commenter recommended CMS require providers to report suspicion of a crime to law enforcement. A commenter also questioned whether an investigative agency includes law enforcement. Additionally, a few commenters also recommended that collaboration with the designated Protection & Advocacy (P&A) system for the State be included in the data sources under § 441.302(a)(6)(i)(D), citing that P&A systems have the authority to investigate incidents of abuse and neglect of individuals with developmental disabilities if the incidents are reported to the system or if there is probable cause to believe that the incidents occurred.

Response: While we intend that § 441.302(a)(6)(i)(D) establishes the minimum requirements for States to use certain data sources to detect unreported critical incidents, States retain flexibility to use additional data sources, such as police and law enforcement data and P&A systems, to identify critical incidents that are unreported by providers. However, we decline to include additional data sources in the regulation at this time. We are concerned that it would be difficult for States to use non-Medicaid data sources, such as data from P&A systems and law enforcement records, to effectively identify unreported critical incidents for Medicaid beneficiaries and that such requirements would be administratively and operationally

burdensome for States to implement. At § 441.302(a)(6)(i)(D), we proposed to require that States use claims data, Medicaid Fraud Control Unit data, and data from other State agencies to the extent permissible under applicable State law to identify critical incidents that are unreported by providers and occur during the delivery of section 1915(c) waiver program services, or as a result of the failure to deliver authorized services, identifying Adult Protective Services or Child Protective Services as examples of State agencies. We encourage the State to include additional State agency data sources to detect unreported critical incidents as defined at § 441.302(a)(6)(i)(D) as appropriate.

Comment: A couple commenters stated that CMS should direct States to take definitive enforcement actions to address provider compliance with the incident management requirements. One commenter proposed to penalize HCBS providers that do not timely report critical incidents by imposing monetary penalties or suspension from the Medicaid program. Another commenter recommended that we allow States to implement an escalation of remedies to address provider reporting, up to and including a separate investigation with sanctions, if necessary.

Response: We reiterate that States already have broad authority to create penalties, whether monetary or non-monetary, for providers that have violated their obligations as set forth by the State Medicaid program.

After consideration of public comments we received, we are finalizing our proposal at § 441.302(a)(6)(i)(D), with a modification to require providers to report to the State, within State-established timeframes and procedures, any critical incident that occurs during the delivery of services authorized under section 1915(c) of the Act and as specified in the **beneficiary's** (instead of waiver participant's) person-centered service plan, or occurs as a result of the failure to deliver services authorized under section 1915(c) of the Act and as specified in the **beneficiary's** (instead of waiver participant's) person-centered service plan. (New language identified in bold.) We are also finalizing § 441.302(a)(6)(i)(D) with minor formatting changes to conclude § 441.302(a)(6)(i)(D) with a semi-colon.

f. Critical Incident Data Sharing (§ 441.302(a)(6)(i)(E))

At § 441.302(a)(6)(i)(E), we proposed States share information, consistent with the regulations in 42 CFR part 431, subpart F on the status and resolution of investigations. We set the expectation that data sharing could be accomplished through the use of information sharing agreements with other entities in the State responsible for investigating critical incidents if the State refers critical incidents to other entities for investigation.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters recommended CMS provide technical assistance related to the data sharing requirements. Commenters noted data sharing barriers in and between the State, agencies, and divisions within in the same agency, influencing successful implementation of the proposed requirements at § 441.302(a)(6)(i)(G).

Response: We appreciate these comments identifying the need for technical assistance related to data and information sharing agreements. We will take this feedback into consideration when developing resources for States on the incident management system requirements.

Further, we generally note that the State is responsible for ensuring its critical incident system(s) comply with all applicable Federal and State laws and regulations governing confidentiality, privacy, and security of records obtained, maintained, and disclosed via this incident management system.

After consideration of public comments, we are finalizing the proposed § 441.302(a)(6)(i)(E) as proposed, with a minor technical modification to clarify that mention of critical incident in § 441.302(a)(6)(i)(E) refers to critical incidents as defined in paragraph (a)(6)(i)(A) of this section (meaning § 441.302).

g. Separate Investigation of Critical Incidents (§ 441.302(a)(6)(i)(F))

At § 441.302(a)(6)(i)(F), we proposed to require the State be required to separately investigate critical incidents if the investigative agency fails to report the resolution of an investigation within State-specified timeframes. These proposed requirements are intended to ensure that the failure to effectively share information between State agencies or other entities in the State responsible for investigating incidents does not impede a State's ability to effectively identify, report, triage, investigate, resolve, track, and trend critical incidents, particularly where there could be evidence of serious harm or a pattern of harm to a section 1915(c) waiver program participant for which a provider is responsible.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters expressed serious concerns about the requirements we proposed at § 441.302(a)(6)(i)(F), that the State is required to separately investigate critical incidents if the investigative agency fails to report the resolution of an investigation within State-specified timeframes. Commenters recognized the importance of cross-agency collaboration but identified that the timeframes for investigations by investigative agencies, such as Adult Protective Services and Child Protective Services, can be prolonged. Further, opening a separate concurrent investigation at the State level, if the investigative agency fails to report the resolution of an investigation within State-specified timelines, could compromise the integrity of both investigations. Some commenters questioned the feasibility of the requirements at § 441.302(a)(6)(i)(F) due to State statutory provisions around investigative agency responsibilities and allowable data sharing.

Response: These proposed requirements are intended to ensure that the failure to effectively share information between State agencies or other entities in the State responsible for investigating incidents does not impede a State Medicaid agency's ability to effectively identify, report, triage, investigate, resolve, track, and trend critical incidents to protect the health and welfare of HCBS beneficiaries. We believe that requiring the State to separately investigate critical incidents if the investigative agency fails to report the resolution of an investigation within State-specified timeframes will strengthen the ability of the State Medicaid agency to act quickly and/or separately if investigations by Adult Protective Services, Child Protective Services, or other State agencies are taking longer to address and resolve. Further, it will ensure that the State has the information it needs to take action to protect beneficiary health and safety if a provider is responsible (intentionally or unintentionally) for causing harm to beneficiaries or putting beneficiaries at risk of harm. Additionally, we note that the State Medicaid agency may have the authority to take certain actions against the provider (such as suspend their Medicaid enrollment) that other State agencies, such as Adult Protective

Services or Child Protective Services, are unable to take.

We have provided States with flexibility to establish State-specified timelines to separately investigate critical incidents if the investigative agency fails to report the resolution of an investigation and encourage States to take into account specific nuances that may impact the timelines.

After consideration of public comments, we are finalizing the proposed § 441.302(a)(6)(i)(F) as proposed.

h. Reporting (§§ 441.302(a)(6)(i)(G) and 441.302(a)(6)(ii))

Section 1902(a)(6) of the Act requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports. Under our authority at section 1902(a)(6) of the Act, we proposed to modernize the health and welfare reporting by requiring all States to report on the same Federally prescribed quality measures as opposed to the State-developed measures, which naturally vary State by State. Specifically, at § 441.302(a)(6)(i)(G), we proposed to require that States meet the reporting requirements at § 441.311(b)(1) related to the performance of their incident management systems. We discuss these reporting requirements in our discussion of proposed § 441.311(b)(1). Further, under our authority at sections 1915(c)(2)(A) and 1902(a)(19) of the Act, we proposed to codify a minimum performance level to demonstrate that States meet the requirements at § 441.302(a)(6). Specifically, at § 441.302(a)(6)(ii), we proposed to require that States demonstrate that: an investigation was initiated, within State-specified timeframes, for no less than 90 percent of critical incidents; an investigation was completed and the resolution of the investigation was determined, within State-specified timeframes, for no less than 90 percent of critical incidents; and corrective action was completed, within State-specified timeframes, for no less than 90 percent of critical incidents that require corrective action. This minimum performance level strengthens health and welfare reporting requirements while taking into account that there may be legitimate reasons for delays in investigating and addressing critical incidents.

In the proposed rule (88 FR 27980), we considered whether to allow good cause exceptions to the minimum performance level in the event of a natural disaster, public health emergency, or other event that would negatively impact a State's ability to achieve a minimum 90 percent. We opted not to propose good cause exceptions because the minimum 90 percent performance level accounts for various scenarios that might impact a State's ability to achieve these performance levels, and there are existing disaster authorities that States could utilize to request a waiver of these requirements in the event of a public health emergency or a disaster.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A couple of commenters expressed concern about implementing the performance levels at the 90 percent threshold at § 441.302(a)(6)(ii). Alternatively, one commenter recommended the performance level should instead be 100 percent to protect the health and welfare of HCBS beneficiaries, since the minimum performance level to demonstrate that States meet the requirements at § 441.302(a)(6) should gauge State performance by how efficiently they conduct critical incident investigations.

Response: We believe the performance levels at the 90 percent threshold sets a high, but achievable standard, for complying with the requirements at § 441.302(a)(6)(ii). Our intention in proposing minimum performance requirements at § 441.302(a)(6)(ii) was to provide a standard by which we could oversee, and hold States accountable, for complying with the requirements for an incident management system that we are finalizing at § 441.302(a)(6). Further it, was intended to strengthen the critical incident requirements while also recognizing that there may be legitimate reasons why critical incident processes occasionally are not completed timely in all instances. However, it is our expectation that States make reasonable efforts to ensure every critical incident is investigated, resolved, and (if necessary) subject to corrective action within State-specified timeframes.

Comment: A few commenters suggested CMS include a good-cause exception to the incident management performance level for certain instances that fall outside of the specified performance standards for appropriate reasons, such as for resource challenges or when the investigating agency requests that the State refrain from contact due to an ongoing and active investigation. Alternatively, a few commenters supported the approach in the proposed rule to not allow good-cause exceptions to the incident management performance level, observing that the 90 percent minimum performance level already gives States leeway for unexpected occurrences.

Response: We reiterate our belief that the 90 percent minimum performance level sets a high, but achievable standard for States' incident management systems. We underscore that the minimum 90 percent performance level accounts for various scenarios that might impact the State's ability to achieve these performance levels, and there are existing disaster authorities that States could utilize to request a waiver of these requirements in the event of a public health emergency or a disaster. The 90 percent minimum performance level is intended to strengthen incident management system requirements. We also recognize that there may be legitimate reasons why incident management processes occasionally are not completed timely in all instances. We reiterate that our expectation is that States make reasonable efforts to ensure every critical incident is investigated, resolved, and (if necessary) subject to corrective action within State-specified timeframes.

After consideration of public comments, we are finalizing our proposals at §§ 441.302(a)(6)(i)(G) and 441.302(a)(6)(ii) as proposed.

i. Applicability Date

We proposed at § 441.302(a)(6)(iii) to provide States with 3 years to implement these requirements in FFS delivery systems following the effective date of the final rule. For States with managed care delivery systems under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and that include HCBS in the MCO's, PIHP's, or PAHP's contract, we proposed to provide States until the first rating period that begins on or after 3 years after the effective date of the final rule to implement these requirements.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed concerns about the burden they believe will be associated with the proposed provision to implement the incident management requirements at § 441.302(a)(6) within 3 years following the effective date of the final rule. Commenters stated that implementation of the incident management requirements as proposed at § 441.302(a)(6)(i)(B) could require

potential State statute and regulatory amendments, lead time for securing additional technology resources, and operational and workflow changes. Commenters requested CMS consider alternative effective dates for the incident management system ranging from 4 to 7 years, with the most frequent suggestions at 4 to 5 years to address these concerns.

Response: We believe that 3 years for States to comply with the requirements at § 441.302(a)(6) is realistic and achievable for most of the incident management provisions. However, we agree that the proposed 3-year implementation timeframe for States to comply with the electronic incident management requirements at § 441.302(a)(6)(i)(B) could create hardships for States. We agree that States and managed care plans may require a timeframe longer than 3 years to address funding needs, policy changes, IT procurements, and other systems changes, necessary to implement an electronic incident management system as required at § 441.302(a)(6)(i)(B), which may necessitate 5 years.

After consideration of public comments, we are finalizing § 441.302(a)(6)(iii) with minor modifications to correct erroneous uses of the word ''effective.'' We are retitling the requirement at § 441.302(a)(6)(iii) as Applicability date (rather than Effective date). We are also modifying the applicability date to require that States must comply with the requirements in paragraph (a)(6) beginning 3 years from the effective date of this final rule, except for the requirement at paragraph (a)(6)(B) of this section, with which the State must comply beginning 5 years from the effective date of the final rule. In addition, we are making a technical correction to clarify that the applicability dates in § 441.302(a)(6)(iii) apply only to the requirements in § 441.302(a)(6). Additionally, we are also finalizing with modification the language pertaining to managed care delivery systems to improve accuracy and alignment with common phrasing in managed care contracting policy at § 441.302(a)(6)(iii).

j. Application to Other Authorities

At § 441.302(a)(6)(iii), we proposed to apply these requirements to services delivered under FFS or managed care delivery systems. Section 2402(a)(3)(A) of the Affordable Care Act requires States to improve coordination among, and the regulation of, all providers of Federally and State-funded HCBS programs to achieve a more consistent administration of policies and procedures across HCBS programs. In the context of Medicaid coverage of HCBS, it should not matter whether the services are covered directly on an FFS basis or by a managed care plan to its enrollees. The requirement for consistent administration should require consistency between these two modes of service delivery. We proposed that a State must ensure compliance with the requirements in § 441.302(a)(6) with respect to HCBS delivered both under FFS and managed care delivery systems.

Section 2402(a)(3)(A) of the Affordable Care Act requires States to improve coordination among, and the regulation of, all providers of Federally and State-funded HCBS programs to achieve a more consistent administration of policies and procedures across HCBS programs. In accordance with the requirement of section 2402(a)(3)(A) of the Affordable Care Act for States to achieve a more consistent administration of policies and procedures across HCBS programs and because of the importance of assuring health and welfare for other HCBS State plan options, we proposed to include the incident management requirements at § 441.302(a)(6) within the applicable regulatory sections, including section 1915(j), (k), and (i) State plan services at §§ 441.464(e), 441.570(e), and 441.745(a)(1)(v), respectively. We note that a conforming reference to § 441.745(b)(1)(i), although not discussed in preamble of the proposed rule, was included in the proposed rule (88 FR 28086); the reference supports the application of incident management requirements to section 1915(i) services. Consistent with our proposal for section 1915(c) waivers, we based on our authority under section 1902(a)(19) of the Act to assure that there are safeguards for beneficiaries. We believe the same arguments for these requirements for section 1915(c) waivers are equally applicable for these other HCBS authorities.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the requirements at § 441.302(a)(6)(iii), expressing that States must ensure compliance with the requirements in § 441.302(a)(6) with respect to HCBS delivered both in FFS and managed care delivery systems, noting there is no meaningful difference between abuse, neglect, or exploitation perpetrated by a provider paid through a managed care plan or by a provider paid through a FFS delivery system. One commenter recommended we assist States in developing instructions for State incident management systems for work with Medicaid managed care plans and contracted providers in implementing the requirements in § 441.302(a)(6).

Response: We appreciate the support for our proposal. We will take this feedback into consideration when developing technical assistance and other resources for States on the incident management system requirements.

After consideration of public comments received, we are finalizing the proposal at § 441.302(a)(6)(iii) for HCBS delivered under both FFS and managed care delivery systems.

Comment: Several commenters supported the proposal to apply the incident management system requirements at § 441.302(a)(6) to sections 1915(i), (j) and (k) authorities. Commenters expressed that equally applicable requirements for States across waiver authorities can ensure better access, equity, quality, and reporting for HCBS beneficiaries.

Response: We appreciate the support for our proposal.

Comment: A few commenters responded to our request for comment on whether we should establish similar health and welfare requirements for section 1905(a) State plan personal care, home health, and case management services. Several commenters supported the proposal not to extend the incident management requirements at § 441.302(a)(6) to section 1905(a) services and expressed that applying these requirements to State plan benefits would pose critical challenges for State Medicaid and other operating agencies, due to varying levels of HCBS provided and different data reporting infrastructure States have for 1905(a) services. A few commenters recommended that CMS apply the incident management system requirements to mental health rehabilitative services delivered under section 1905(a) State plan authority. A couple of commenters suggested that mental health rehabilitative services are considered home- and community-based services under the broader definition enacted by Congress in the American Rescue Plan Act of 2021. They also indicated that many Medicaid beneficiaries with mental health disorders and disabilities receiving services under the section 1905(a) authority would benefit from the beneficiary protections afforded through the incident management system requirements at § 441.302(a)(6).

Response: At this time, we are not mandating inclusion of section 1905(a) services in the State requirements for incident management systems, due to the statutory and regulatory differences between services authorized under sections 1905(a) and 1915 of the Act. That said, we are not persuaded by the argument that including section 1905(a) services would simply be too much work, as we do believe it is critical that Medicaid beneficiaries have protections for freedom from harm. We acknowledge that many beneficiaries, particularly those receiving mental health services, are served by section 1905(a) services, and encourage States to consider development of critical incident processes to address protections for beneficiaries from harm or events that place a beneficiary at risk of harm.

After consideration of public comments, we are finalizing application of the requirements at § 441.302(a)(6) to other HCBS program authorities within the applicable regulatory sections, including section 1915(j), (k), and (i) State plan services. We are finalizing the requirements at §§ 441.464(e), 441.570(e), and 441.745(a)(1)(v) and (b)(1)(i) as proposed, with minor modifications to clarify that the references to section 1915(c) of the Act are instead references to section 1915(j), 1915(k), and 1915(i) of the Act, respectively.

k. Summary of Finalized Requirements

After consideration of the public comments, we are finalizing the requirements at §§ 441.302(a)(6), as follows:

- We are finalizing § 441.302(a)(6)(i)(A) as proposed with the following minor modifications: a minor formatting modification at § 441.302(a)(6)(i)(A)(3) to correct an improper italicization; a minor technical modification at § 441.302(a)(6)(i)(A)(5) to correct missing punctuation; and a minor formatting modification to conclude § 441.302(a)(6)(i)(A)(6) with a semi-colon.
- We are finalizing § 441.302(a)(6)(i)(B) as proposed with the following minor modifications: adding the word ''Enables'' to § 441.302(a)(6)(i)(B) and striking it from § 441.302(a)(6)(i)(B)(1); and minor formatting modifications to conclude § 441.302(a)(6)(i)(B)(2) and (3) with a semi-colon.
- We are finalizing the requirements at § 441.302(a)(6)(i)(C) with a modification to require providers to report to the State, within State-established timeframes and procedures, any critical incident that occurs during the delivery of services authorized under section 1915(c) of the Act and as specified in the beneficiary's person-centered service plan, or occurs as a result of the failure to deliver services authorized under section 1915(c) of the Act and as specified in the beneficiary's person-centered service plan. We are also finalizing § 441.302(a)(6)(i)(C) with a minor formatting change so that it concludes with a semi-colon.
- We are finalizing the requirements at § 441.302(a)(6)(i)(D, with a modification to require providers to report to the State, within State-established timeframes and procedures, any critical incident that occurs during the delivery of services authorized under section 1915(c) of the Act and as specified in the beneficiary's person-centered service plan, or occurs as a result of the failure to deliver services authorized under section 1915(c) of the Act and as specified in the beneficiary's person-centered service plan. We are also finalizing § 441.302(a)(6)(i)(D) with a minor formatting change so that it concludes with a semi-colon.
- We are finalizing the requirement at § 441.302(a)(6)(i)(E) with a minor formatting modification to change a reference to § 441.302(a)(6)(i)(A) to paragraph (a)(6)(i)(A).
- We are finalizing the requirements at § 441.302(a)(6)(i)(F) and (G) and (a)(6)(ii) as proposed.
- We are finalizing the requirement at § 441.302(a)(6)(iii) with modifications to specify that States must comply with the requirements in paragraph (a)(6) beginning 3 years from the effective date of this final rule; except for the requirement at paragraph (a)(6)(B) of this section, with which the State must comply beginning 5 years after the date that is the effective date of this final rule; and in the case of the State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes HCBS in the MCO's, PIHP's, or PAHP's contract, the first rating period for contracts with the MCO, PIHP, or PAHP beginning on or after 3 years from the effective date of this final rule, except for the requirement at paragraph (a)(6)(B) of this section, with which the first rating period for contracts with the MCO, PIHP, or PAHP beginning on or after 5 years from the effective date of this final rule.
- We are finalizing the requirements at §§ 441.464(e), 441.570(e), and 441.745(a)(1)(v) and (b)(1)(i) with minor modifications to clarify that the references to section 1915(c) of the Act are instead references to section 1915(j), 1915(k), and 1915(i) of the Act, respectively.

4. Reporting (§ 441.302(h))

As discussed earlier in section II.B.1. of this rule, section 2402(a)(3)(A) of the Affordable Care Act requires HHS to promulgate regulations to ensure that States develop HCBS systems that are designed to improve coordination among, and the regulation of, all providers of Federally and State-funded HCBS programs to achieve a more consistent administration of policies and procedures across HCBS programs. We also believe that standardizing reporting across HCBS authorities will streamline and simplify reporting for providers, improve States' and CMS's ability to assess HCBS quality and performance, and better enable States to improve the quality of HCBS programs through the availability of comparative data. Further, section 1902(a)(6) of the Act requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports.

To avoid duplicative or conflicting reporting requirements at § 441.302(h), we proposed to amend § 441.302(h) by removing the following language: ''annually''; ''The information must be consistent with a data collection plan designed by CMS and must address the waiver's impact on -''; and by removing paragraphs (1) and (2) under § 441.302(h). Further, we proposed to add '', including the data and information as required in § 441.311'' at the end of the new amended text, ''Assurance that the agency will provide CMS with information on the waiver's impact.'' By making these changes, we proposed to consolidate reporting expectations in one new section at proposed § 441.311, described in section II.B.7. of the proposed rule, under our authority at section 1902(a)(6) of the Act and section 2402(a)(3)(A) of the Affordable Care Act. As noted earlier in section II.B.1. of the proposed rule, this reporting will supersede existing reporting for section 1915(c) waivers and standardize reporting across section 1915 HCBS authorities.

We did not receive specific comments on this proposal.

We are finalizing our proposed amendment of § 441.302(h) as proposed.

We did receive comments on proposed § 441.311, described in section II.B.7. of this rule, which establishes a new Reporting Requirements section. Comments on this proposal and our

responses are summarized in section II.B.7. of this final rule.

5. HCBS Payment Adequacy (§§ 441.302(k), 441.464(f), 441.570(f), 441.745(a)(1)(vi))

Section 1902(a)(30)(A) of the Act requires State Medicaid programs to ensure that payments to providers are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available to beneficiaries at least to the extent as to the general population in the same geographic area. Access to most HCBS generally requires hands-on and in-person services to be delivered by direct care workers. Direct care workers are referred to by various names, such as direct support professionals, personal care attendants, and home health aides, within and across States. They perform a variety of roles, including nursing services, assistance with activities of daily living (such as mobility, personal hygiene, and eating) and instrumental activities of daily living (such as cooking, grocery shopping, and managing finances), behavioral supports, employment supports, and other services to promote community integration for older adults and people with disabilities. We discuss the definition of direct care workers in more detail below in the context of our proposed definition of direct care workers.

Direct care workers typically earn low wages and receive limited benefits [76] [77] [78] contributing to a shortage of direct care workers and high rates of turnover in this workforce, which can limit access to and impact the quality of HCBS. Workforce shortages can also reduce the cost-effectiveness of services for State Medicaid agencies that take into account the actual cost of delivering services when determining Medicaid payment rates, such as by increasing the reliance on overtime and temporary staff, which have higher hourly costs than non-overtime wages paid to permanent staff. Further, an insufficient supply of HCBS providers can prevent individuals from transitioning from institutions to home and community-based settings and from receiving HCBS that can prevent institutionalization. HCBS is, on average, less costly than institutional services,[79] [80] and most older adults and people with disabilities prefer to live in the community. Accordingly, limits on the availability of HCBS lessen the ability for State Medicaid programs to deliver LTSS in a cost-effective, beneficiary friendly manner.

Shortages of direct care workers and high rates of turnover also reduce the quality of HCBS. For instance, workforce shortages can prevent individuals from receiving needed services and, in turn, lead to poorer outcomes for people who need HCBS. Insufficient staffing can also make it difficult for providers to achieve quality standards.[81] High rates of turnover can reduce quality of care,[82] including through the loss of experienced and qualified workers and by reducing continuity of care for people receiving HCBS,[83] which is associated with the reduced likelihood of improvement in function among people receiving home health aide services.[84]

While workforce shortages have existed for years, the COVID–19 pandemic exacerbated the problem, leading to higher rates of direct care worker turnover (for instance, due to higher rates of worker-reported stress), an inability of some direct care workers to return to their positions prior to the pandemic (for instance, due to difficulty accessing child care or concerns about contracting COVID–19 for people with higher risk of severe illness), workforce shortages across the health care sector, and wage increases in retail and other jobs that tend to draw from the same pool of workers.[85] [86] [87] Further, demand for direct care workers is expected to continue rising due to the growing needs of the aging population, the changing ability of aging caregivers to provide supports, the increased provision of services in the most integrated community setting rather than institutional services, and a decline in the number of younger workers available to provide services.[88] [89] [90]

Section 2402(a) of the Affordable Care Act requires the Secretary of HHS to ensure that all States receiving Federal funds for HCBS, including Medicaid, develop HCBS systems that are responsive to the needs and choices of beneficiaries receiving HCBS, maximize independence and self-direction, provide coordination for and support each person's full engagement in community life, and achieve a more consistent and coordinated approach to the administration of policies and procedures across public programs providing HCBS.[91] In particular, section 2402(a)(1) of the Affordable Care Act requires States to allocate resources for

[76] MACPAC Issue Brief. State Efforts to Address Medicaid Home- and Community-Based Services Workforce Shortages. March 2022. Accessed at *https://www.macpac.gov/wp-content/uploads/2022/03/MACPAC-brief-on-HCBS-workforce.pdf*.

[77] Campbell, S., A. Del Rio Drake, R. Espinoza, K. Scales. 2021. Caring for the future: The power and potential of America's direct care workforce. Bronx, NY: PHI *http://phinational.org/wp-content/uploads/2021/01/Caring-for-the-Future-2021-PHI.pdf*.

[78] We recognize that there are workforce shortages that may impact access to other Medicaid-covered services aside from HCBS. We are focusing in this rule on addressing workforce shortages in HCBS and continue to assess the feasibility and potential impact of other actions to address workforce shortages in other parts of the health care sector.

[79] Reaves, E.L., & Musumeci, M.B. December 15, 2015. *Medicaid and Long-Term Services and Supports: A Primer.* Kaiser Family Foundation. Accessed at *https://www.kff.org/medicaid/report/medicaid-and-long-term-services-and-supports-a-primer/*.

[80] Kim, M–Y, Weizenegger, E., & Wysocki, A. July 22, 2022. *Medicaid Beneficiaries Who Use Long-Term Services and Supports: 2019.* Chicago, IL: Mathematica. Accessed at *https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltss-user-brief-2019.pdf*.

[81] American Network of Community Options and Resources (ANCOR). 2021. The state of America's direct support workforce 2021. Alexandria, VA: ANCOR. Accessed at *https://www.ancor.org/sites/default/files/the_state_of_americas_direct_support_workforce_crisis_2021.pdf*.

[82] Newcomer R, Kang T, Faucett J . Consumer-directed personal care: comparing aged and non-aged adult recipient health-related outcomes among those with paid family versus non-relative providers. Home Health Care Serv Q. 2011;30(4):178– 97.

[83] Campbell, S., A. Del Rio Drake, R. Espinoza, K. Scales. 2021. Caring for the future: The power and potential of America's direct care workforce. Bronx, NY: PHI *http://phinational.org/wp-content/uploads/2021/01/Caring-for-the-Future-2021-PHI.pdf*.

[84] Russell D, Rosati RJ, Peng TR, Barrón Y, Andreopoulos E . Continuity in the provider of home health aide services and the likelihood of patient improvement in activities of daily living. Home Health Care Manage Pract. 2013;25(1):6–12.

[85] MACPAC Issue Brief. State Efforts to Address Medicaid Home- and Community-Based Services Workforce Shortages. March 2022. Accessed at *https://www.macpac.gov/wp-content/uploads/2022/03/MACPAC-brief-on-HCBS-workforce.pdf*.

[86] Campbell, S., A. Del Rio Drake, R. Espinoza, K. Scales. 2021. Caring for the future: The power and potential of America's direct care workforce. Bronx, NY: PHI *http://phinational.org/wp-content/uploads/2021/01/Caring-for-the-Future-2021-PHI.pdf*.

[87] American Network of Community Options and Resources (ANCOR). 2021. The state of America's direct support workforce 2021. Alexandria, VA: ANCOR. Accessed at *https://www.ancor.org/sites/default/files/the_state_of_americas_direct_support_workforce_crisis_2021.pdf*.

[88] MACPAC Issue Brief. State Efforts to Address Medicaid Home- and Community-Based Services Workforce Shortages. March 2022. Accessed at *https://www.macpac.gov/wp-content/uploads/2022/03/MACPAC-brief-on-HCBS-workforce.pdf*.

[89] Campbell, S., A. Del Rio Drake, R. Espinoza, K. Scales. 2021. Caring for the future: The power and potential of America's direct care workforce. Bronx, NY: PHI *http://phinational.org/wp-content/uploads/2021/01/Caring-for-the-Future-2021-PHI.pdf*.

[90] Centers for Medicare & Medicaid Services. November 2020. Long-Term Services and Supports Rebalancing Toolkit. Accessed at *https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltss-rebalancing-toolkit.pdf*.

[91] Section 2402(a) of the Affordable Care Act—Guidance for Implementing Standards for Person-Centered Planning and Self-Direction in Home and Community-Based Services Programs. Accessed at *https://acl.gov/sites/default/files/news%202016-10/2402-a-Guidance.pdf*.

services in a manner that is responsive to the changing needs and choices of beneficiaries receiving HCBS, while section 2402(a)(3)(B)(iii) of the Affordable Care Act requires States to oversee and monitor HCBS system functions to assure a sufficient number of qualified direct care workers to provide self-directed personal assistance services. To comply with sections 2402(a)(1) and 2402(a)(3)(B)(iii) of the Affordable Care Act, States must have a sufficient direct care workforce to be able to deliver services that are responsive to the changing needs and choices of beneficiaries, and, specifically, a sufficient number of qualified direct care workers to provide self-directed personal assistance services. We proposed requirements across section 1915(c), (i), (j) and (k) HCBS programs to further this outcome.

a. Assurance of Sufficient Rates (§ 441.302(k))

Consistent with section 1902(a)(30)(A) of the Act and sections 2402(a)(1) and 2402(a)(3)(B)(iii) of the Affordable Care Act, we proposed to require at § 441.302(k) that State Medicaid agencies provide assurance that payment rates for certain HCBS authorized under section 1915(c) of the Act are sufficient to ensure a sufficient direct care workforce (defined and explained later in this section of the rule) to meet the needs of beneficiaries and provide access to services in accordance with the amount, duration, and scope specified in the person-centered service plan, as required under § 441.301(c)(2). We believe that this proposed requirement supports the economy, efficiency, and quality of HCBS authorized under section 1915(c) of the Act, by ensuring that a sufficient portion of State FFS and managed care payments for HCBS go directly to compensation of the direct care workforce.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A significant number of commenters raised the issue of State Medicaid rates for homemaker, home health aide, and personal care services. Many commenters suggested that requiring that a sufficient portion, or even requiring a specific percent, of Medicaid payments be spent on compensation for direct care workers will not address rate sufficiency, which they regard as the underlying cause of low wages for direct care workers. Even commenters who were supportive of § 441.302(k) generally or the proposed minimum performance level at § 441.302(k)(3) (discussed further below) acknowledged that the policies may be more successful if they coincided with rate increases to ensure that providers' service operations remain fully supported. Many commenters recommended that as an alternative to (or in addition to) this proposal, we create requirements that States regularly review and update or increase their rates.

Several commenters were concerned that wages for direct care workers will not increase if the underlying Medicaid payment rates for the services remain low and are not increased. However, one commenter suggested that if a State's Medicaid rates are low, this places even greater importance on ensuring that as much of the rate as possible is going to compensation for direct care workers.

A few commenters expressed the belief that the accountability and transparency created by the proposal, in addition to the associated reporting requirement we proposed at § 441.311(e) (discussed further in section II.B.7. of this rule), would encourage providers to pass more of their Medicaid payments along to direct care worker wages. A few commenters offered anecdotal observations that, when their State allocated additional funds to HCBS providers, the commenters believed the increased funding was not passed along to direct care worker wages. One commenter noted that a permanent payment adequacy requirement is preferable to the temporary pass-through policies that have been enacted for one-time rate increases, because a permanent requirement would not be dependent on rate increases.

Response: While section 1902(a)(30)(A) of the Act does not provide us with authority to require specific payment rates or rate-setting methodologies, section 1902(a)(30)(A) of the Act does provide us with authority to oversee that States assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan, at least to the extent that such care and services are available to the general population in the geographic area. We did not propose to establish, and are not finalizing, specific payment rates for HCBS under the Medicaid program. Instead, we reiterate that under section 1902(a)(30)(A) of the Act payments must be sufficient to recruit and retain enough providers to ensure care and services are available to beneficiaries; we proposed to implement this requirement by specifying a percentage of Medicaid payments be spent on compensation to direct care workers. We believe this policy will also promote, and be consistent with, economy, efficiency, and quality of care.

Broadly speaking, we also do not believe that simply increasing rates alone, without setting guardrails for how the payments are allocated, would ensure that direct care workers' wages will increase. Rather, we agree with commenters who believed that, regardless of the underlying Medicaid rate, requiring a certain amount of Medicaid payments be spent on compensation will help ensure that Medicaid payments are distributed in a way that supports direct care workers, including their recruitment and retention, to the greatest extent possible. While we did not propose, and are not finalizing, a requirement that State Medicaid agencies increase their rates, we anticipate that States will examine their rates to assure they are sufficient to support the direct care workforce to comply with the policy we proposed and are finalizing with modifications, as discussed further herein. We also direct commenters to the proposals discussed in section II.C. of this final rule, which includes a number of provisions related to rate transparency that are intended to support FFS rate sufficiency.

Comment: One commenter recommended that we revise § 441.302(k) to specify that rates must be sufficient to ensure a sufficient number of providers, including members of the direct care workforce. The commenter stated that this revision would match the broader term ''provider'' in section 1902(a)(30)(A) of the Act while highlighting the importance of the direct care workforce.

Response: We appreciate the commenter's feedback, but we decline to make the recommended revision. At this time, we want to make the focus of the requirement explicitly on the individuals who are part of the direct care workforce, whether they act as individual providers (such as by working as an independent contractor), are employed by a provider entity, or otherwise. We agree with the commenter that section 1902(a)(30)(A) of the Act requires that Medicaid payments must be sufficient to enlist enough providers so that care and services are available to beneficiaries at least to the extent that such care and services are available to the general population in the geographic area. We note that section 1902(a)(30)(A) of the Act also requires that States assure that payments are consistent with efficiency, economy, and quality of care. We agree that enrolling sufficient numbers of

providers is critical to Medicaid service delivery, and that providers in turn may not be able to deliver services if they do not have a sufficient number of direct care workers. As noted in a previous response, we proposed to implement these requirements by specifying a percentage of Medicaid payments be spent on compensation to direct care workers. We believe this policy will promote, and be consistent with, economy, efficiency, and quality of care, as required by statute at section 1902(a)(3)(A) of the Act.

Comment: One commenter requested clarification on whether the payment adequacy requirement applies only to the voluntary, nonprofit sector or whether it also applies to State-operated services.

Response: Given the varied nature of HCBS programs, we specifically proposed for the payment adequacy requirement to apply broadly to compensation paid to direct care workers by providers receiving payments for furnishing homemaker, home health aide, or personal care services from the State; we did not propose to apply these requirements to only certain types of providers or their ownership arrangements. We specifically proposed at § 441.302(k)(1)(ii)(G) (which we are finalizing at § 441.302(k)(1)(ii) as discussed later in this section) that a direct care worker, to whom this requirement would apply, may be employed by or contracted with a Medicaid provider, State agency, or third party or delivering services under a self-directed service model. The requirements we proposed, and are finalizing in this section II.B.5, under § 441.302(k) require States to assure that payment rates are adequate to ensure a sufficient direct care workforce by, in turn, ensuring that providers spend a certain percentage of their total payments for certain HCBS on compensation for direct care workers furnishing those HCBS.

After consideration of the comments received, we are finalizing the assurance requirement at § 441.302(k) with modifications as discussed in this section II.B.5 of this final rule. We are finalizing the language we proposed in the introductory paragraph at § 441.302(k) with technical modifications so that it is clear that the reference to person-centered service plans is to beneficiaries' person-centered service plans. The finalized language at § 441.302(k) will read: *HCBS payment adequacy.* Assurance that payment rates are adequate to ensure a sufficient direct care workforce to meet the needs of beneficiaries and provide access to services in the amount, duration, and scope specified in beneficiaries' person-centered service plans.

b. Minimum Performance Requirement and Flexibilities (§ 441.302(k)(2), (3), (4), (5), and (6))

Our proposal at § 441.302(k)(2) and (3) was designed to affect the inextricable link between sufficient payments being received by the direct care workforce and access to and, ultimately, the quality of HCBS received by Medicaid beneficiaries. We believe that this proposed requirement would not only benefit direct care workers but also individuals receiving Medicaid HCBS because supporting and stabilizing the direct care workforce will result in better qualified employees, lower turnover, and a higher quality of care. The direct care workforce must be able to attract and retain qualified workers in order for beneficiaries to access providers of the services they have been assessed to need and for the direct care workforce to be comprised of workers with the training, expertise, and experience to meet the diverse and often complex HCBS needs of individuals with disabilities and older adults. Without access to a sufficient pool of direct care workers, individuals are forced to forgo having their needs met, or have them addressed by workers without sufficient training, expertise, or experience to meet their unique needs, both of which could lead to worsening health and quality of life outcomes, loss of independence, and institutionalization.[92] [93] [94] [95] Further, we believe that ensuring adherence to a Federal standard of the percentage of Medicaid payments going to direct care workers is a concrete step in recruitment and retention efforts to stabilize this workforce by enhancing salary competitiveness in the labor market. In the absence of such requirements, we may be unable to support and stabilize the direct care workforce because we would not be able to ensure that the payments are used primarily and substantially to pay for care and services provided by direct care workers. Therefore, at § 441.302(k)(3)(i), we proposed to require that at least 80 percent of all Medicaid payments, including but not limited to base payments and supplemental payments, with respect to the following services be spent on compensation to direct care workers: homemaker services, home health aide services, and personal care services.[96]

While many States have already voluntarily established such minimums for payments authorized under section 1915(c) of the Act,[97] we believe a Federal standard would support ongoing access to, and quality and efficiency of, HCBS. Our proposal was based on feedback from States that have implemented similar requirements for payments for certain HCBS under section 9817 of the ARP [98] or other State-led initiatives. We refer readers to our proposed rule for more specific discussion of the feedback we received from States regarding their implementation of similar requirements (88 FR 27984).

We focused our proposed requirement on homemaker services, home health aide services, and personal care services because they are services for which we

[92] MACPAC Issue Brief. State Efforts to Address Medicaid Home- and Community-Based Services Workforce Shortages. March 2022. Accessed at *https://www.macpac.gov/wp-content/uploads/2022/03/MACPAC-brief-on-HCBS-workforce.pdf.*

[93] Campbell, S., A. Del Rio Drake, R. Espinoza, K. Scales. 2021. Caring for the future: The power and potential of America's direct care workforce. Bronx, NY: PHI *http://phinational.org/wp-content/uploads/2021/01/Caring-for-the-Future-2021-PHI.pdf.*

[94] American Network of Community Options and Resources (ANCOR). 2021. The state of America's direct support workforce 2021. Alexandria, VA: ANCOR. Accessed at *https://www.ancor.org/sites/default/files/the_state_of_americas_direct_support_workforce_crisis_2021.pdf.*

[95] Chong, N., I. Akorbirshoev, J. Caldwell, H.S. Kaye, and M. Mitra. 2021. The relationship between unmet need for home and community-based services and health and community living outcomes. Disability Health Journal. Accessed at *https://www.sciencedirect.com/science/article/abs/pii/S1936657421001953.*

[96] We note that section 2402(a) of the Affordable Care Act applies broadly to all HCBS programs and services funded by HHS. Further, section 2402(a) does not include limits on the scope of services, HCBS authorities, or other factors related to its use of the term HCBS. Therefore, we believe that there is no indication that personal care, homemaker, and home health aide services would fall outside the scope of section 2402(a).

[97] For instance, as part of their required activities to enhance, expand, or strengthen HCBS under ARP section 9817, some States have required that a minimum percentage of rate increases and supplemental payments go to the direct care workforce. See *https://www.medicaid.gov/medicaid/home-community-based-services/guidance/strengthening-and-investing-home-and-community-based-services-for-medicaid-beneficiaries-american-rescue-plan-act-of-2021-section-9817/index.html* for more information on ARP section 9817.See *https://www.medicaid.gov/medicaid/home-community-based-services/guidance/strengthening-and-investing-home-and-community-based-services-for-medicaid-beneficiaries-american-rescue-plan-act-of-2021-section-9817/index.html* for more information on ARP section 9817.

[98] Information on State activities to expand, enhance, or strengthen HCBS under ARP section 9817 can be found on *Medicaid.gov* at *https://www.medicaid.gov/medicaid/home-community-based-services/guidance/strengthening-and-investing-home-and-community-based-services-for-medicaid-beneficiaries-american-rescue-plan-act-of-2021-section-9817/index.html.*

expect that the vast majority of payment should be comprised of compensation for direct care workers. These services are comprised of individualized supports for Medicaid beneficiaries delivered by direct care workers and generally have low equipment or supply costs relative to other services. Further, these are services that would most commonly be conducted in individuals' homes and general community settings. As such, there should be low facility or other indirect costs associated with the services. We requested comment on the following options for the minimum percentage of payments that must be spent on compensation to direct care workers for homemaker services, home health aide services, and personal care services: (1) 75 percent; (2) 85 percent; and (3) 90 percent. If an alternate minimum percentage was recommended, we requested that commenters provide the rationale for that minimum percentage.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters (regardless of whether they supported the overall proposal itself) applauded our acknowledgement of, and efforts to address, HCBS workforce shortages, which many commenters characterized as a ''crisis.'' Many commenters appeared to agree that wages to direct care workers are generally low, and that these low wages contribute to overall workforce challenges. Both providers and beneficiaries submitted comments detailing struggles they have had in hiring and retaining qualified direct care workers. Some of these commenters described the frustration of having to constantly recruit and train new direct care workers. Some commenters described having to turn away new clients due to staff shortages, and beneficiaries reported experiencing delays or reductions in their services due to difficulty in finding direct care workers to provide the services. Many direct care workers also submitted personal examples of the hardships caused by financial strain due to inadequate pay, including having to work long hours at multiple jobs to earn extra income, missing time with their own families, struggling to pay bills, risking exposure to (or contracting) COVID–19, and experiencing burnout and psychological stress. A few of these commenters indicated they had left the direct care workforce due to low wages.

Several commenters stated that the proposed minimum performance requirement, if finalized, would likely lead to increases in wages for direct care workers and strengthen the workforce, which in turn could improve the quality of HCBS. In particular, a number of commenters noted the potential for the proposal to have a positive impact on workers who are Black, other people of color, and women, who are disproportionately represented in the direct care workforce—groups that have historically experienced low wages due to discrimination.

Commenters were able to draw anecdotal connections between wages and worker retention. A few providers, for instance, noted that they had made efforts to increase their workers' wages, and observed that the increase in wages had a positive impact on their staff retention and the number of beneficiaries the providers were able to serve.

A few other commenters noted that there are other factors that may contribute to worker shortages, and recommended that we continue to partner with the Administration for Community Living and other Federal agencies to promote a comprehensive, integrated campaign that addresses multiple facets of the workforce shortage, including promotion of and improvement of social valuation of this work, support of workforce pipelines, changes to immigration policy, and creative strategies for atypical workforce development.

Response: We thank commenters for sharing their personal experiences and perspectives on how they have been affected by the direct care workforce shortage and the low wages paid to many direct care workers. We share the belief that this requirement will create a foundation of support for the direct care workforce, which we believe is fundamental to HCBS delivery. We focused in this proposal on compensation for direct care workers because, as we noted above and many commenters confirmed anecdotally, many direct care workers have been paid low wages for a long time.[99] [100] We recognize that other factors also play important roles in worker retention and shortages. While we will continue to partner with other Federal agencies to address these issues, some of the factors affecting the workforce lie outside of our regulatory purview and are outside of the scope of this proposal.

Comment: A significant number of commenters provided feedback on the idea of having a national minimum performance level (separate from providing comment on what the percentage should be). One commenter, representing several State agencies, supported the intent of the proposal and indicated that the proposed requirements could ''improve recruitment, retention and economic security of the HCBS direct care workforce.'' While offering cautions, the commenter indicated that many States generally support a single national minimum performance requirement, but they also recommended that we consider providing States with flexibility related to the requirement based on provider size, rural/urban status, and risk of closure.

Many commenters expressed concerns that a single national minimum performance level could fail to take into account various factors that might affect the percent of Medicaid payments that is spent on compensation for direct care workers including substantial differences among HCBS waiver programs, such as size, services, populations, service area, and staffing needs; State requirements for providers, such as differences in business operations requirements, licensure costs, staff training requirements, or whether States require providers to maintain physical office space; and local economic environments, including cost of living, taxes, and wage laws. Many commenters requested that we not finalize a minimum performance level, so that providers may be allowed flexibility to allocate their Medicaid payments as they determine to be appropriate. One commenter, while acknowledging a workforce crisis, noted that Area Agencies on Aging and provider organizations are taking steps to improve recruitment and retention and that a Federal mandate such as the 80 percent minimum performance level proposed in the rule is unnecessary, may have unintended consequences, and may complicate State and local efforts currently underway.

Response: After consideration of public comments as described in this section II.B.5 of this rule, we are finalizing a national minimum performance level in this final rule. We believe that not doing so would fail to help address the chronic shortages in the HCBS direct care workforce. In this context, the status quo amounts to minimal oversight over how much of the Medicaid payment is going to support the direct care workers who are

[99] MACPAC Issue Brief. State Efforts to Address Medicaid Home- and Community-Based Services Workforce Shortages. March 2022. Accessed at *https://www.macpac.gov/wp-content/uploads/2022/03/MACPAC-brief-on-HCBS-workforce.pdf.*

[100] Campbell, S., A. Del Rio Drake, R. Espinoza, K. Scales. 2021. Caring for the future: The power and potential of America's direct care workforce. Bronx, NY: PHI *http://phinational.org/wp-content/uploads/2021/01/Caring-for-the-Future-2021-PHI.pdf.*

performing the core activities of homemaker, home health aide, and personal care services. While some States have already implemented initiatives to ensure that a certain percentage of Medicaid payments or rate increases are going to direct care worker compensation, as noted above, we believe a Federal requirement is necessary and would be more effective to promote consistency and transparency nationwide.

We agree that there may be State or local circumstances that impact the percent of Medicaid payments that is spent on compensation for direct care workers. Where possible, we have built flexibilities into this requirement as discussed further in this section II.B.5 to ensure that it addresses certain differences among HCBS programs and providers. Specifically, as we discuss in detail later in this section, we are modifying the policy we proposed at § 441.302(k) by: (1) adding a definition of excluded costs at § 441.302(k)(1)(iii) to ensure certain costs are not included in the minimum performance level calculation of the percentage of Medicaid payments to providers that is spent on compensation for direct care workers; (2) revising the definition of direct care worker proposed at § 441.301(k)(1)(ii) to clarify that clinical supervisors are included in the definition of direct care workers; (3) revising § 441.302(k)(3)(ii) to allow States to set a separate minimum performance level for small providers; (4) adding a new provision at § 441.302(k)(4) to provide an option for States to develop reasonable, objective criteria to identify small providers to meet a small provider minimum performance level set by the State; (5) adding a new provision at § 441.302(k)(5) to allow States to develop reasonable, objective criteria to exempt certain providers from meeting the minimum performance level requirement; and (6) adding a new provision at § 441.302(k)(7) to exempt the Indian Health Service (IHS) and Tribal health programs subject to 25 U.S.C. 1641 from the HCBS payment adequacy requirements at § 441.302(k). The specific modifications and the rationale for these modifications are discussed in greater detail in this section II.B.5. of the final rule.

Further, we are modifying the policy we proposed at § 441.302(k) to require States to comply with this HCBS payment adequacy policy beginning 6 years after the effective date of this final rule, rather than the 4 years we proposed. (We discuss this modification to § 441.302(k)(4), being redesignated as § 441.302(k)(8), in section II.B.5.h., of this rule.) We will continue to use our standard enforcement tools and discretion, as appropriate, when States must comply with § 441.302(k).

Ultimately, while we agree that providers generally have flexibility to determine how to spend their Medicaid payments, we believe it is important to reiterate the parameters for payment rates required under section 1902(a)(30)(A) of the Act. Section 1902(a)(30)(A) of the Act requires that payment rates must be economic and efficient; they must not be so high as to be uneconomic or inefficient. This provision also requires payment rates to be consistent with quality of care and sufficient to enlist enough providers to ensure a specified level of access to services for beneficiaries; rates must not be so low as to impermissibly limit beneficiaries' access to care or the quality of care they receive. The Supreme Court in *Armstrong* v. *Exceptional Child Center, Inc.,* in considering this provision, recognized that Congress was ''explicitly conferring enforcement of this judgment-laden standard upon the Secretary[,] . . . thereby achieving 'the expertise, uniformity, widespread consultation, and resulting administrative guidance that can accompany agency decision-making.' '' [101] We believe that implementing this statutory requirement includes some degree of oversight into how providers are allocating the Medicaid payments that they receive for delivering HCBS to beneficiaries. For example, if providers are spending a high proportion of their Medicaid payments on compensation to direct care workers but beneficiaries have difficulty accessing services and quality is compromised due to an insufficient number of direct care workers, then the payment rate may be too low to satisfy section 1902(a)(30)(A). Conversely, if concerns about access to and quality of services were not present and providers were spending a low proportion of their Medicaid payments on compensation to direct care workers, then the Medicaid payment rate may exceed a level that is economic and efficient, contributing to overhead spending and/or operating margin at levels higher than needed to ensure access and quality.

Comment: While several commenters agreed that a national minimum performance level is authorized by section 1902(a)(30) of the Act, a few other commenters disagreed that this policy is authorized by section 1902(a)(30) of the Act. These latter commenters noted that section 1902(a)(30)(A) of the Act requires each State plan for medical assistance to provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan as may be necessary to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area. As such, these commenters contended that this statutory provision applies to State plans, not to CMS, and speaks to the adequacy of payments to Medicaid-enrolled healthcare providers, not the providers' workforce. They stated that section 1902(a)(30)(A) of the Act cannot be read to delegate authority to us to prescribe specific wage pass-through requirements that States must impose upon providers.

Response: We believe that the statutes we cited support the components of our proposal. Regarding the applicability of section 1902(a)(30)(A) of the Act, we refer readers to our prior discussion of section 1902(a)(30)(A) of the Act in section II.B.5.a. of this rule. As we noted in that discussion, section 1902(a)(30)(A) of the Act provides us with authority to oversee that States assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan, at least to the extent that such care and services are available to the general population in the geographic area. We did not propose to establish, and are not finalizing, specific payment rates. Instead, we proposed that States demonstrate that payments are sufficient to ensure care and services are available to beneficiaries by specifying a percentage of Medicaid payments that States must ensure is spent on compensation to direct care workers. We believe this policy will also promote, and be consistent with, economy, efficiency, and quality of care. We also disagree that section 1902(a)(30)(A) of the Act speaks only to provider enrollment. We believe that setting a performance level at which States support their State plan assurance that payments are consistent with efficiency, economy, and quality of care is an appropriate use of our oversight authority under section 1902(a)(30)(A) of the Act.

Comment: A few commenters agreed that sections 2402(a)(1) and 2402(a)(3) of the Affordable Care Act authorize the creation of a national minimum

[101] *Armstrong* v. *Exceptional Child Center, Inc.,* 575 U.S. 320, 328–29 (2015) (internal citations omitted).

performance requirement to support the direct care workforce. However, a few commenters disagreed with this application of section 2402(a)(1) of the Affordable Care Act. These commenters noted that section 2402(a)(1) of the Affordable Care Act requires the Secretary of the Department of Health and Human Services (HHS) to promulgate regulations to ensure that all States develop service systems that are designed to allocate resources for services in a manner that is responsive to the changing needs and choices of beneficiaries receiving non-institutionally-based long-term services and supports and that provides strategies for beneficiaries receiving such services to maximize their independence, including through the use of client-employed providers. Commenters stated that, although this provision speaks to HHS's authority to promulgate regulations, those regulations must pertain to ensuring that States develop systems to appropriately allocate resources to the types of services their beneficiaries need. These commenters contended that section 2402 of the Affordable Care Act allows HHS to, for example, require States to assess whether they should provide services such as delivering healthy meals to certain populations or allow beneficiaries to hire a family member to assist them (and fund the wages), but it does not provide HHS the authority to require States to impose upon providers wage pass-through requirements that are set at a specific minimum performance level.

Response: We disagree with commenters' interpretation of section 2402(a)(1) of the Affordable Care Act. Section 2402(a)(1) of the Affordable Care Act requires States to allocate resources for services in a manner that is responsive to the changing needs and choices of beneficiaries receiving HCBS. As discussed throughout this section, one of the most fundamental ways that HCBS programs meet the needs of beneficiaries is by having a sufficient direct care workforce to provide the services beneficiaries have been assessed to need. Without an adequate supply of workers, beneficiaries may not be able to access all the services that they need and that fully reflect their choices or preferences. We believe that setting a benchmark that helps measure whether Medicaid payments are being allocated in a way that is responsive to the HCBS workforce shortage and supports essential aspects of HCBS delivery is an appropriate application of our authority under section 2402(a)(1) of the Affordable Care Act.

Comment: One commenter did not agree that section 2402(a)(3)(B)(iii) of the Affordable Care Act authorized the application of a minimum performance requirement. The commenter noted that section 2402(a)(3)(B)(iii) of the Affordable Care Act requires the Secretary of HHS to promulgate regulations to ensure that all States develop service systems that are designed to improve coordination among, and the regulation of, all providers of such services under Federally and State-funded programs in order to oversee and monitor all service system functions to assure an adequate number of qualified direct care workers to provide self-directed personal assistance services. The commenter stated that this statutory provision both bestows authority upon HHS to promulgate regulations and specifically references the need to ensure an adequate number of direct care workers. However, the commenter noted that, like section 2402(a)(1) of the ACA, section 2402(a)(3)(B)(iii) specifies that HHS's role—and its authority to promulgate such regulations—is limited to ensuring that States develop service systems that assure an adequate number of qualified direct care workers to provide self-directed personal assistance services. The commenter also stated that this statutory provision applies only to the self-directed service delivery model and does not authorize HHS to promulgate wage pass-through requirements with respect to services delivered by provider agencies. The commenter stated, generally, that the Medicaid program's fundamental premise is to allow each State or Territory the ability to tailor its program to reflect its unique needs, and that this is at odds with a requirement for States to direct providers' behavior.

Response: We generally disagree with the commenter's analysis of section 2402(a)(3)(B)(iii) of the Affordable Care Act that it does not authorize the application of a minimum performance requirement. Section 2402(a)(3)(B)(iii) of the Affordable Care Act requires States to oversee and monitor HCBS system functions to assure there is a sufficient number of qualified direct care workers to provide self-directed personal assistance services. We believe that, to comply with this statutory requirement, States must have a sufficient direct care workforce to be able to deliver services that are responsive to the changing needs and choices of beneficiaries (regardless of delivery model), and, specifically, States must have a sufficient number of qualified direct care workers to provide self-directed personal assistance services. In other words, an insufficient direct care workforce generally will impact whether a State has a sufficient number of qualified direct care workers to provide self-directed personal assistance services in compliance with this requirement. However, we do agree that section 2402(a)(3)(B)(iii) of the Affordable Care Act speaks specifically to self-directed services. We cited this authority for the purposes of supporting our inclusion of self-directed services in this proposal.

As noted in prior responses, we believe that section 1902(a)(30)(A) of the Act and 2402(a)(1) of the Affordable Care Act authorize us to set parameters or benchmarks for HCBS expenditures (both including and in addition to expenditures for self-directed personal care services). Section 1902(a)(30)(A) of the Act provides us with authority to oversee that States assure that Medicaid payments for services are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan, at least to the extent that such care and services are available to the general population in the geographic area. Section 2402(a)(1) of the Affordable Care Act requires HHS to ensure States to allocate resources for services in a manner that is responsive to the changing needs and choices of beneficiaries receiving HCBS. States retain flexibility in how they construct their HCBS systems. Rather, we believe the minimum performance requirement we proposed, and are finalizing with modifications in this section II.B.5, sets a benchmark to help us determine whether States are ensuring that their HCBS systems are allocating sufficient resources to support the direct care workforce to ensure there are sufficient providers so that care and services are available to beneficiaries and that these services are consistent with efficiency, economy, and quality of care. We believe that setting such a benchmark that helps measure whether Medicaid payments are being allocated in a way that is responsive to the HCBS workforce shortage and supports essential aspects of HCBS delivery is an appropriate application of our authority under section 2402(a)(1) of the Affordable Care Act and applies to other HCBS in addition to the self-directed personal care services specifically addressed in section 2402(a)(iii)(B).

Comment: A number of commenters stated that we did not provide enough data to support the proposal for an 80 percent minimum performance level. One commenter suggested that by not providing sufficient data to support the

proposal, we have not fulfilled our obligations under the Administrative Procedure Act.

A number of commenters recommended we collect more data before finalizing a certain percent for the national minimum performance level. Some commenters suggested that a State-by-State analysis of rates and the potential impact of a minimum performance level would need to be performed before setting a minimum performance level. A few of these commenters suggested that helpful data could be collected from States' rate studies, HCBS waiver rates, provider cost reports, or the data we proposed in the proposed rule to be reported to us (including our proposals at § 441.311(e) and § 447.203, which we discuss in sections II.B.7. and II.C. of this rule, respectively). One commenter suggested using the electronic visit verification (EVV) system [102] as a tool for gathering relevant data. Several commenters also suggested that any additional data collection performed to support a national minimum performance level be used to assess unintended consequences of such a level.

A few commenters questioned the specific data relied on for the proposal of an 80 percent minimum performance level. They noted concerns including:

- A lack of support for the claim in the proposed rule that some States have set wage pass-through requirements as high as 90 percent;
- Use of data on the American Rescue Plan Act of 2021 section 9817 funds by a few States to increase worker wages, which have only been relatively recently distributed, and thus reflect limited data;
- State wage pass-through requirements as part of their activities to enhance, expand, or strengthen HCBS under section 9817 the American Rescue Plan Act of 2021were generally only applied to temporary rate increases, not entire rates; and
- Minnesota and Illinois, two States that have wage pass-through requirements, have their requirements set at 72 percent and 77 percent, respectively, and both use different definitions of compensation or direct care worker than what was proposed.

Response: As discussed in the proposed rule (88 FR 27982), we based our proposal on feedback from States that have implemented similar requirements for payments for certain HCBS under section 9817 of the ARP [103] or other State-led initiatives. For example, as noted by commenters, Minnesota has established a minimum threshold of 72.5 percent,[104] while Illinois has implemented a minimum threshold of 77 percent, for similar requirements for HCBS payments as we proposed.[105] To further clarify the data that we used to inform our proposal, which was referenced in footnote 81 in the proposed rule (88 FR 27983 to 27984), we note the following examples of different types of States' wage pass-through requirements that States added to spending plans for ARP section 9817:

- Indiana announced a Direct Service Workforce Investment Grant in which 95 percent of the grant funds must be spent on direct service professionals.[106]
- Massachusetts required that HCBS providers use 90 percent of a rate increase to support their direct care workers.[107]
- North Carolina required that 80 percent of its rate increases for certain HCBS be spent on direct care worker wages.[108]
- West Virginia set different wage pass-through requirements (ranging from 50 percent to 100 percent) for the amount of the rate increase that would be allocated to direct care workers providing services to beneficiaries in several of the State's waiver programs.[109]

We acknowledge that we are unable to present a State-by-State study of the impact of a specific minimum performance level on all State Medicaid programs and providers. The variability among HCBS programs (including staffing requirements, service definitions, and rate methodologies) poses challenges to performing and presenting a multi-State analysis of the allocation of Medicaid payments to direct care workers using existing available data, such as rate studies or cost reports. We also note that information from EVV system reporting would only pertain to use of personal care services or home health aide services (not homemaker services) and would not speak to rates. We agree that the reporting requirement we proposed, and are finalizing in this rule, at § 441.311(e) may generate standardized data that is more amenable to national comparisons.

We also believe that the reporting requirement at § 441.311(e) may yield important data that will support transparency around the portion of Medicaid payments being shared with direct care workers; such transparency in and of itself may well encourage States and providers to look critically at their rates and how they are allocated. Further, we believe that gathering and sharing data about the amount of Medicaid dollars that are going to the compensation of workers is a critical step in understanding the ways we can enact policies that support the direct care workforce and thereby help advance access to high quality care for Medicaid beneficiaries. However, we believe that a reporting requirement alone will not be as effective at stabilizing the direct care workforce.

We believe that compensation levels are a significant factor in the creation of a stable workforce, and that a stable workforce will result in better qualified employees, lower turnover, and safer and higher quality care. If individuals are attracted to the HCBS workforce and incentivized to remain employed in it with sufficient compensation, the workforce is more likely to be comprised of workers with the training, knowledge, and experience to meet the diverse and often complex needs of individuals with disabilities and older adults receiving HCBS. A stable and qualified workforce will also enable beneficiaries to access providers of the services they have been assessed to need. As noted in an earlier comment

[102] Section 12006 of the 21st Century Cures Act (Pub. L. 114–255) requires States to have EVV systems for Medicaid personal care services and home health care services.

[103] Information on State activities to expand, enhance, or strengthen HCBS under ARP section 9817 can be found on *Medicaid.gov* at *https://www.medicaid.gov/medicaid/home-community-based-services/guidance/strengthening-and-investing-home-and-community-based-services-for-medicaid-beneficiaries-american-rescue-plan-act-of-2021-section-9817/index.html.*

[104] See *https://www.revisor.mn.gov/statutes/cite/256B.85/pdf* for more information.

[105] See *https://casetext.com/regulation/illinois-administrative-code/title-89-social-services/part-240-community-care-program/subpart-t-financial-reporting/section-2402040-minimum-direct-service-worker-costs-for-in-home-service* for more information.

[106] Indiana Family and Social Services Administration, ''HCBS Enhanced FMAP Spending Plan: Direct Service Workforce Investment Grant Program,'' *https://www.in.gov/fssa/ompp/hcbs-enhanced-fmap-spending-plan/.*

[107] Massachusetts Executive Office of Health and Human Services, ''Strengthening Home and Community Based Services and Behavioral Health Services Using American Rescue Plan (ARP) Funding,'' *https://www.mass.gov/info-details/strengthening-home-and-community-based-services-and-behavioral-health-services-using-american-rescue-plan-arp-funding.*

[108] North Carolina Department of Health and Human Services, North Carolina ''January 2023 Quarterly Report for the Implementation of the American Rescue Plan Act of 2021, Section 9817—10% FMAP Increase for HCBS'' *https://medicaid.ncdhhs.gov/hcbs-spending-plan-narrative-january-2023/download?attachment.*

[109] West Virginia Department of Health and Human Resources, ''Spending Plan for Implementation of American Rescue Plan Act of 2021, Section 9817.'' *https://dhhr.wv.gov/bms/News/Documents/WV%20State%20ARP%20HCBS%20Spending%20Plan.pdf.*

summary, commenters almost unanimously agreed that the direct care workforce shortage is posing extensive challenges to HCBS access and quality of care. We believe that setting a minimum performance requirement that we have determined to be reasonable based on available information (and is supported by many commenters) is an appropriate exercise of our responsibility to oversee the sufficiency of Medicaid payments under section 1902(a)(30)(A) of the Act and States' allocation of resources under section 2402(a) of the Affordable Care Act.

We agree that the data from States that implemented wage pass-throughs through activities in their ARP section 9817 spending plans is relatively recent. However, we do not believe that data should be disqualified simply because it was generated recently; such data is likelier to provide a more current snapshot of States' Medicaid rates and the needs of their direct care workforce.

We also agree that States applied wage pass-through requirements to rate increases that they were implementing as part of their ARP section 9817 spending plans and that at least some of these wage pass-through requirements were temporary. As such, these percentages might not be as relevant to the selection of a minimum performance level as a permanent wage pass-through requirement applied to the entire Medicaid rate. That said, we do believe that these data are useful for illustrating that the need to support direct care workers' wages is relevant across the country, and that States and interested parties have not only identified increases in wages for direct care workers as a priority, but they have also identified allocating specific portions of Medicaid rates as an appropriate mechanism for addressing low wages. We echo a comment summarized earlier that the advantage of establishing a permanent minimum performance requirement is that it creates a stable support for the direct care workforce, rather than intermittent increases in compensation that are dependent on specific actions taken by State or Federal legislatures.

As observed by some commenters, the percent we proposed, at 80 percent, is slightly higher than the wage pass-through requirements set by Minnesota and Illinois. We believe that the 80 percent minimum performance level we are finalizing is informed by the current range of the wage pass-through requirements set by those States, but is set slightly higher to encourage further steps towards improving compensation for workers. We also note that we are not required to replicate precisely what certain States have done.

We continue to believe 80 percent is the feasible performance level to ensure that payments made for Medicaid HCBS are appropriately allocated to direct care workers' compensation to ensure sufficient providers for beneficiaries to access HCBS as approved in their person-centered plans. However, given that the 80 percent minimum performance is higher than what States have currently set in terms of permanent wage pass-through requirements, we will provide States with additional time to come into compliance with the 80 percent performance level. We are finalizing at § 441.302(k)(8) a modification to the applicability date for § 441.302(k) to indicate that States must comply with this requirement at § 441.302(k) beginning 6 years after the effective date of this rule, rather than 4 years as proposed. We will continue to use our standard enforcement tools and discretion, as appropriate, when States must comply with § 441.302(k). As discussed in greater detail below, we are also finalizing additional flexibilities that States, at their option, may utilize to apply a different percentage for small providers and exempt certain providers that experience hardships from the State's calculation for meeting these performance levels. We also describe below an exemption of the Indian Health Service (IHS) and Tribal health programs subject to 25 U.S.C. 1641 from the HCBS payment adequacy requirements.

Comment: A significant number of commenters stated that an 80 percent minimum performance level, if finalized, would not leave providers enough money for costs associated with administrative tasks, programmatic activities, supervision, technology, office or facility expenses, training, or travel reimbursement. Many commenters noted the 80 percent minimum performance level would result in unintended consequences—namely that affected HCBS providers would cut back on services, limit or stop serving Medicaid beneficiaries, or close altogether. A few commenters expressed concern that our proposal would result in fewer new providers enrolling as Medicaid HCBS providers. Many commenters worried that such reductions in available services or the provider pool would reduce, rather than increase, beneficiaries' access to high-quality HCBS. A few commenters worried that HCBS provider closures, as a result of the proposed policy, could result in more beneficiaries moving into institutional settings.

Several commenters also expressed the belief that the 80 percent minimum performance level would discourage innovation among providers. One commenter suggested that providers would be penalized if they relied on assistive technology, remote supports, or other technology solutions to support beneficiaries in lieu of human assistance.

Response: We thank commenters for their feedback. As discussed in greater detail later in this section, we are modifying the policy we proposed at § 441.302(k)(3) to establish certain exceptions from the minimum performance level, and to establish a 6-year effective date, rather than the 4 years we had proposed. We will continue to use our standard enforcement tools and discretion, as appropriate, when States must comply with § 441.302(k). As discussed in greater detail below, we are also: (1) adding a definition of excluded costs at § 441.302(k)(1)(iii) to exclude certain costs from the minimum performance level calculation of the percentage of Medicaid payments to providers that is spent on compensation for direct care workers; (2) revising the definition of direct care worker proposed at § 441.301(k)(1)(ii) to clarify that clinical supervisors are included in the definition of direct care workers; (3) revising § 441.302(k)(3)(ii) to allow States to set a separate minimum performance level for small providers; (4) adding a new provision at § 441.302(k)(4) to provide an option for States to develop reasonable, objective criteria to identify small providers to meet a small provider minimum performance level set by the State; (5) adding a new provision at § 441.302(k)(5) to allow States to develop reasonable, objective criteria to exempt certain providers from meeting the minimum performance level requirement; and (6) adding a new provision at § 441.302(k)(7) to exempt the Indian Health Service (IHS) and Tribal health programs subject to 25 U.S.C. 1641 from the HCBS payment adequacy requirements at § 441.302(k).

We believe that these amended requirements will address some commenters' concerns about leaving providers sufficient administrative funds for certain personnel and administrative activities and will meet the needs of providers that are small or experiencing other challenges in meeting the minimum performance level.

We always encourage providers to find innovative ways to deliver services but believe that these services (even if delivered with the assistance of

technology or telehealth) at their core require direct care workers to provide them. It is difficult to imagine how strategies that do not aim to stabilize direct care worker wages would improve the efficacy or quality of these services. We do believe, however, that placing a limit on the amount of the Medicaid payment going to expenses other than direct care worker compensation could encourage innovative efforts to improve and streamline administrative activities.

In response to commenters' concerns that this proposal would have the unintended consequence of causing program cuts or provider closures, we do not believe this outcome would be the result from implementing the proposed minimum performance level. We believe that the current environment—in which providers and beneficiaries routinely struggle to find qualified direct care workers, and direct care workers leave the HCBS workforce for better-paying jobs—poses a significant threat to access and community integration because there are an insufficient number of direct care workers to meet beneficiaries' needs. In addition, the direct care worker shortage threatens beneficiary access to services and community integration as such shortage may lead to provider closures if providers are unable to find enough workers to deliver services. This shortage also threatens service quality through the loss of well-trained and experienced direct care workers, if left unaddressed. Further, we believe that the modifications we are finalizing to this requirement will help to mitigate these concerns.

Comment: Some commenters (including beneficiaries, providers, labor organizations, disability or legal advocacy organizations, and research and policy organizations) agreed that 80 percent was an appropriate or reasonable payment adequacy requirement. A couple of these commenters based their support on personal experience, including a few who indicated that they were providers, and stated that 80 percent was an achievable minimum performance level. A few commenters pointed out that the medical loss ratio (MLR) for managed care is 85 percent. One commenter suggested that the minimum performance level be increased to 85 percent to align with the MLR. One commenter recommended that the 80 percent standard should account for necessary administration of HCBS programs, including training. This commenter stated that, if it does not account for necessary administration, the payment rates that States and managed care programs have established are likely too low. The commenter also recommended that, once the requirement is implemented, we review whether the percentage should be higher than 80 percent.

A number of commenters suggested alternative, lower minimum performance levels. Several commenters (including providers, State Medicaid agencies, a labor organization, and an advocacy organization) suggested minimum performance levels ranging from 70 percent to 75 percent. A few of the commenters who recommended 75 percent self-identified as providers and believed that 75 percent was achievable based on their own experiences and expenditure calculations. One commenter recommended we mandate a 72.35 percent minimum performance level and change the definition of compensation to exclude the 7.65 percent employer share of FICA taxes for direct care workers; the commenter believed this would reduce confusion regarding employers' shares of taxes and align the definition of compensation with that used by some States. A few commenters recommended 70 percent based on experience with rate studies or provider expenditures in their States.

Several commenters, including providers and commenters representing State agencies, recommended setting a minimum performance level at either 60 percent or 65 percent, based on the commenters' personal experience running a provider agency or overseeing provider agencies. One commenter suggested a minimum performance level of 60 percent based on a hypothetical analysis of one State's HCBS rates and projected expenditures.

While not making specific recommendations, several commenters (mostly providers and State Medicaid agencies) submitted comments that included anecdotal data of what providers spend on compensation; these percentages ranged from 55 to 81 percent.

Response: We thank commenters for engaging in this issue, including sharing their own experiences allocating Medicaid payments. While we found the feedback provided by commenters instructive, both the range of recommendations and the anecdotal nature of information supporting most of the recommendations prevented us from relying on the recommendations to finalize additional modifications to the proposed minimum performance at the provider level requirement at § 441.302(k)(3).

We do not agree that we should increase the minimum performance level upward to match the 85 percent MLR required in managed care as the MLR is a calculation and associated reporting requirement for Medicaid managed care contracts in accordance with § 438.8 and is not specific to HCBS.

Additionally, as discussed previously and in more detailed responses below, we are finalizing some modifications related to the exclusion of certain costs, the inclusion of clinical supervisors in the definition of direct care workers, and options for a small provider minimum performance level and hardship exemptions for some providers that will change somewhat the impact of the minimum performance level. Further, we are modifying the policy we proposed at § 441.302(k) to establish certain exceptions from the minimum performance level proposed at § 441.302(k)(3), and requiring States to comply beginning 6 years after the effective date of this final rule, rather than the 4 years we had proposed. We will continue to use our standard enforcement tools and discretion, as appropriate, when the minimum performance level requirement go into effect. We believe these modifications are necessary to balance the goal of stabilizing the direct care workforce with the operational realities faced by providers of varying sizes and locations.

Comment: A few commenters suggested that the minimum performance level, if finalized, should be applied at the State level, rather than the provider level. Commenters suggested that applying the minimum performance level at the State level would create some flexibility, as this would require only that all providers in the State meet the minimum performance level in aggregate. However, a few other commenters recommended that we clarify that the minimum performance level applies at the provider level.

Response: We clarify that we intended to propose that the minimum performance level policy would apply at the provider level, meaning that the State must ensure that each provider spends Medicaid payments they receive for certain HCBS on direct care worker compensation in accordance with the minimum performance level requirement. As noted previously, we believe it is important for States to hold providers individually accountable for how they allocate their Medicaid payments and are finalizing other policies, discussed below and elsewhere in this section II.B.5. of the final rule, for States to accommodate providers that need additional flexibility. We note that there was an error in the heading of § 441.302(k)(3), which was proposed

as ''Minimum performance at the State level.'' We apologize for any confusion this may have caused; we believe that most commenters, based on their comments, understood the minimum performance requirement to apply at the provider level. Accordingly, we are finalizing § 441.302(k)(3) with modification by revising the heading for § 441.302(k)(3) to read ''Minimum performance at the provider level,'' as it was originally intended to read.

Additionally, to ensure that it is understood that the minimum performance level that must be met by the State is calculated as the percentage of total payment (not including excluded costs, which are discussed in greater detail in section II.B.5.d. of this final rule) to a **provider** for furnishing homemaker, home health aide, or personal care services, as set forth at § 440.180(b)(2) through (4), represented by **the provider's** total compensation to direct care workers. (New text in bold font).

Comment: A significant number of commenters worried that a national minimum performance level, regardless of the percentage, would have a disparate impact on providers that are small, new, in rural or underserved areas, or run by/for people from specific underserved communities (such as indigenous people) or individuals for whom English is a second language. Some commenters worried that the proposal favors large providers and would lead to consolidation of providers. A few other commenters worried that this would mean that beneficiaries would have fewer choices of providers and have to work with larger corporate providers. One commenter worried that a national minimum performance level would have a disparate impact on agency providers (which may have more overhead costs), as opposed to providers of self-directed services.

A number of commenters requested that if we finalize a national payment adequacy requirement, we include additional flexibilities to minimize unintended consequences on certain providers, particularly small and rural providers. One commenter suggested that we allow for ''hardship exemptions'' on a case-by-case basis. One commenter suggested that we allow States to exempt providers that pay workers 200 percent of the Federal Poverty Level. Another commenter suggested that we exempt States from the payment adequacy requirement if the State has a minimum hourly base wage of $15 per hour applicable to direct care workers delivering the affected services.

Other commenters recommended adjustments to the national minimum performance level, rather than exemptions. A few commenters suggested that we allow for a variable payment adequacy requirement or for ''scaling'' of the minimum performance level, adjusted for different provider sizes or different types of services. A few other commenters recommended requiring a range to identify rates, which could vary by provider size, number of Medicaid beneficiaries served, rural or urban status, hardship status (risk of closure), or other characteristics. One commenter suggested the rate could vary by delivery system or service type. A number of commenters recommended that we allow States to set their own payment adequacy requirement.

A small number of commenters raised concerns that requiring a minimum performance level would conflict with 25 U.S.C. 1641, governing how IHS and Tribal health programs (as defined in 25 U.S.C. 1603(25)) may use Medicare and Medicaid funds, and other applicable laws providing for Tribal self-governance and self-determination. One commenter recommended that we exempt IHS and Tribal health programs from the requirement.

Response: We believe that at least some of commenters' concerns about provider impact may be alleviated by some of the modifications we are finalizing to our proposed policy in this section II.B.5. of the final rule. In particular, we are excluding travel costs from the calculation of the minimum performance level, as increased travel expenses were cited as a primary concern for rural providers. (We refer readers to the discussion of the definition of compensation and excluded costs in section II.B.5.d. of this rule, below.)

We note that the purpose of this proposal is not to set a particular wage for direct care workers, but to ensure that Medicaid payments are being allocated in ways that promote efficiency, economy, and quality of care. We believe that all States are accountable to this requirement and should hold their providers accountable. However, we also agree that some small providers may experience additional challenges in meeting a payment adequacy requirement, as any fixed costs must be covered by a smaller pool of revenues than for larger providers, and small providers have fewer opportunities for administrative efficiencies than larger providers do. We share commenters' desires that the minimum performance level not have a disparate impact on small providers, new providers that may still be developing their processes, providers that may, for various reasons, have additional administrative tasks (such as an increased need for interpreter or translation services), or providers that face disparately high costs, such as providers that may have to pay for temporary lodging for direct care workers delivering services to clients in extremely rural areas.

While we are finalizing a minimum performance level at § 441.302(k)(3)(i) as previously discussed that States must apply to most of their providers, we also agreed with commenters' suggestions. We are finalizing our policy with modifications at § 441.302(k)(3)(ii) to provide that States may apply a different minimum percentage to small providers that the States develop in accordance with requirements at § 441.302(k)(4). These modifications at § 441.302(k)(3)(ii) and (k)(4) will allow States the option to require a reasonable number of small providers, as defined using reasonable, objective criteria set by the State through a transparent process that must include public notice and opportunities for comment from interested parties, to meet a different minimum performance level. This separate minimum performance level would also be set by the State based on reasonable, objective criteria through a transparent process that must include public notice and opportunities for comment from interested parties. In order to apply a small provider minimum performance level, States must ensure it is supported by data or other reasonable factors in the State. We also note that States would still need to collect and report data as required in § 441.302(k)(2) and § 441.311(e) (discussed in section II.B.7. of this rule) for providers subject to the small provider minimum performance level.

Further, under our authority at section 1902(a)(6) of the Act, we are finalizing an additional provision at § 441.302(k)(6)(i), to require that States that establish a small provider minimum performance level in accordance with § 441.302(k)(4) must report to CMS annually, in the form and manner, and at a time, specified by CMS, on the following: the State's small provider criteria; the State's small provider minimum performance level; the percent of providers of services set forth at § 440.180(b)(2) through (4) that qualify for the small provider performance level; and a plan, subject to CMS review and approval, for small providers to meet the minimum performance requirement at § 441.302(k)(3)(i) within a reasonable period of time.

We also agree with commenters that some providers may experience hardships with meeting a payment adequacy requirement because, for instance, they are new to serving Medicaid beneficiaries and thus have not had time to develop administrative efficiencies. Additionally, we agree that special attention needs to be paid where a provider may be at risk of closure and could cause beneficiaries to lose access to HCBS in a particular area. We also agree that States are best positioned to identify the nature of the hardships and which providers are experiencing these hardships. As a result, we are finalizing a modification at § 441.302(k)(5) to allow States to develop reasonable, objective criteria through a transparent process to exempt from the minimum performance requirement at § 441.302(k)(3) a reasonable number of providers determined by the State to be facing extraordinary circumstances that prevent their compliance with § 441.302(k)(3). The State must develop these criteria through a transparent process that includes public notice and opportunities for comment from interested parties. If a provider meets the State's hardship exemption criteria, the provider should be excluded from the State's calculation of the minimum performance level at § 441.302(k)(3). We note that we expect that most providers would be subject to a hardship exemption on a temporary basis, and that States would still need to collect and report data as required in § 441.302(k)(2) and § 441.311(e) for providers with hardship exemptions.

Further, under our authority at section 1902(a)(6) of the Act, we are finalizing an additional provision at § 441.302(k)(6)(ii) to require that States that provide a hardship exemption to providers facing extraordinary circumstances must report to CMS annually, in the form and manner, and at a time, specified by CMS, on the State's hardship criteria, the percentage of providers of services set forth at § 440.180(b)(2) through (4) that qualify for a hardship exemption, and a plan, subject to CMS review and approval, for reducing the number of providers that qualify for a hardship exemption within a reasonable period of time.

We plan to issue guidance on both the small provider performance level and the hardship exemption and encourage States to consult with CMS as they develop their criteria. However, we note that, for States in which a small proportion of providers (less than 10 percent of the total number of providers of services at § 440.180(b)(2) through (4)) qualify for either the small provider performance level or a hardship exemption, CMS may waive the requirements, at § 441.302(k)(6)(i)(D), for States to report on a plan for small providers to meet the minimum performance level at § 441.302(k)(3)(i) within a reasonable period of time, and at § 441.302(k)(6)(ii)(C), for States to report on a plan for reducing the number of providers that qualify for a hardship exemption within a reasonable period of time. We are finalizing this waiver at § 441.302(k)(6)(iii).

In addition, we are modifying the date for when States must comply with the requirements at § 441.302(k) to be beginning 6 years after the effective date of the final rule, rather than the 4 years we had proposed. (We refer readers to our discussion in II.B.5.h. of this rule.) We will continue to use our standard enforcement tools and discretion, as appropriate, when the minimum performance level requirement goes into effect.

Finally, we are persuaded by commenters who raised concerns about interactions between statutory requirements for IHS and certain Tribal health programs health programs subject to 25 U.S.C. 1641 and the proposed requirement at § 441.302(k). Congress has already passed laws, such as 25 U.S.C. 1641, specifying how IHS and Tribal health programs (as defined in 25 U.S.C. 1603(25)) are to use their Medicaid collections. Because Congress has already specified how such funds must be used, we are finalizing an exemption at § 441.302(k)(7) to the HCBS payment adequacy requirements at § 441.302(k) for IHS and Tribal health programs subject to 25 U.S.C. 1641.

After consideration of the comments received, we are finalizing § 441.302(k)(3) with modifications, as well as finalizing new requirements at § 441.302(k)(4), (5), and (6). The requirements we are finalizing with modifications are as follows:

We are finalizing § 441.302(k)(3) with several modifications to retitle the requirement as *Minimum performance at the provider level* and clarify the components of the required calculation and the services that fall within this requirement. We also made modifications at § 441.302(k)(3) to clarify that excluded costs are not included in the calculation of the percentage of total payments to a provider that is spent on compensation to direct care workers and to specify the specific services (homemaker, home health aide, and personal care services) to which the payment adequacy requirement applies. We are also modifying § 441.302(k)(3) to note the exceptions to the minimum performance level that we are adding at (k)(5) (hardship exemption) and (k)(7) (IHS and Tribal health programs subject to 25 U.S.C. 1641). As finalized, § 441.302(k)(3) specifies that, **except as provided in paragraphs (k)(5) and (7)**, the State must meet the following minimum performance level as applicable, calculated as the percentage of total payment (not including excluded costs) *to a provider* for furnishing homemaker, home health aide, or personal care services, as set forth at § 440.180(b)(2) through (4), represented by the *provider's* total compensation to direct care workers. (New text in bold font).

We are modifying the language at § 441.302(k)(3)(i) to read that the minimum performance level of 80 percent applies to all payments to a provider, except as provided in paragraph (k)(3)(ii). We are finalizing a new requirement at § 441.302(k)(3)(ii) to read that at the State's option, for providers determined by the State to meet its State-defined small provider criteria in paragraph (k)(4)(i) of this section, the State must ensure that each provider spends the percentage set by the State in accordance with paragraph (k)(4)(ii) of this section of total payments the provider receives for services it furnishes as described in paragraph (k)(3) of this section on total compensation for direct care workers who furnish those services.

We are redesignating the applicability date we proposed at § 441.302(k)(4) as § 441.302(k)(8), as discussed further in section II.B.5.f. of this rule. We are finalizing a new § 441.302(k)(4) and adding new paragraphs (i) and (ii) to provide an option for States to develop reasonable, objective criteria through a transparent process to identify small providers to meet the State-defined small provider minimum performance level; require that the transparent process for developing criteria to identify providers that meet the small provider minimum performance level must include public notice and opportunities for comment from interested parties; and require that the small provider minimum performance level be set based on reasonable, objective criteria the State develops through a transparent process that includes public notice and opportunities for comment from interested parties.

We are finalizing a new § 441.302(k)(5) to allow States to develop reasonable, objective criteria through a transparent process to exempt from the minimum performance requirement at § 441.302(k)(3) a reasonable number of providers determined by the State to be facing

extraordinary circumstances that prevent their compliance with § 441.302(k)(3). The State must develop these criteria through a transparent process that includes public notice and opportunities for comment from interested parties. If a provider meets the State's hardship exemption criteria, the provider should be excluded by the State from its calculation of the State's compliance with the minimum performance level at § 441.302(k)(3).

We are finalizing a new provision at § 441.302(k)(6) to require States to report on their development and use of the small provider minimum performance level and hardship exemption. Specifically, at § 441.302(k)(6)(i), States that establish a small provider minimum performance level in accordance with § 441.302(k)(4) must report to CMS annually, in the form and manner, and at a time, specified by CMS, on the following: the State's small provider criteria; the State's small provider minimum performance level; the percent of providers of services at § 440.180(b)(2) through (4) that qualify for the small provider performance level; and a plan, subject to CMS review and approval, for small providers to meet the minimum performance requirement at § 441.302(k)(3)(i) within a reasonable period of time. We are also requiring at § 441.302(k)(6)(ii) that States that provide a hardship exemption to providers facing extraordinary circumstances must report to CMS annually, in the form and manner, and at a time, specified by CMS, on the State's hardship criteria, the percentage of providers of services at § 440.180(b)(2) through (4) that qualify for a hardship exemption, and a plan, subject to CMS review and approval, for reducing the number of providers that qualify for a hardship exemption within a reasonable period of time. Additionally, we are finalizing a waiver at § 441.302(k)(6)(iii) that specifies that CMS may waive the reporting requirements in paragraphs (6)(i)(D) or (6)(ii)(C), as applicable, if the State demonstrates it has applied the small provider minimum performance level at § 441.302(k)(4)(ii) or the hardship exemption at § 441.302(k)(5) to a small proportion of the State's providers.

Finally, we are finalizing a new § 441.302(k)(7) specifying that the Indian Health Service and Tribal health programs subject to the requirements at 25 U.S.C. 1641 are exempt from the requirements at § 441.302(k).

c. Other Services (§ 441.302(k)(3))

We considered whether the requirements we proposed at § 441.302(k)(3)(i) related to the percent of Medicaid payments going to the direct care workforce should apply to other services in addition to homemaker, home health aide, or personal care services (as set forth at § 440.180(b)(2) through (4)), such as adult day health, habilitation, day treatment or other partial hospitalization services, psychosocial rehabilitation services, and clinic services for individuals with chronic mental illness. However, these services may have facility or other indirect costs for which we do not have adequate information to determine a minimum percent of the payment that should be spent on compensation for the direct care workforce. We requested comment on whether the proposed requirements at § 441.302(k)(3)(i) related to the percent of payments going to the direct care workforce should apply to other services listed at § 440.180(b). In particular, in recognition of the importance of services provided to individuals with intellectual or developmental disabilities, we requested comment on whether the proposed requirements at § 441.302(k)(3)(i) related to the percent of payments going to the direct care workforce should apply to residential habilitation services, day habilitation services, and home-based habilitation services.

We also requested comment on the following options for the minimum percentage of payments that must be spent on compensation to direct care workers for each specific service that this provision should apply if this provision should apply to other services at § 440.180(b): (1) 65 percent; (2) 70 percent; (3) 75 percent; and (4) 80 percent. Specifically, we requested that commenters respond separately on the minimum percentage of payments for services delivered in a non-residential community-based facility, day center, senior center, or other dedicated physical space, which would be expected to have higher other indirect costs and facility costs built into the Medicaid payment rate than other HCBS. If an alternate minimum percentage is recommended, we requested that commenters provide the rationale for that minimum percentage.

We further clarified that we were requesting comment on a different range of options for the other services at § 440.180(b) than for the services at § 440.180(b)(2) through (4) because we expect that some of the other services at § 440.180(b), such as adult day health and day habilitation services, may have higher other indirect costs and facility costs than the services at § 440.180(b)(2) through (4). We also requested that commenters respond separately on the minimum percentage of payments for facility-based residential services and other facility-based round-the-clock services that have other indirect costs and facility costs that would be paid for at least in part by room and board payments that Medicaid does not cover. If a minimum percentage is recommended for any services, we requested that commenters provide the rationale for that minimum percentage.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: One commenter requested additional clarification on how the services we proposed to be included in the requirements at § 441.302(k)(3) were selected. One commenter suggested that we only apply the minimum performance requirement to personal care services. The commenter suggested we could align the requirement with the EVV system reporting requirement,[110] which applies to personal care services, including personal care services delivered as part of habilitation services.

Response: The priority of this proposal is to support the direct care workforce, and to this end we have focused on accountability for services that rely on direct care workers to perform the core activities. As noted in the background discussion of this provision and in previous responses, the services subject to the minimum performance requirement were selected because they are unlikely to have facility costs as part of the rate or as a component of the core service. We also note that the data we reviewed when determining an appropriate minimum performance requirement focused on home-based services, not facility-based services. Additionally, as identified in an analysis performed by CMS, the three services we proposed to be subject to this requirement at § 441.302(k) fall within the taxonomy of home-based services, which are both high-volume and high-cost.[111] Thus, we believe that targeting these services will maximize the impact of this requirement by addressing the needs of many beneficiaries and promoting better oversight of the allocation of Medicaid rates for frequently used services. Given these similarities among homemaker, home health aide, and personal care

[110] Section 12006 of the 21st Century Cures Act (Pub. L. 114–255).

[111] Centers for Medicare & Medicaid Services. ''Trends in Rate Methodologies for High-Cost, High Volume Taxonomies.'' *https://www.medicaid.gov/sites/default/files/2019-12/trends-in-rate-august-2017.pdf.* Last access October 2, 2023.

services, we cannot find a justification for removing homemaker and home health aide services from this requirement.

Comment: A few commenters requested that we provide a more specific definition of personal care services. Commenters noted that States do not always use HCBS taxonomies consistently, and personal care services can be applied to a different constellation of activities in different waivers. Similarly, one commenter noted that the lack of definitions in the proposed rule for homemaker, home health aide, and personal care services is problematic because States do not use these terms consistently and use a variety of different terms to describe these services.

Response: We understand that States have service definitions for homemaker, home health aide, and personal care services that differ from the definition of homemaker, home health aide, and personal care services in the section 1915(c) waiver Technical Guide [112] and that States do not always use these terms consistently. However, codifying definitions of homemaker, home health aide, and personal care services would have broad implications for State's HCBS programs that would extend beyond the HCBS payment adequacy requirements in this final rule. We will provide additional subregulatory guidance and technical assistance to aid in implementation of the HCBS payment adequacy requirements and may consider addressing in future rulemaking.

Comment: Many commenters responded to our solicitation for comment on whether we should include habilitation services in the services subject to the minimum performance requirement. Most commenters who responded did not believe that habilitation services should be included in the requirement. They echoed our concerns that these services are likelier to include at least some activities in a provider-operated facility or residential setting, which changes the expected costs of providing and allocation of the payment for these services.

Much of the public feedback around habilitation services focused on the facility or residential portion of those services. Commenters noted that rent, utilities, property maintenance, and other costs associated with residential or facility-based services can vary significantly. One commenter suggested that if residential habilitation was included in the minimum performance requirement, the minimum performance level for residential habilitation should be set at 75 percent to account for additional administrative costs. A few other commenters suggested that a different minimum performance level should be set for habilitation services, if included, but did not specify a particular percentage.

Some commenters also suggested that residential services might require more, or different staffing levels, as well as different types of staff than home-based services, which might change the necessary minimum performance level. Commenters disagreed, however, on whether these staffing differences would necessitate a higher or lower minimum performance level than for in-home services, and commenters did not recommend a percentage to specifically address the perceived differences in staffing. One commenter objected to any discussion of residential settings, out of concern that this would appear to promote congregate settings in violation of the home and community-based settings requirements; the commenter stated that all services should be provided in the community.

Several commenters recommended that we not apply the minimum performance level at § 441.302(k)(3)(i) to habilitation services and encouraged us to collect data on the percent of payments for habilitation services.

Response: We believe that the comments we received affirm our decision not to apply the HCBS payment adequacy policy we are finalizing at § 441.302(k) to habilitation or other facility-based services (in which services are delivered in a provider-operated physical location and for which facility-related costs are included in the Medicaid payment rate) due to the number of additional or variable expenses associated with facility-based services. While outside the scope of this final rule, we refer readers to and our requirements for, and the criteria of, a home and community-based setting at § 441.301(c)(4) and (5).

We agree with commenters that additional data collection on habilitation services would be useful. Please refer to the discussion of § 441.311(e) in section II.B.7. of this rule, below.

Comment: Although not necessarily supporting the inclusion of habilitation services in the minimum performance requirement, commenters worried about the impact on beneficiaries receiving habilitation services, who are largely individuals with intellectual or developmental disabilities or behavioral health needs. Some commenters stated that direct care workers who had been providing habilitation services might switch to working for providers that offer homemaker, home health aide, or personal care services because they believed that the requirements at § 441.302(k), if finalized, would lead to increased wages paid to these workers or to Medicaid agencies allocating more resources for these services. One commenter speculated that, if a lower minimum performance level was set for residential habilitation, this would encourage more services to be provided in congregate settings because providers would try to take advantage of the lower minimum performance level. Several commenters that provided services to people with intellectual disabilities and people with mental illness suggested we amend § 441.302(k)(3)(i) to specify an exclusion for direct care workers (or direct service professionals) providing services for individuals with intellectual and developmental disabilities or severe mental illness, as they believed that many of these services are delivered as facility-based habilitation services; the commenters were concerned that these providers have additional non-compensation expenses that are not considered by the proposal, and that it was unclear whether facility-based services were already excluded from the proposal.

Response: We agree that, by excluding habilitation services from this requirement, we are excluding services that are used more frequently by certain populations. This was not our intent, and we do not intend to explicitly exclude certain services from this requirement on the basis of the population receiving the service. However, as noted above, because of differences in these services, we do not believe we can set an appropriate minimum performance level for these services at this time. Although we are not requiring that habilitation or other facility-based services (in which services are delivered in a provider-operated physical location and for which facility-related costs are included in the Medicaid payment rate) be included in the minimum performance requirement, States are able to set wage pass-through requirements of their own for such services to promote the stability of the workforce; we also believe that States may naturally adjust rates or wages in other services in response to the implementation of the minimum performance requirement for homemaker, home health aide, and personal care services.

[112] See Centers for Medicare & Medicaid Services, ''Application for a § 1915(c) Home and Community Based Waiver: Instructions, Technical Guide and Review Criteria.'' January 2019. Available *at https://wms-mmdl.cms.gov/WMS/help/35/Instructions_TechnicalGuide_V3.6.pdf.*

Comment: One commenter expressed a concern that the minimum performance requirement would apply to skilled nursing facilities. Several commenters requested that we clarify in § 441.302(k)(3)(i) that direct care workers would be excluded from the minimum performance requirement if they are providing services in residential settings. One commenter requested that we clarify that assisted living facilities or assisted living services are not included in the minimum performance requirement, while another commenter raised concern about a lack of clarity about whether the requirement applies to assisted living facilities.

Response: The requirements we are finalizing in this section II.B. of this rule only apply to HCBS, and the minimum performance requirement at § 441.302(k)(3) applies specifically to homemaker, home health aide, and personal care services as set forth at § 440.180(b)(2) through (4). However, while the minimum performance requirement would not apply to institutional services (because those are not HCBS), we decline to explicitly restrict the application of this requirement on the basis of different community-based settings. As we noted in prior responses, we selected homemaker, home health aide, and personal care services because these are typically services delivered in the home. However, we acknowledge that beneficiaries may live in different residential settings that are considered homes, and that these services may be bundled with other services delivered to beneficiaries in residential settings.

Comment: A number of commenters requested that we add private duty nursing to the services subject to the minimum performance requirement.

Response: We believe that at least some commenters may be referring to private duty nursing as defined at section 1905(a)(8) of the Act and § 440.80 of our regulations. As discussed in greater detail below in section II.B.5.g. of this rule, we are not planning to require that the minimum performance level be applied to services authorized under section 1905(a) at this time. We note that home health aide services, included in § 440.180(b)(3) but authorized as part of a section 1915(c) waiver, are included in the minimum performance requirement. It is possible that some services that commenters are characterizing as ''private duty nursing'' may fall within the category of a section 1915(c) home health aide service, even as we acknowledge that Federal requirements for private duty nursing specify that these are skilled care services provided by a registered nurse or licensed practical nurse.

Comment: A few commenters recommended that we apply the minimum performance requirement to a number of other services that are experiencing staffing shortages, including: job supports; respite provided in the community; community habilitation services; in-home cognitive rehabilitation therapy; and in-home physical, occupational and speech therapy services. A few commenters suggested, without specifying which services, that the minimum performance requirement ought to be expanded to other services, or that it would be easier to administer if applied to a broader array of services than just homemaker, home health aide, and personal care services.

Response: We thank the commenters for their suggestions and will take them under consideration for potential future rulemaking. As we noted earlier in this section of the final rule, we selected homemaker, home health aide, and personal care services because they are services for which we expect that the vast majority of payment to be comprised of compensation for direct care workers. Further, they are high-volume and high-cost services,[113] and as a result, we believe that targeting these services will maximize the impact of this requirement by addressing the needs of many beneficiaries and promoting better oversight of the allocation of Medicaid rates for frequently used services. We note that States are able to apply wage pass-through requirements to additional services if they choose.

After consideration of the comments received, we are finalizing our proposed language at § 441.302(k)(3) to apply the minimum performance requirement to homemaker, home health aide, and personal care services as set forth at § 440.180(b)(2) through (4).

d. Definition of Compensation (§ 441.302(k)(1)(i))

At § 441.302(k)(1)(i), we proposed to define compensation to include salary, wages, and other remuneration as defined by the Fair Labor Standards Act and implementing regulations (29 U.S.C. 201 *et seq.,* 29 CFR parts 531 and 778), and benefits (such as health and dental benefits, sick leave, and tuition reimbursement). In addition, we proposed to define compensation to include the employer share of payroll taxes for direct care workers delivering services under section 1915(c) waivers. We considered whether to include training or other costs in our proposed definition of compensation. However, we determined that a definition that more directly assesses the financial benefits to workers would better ensure that a sufficient portion of the payment for services went to direct care workers, as it is unclear that the cost of training and other workforce activities is an appropriate way to quantify the benefit of those activities for workers. We requested comment on whether the definition of compensation should include other specific financial and non-financial forms of compensation for direct care workers.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A couple of commenters noted support for our definition of compensation and encouraged us to finalize the definition as proposed.

Response: We thank the commenters for their support.

Comment: Several commenters expressed concern that workers' overtime pay would not be considered part of the definition of compensation.

Response: Our definition of compensation as proposed at § 441.302(k)(1)(i)(A) included salary, wages, ''and other remuneration as defined by the Fair Labor Standards Act'' and its regulations. As the Fair Labor Standards Act includes overtime pay in its definition of wages, overtime pay therefore is included in our definition of compensation as well.

Comment: Many commenters supported the inclusion of health and dental insurance and sick leave in the definition of benefits at § 441.302(k)(1)(i)(B). A few commenters requested that life insurance, disability insurance, and retirement contributions also be added to this definition. Several commenters also requested clarification as to whether paid time off was included in the definition of compensation, and a few suggested that it should be included.

One commenter noted that our definition of compensation was too broad, particularly the use of the term ''such as'' when describing the inclusion of benefits. The commenter expressed concern that employers could over-include items in compensation by calling them ''benefits.'' One commenter worried that if too many benefits were included in compensation, this would reduce workers' take-home pay.

One commenter expressed concerns that it will be difficult for State

[113] Centers for Medicare & Medicaid Services. ''Trends in Rate Methodologies for High-Cost, High Volume Taxonomies.'' *https://www.medicaid.gov/sites/default/files/2019-12/trends-in-rate-august-2017.pdf.* Last access October 2, 2023.

Medicaid agencies to quantify benefits included in direct care worker compensation.

Response: We believe that all the items identified by these commenters—life insurance, disability insurance, retirement, and paid time off—would be reasonably considered part of compensation. In its glossary, the Bureau of Labor Statistics (BLS) defines compensation as ''employer costs for wages, salaries, and employee benefits,'' and notes that the National Compensation Survey includes the following categories in employee benefits: insurance (life insurance, health benefits, short-term disability, and long-term disability insurance); paid leave (vacations, holidays, and sick leave); and retirement (defined benefit and defined contribution plans).[114] We believe the items suggested by the commenters align with our intent and are reflected by a common understanding of ''benefits'' as exemplified in the BLS glossary.

To help clarify what is meant by ''benefits,'' we are modifying the language we proposed at § 441.302(k)(1)(i)(B) in this final rule. We are retaining ''health and dental benefits'' but also are adding to the list ''life and disability insurance.'' We note that the definition used by BLS simply refers to health benefits, life insurance, and different types of disability insurance collectively as ''insurance,'' but we believe that spelling out examples of types of insurance is useful here. In the context of our definition, ''insurance'' listed by itself might be unclear (since it could be confused with other types of insurance that would not be considered compensation, like employers' liability insurance), and we wish to make it clear that the benefits must benefit the employee directly. We are also modifying ''sick leave'' to the broader term ''paid leave,'' as this should be understood to cover any time for which the employee is paid, whether it be for sick leave, holidays, vacations, and so forth. We also are adding retirement, which we believe is also a useful blanket term for different types of retirement plans or contributions on the employee's behalf. After consideration of public comments, we are finalizing § 441.302(k)(1)(i)(B) with modification to specify that compensation includes benefits, such as health and dental benefits, life and disability insurance, paid leave, retirement, and tuition reimbursement.

When proposing that benefits be included in the definition of compensation, we intentionally included the phrase ''such as'' to indicate that the examples of benefits provided in the definition is not exhaustive. We did not attempt to list all possible benefits in the regulatory definition, as we believe that would run the risk of creating a definition that is too narrow. We plan to provide technical assistance to States on how to help ensure that providers are applying a reasonable definition of ''benefits'' and are only counting expenses thereunder that would reasonably be considered an employee benefit.

Comment: Some commenters supported including employers' share of payroll taxes in the definition of compensation at § 441.302(k)(1)(i)(C). However, several commenters recommended that this expense be removed from the definition, as these are not expenses included in employees' take-home pay and are the responsibility of the employer. Several commenters requested that employers' contributions to worker's compensation and unemployment insurance be included in the definition of compensation.

Response: It is our intent to include employers' payroll tax contributions for unemployment insurance and workman's compensation (as well as payments required by the Federal Insurance Compensation Act) under § 441.302(k)(1)(i)(C) and thus as part of our definition of compensation for the purposes of the requirements at § 441.302(k). While not necessarily paid directly to the workers, these expenses are paid on their behalf. We also note, for instance, that per the BLS, the National Compensation Survey calls these payroll taxes ''legally mandated employee benefits'' and includes them as part of the definition of ''employee benefits'' for the purposes of determining compensation.[115] We plan to provide technical assistance to States on how to help ensure that providers are including payroll tax contributions for unemployment insurance and workman's compensation when reporting on compensation to workers.

Comment: Several commenters noted support for including tuition reimbursement in the definition of compensation. Several commenters suggested that costs associated with continuing education should also be included as compensation.

Response: We appreciate the commenters' support. We believe the term ''tuition reimbursement'' is broad enough to cover a variety of scenarios in which a provider may choose to reimburse a worker for tuition costs incurred either prior to or during their period of employment.

Comment: A number of commenters supported either including training in the definition of compensation or excluding training from the administrative and other expenses that are not considered compensation under this rule. Some of these commenters noted that certain types of services or programs might involve additional training for staff, such as services delivered to beneficiaries with complex needs. One commenter suggested that raising workers' wages will not necessarily increase service quality if it is not accompanied by better training for staff. Another commenter worried that providers could decide to cut back on training in order to meet the minimum performance level, which could endanger workers. Commenters cited examples of trainings, including in-service trainings and cardiopulmonary resuscitation trainings, as being critical for caring for beneficiaries. Several commenters suggested that direct care workers who serve beneficiaries with higher-acuity needs may require additional training than other direct care workers.

Commenters suggested that, if training was included in the definition of ''compensation'' (or was excluded from administrative and other expenses that are not considered compensation under this rule), training should be defined to include time spent in training, training materials, trainers, and training facilities.

Conversely, one commenter stated that if training was included in the definition of compensation, the minimum performance level should be adjusted further upward (above 80 percent). One commenter stated that if training was included as compensation to direct care workers, this cost should be restricted to the time workers spend in training and not include training materials and payments made to the trainer. One commenter stated that the cost of onboarding new staff should not be considered ''training.'' One commenter expressed skepticism that training was truly a major cost for providers.

Response: We clarify that the time direct care workers spend in training would already be accounted for in the definition of compensation. We agree with commenters on several points: that training is critical to the quality of services; that training needs might vary across (or even within) States' Medicaid HCBS programs, depending on the nature of the services or the acuity of

[114] See BLS ''Glossary'' at *https://www.bls.gov/bls/glossary.htm.*

[115] See BLS ''Glossary'' at *https://www.bls.gov/bls/glossary.htm.*

the beneficiaries served; that training costs may be difficult to standardize; and that worker training is essential to quality, as well as the health and safety of both the direct care worker and the beneficiary. We do not want to encourage providers to reduce training to cut administrative costs.

However, we are also reluctant upon considering comments to treat all training costs as ''compensation'' to the direct care worker. Trainings, as commenters noted, are often required as part of the job and may vary depending on the services or the needs of the beneficiaries they serve. We are concerned that including training costs in the definition of compensation could mean that direct care workers with higher training requirements would see more of their ''compensation'' going to training expenses, which could cause them to receive lower take-home pay than colleagues with fewer training requirements.

Rather than include training costs in the definition of compensation at § 441.302(k)(1)(i)), we are creating a new definition at § 441.302(k)(1)(iii) to define excluded costs for the purposes of the payment adequacy requirement at § 441.302(k)(3). Excluded costs are those that are not included in the State's calculation of the percentage of Medicaid payments that is spent on compensation for direct care workers required at § 441.302(k)(3). In other words, States would ensure providers deduct these costs from their total Medicaid payments before performing the calculation. We are specifying at § 441.302(k)(3)(iii) that excluded costs are limited to: training costs (such as costs for training materials or payment to qualified trainers); travel costs for direct care workers (such as mileage reimbursement or public transportation subsidies); and costs of personal protective equipment for direct care workers. This would mean that providers could deduct the total eligible training expenses, travel costs, and personal protective equipment for direct care workers from the total payments they receive for homemaker, home health aide, and personal care services before the compensation percentage is determined for the minimum performance level as required under § 441.302(k)(3).

The training costs that are excluded costs under § 441.302(k)(1)(iii) are limited to those costs associated with the training itself (such as qualified trainers and materials) and are distinct from the compensation paid to a direct care worker participating in the training as part of their employment duties under § 441.302(k)(1)(i).

Comment: One commenter requested clarification as to whether travel expenses were part of the definition of ''compensation.'' Many commenters stated that travel or transportation expenses should be included in the definition of compensation, or not treated as an administrative expense. Many commenters also expressed the concern that it would be difficult to cover the cost of travel as part of administrative expenses and other expenses that are not considered compensation under this rule, especially in rural areas where direct care workers may have to travel large distances to visit clients or transport them to appointments. A few commenters worried that if travel were considered an administrative expense, providers would be reluctant to serve beneficiaries outside of a narrow service area to save on travel expenses. A number of direct care workers shared experiences of having to pay for gas out-of-pocket when they transported beneficiaries and having to shoulder the financial burden of wear-and-tear on their cars. One commenter noted that travel costs are frequently included in rate calculations. Several commenters suggested that ''travel,'' if included in the definition of compensation, should include time workers spent travelling, mileage reimbursement, and public transportation reimbursement.

However, a few commenters specifically noted that travel should not be considered part of the definition of compensation. One commenter noted that due to the variability of travel costs, it would be difficult to include travel in a standardized definition of compensation.

Response: We agree with commenters that certain travel-related expenses should not be considered compensation to direct care workers. Travelling to beneficiaries' homes or assisting them in the community is an essential function of the job, and thus, travel reimbursement is not for the direct care worker's personal benefit.[116] We also agree that travel costs will vary significantly by region and even by beneficiary. We too are concerned that including travel in the definition of compensation could mean that direct care workers with higher travel demands would see more of their compensation going to travel, which could cause them to receive lower take-home pay than colleagues with lower travel demands.

At the same time, we are aware of the critical importance of travel to the delivery of these services and do not want to create unintended consequences. We are persuaded by commenters' concerns that counting travel as an administrative expense could induce some providers to stop serving beneficiaries that live outside certain regions. We would also be concerned if direct care workers were expected to shoulder the financial burden of travel out-of-pocket, as appears to be happening in some cases now.

To preserve beneficiary access to services and avoid burden or disparate impact on beneficiaries, direct care workers, and providers in rural or underserved areas, we are excluding travel costs in this final rule from the calculation of the percent of Medicaid payments for certain services going to compensation for direct care workers. This means that providers can deduct the total travel expenses for direct care workers that providers incur from the total Medicaid payments they receive before the compensation percentage is determined.

In order to reflect the exclusion of travel costs from the payment calculation, we are adding a new § 441.302(k)(1)(iii)(B) that specifies that travel costs (such as reimbursement for mileage or public transportation) may be considered an excluded cost for the purposes of the minimum performance requirement at § 441.302(k)(3). The travel costs that are excluded costs under § 441.302(k)(1)(iii) are limited to those costs associated with the travel itself (such as reimbursement for mileage or public transportation) and are distinct from the compensation paid to a direct care worker for any time spent traveling as part of their employment duties under § 441.302(k)(1)(i). Please refer to our discussion in an earlier response regarding the new definition of excluded costs at § 441.302(k)(1)(iii) and its effect for the calculation required at § 441.302(k)(3).

Comment: Several commenters expressed concerns about covering the cost of vehicle purchases or maintenance as an administrative expense. One commenter suggested that if travel were included in the definition of compensation, it should include the cost of vehicles or vehicle maintenance.

Response: We note that the payment adequacy requirement applies to Medicaid payments for homemaker services, home health aide services, and personal care services. In our

[116] *See* 29 U.S.C. 207(e)(2) (permitting employers to exclude ''reasonable payments for traveling expenses'' when determining an employee's regular rate of pay under the FLSA); *see also* 29 CFR 778.217 (same).

experience, it is rare that providers would be purchasing vehicles for these services or that vehicle purchases would be part of the rate. We do not expect that the cost of vehicles would be part of excludable travel costs, but we plan to provide technical assistance to States on a case-by-case basis.

Comment: Several commenters noted that personal protective equipment (PPE) for staff should be counted as compensation or that these expenses should not count as an administrative expense. Several direct care workers also shared experiences of having to provide their own PPE during the COVID–19 public health emergency (PHE), and the harms caused to them both physically and financially by contracting COVID–19.

Response: We agree, particularly given the recent experience with the COVID–19 PHE, that PPE should not be treated as an administrative expense. Providing direct care workers with adequate PPE is critical for the health and safety of both the direct care workers and the beneficiaries they serve. We also do not believe that direct care workers should have to pay for PPE out-of-pocket or that it is considered part of their compensation.

Similar to our approach with training and travel above, we are excluding the cost of PPE for direct care workers in this final rule from the calculation of the percentage of payments spent on compensation for direct care workers. In order to reflect the exclusion of PPE costs from the payment calculation, we are adding new §§ 441.302(k)(1)(iii) that specifies that PPE costs for direct care workers may be considered an excluded cost for the purposes of the minimum performance requirement at § 441.302(k). Please refer to our discussion in an earlier response regarding the new definition of excluded costs at § 441.302(k)(1)(iii) and its effect for the calculation required at § 441.302(k)(3).

Comment: Several commenters requested clarification as to what activities and costs would not be counted as compensation under this rule. A significant number of commenters described other activities or costs they believed should count as compensation, should not be counted as part of non-compensation costs, or simply would not be affordable if providers were left with only 20 percent of the Medicaid rate for personal care, homemaker, or home health aide services. These included costs associated with:

- Administration, including wages paid to administrative and human resources staff, who perform activities such as billing, payroll processing, contracts management, or scheduling client appointments;
- Other business expenses, such as organization accreditation, liability insurance, and licensure.
- Human resources activities, including recruitment activities or advertising for new staff.
- Background checks, drug screening, and medical screening for employees (such as testing staff for tuberculosis prior to starting service delivery).
- Office space and utilities (especially for providers that are required by State law to have a physical office).
- Office supplies, medical supplies, food, or other out-of-pocket expenses for clients, IT, mobile devices (including those used for electronic visit verification), and staff uniforms.
- Non-cash awards to direct care workers, such as parties, staff retreats, gifts for staff, Employee Assistance Programs, or other wellness programs.
- Recordkeeping and complying with quality measures and other reporting requirements.

Commenters noted that these costs are essential to operating a service organization. Commenters also noted that at least some of these costs, such as office space, are fixed costs, or costs that are beyond providers' control.

Response: We believe that most of the items listed above would qualify as administrative expenses, but some activities may be considered compensation or excluded costs under the definitions we are finalizing at § 441.302(k)(1), depending on the context. We clarify that, by designating activities as administrative and other expenses that are not considered compensation under this rule, we do not suggest that they are inessential. However, we also believe, as has been discussed in prior responses, that a vast majority of the payment for homemaker, home health aide, and personal care services must be spent supporting core activities that are performed by direct care workers. As noted by commenters in earlier comment summaries, we also do not want States to allow providers to add so many non-cash benefits to a worker's compensation that their take-home pay is excessively reduced. We plan to provide technical assistance to States to help ensure that States understand what are considered administrative and other expenses that are included in the percentage calculation and what are considered excluded costs.

Comment: Several commenters raised concerns that wages spent for staff conducting certain beneficiary support activities would not be considered compensation. These activities include completing person-centered service plans or scheduling client appointments.

Response: We believe that some of the activities described by commenters are activities that would be performed by staff who would classify as direct care workers, as we proposed to define at § 441.302(k)(1)(ii). We refer readers to our discussion of our proposed definition of direct care workers in the next section below. We plan to provide technical assistance to help States appropriately identify direct care workers and, separately, administrative staff, administrative activities, and other costs that are not considered compensation under this rule.

Comment: A few commenters expressed the concern that employers will shift more administrative activities to direct care workers, to avoid having these activities fall under administrative and other costs that are not considered compensation under this rule. The commenter stated that this could increase burnout for direct care workers.

Response: As discussed earlier, the definition of compensation we proposed, and are finalizing with modification, includes all compensation paid to direct care workers for activities related to their roles as direct care workers. States should ensure providers do not count in the percentage calculation at § 441.302(k)(3) compensation for the time that workers spend on administrative or other tasks unrelated to their roles as direct care workers as compensation to direct care workers. We would not view as permissible under this regulation the shifting of administrative tasks to direct care workers as a way to inflate compensation for direct care workers. However, providers can count as compensation to direct care workers the time that direct care workers spend on tasks, including administrative tasks, such as completing timecards, that are directly related to their roles as direct care workers in providing services to beneficiaries. We plan to provide States with technical assistance on how to accurately capture compensation for workers who provide direct care and perform administrative or other roles. However, we decline to make changes in this final rule based on these comments.

Comment: Several commenters requested clarification on what was included in the denominator of the calculation (in other words, what is meant by ''payments'' when calculating the percent of payments being spent on compensation for direct care workers). One commenter suggested that rather

than requiring 80 percent of Medicaid payments be spent on compensation, we require that 80 percent of all revenue be spent on compensation. One commenter requested clarification about whether, for managed care delivery systems, payment is the State's capitation payment to the MCO or the MCO's payment to the home care provider agency. The commenter also recommended that we require States to set a minimum payment rate that MCOs or other entities pay home care agencies and that the minimum rates be set at a level to pay workers the locally required minimum wage and other compensation as defined in the regulation, and for the home care agency to reserve 20 percent overhead.

A few commenters made specific suggestions for parameters of what should be included or excluded in the denominator, such as:

- Only collected revenue (and not billed charges) would be considered as base or supplemental payments;
- Excluding refunded or recouped payments from current or prior years based on program financial audits;
- Excluding chargebacks; and
- Excluding bad debt.

Response: For Medicaid FFS payments in the denominator of the calculation should include base and supplemental payments (as described in SMDL 21–006 [117]). Those base and supplemental payments should only include payments actually collected, or revenue, rather than billed charges. In addition, refunded or recouped payments from current or prior years based on program financial audits, chargebacks, and bad debt should be excluded from those base and supplemental payment amounts. We are available to provide States with technical assistance related to calculating payments for the purpose of determining the percent of all payments that is spent on compensation.

For Medicaid managed care, payments refer to payments from the managed care plan to the provider and not the capitation payment from the State to the managed care plan. Further, for Medicaid managed care, payments in the denominator of the calculation should include only those payments actually collected and exclude refunded or recouped payments from current or prior years based on program financial audits, chargebacks, and bad debt. We note that section 1902(a)(30)(A) of the Act does not provide us with authority to require specific payment rates or rate-setting methodologies.

As discussed throughout this section (II.B.5), we proposed the requirements at § 441.302(k) using our authority under section 1902(a)(30)(A) of the Act, which requires State Medicaid programs to ensure that payments to providers are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available to beneficiaries at least to the extent as to the general population in the same geographic area. We believe section 1902(a)(30)(A) of the Act speaks specifically to Medicaid payments, not to all revenue received by providers (which may be from various sources); thus, we decline to modify the requirement to affect non-Medicaid revenues.

Comment: One commenter requested that revenue from value-based care (VBC) arrangements in managed care be exempt from the calculation so as not to disrupt State or managed care efforts moving toward VBC or to disincentivize providers from pursuing innovative strategies to improve health and financial outcomes such as lowering emergency room visits, inpatient utilization, and admissions from HCBS to inpatient settings such as nursing facilities. The commenter also noted that providers must make numerous additional investments above and beyond typical compensation rates for a VBC or pay-for-performance (PFP) arrangement to work. Additionally, the commenter noted, VBC and PFP programs rely on lengthy cycles of data, tracking, analysis, and reconciliation before additional payments are made. The commenter stated that, if these types of payments are included in the denominator of the calculation, this will prove disruptive to these programs.

Response: We appreciate the commenter raising these concerns and agree that VBC, PFP, and other unique payment arrangements that reward and support quality over quantity are important, and it was not our intention to appear to discourage them or minimize their value. However, given the wide-ranging designs of such payments and that most HCBS are often not included in these arrangements, we are not requiring a specific way to address them in this final rule. We also decline to adopt the commenter's suggestion to exempt revenue from VBC arrangements in managed care from the calculation of the percent of Medicaid payments for certain HCBS that is spent on compensation of direct care workers, as such an exemption would undermine the intent of the proposal and the usefulness of the data for assessing the percentage of all Medicaid payments for certain HCBS that is spent on compensation for direct care workers. We plan to provide States with technical assistance as needed on how to include revenues from VBC, PFP, and other unique payment arrangements in the calculation.

After consideration of the comments received, we are finalizing § 441.302(k)(1)(i) with a modification to clarify at § 441.302(k)(1)(i)(B) that compensation includes benefits, such as health and dental benefits, life and disability insurance, paid leave, retirement, and tuition reimbursement.

We are also finalizing a new definition at § 441.302(k)(1)(iii) to define excluded costs, which are costs that are not included in the calculation of the percentage of Medicaid payments that is spent on compensation for direct care workers. In other words, States must ensure providers deduct these costs from their total Medicaid payments before performing the calculation required at § 441.302(k)(3)). Such costs are limited to: (A) Costs of required trainings for direct care workers (such as costs for qualified trainers and training materials); (B) Travel costs for direct care workers (such as mileage reimbursement or public transportation subsidies) provided to direct care workers; and (C) Costs of personal protective equipment for direct care workers.

e. Definition of Direct Care Worker (§ 441.302(k)(1)(ii))

At § 441.302(k)(1)(ii), we proposed to define direct care workers to include workers who provide nursing services, assist with activities of daily living (such as mobility, personal hygiene, eating) or instrumental activities of daily living (such as cooking, grocery shopping, managing finances), and provide behavioral supports, employment supports, or other services to promote community integration. Specifically, we proposed to define direct care workers to include nurses (registered nurses, licensed practical nurses, nurse practitioners, or clinical nurse specialists) who provide nursing services to Medicaid-eligible individuals receiving HCBS, licensed or certified nursing assistants, direct support professionals, personal care attendants, home health aides, and other individuals who are paid to directly provide services to Medicaid beneficiaries receiving HCBS to address activities of daily living or instrumental activities of daily living, behavioral supports, employment supports, or

[117] CMS State Medicaid Director Letter: SMDL 21–006. December 2021. New Supplemental Payment Reporting and Medicaid Disproportionate Share Hospital Requirements under the Consolidated Appropriations Act, 2021. Available at *https://www.medicaid.gov/sites/default/files/2021-12/smd21006.pdf.*

other services to promote community integration. We further identified in the preamble of the proposed rule that our definition of direct care worker is intended to exclude nurses in supervisory or administrative roles who are not directly providing nursing services to people receiving HCBS.

Our proposed definition of direct care worker was intended to broadly define such workers to ensure that the definition appropriately captures the diversity of roles and titles across States that direct care workers may have. We included workers with professional degrees, such as nurses, in our proposed definition because of the important roles that direct care workers with professional degrees play in the care and services of people receiving HCBS, and because excluding workers with professional degrees may increase the complexity of reporting, and may unfairly punish States, managed care plans, and providers that disproportionately rely on workers with professional degrees in the delivery of HCBS. We also proposed to define direct care workers to include individuals employed by a Medicaid provider, State agency, or third party; contracted with a Medicaid provider, State agency, or third party; or delivering services under a self-directed service model. This proposed definition is in recognition of the varied service delivery models and employment relationships that can exist in HCBS waivers. We requested comment on whether there are other specific types of direct care workers that should be included in the definition, and whether any of the types of workers listed should be excluded from the definition of direct care worker.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported finalizing the definition of direct care worker as proposed. However, one commenter opposed the entire definition. The commenter noted that the definition, which resembles a definition of direct care worker used by the Department of Labor, is distinguishable from the definition used by the Bureau of Labor Statistics. The commenter recommended that no definition should be finalized until there has been an interagency workgroup to review and coordinate the different definitions.

Response: As discussed earlier in this section II.B.5.e. of this rule, our proposed definition of direct care worker was intended to capture the diversity of roles and titles across States that direct care workers may have. It was also intended to include individuals in the varied service delivery models and employment relationships that can exist in HCBS waivers. As discussed later in this section II.B.5.e. of this rule, we are finalizing the definition of direct care worker largely as proposed with a modification to clarify that direct care workers include nurses and other staff providing clinical supervision, as we do not want to discourage clinical oversight that contributes to the quality of services by creating a disincentive for providers to hire clinicians when necessary. We believe that the definition of direct care worker, as finalized, appropriately defines direct care worker for the specific purposes of the requirements in § 441.302(k), and we note that it was subject to interagency review.

Comment: Several commenters supported including clinicians (such as those we proposed at § 441.302(k)(1)(ii)(A)) in the definition of direct care worker. Commenters noted that providers are often required to have clinicians on staff and that such clinicians are critical to ensuring quality of care. A few commenters, however, expressed ambivalence or reservations about including clinicians in the definition of direct care worker. One commenter noted that some States do not include nurses in their State definitions of direct care worker. A few commenters observed that because clinicians (including nurses) generally earn higher wages, providers that employ clinicians will have an easier time reaching the minimum performance level for direct care worker compensation or that the higher wages of clinicians will mask the lower wages of direct care workers who do not have professional degrees and generally earn lower wages.

Response: We continue to believe it is appropriate to include clinicians (such as registered nurses, licensed practical nurses, nurse practitioners, or clinical nurse specialists) in the definition of direct care worker and are finalizing the definition in this final rule with these clinicians included. There is a shortage of nurses and other clinicians delivering HCBS, and we believe it is important to support these members of the HCBS workforce (especially as they also work directly with beneficiaries). We echo observations from commenters that some services are required to be delivered or monitored by clinicians. We also would not want to discourage clinical oversight that contributes to the quality of services by creating a disincentive for providers to hire clinicians when necessary. Therefore, we are clarifying that our definition of direct care worker is intended to include nurses and other staff who directly provide services to beneficiaries or who provide clinical supervision. However, consistent with the proposed rule, our definition is intended to exclude staff who provide administrative supervision. We are finalizing a modification at the end of § 441.302(k)(1)(ii)(F) to specifically include nurses and other staff providing clinical supervision.

Comment: One commenter suggested that if a State requires that a program employ a nurse to perform occasional beneficiary visits, the State should pay the nurses directly, rather than requiring the providers to pay them.

Response: We thank the commenter for this suggestion. While we do not intend to establish specific requirements for how States pay for services provided by nurses, we agree that this could be a solution for States that would prefer for providers to reach the payment adequacy requirement without relying on salaries for clinical staff. We decline to make changes in this final rule based on this comment.

Comment: A number of commenters requested that we include private duty nurses, including registered nurses, licensed practical nurses, and certified nursing assistants, in the definition of direct care worker.

Response: We note that private duty nurses are not necessarily a separate category of worker, but rather registered nurses, licensed practical nurses, or certified nursing assistants who provide services classified and billed as private duty nursing. As a technical matter, we clarify that only registered nurses and licensed practical nurses may provide private duty nursing services authorized under § 440.80. As discussed above, these types of clinicians are included in the definition of direct care worker in § 441.302(k)(1)(i)(A) so long as they are providing one of the three HCBS services specified in the minimum performance requirement (homemaker, home health aide, or personal care services). However, private duty nursing is not one of the services we have proposed, and are finalizing, for application of this the minimum performance requirement.

Comment: Many commenters recommended that nurse supervisors be included in the definition of direct care workers. Several of these commenters noted that these are required positions for their programs. Some commenters observed that nurse supervisors perform important activities like supervising and training other direct care workers,

coordinating beneficiaries' care, or completing documentation and other paperwork specific to beneficiaries' care (as opposed to paperwork related to business administration). Several commenters stated that clinical supervision is critical to the quality of HCBS. A few commenters noted that nurse supervisors sometimes visit beneficiaries or provide direct services when filling in for absent direct care workers.

One commenter noted support for excluding general administrative or supervisory staff from the definition of direct care workers. A few commenters expressed concerns about the exclusion of administrative or supervisory staff who may sometimes also provide services to beneficiaries. Some of these commenters noted that especially during workforce shortages, administrative staff or supervisors may fill in for direct care workers. A couple of commenters requested clarification on how wages for staff who perform both direct care work and administrative or supervisory work should be counted for the purposes of complying with the minimum performance level. One commenter requested clarification on whether first line supervisors of direct support professionals are included in the definition of direct care workers.

Several commenters stated that they opposed the exclusion of supervisory or managerial staff because these are required positions for their programs. Several commenters noted that staff who provide supervision or perform administrative tasks, such as understanding and reviewing compliance and other regulatory requirements, are critical to quality. One commenter expressed the concern that excluding supervisory or managerial staff from the 80 percent minimum performance level would mean that providers would have to lower the salaries of these positions, and then in turn may have trouble filling these positions. One commenter raised concerns about ''wage compression,'' with providers reducing wages for higher-skilled jobs or paying these jobs more like entry-level jobs.

Response: We are persuaded that nurses or other staff who provide clinical oversight and training for direct care workers participate in activities directly related to beneficiary care (such as completing or reviewing documentation of care), are qualified to provide services directly to beneficiaries, and periodically interact with beneficiaries should be included in the definition of direct care workers at § 441.302(k)(1)(ii). As noted earlier, we are modifying our definition of direct care worker at § 441.302(k)(1)(ii)(F) to clarify that it includes nurses and other staff providing clinical supervision. However, consistent with the proposed rule, our definition is intended to exclude staff who provide administrative supervision (such as overseeing business operations).

While we acknowledge that administrative staff and administrative supervisors are often required staff and perform essential functions (including quality and compliance reporting and recordkeeping), we believe it is critical for the economic and efficient use of Medicaid funds that the vast majority of Medicaid payment for homemaker, home health aide, and personal care services must go to supporting the core activities of that service; the core activities of homemaker, home health aide, and personal care services are performed by direct care workers. As discussed above, evidence specifically shows that direct care workers are paid low wages and, thus, our priority is ensuring a greater share of Medicaid payments go to direct care workers' compensation. If there is an insufficient number of direct care workers employed by a provider, then those HCBS cannot be delivered, and beneficiaries may not be able to access the HCBS they need. We will continue to partner with States to help providers find efficient ways to support their administrative and reporting requirements.

Comment: Many commenters expressed concern that direct support professionals were excluded from the definition of direct care worker, as direct care workers are often associated with provision of services to older adults and people with physical disabilities, while direct service professionals typically provide services to people with intellectual and developmental disabilities.

Response: We note that direct support professionals are explicitly included in the definition of direct care worker at § 441.302(k)(1)(ii)(C), so there is no need to further modify the definition of direct care worker in response to these comments. If someone designated by their State as a direct support professional provides a service that is subject to the minimum performance requirement, their compensation will be included in the calculation for the minimum performance level.

Comment: One commenter suggested that payments to contract employees should not count toward the minimum performance level.

Response: Given the varied nature of HCBS programs, we specifically proposed for the definition of direct care worker at § 441.302(k)(1)(ii)(G) to encompass a broad array of employment relationships. We cannot find sufficient justification for excluding certain types of employment relationships from this requirement and are finalizing our definition of direct care worker to include individuals employed by a Medicaid provider, State agency, or third party; contracted with a Medicaid provider, State agency, or third party; or delivering services under a self-directed service model, as proposed. However, we are making a technical modification for clarity to not finalize § 441.302(k)(1)(ii)(G) and to add language proposed at § 441.302(k)(1)(ii)(G) to the end of § 441.302(k)(1)(ii).

Comment: One commenter opposed including workers who deliver services via a self-directed services delivery model in the definition of direct care workers. They noted that including these workers would ''chip away at the uniqueness at the heart of the self-direction paradigm,'' unintentionally burden self-directed employers and employees, reduce autonomy by introducing a single title for a wide variety of caregiving types, and would not recognize the flexible and interdependent nature of self-direction or the fact that Medicaid beneficiaries who self-direct their services do not retain the funds that remain in budgets at the end of the year.

Response: We thank the commenter for raising their concerns. We decline to make modifications to the definition of direct care worker to exclude direct care workers providing services in self-directed services delivery models generally. We believe it is important for States to have a sufficient direct care workforce to be able to deliver services that are responsive to the changing needs and choices of beneficiaries, as required by section 2402(a)(1) of the Affordable Care Act, regardless of whether they are receiving services through a self-directed services delivery model or a model that is not self-directed. Further, we believe it is important for States to have a sufficient number of qualified direct care workers to provide self-directed personal assistance services, as required by section 2402(a)(3)(B)(iii) of the Affordable Care Act.

However, we do agree that there are certain self-directed services delivery models for which the minimum performance level at (k)(3) would not be appropriate. We intend to apply the requirements at § 441.302(k)(3) to models in which the beneficiary directing the services is not setting the payment rate for the worker (such as

agency-provider models). We do not intend to apply the requirements to self-directed services delivered through models in which the beneficiary sets the payment rate for the worker (such as in individual budget authority models). In the latter scenario, we expect that all or nearly all of that payment rate routinely is spent on the direct care worker's compensation. We are finalizing a new requirement at § 441.302(k)(2)(ii) that clarifies this policy; this requirement is discussed in greater detail in section II.B.5.g. of this final rule.

After consideration of the comments received, we are finalizing the definition of direct care worker at § 441.302(k)(1)(ii) with technical modifications for clarity to change the term, Medicaid-eligible individuals, to the term, Medicaid beneficiaries, in both § 441.302(k)(1)(ii)(A) and (F). We are finalizing § 441.302(k)(1)(ii) with a modification at the end of § 441.302(k)(1)(ii)(F) to provide that direct care workers include nurses and other staff providing clinical supervision. The finalized revised text at § 441.302(k)(1)(ii)(F) will read: Other individuals who are paid to provide services to address activities of daily living or instrumental activities of daily living, behavioral supports, employment supports, or other services to promote community integration directly to Medicaid beneficiaries receiving HCBS available under this subpart, including nurses and other staff providing clinical supervision. We are making a technical modification to not finalize § 441.302(k)(1)(ii)(G) and add language proposed at § 441.302(k)(1)(ii)(G) to the end of § 441.302(k)(1)(ii) to clarify that a direct care worker may be employed by a Medicaid provider, State agency, or third party; contracted with a Medicaid provider, State agency, or third party; or delivering services under a self-directed service model.

f. Reporting (§ 441.302(k)(2))

Section 1902(a)(6) of the Act requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports. At § 441.302(k)(2), under our authority at section 1902(a)(6) of the Act, we proposed to require that States demonstrate that they meet the minimum performance level at § 441.302(k)(3)(i) through new Federal reporting requirements at § 441.311(e). We discuss these reporting requirements in our discussion of proposed § 441.311(e) in section II.B.7 of this final rule.

We received public comments on these proposals. The following is a summary of the comments we received and our responses. We also direct the reader to the discussion of § 441.311(e) in section II.B.7. of this final rule for additional comments and responses.

Comment: A number of commenters, while not supporting the minimum performance requirement, did express support for the requirement that States must collect and report data on the percent of Medicaid payments for certain HCBS going to compensation of direct care workers. Commenters noted this reporting could yield important data about the compensation to workers and allow for national comparisons.

Response: We agree with commenters that the reporting requirement proposed at § 441.311(e) will yield important data about compensation to workers that will help support the HCBS direct care workforce and promote better oversight of how Medicaid payments for certain services are used.

We note that, while several commenters encouraged us to finalize the reporting requirement at § 441.311(e) without finalizing the minimum performance requirement at § 441.302(k)(3), no commenter suggested that we finalize the minimum performance requirement without a reporting requirement. We believe that the reference included in § 441.302(k)(2) to the reporting requirement at § 441.311(e) is necessary for CMS to oversee States' compliance with the minimum performance requirement at § 441.302(k)(3); however, the reporting requirement at § 441.311(e) is distinct and severable from the minimum performance requirement at § 441.302(k). As discussed in more detail in section II.B.7, the reporting requirement at § 441.311(e), which we are finalizing with modifications, addresses a broader universe of services than is included in the minimum performance level at § 441.302(k)(3) and has an earlier applicability date than the date we are finalizing at § 441.302(k)(8) (discussed later in this section). While we are finalizing both the minimum performance requirement at § 441.302(k)(3) and the payment adequacy reporting requirement, as amended, at § 441.311(e), these represent distinct policies, and we believe that the reporting requirement can (and will) function independently from the minimum performance requirement.

Comment: Several commenters suggested that we add a requirement to § 441.302(k)(2) that would require States, as part of their assurances of compliance with the minimum percentage requirement, to acknowledge and explain any differences between the actual payment rates for home care services and the rate most recently recommended by the interested parties' advisory group under § 447.203(b)(6) of this final rule and discussed in section II.C. of this rule. The commenters suggested that if the actual rate is lower than the recommended rate, the State would also need to explain why it is sufficient to ensure access to services.

Response: Although the interested parties' advisory group will provide an invaluable perspective on the adequacy of rates, as discussed in greater detail later in this preamble, the role of the group finalized at § 447.203(b)(6) is advisory. States will not be required to follow the recommendations of the group. We believe the policies as we are finalizing strike the right balance of accountability and flexibility for wholly new rate processes. We further note the recommendations of the interested parties' advisory group will be posted publicly for review. Finally, we note that we are also finalizing steps a State must take to demonstrate adequate access to services when proposing a rate reduction or restructuring in circumstances that could result in diminished access to care.

After consideration of the comments received, we are finalizing § 441.302(k)(2) with modifications. For reasons discussed in section II.B.5.g. of this final rule, at § 441.302, we are redesignating paragraph (k)(2) as paragraph (k)(2)(i) to allow for the addition of a new requirement at paragraph (k)(2)(ii) regarding treatment of certain payment data under self-directed services delivery models.

As discussed in section II.B.5.b. of this rule, we are finalizing reporting requirements at § 441.302(k)(6) to ensure accountability in the States' use of the small provider minimum performance level and hardship exemptions. To clarify that States must comply with this requirement, as well as the reporting requirement at § 441.311(e), we are finalizing references to § 441.302(k)(6) in § 441.302(k)(2)(i). We also are finalizing a technical modification for clarity that the State must demonstrate **annually**, consistent with the reporting requirements at §§ 441.302(k)(6) and 441.311(e), that they meet the minimum performance level at § 441.302(k)(3). (New text in bold font).

g. Application to Other Authorities (Proposed at § 441.302(k)(4), Finalized at § 441.302(k)(8); and §§ 441.464(f), 441.570(f), and 441.745(a)(1)(vi))

At § 441.302(k)(4), we proposed to apply the HCBS requirements described in the proposed rule to services delivered under FFS or managed care delivery systems. As discussed earlier in section II.B.1. of this preamble, section 2402(a)(3)(A) of the Affordable Care Act requires States to improve coordination among, and the regulation of, all providers of Federally and State-funded HCBS programs to achieve a more consistent administration of policies and procedures across HCBS programs. In the context of Medicaid coverage of HCBS, it should not matter whether the services are covered directly on an FFS basis or by a managed care plan to its enrollees. The requirement for consistent administration should require consistency between these two modes of service delivery. We accordingly proposed to specify that a State must ensure compliance with the requirements in § 441.302(k) with respect to HCBS delivered both under FFS and managed care delivery systems.

Similarly, because workforce shortages exist under other HCBS authorities, which include many of the same types of services to address activities of daily living or instrumental activities of daily living as under section 1915(c) waiver authority, we proposed to include these requirements within the applicable regulatory sections. Specifically, we proposed to apply the proposed requirements at § 441.302(k) to section 1915 (j), (k), and (i) State plan at §§ 441.464(f), 441.570(f), and 441.745(a)(1)(vi), respectively. Consistent with our proposal for section 1915(c) waivers, we proposed these requirements based on our authority under section 1902(a)(30)(A) of the Act to ensure payments to HCBS providers are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available to beneficiaries at least to the extent as to the general population in the same geographic area. We believed the same arguments for proposing these requirements for section 1915(c) waivers are equally applicable for these other HCBS authorities. We requested comment on the application of payment adequacy provisions across section 1915(i), (j), and (k) authorities. As noted earlier in section II.B.4. of the proposed rule, to accommodate the addition of new language at § 441.464(e) and (f), we proposed to renumber existing § 441.464(e) as paragraph (g) and existing § 441.464(f) as paragraph (h). We requested comment on whether we should exempt, from these requirements, services delivered using any self-directed service delivery model under any Medicaid authority.

We considered whether to also apply these proposed payment adequacy requirements to section 1905(a) ''medical assistance'' State plan personal care and home health services. However, we did not propose that these requirements apply to any section 1905(a) State plan services based on State feedback that they do not have the same data collection and reporting capabilities in place for section 1905(a) services as they do for section 1915(c), (i), (j), and (k) services. Further, the vast majority of HCBS is delivered under section 1915(c), (i), (j), and (k) authorities, while only a small percentage of HCBS nationally is delivered under section 1905(a) State plan authorities. We requested comment on whether we should apply these requirements to section 1905(a) State plan personal care and home health services.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported holding providers delivering care in managed care delivery systems accountable for paying a sufficient amount to direct care workers. A few commenters requested that we clarify how this requirement would apply to MCOs, PIHPs, and PAHPs. One commenter noted that managed care plans do not control the payment rates that contracted providers pay their direct care workers.

A few commenters requested that we clarify managed care plans' responsibility for tracking and reporting expenditures. A few commenters expressed concern that this proposal would pose particular reporting or accounting burdens for providers that participate in multiple Medicaid managed care plans, serve non-Medicaid clients, or receive bundled payments.

Response: We acknowledge commenters' broad concerns about how these requirements will apply to managed care plans and will provide technical assistance regarding specific questions as they are raised during implementation. However, we are finalizing our proposal to apply the requirements at § 441.302(k) to both managed care and FFS delivery systems. We clarify here that the requirements in § 441.302(k) are the ultimate responsibility of States, regardless of whether their HCBS are delivered through an FFS delivery system, managed care delivery system, or both. The minimum performance requirement applies at the provider level, not the managed care plan level. We expect that States will develop an appropriate process with their managed care plans should the State determine that managed care plans have some role in activities such as the data collection or reporting required in § 441.302(k)(2) (being finalized as § 441.302(k)(2)(i)). We agree that managed care plans do not control payment rates that contracted providers pay their direct care workers and reiterate that the focus of § 441.302(k) is on the percentage of the payment to providers that is passed along as compensation to direct care workers.

We plan to provide technical assistance to States with managed care delivery systems to minimize provider reporting and accounting burden and to address questions related to bundled payments that include the affected services (homemaker, home health aide, and personal care services).

Comment: A few commenters specifically noted support for applying the payment adequacy requirement to programs authorized under all section 1915 authorities. One commenter did not support applying this requirement to ''all 1915 waiver authorities'' but did not provide a specific rationale for their recommendation.

Response: We are finalizing §§ 441.464(f), 441.570(f), and 441.745(a)(1)(vi) (applying § 441.302(k) to section 1915(j), (k) and (i) services, respectively) with minor technical modifications as noted later in this section II.B.5.g. of this final rule.

Comment: A number of commenters expressed concerns about the application of the minimum performance level to self-directed services authorized under sections 1915(j) and 1915(k) of the Act. A few commenters, while not necessarily suggesting that self-directed services should be excluded from the payment adequacy requirement, believed that it would take more time and additional guidance to implement the requirement for self-directed services.

Some commenters raised concerns about the application of the requirement to specific models of self-direction, particularly the self-directed model with service budget (as defined in § 441.545(b)) (often referred to as the individual budget authority model), in which the beneficiary sets the direct care worker's wages. Some commenters worried that the application of the minimum performance level to such

models would put the individual beneficiary in the position of acting as a provider for this purpose. Other commenters were concerned that if the minimum performance level was applied to these self-directed services delivery models, beneficiaries would have to apply a set percent of their budget to compensation of workers and thus would lose the flexibility of determining how their budget was spent or what to pay their direct care workers. One commenter pointed out that beneficiaries in self-directed services delivery models do not personally keep unspent funds and, thus, do not stand to profit by lowering direct care workers' wages. A few commenters also requested clarification of how the payment adequacy requirement would impact the co-employment relationship in self-directed services. One commenter noted that the vast majority of HCBS furnished under self-directed services delivery models are paid so that the entire payment rate goes toward direct care worker's wages and other associated costs such as employer taxes, workers' compensation, and other employer requirements such as State-mandated paid sick leave, while payment for financial management services is paid separately. In these models, nearly 100 percent of the payment rate goes toward the direct care worker's wages and associated costs, which would create an unfair comparison to agency-directed services.

A few commenters noted that it would be undesirable to apply the minimum performance level to HCBS furnished via self-directed services delivery models because these services involve additional activities and costs not associated with other types of services. These commenters noted that services furnished via self-directed services delivery models involve more training and human resources support for the beneficiaries to help them hire and direct their workers. One commenter stated that the proposed minimum performance level of 80 percent would be too high to accommodate other non-compensation activities included in self-directed services delivery models, such as employment or day activities, case management, and back up supports.

On the other hand, some commenters noted that self-directed services delivery models should be included in the payment adequacy requirements and that it is important to support compensation for direct care workers who provide HCBS via self-directed services delivery models. One commenter noted that most personal care services in the commenter's State are furnished via self-directed services delivery models.

Response: We agree with commenters that the minimum performance requirement may be difficult to apply (and, in fact, may simply be inapplicable) to self-directed services delivery models with service budget authority in which the beneficiary directing the services sets the worker's wages as the payment rate for the service (such as models meeting the definition of § 441.545(b) for section 1915(k) services, or self-directed services typically authorized under the section 1915(j) authority).

We also agree with one commenter who noted that, because of the separate payment of financial management services, nearly all of the payments for personal care, homemaker, and home health aide services furnished via self-directed services delivery models with service budget authority are spent on compensation for direct care workers. We believe that applying the minimum performance requirement to such models would be ineffectual and an unnecessary burden on States.

We believe the minimum performance requirement is appropriate when applied to a Medicaid rate for self-directed services that includes both compensation to direct care workers and administrative activities and in which the beneficiary did not set the payment rate for the worker.

We note that at least some of the ''non-compensation activities'' identified by one commenter, such as employment or day activities and case management, do not appear to fall under the specific services to which we proposed, and are finalizing, for the minimum performance requirement to apply, and therefore, they would not likely be subject to the minimum performance requirement as finalized.

To clarify the application of § 441.302(k) to HCBS furnished via self-directed services delivery models, we are finalizing a new requirement at § 441.302(k)(2)(ii), specifying that, if the State provides that homemaker, home health aide, or personal care services, as set forth at § 440.180(b)(2) through (4), may be furnished under a self-directed services delivery model in which the beneficiary directing the services sets the direct care worker's payment rate, then the State does not include such payment data in its calculation of the State's compliance with the minimum performance levels at paragraph (k)(3).

We are finalizing the general application of § 441.302(k) to HCBS authorized under section 1915(j), (k), and (i) authorities, with the understanding that some services delivered under these authorities will fall under the exception for self-directed services delivery models being finalized at § 441.302(k)(2)(ii).

We note that the exception at § 441.302(k)(2)(ii) directs States to exclude certain data from the specified excluded self-directed services models when establishing compliance with the minimum performance level or small provider performance level at § 441.302(k)(3). We believe, however, that the regulation text at § 441.302(k) requiring States to assure that payment rates are adequate to ensure a sufficient direct care workforce to meet the needs of beneficiaries and provide access to services in the amount, duration, and scope specified in beneficiaries' person-centered service plans applies to all self-directed services models offered under all section 1915 authorities.

Comment: Commenters were mixed in their support for excluding section 1905(a) services from the payment adequacy requirement. A few commenters expressed strong support for extending the payment adequacy requirement to services authorized under section 1905(a), particularly commenters writing from States in which larger numbers of beneficiaries receive section 1905(a) State plan services. One commenter expressed concern that not including section 1905(a) services would disproportionately exclude direct care workers providing services to children or adults with intellectual and developmental disabilities. One commenter noted that section 1902(a)(6) of the Act gives CMS the authority to apply the requirement section 1905(a) services.

However, several commenters did not support applying the requirement to section 1905(a) State plan services. Many of these commenters simply did not support applying the minimum performance requirement to services under any authority. A few commenters agreed with our concerns that applying the payment adequacy requirement to section 1905(a) State plan services would pose a particular burden on States due to differences in how these services are delivered and monitored.

Several commenters expressed concerns about potential unintended consequences of not applying the minimum performance requirement to section 1905(a) State plan services. In particular, some commenters raised concerns that direct care workers would stop working for providers that deliver section 1905(a) services, in favor of working for providers that were subject to the minimum performance requirement. On the other hand, a few

commenters worried that providers would stop providing services under section 1915 authorities and switch to providing section 1905(a) services to avoid having to comply with the payment adequacy requirement.

Response: At this time, we are not requiring the application of the HCBS payment adequacy requirements at § 441.302(k) to section 1905(a) services. Given our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will take these comments under consideration for any potential future rulemaking regarding section 1905(a) services.

Comment: One commenter requested clarification as to whether the payment adequacy requirements would apply to services delivered under section 1115 authority.

Response: At § 441.302(k)(4) (which we are finalizing at § 441.302(k)(8)), we proposed to apply these requirements to services delivered under FFS or managed care delivery systems, including those authorized under section 1115(a) of the Act. We are finalizing this requirement in this final rule, with modifications as noted herein, including retaining the application to managed care delivery systems authorized section 1115(a).

After consideration of public comments, and for reasons discussed in sections II.B.5.b. and II.B.5.h. of this rule, we are finalizing § 441.302(k)(4) with modifications to redesignate § 441.302(k)(4) as § 441.302(k)(8) and change the date for States to comply with the requirements at § 441.302(k) from 4 years to 6 years. We are finalizing § 441.302(k)(8) with minor modifications to correct erroneous uses of the word ''effective.'' We are retitling the requirement at § 441.302(k)(8) as Applicability date (rather than Effective date). We are also modifying the language at § 441.302(k)(8) to specify that States must comply with the requirements in § 441.302(k) beginning 6 years after the effective date of this final rule, rather than stating that § 441.302(k)(8) is effective 6 years after the effective date of the final rule. In addition, we are finalizing technical modifications to the language pertaining to the applicability date for States providing services through managed care delivery systems to improve accuracy and alignment with common phrasing in managed care contracting policy.

As finalized, the redesignated § 441.302(k)(8) reads: *Applicability date.* **States must comply with the** requirements **set forth in paragraph (k) of this section** beginning *6* years after the effective date of this paragraph; and in the case of the State that implements a managed care delivery system under the authority of section 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes **homemaker, home health aide, or personal care services, as set forth at § 440.180(b)(2) through (4)** in the MCO's, PIHP's, or PAHP's contract, ***the first rating period for contracts with the MCO, PIHP, or PAHP beginning*** on or after **the date that is** *6* years after the **effective** date of this paragraph. (New language identified in bold.)

After consideration of the comments, as noted above in this section, we are finalizing a requirement at § 441.302(k)(2)(ii) specifying that if the State provides that homemaker, home health aide, or personal care services, as set forth at § 440.180(b)(2) through (4), may be furnished under a self-directed services delivery model in which the beneficiary directing the services sets the direct care worker's payment rate, then the State does not include such payment data in its calculation of the State's compliance with the minimum performance levels at paragraph (k)(3).

We are finalizing the application of § 441.302(k) to section 1915(j), (k), and (i) services with minor modifications. We are finalizing a technical modification to clarify that the reference to person-centered service plans in §§ 441.464(f), 441.570(f), and 441.745(a)(1)(vi) is to beneficiaries' person-centered service plans. We are also clarifying in §§ 441.464(f), 441.570(f), and 441.745(a)(1)(vi) that while § 441.302(k) applies to services delivered under these authorities, references to section 1915(c) of the Act are instead references to sections 1915(j), (k), or (i), as appropriate.

Additionally, to ensure application of all relevant requirements of § 441.302(k) to section 1915(i) and (k) authorities, we are also finalizing a modification to §§ 441.474(c), 441.580(i) and 441.745(a)(1)(vii) to clarify that the reporting requirement at § 441.302(k)(6) applies to section 1915(j), (k) and (i) authorities, respectively. (We note that discussion of the finalization of §§ 441.474(c), 441.580(i) and 441.745(a)(1)(vii) is in II.B.7. of this final rule.) We note that while we are applying the requirement at § 441.302(k)(6) to section 1915(j), (k), and (k) authorities, States would only be required to comply with this reporting requirement if the State provided services under these authorities described in § 441.302(k)(2)(i) and if the State meets the other criteria set forth in § 441.302(k)(6).

h. Applicability Date (Proposed at § 441.302(k)(4), Being Finalized at § 441.302(k)(8))

As noted throughout the HCBS provisions in this preamble, we recognize that many States may need time to implement these requirements, including to amend provider agreements or managed care contracts, make State regulatory or policy changes, implement process or procedural changes, update information systems for data collection and reporting, or conduct other activities to implement these proposed payment adequacy requirements. We expect that these activities will take longer than similar activities for other HCBS provisions in the rule. Further, we expect that it will take a substantial amount of time for managed care plans and providers to establish the necessary systems, data collection tools, and processes necessary to collect the required information to report to States. As a result, we proposed at § 441.302(k)(4), to provide States with 4 years to implement these requirements in FFS delivery systems following the effective date of the final rule. For States that implement a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and include HCBS in the MCO's, PIHP's, or PAHP's contract, we proposed to provide States until the first rating period for contracts with the MCO, PIHP, or PAHP, beginning on or after 4 years after the effective date of the final rule to implement these requirements. Similar to our rationale in other sections, this proposed timeline reflects feedback from States and other interested parties that it could take 3 to 4 years for States to complete any necessary work to amend State regulations and work with their State legislatures, if needed, as well as to revise policies, operational processes, information systems, and contracts to support implementation of the proposals outlined in this section. We also considered the overall burden of the proposed rule as a whole in proposing the effective date for the payment adequacy provision. We invited comments on the overall burden associated with implementing this section, whether this timeframe is sufficient, whether we should require a shorter timeframe (such as 3 years) or longer timeframe (such as 5 years) to implement the payment adequacy provisions and if an alternate timeframe is recommended, the rationale for that alternate timeframe.

We received public comments on these proposals. The following is a

summary of the comments we received and our responses.

Comment: A few commenters supported our proposal that the minimum performance requirement go into effect four years after the publication of this final rule. One commenter noted that 4 years should be sufficient time for States and providers to make necessary adjustments. A few commenters noted that 4 years was too long, given the urgency of the workforce shortage. One commenter suggested that we require the minimum performance requirement go into effect January 1, 2025, while another commenter suggested a 2-year effective date. One commenter suggested the requirement should go into effect in 3 years, to align with some of the other proposed effective dates in this rule.

Other commenters recommended that we allow for a longer effective date, such as 6 years. Commenters noted that large-scale changes, such as what would be required to comply with the minimum performance requirement, would take time.

Several commenters suggested that compliance with the minimum performance requirement be phased in over time to give providers and States an opportunity to adjust their systems and policies.

Response: While we are sympathetic to commenters' sense of urgency regarding the workforce shortage, we do not believe it is realistic for States to comply with the requirements earlier than the proposed four years. We agree with commenters that, for some States, ensuring that a minimum percent of Medicaid payments go to direct care worker compensation (and tracking compliance with this requirement) will require a period of adjustment. We do expect that providers should already be aware of their Medicaid revenues and what they pay their workers; however, we acknowledge that they may not already be reporting this information to the States and that the States will need to work with their providers to develop an appropriate reporting mechanism. We also understand that some providers will have to adjust how they operate their business in order to meet the required minimum performance level. We also acknowledge that we will need to provide additional subregulatory guidance and technical assistance to aid in implementation.

We agree with commenters that a slightly longer date for States to comply with the requirements is necessary. We believe that the complementary reporting requirement at § 441.311I (discussed in section II.B.7. of this rule) can be leveraged to create a transition period to aid States in their compliance with § 441.302(k)(3). As such, we are finalizing § 441.302(k)(8) with a modification to change the date for States to comply with the requirements from 4 years to 6 years. The data collected as part of § 441.311(e) will give States feedback on how close they are to reaching the minimum performance level and will help CMS develop targeted technical assistance for States that are farther away from attaining compliance. For States electing to create a State-defined minimum performance level for small providers, this period between reporting and performance will also allow States to make any necessary adjustments to their State-defined minimum performance levels. It will also allow States to make any necessary adjustments to their criteria for hardship exemptions and to identify providers who need hardship exemptions. We will continue to use our standard enforcement tools and discretion, as appropriate, when the requirements at §§ 441.302(k) go into effect.

As noted in section II.B.5.b. and II.B.5.h. of this section, we are creating new requirements at § 441.302(k)(4) through (7) and thus are redesignating proposed § 441.302(k)(4) as § 441.302(k)(8) and finalizing § 441.302(k)(8) with the modifications as noted in section II.B.5.b. of this final rule. We are finalizing § 441.302(k)(8) with minor modifications to correct erroneous uses of the word ''effective.'' We are retitling the requirement at § 441.302(k)(8) as Applicability date (rather than Effective date). We are also modifying the language at § 441.302(k)(8) to specify that States must comply with the requirements in § 441.302(k) beginning 6 years after the effective date of this final rule, rather than stating that § 441.302(k)(8) is effective 6 years after the effective date of the final rule. In addition, we are finalizing technical modifications to the language pertaining to the applicability date for States providing services through managed care delivery systems to improve accuracy and alignment with common phrasing in managed care contracting policy.

i. Summary of Finalized Requirements

After consideration of the public comments, we are finalizing the requirements at § 441.302(k) as follows:

- We are finalizing the assurance requirement at § 441.302(k) with technical modifications.
- We are finalizing § 441.302(k)(1) with a technical modification.
- The definition of compensation at § 441.302(k)(1)(i) (now also at § 441.311(e)(1)(i)) and finalized as proposed, with the exception of § 441.302(k)(1)(i)(B) (now also at § 441.311(e)(1)(i)(B)), which is revised to read: Benefits (such as health and dental benefits, life and disability insurance, paid leave, retirement, and tuition reimbursement).
- The definition of direct care worker at § 441.302(k)(1)(ii) (now also at § 441.311(e)(ii)) is finalized with technical modifications to § 441.302(k)(1)(ii)(A) and (F) (now also at § 441.311(e)(1)(ii)(A) and (F)). We are also finalizing the following addition at the end of § 441.302(k)(1)(ii)(F) (now also at § 441.311(e)(1)(ii)(F)), including nurses and other staff providing clinical supervision. The revised text at § 441.302(k)(1)(ii)(F) (now also at § 441.311(e)(1)(ii)(F)) will read as follows: Other individuals who are paid to provide services to address activities of daily living or instrumental activities of daily living, behavioral supports, employment supports, or other services to promote community integration directly to Medicaid beneficiaries receiving home and community-based services available under this subpart, including nurses and other staff providing clinical supervision. In addition, we are making a technical modification to not finalize § 441.302(k)(1)(ii)(G) and add language proposed at § 441.302(k)(1)(ii)(G) to the end of § 441.302(k)(1)(ii) to clarify that a direct care worker may be employed by a Medicaid provider, State agency, or third party; contracted with a Medicaid provider, State agency, or third party; or delivering services under a self-directed services delivery model.
- A definition of excluded costs is finalized at § 441.302(k)(1)(iii) (now also at § 441.311(e)(1)(iii)) as follows:

Excluded costs means costs that are not included in the calculation of the percentage of Medicaid payments to providers that is spent on compensation for direct care workers. Such costs are limited to:

(A) Costs of required trainings for direct care workers (such as costs for qualified trainers and training materials);

(B) Travel costs for direct care workers (such as mileage reimbursement or public transportation subsidies); and

(C) Costs of personal protective equipment for direct care workers.

- Section 441.302(k)(2) is finalized with modifications. We are redesignating the language at § 441.302(k)(2) as § 441.302(k)(2)(i). We are finalizing § 441.302(k)(2)(i) to include references to the reporting requirements that are finalized at

§§ 441.302(k)(6) and 441.311(e) and the exception finalized at § 441.302(k)(2)(ii). We also made a technical modification for clarity that the State must demonstrate **annually,** consistent with the reporting requirements at §§ 441.302(k)(6) and 441.311(e), that they meet the minimum performance level at § 441.302(k)(3). In addition, we made technical modifications for clarity and precision to specify the specific services (homemaker, home health aide, and personal care services) to which the payment adequacy requirement applies and to specify that these requirements apply to services authorized under section 1915(c) of the Act, unless excepted under § 441.302(k)(2)(ii).

- We are finalizing at new requirement at § 441.302(k)(2)(ii) that clarifies that if the State provides that homemaker, home health aide, or personal care services, as set forth at § 440.180(b)(2) through (4), may be furnished under a self-directed services delivery model in which the beneficiary directing the services sets the direct care worker's payment rate, then the State would not include such payment data in its calculation of the State's compliance with the minimum performance levels at paragraph (k)(3).
- Section 441.302(k)(3) is finalized with several modifications to retitle the requirement as ''*Minimum performance at the provider level*'' and clarify the components of the required calculation and the services that fall within this requirement. Section 441.302(k)(3) is also finalized with modifications to clarify that excluded costs are not included in the calculation of the percentage of total payments to a provider that is spent on compensation to direct care workers and to specify the specific services (homemaker, home health aide, and personal care services) to which the payment adequacy requirement applies. We are also modifying § 441.302(k)(3) to note the exceptions to the minimum performance level that we are adding at (k)(5) (hardship exemption) and (k)(7) (IHS and Tribal health programs subject to 25 U.S.C. 1641).
- Section 441.302(k)(3)(i) is finalized with a clarification that the minimum performance level of 80 percent applies to all payments to a provider, except as provided in paragraph (k)(3)(ii).
- Section 441.302(k)(3)(ii) is amended to add an option for States to set a State-defined small provider minimum performance level. As finalized, § 441.302(k)(3)(ii) reads: (ii) At the State's option, providers determined by the State to meet its State-defined small provider criteria in paragraph (k)(4)(i) of this section, the State must ensure that each provider spends the percentage set by the State in accordance with paragraph (k)(4)(ii) of this section of total payments the provider receives for services it furnishes as described in paragraph (k)(3) on total compensation for direct care workers who furnish those services.
- An option for States to develop criteria to identify small providers to meet the State-defined small provider minimum performance level is added at new § 441.302(k)(4).
- An option for States to provide some providers with a hardship exemption is added at new § 441.302(k)(5).
- Reporting requirements are finalized at § 441.302(k)(6), establishing reporting requirements for States that utilize the small provider minimum performance level and hardship exemption options finalized at § 441.302(k)(4)(ii) and (k)(5), as well as a waiver of these requirements that may be granted under certain circumstances.
- An exemption from the requirements at § 441.302(k) is finalized for IHS and Tribal health programs subject to 25 U.S.C. 1641 at § 441.302(k)(7).
- Section 441.302(k)(4) is renumbered as § 441.302(k)(8) and is finalized, with other technical modifications, to specify that States must comply with the requirements set forth at § 441.302(k)(8) beginning 6 years from the effective date of this final Rule.
- We are finalizing §§ 441.464(f), 441.570(f), and 441.745(a)(1)(vi) with technical modification to clarify that the references to person-centered service plans in §§ 441.464(f), 441.570(f), and 441.745(a)(1)(vi) are to beneficiaries' person-centered service plans. We are also finalizing modifications to clarify that § 441.302(k) applies to services delivered under these authorities, except that references to section 1915(c) of the Act are instead references to sections 1915(j), (k), or (i) of the Act, as appropriate.
- We are finalizing a modification to §§ 441.474(c), 441.580(i), and 441.745(a)(1)(vii) to clarify that the reporting requirement at § 441.302(k)(6) applies to section 1915(j), (k) and (i) authorities, respectively.

6. Supporting Documentation Required (§ 441.303(f)(6))

As discussed in the proposed rule (88 FR 27986), States vary in whether they maintain waiting lists for section 1915(c) waivers, and if a waiting list is maintained, how individuals may join the waiting list. Section 1915(c) of the Act authorizes States to set enrollment limits or caps on the number of individuals served in a waiver, and many States maintain waiting lists of individuals interested in receiving waiver services once a spot becomes available. While some States require individuals to first be determined eligible for waiver services to join the waiting list, other States permit individuals to join a waiting list after an expression of interest in receiving waiver services. This can overestimate the number of people who need Medicaid-covered HCBS because the waiting lists may include individuals who are not eligible for services. According to the Kaiser Family Foundation, over half of people on HCBS waiting lists live in States that do not screen people on waiting lists for eligibility.[118]

We have not previously required States to submit any information on the existence or composition of waiting lists, which has led to gaps in information on the accessibility of HCBS within and across States. Further, feedback obtained during various public engagement activities conducted with States and other interested parties over the past several years about reporting requirements for HCBS, as well as feedback received through the RFI[119] discussed earlier, indicate that there is a need to improve public transparency and processes related to States' HCBS waiting lists. In addition, we have found, over the past several years in particular, that some States are operating waiting lists for their section 1915(c) waiver programs despite serving fewer people than their CMS-approved enrollment limit or cap, even though States are expected to enroll individuals up to their CMS-approved enrollment limit or cap before imposing a waiting list. However, because we do not routinely collect information on States' use of waiting lists and the number of people on waiting lists, we are unable to determine the extent to which States are operating such unauthorized waiting lists or to work with States to address these unauthorized waiting lists.

Section 1902(a)(6) of the Act requires State Medicaid agencies to make such reports, in such form and containing such information as the Secretary may from time to time require, and to comply with such provisions as the

[118] Burns, A., M. O'Malley Watts, M. Ammula. A Look at Waiting lists for Home and Community-Based Services from 2016 to 2021. Kaiser Family Foundation. *https://www.kff.org/47f8e6f/.*

[119] CMS Request for Information: Access to Coverage and Care in Medicaid & CHIP. February 2022. For a full list of question from the RFI, see *https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-questions.pdf.*

Secretary may from time to time find necessary to assure the correctness and verification of such reports. Based on the authority found at section 1902(a)(6) of the Act, we proposed to require information from States on waiting lists to improve public transparency and processes related to States' HCBS waiting lists and ensure that we are able to adequately oversee and monitor States' use of waiting lists in their section 1915(c) waiver programs. To address new proposed requirements at § 441.311(d)(1), described in section II.B.7. of this rule, on State reporting on waiting lists, we proposed to amend § 441.303(f)(6) by adding a sentence to the end of the existing regulatory text to require that if the State has a limit on the size of the waiver program and maintains a list of individuals who are waiting to enroll in the waiver program, the State must meet the reporting requirements at § 441.311(d)(1).

We received public comments on these proposals. The following is a summary of the comments we received and our responses. We also received a number of comments on the related reporting requirement at § 441.311(d). Those comments are addressed in section II.B.7.

Comment: A few commenters shared local data and anecdotal experiences about States' waiting lists, which some described as containing thousands of people and requiring beneficiaries to wait for long periods of time, even years, before accessing services. One commenter observed that as demand for HCBS grows, the waiting lists will also grow. A few commenters expressed concerns that the long waiting times may result in beneficiaries having to enter institutional care. Commenters also noted that beneficiaries and their families experience confusion regarding waiting lists, including how long they will have to remain on the waiting list before receiving services; commenters noted that this confusion or lack of transparency can make it difficult for beneficiaries to make informed decisions or plan for future care needs.

A few commenters specifically supported our proposed amendment to § 441.303(f) that would require States to report information on waiting lists for section 1915(c) waiver programs, which commenters believed would contribute to transparency and provide additional data to help make future changes within HCBS programs. Commenters believed that a requirement to report this information would improve CMS's ability to provide oversight and to hold States accountable for waiting list practices. A few commenters believed that creating reporting requirements for waiting lists is a necessary step toward the larger goal of reducing HCBS waiting lists through expansion of HCBS programs. A few commenters noted this information is critical when requesting additional appropriations from State legislatures to expand HCBS programs.

Response: We thank the commenters for their support and for sharing their experiences and perspectives. We agree that collecting and reporting data on waiting lists is a critical step in identifying unmet needs among beneficiaries and can support the efficient administration and expansion of HCBS programs.

Comment: A few commenters expressed opposition to adding a reporting requirement for section 1915(c) waiver programs. Commenters noted concerns that this requirement would necessitate changes in States' data collection processes and IT systems.

Response: We address commenters' concerns in more detail in the discussion of § 441.311(d) in section II.B.7. of this rule. As we note in that section, we have designed the reporting requirement to minimize administrative burden on States while still generating valuable data about waiting lists needed to support transparency and accountability. We plan to offer States technical assistance as needed to help align their current data collection practices with what will be needed to comply with this reporting requirement.

After consideration of the public comments, we are finalizing the requirements at § 441.303(f) as proposed. We note that specific recommendations regarding the reporting requirement are addressed in section II.B.7. as part of the discussion of § 441.311(d).

7. Reporting Requirements (§§ 441.311, 441.474(c), 441.580(i), and 441.745(a)(1)(vii))

Section 1902(a)(6) of the Act requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports. As discussed in section II.B.1. of the proposed rule, in 2014, we released guidance for section 1915(c) waiver programs in which we requested States to report on State-developed performance measures across several domains, as part of an overarching HCBS waiver quality strategy. The 2014 guidance established an expectation that States conduct systemic remediation and implement a Quality Improvement Project when they score below 86 percent on any of their performance measures. Under our authority at section 1902(a)(6) of the Act, we proposed requirements at § 441.311, in combination with other proposed requirements identified throughout the proposed rule, to supersede and fully replace the reporting metrics and the minimum 86 percent performance level expectations for States' performance measures described in the 2014 guidance.

The reporting requirements we proposed in the proposed rule represented consolidated feedback from States, consumer advocates, managed care plans, providers, and other HCBS interested parties on improving and enhancing section 1915(c) waiver performance to integrate nationally standardized quality measures into the reporting requirements, address gaps in existing reporting requirements related to access and the direct service workforce, strengthen health and welfare and person-centered planning reporting requirements, and eliminate annual performance measure reporting requirements that provide limited useful data for assessing State compliance with statutory and regulatory requirements. The intent of the proposed reporting requirements was to allow us to better assess State compliance with the statutory and regulatory requirements for section 1915(c) waiver programs. As indicated at the end of this preamble section, we proposed that the reporting requirements at § 441.311 also apply to State plan options authorized under section 1915(i), (j) and (k) of the Act, as well as to both FFS and managed care delivery systems, unless otherwise indicated.

We proposed, at § 441.311(a), a regulation setting forth the statutory basis and scope of the reporting requirements in § 441.311.

We did not receive comments on § 441.311(a). Based on further consideration, we are finalizing § 441.311(a) with a modification for clarity to remove ''simplification'' and make a minor formatting change to ensure § 441.311(a) aligns directly with the statutory requirement at section 1902(a)(19) of the Act.

We also note that, consistent with statements we made in the introduction of sections II. and II.B. of this final rule regarding severability, we intend that each provision in § 441.311 of this final rule is, as finalized, distinct and severable to the extent it does not rely on another final policy or regulation that we proposed. While we intend that each of the provisions being finalized

within § 441.311, and policies and regulations being finalized elsewhere in this rule, present a comprehensive approach for our oversight of States' Medicaid programs and improving HCBS, we also intend that each reporting requirement within § 441.311 is distinct and severable from one another and from other policies and regulations, being finalized in this rule as well as those rules and regulations currently in effect, to the extent applicable.

Specifically, we proposed, and are finalizing, various reporting requirements in § 441.311 to provide mechanisms for us to oversee States' compliance with other policies being finalized in this rule, such as reporting requirements at § 441.311(b)(1) through (2) for incident management system and critical incident requirements under § 441.302(a)(6), as well as to collect data to support future policy considerations to address the direct care worker shortage at § 441.311(e). While we intend them to be distinct and severable, we are finalizing these reporting requirements in § 441.311 to consolidate them in one place in regulation so they are easier to find. They are not interdependent to the extent each does not rely on another final policy or regulation that we proposed and are finalizing in this rule. We believe that the reporting requirements being finalized herein at § 441.311(b)(1) through (4), (c), (d)(1) and (2), and (e) are each valuable on their own and would provide critical data and oversight even in a circumstance where individual provisions within § 441.311 were not finalized or implemented; however, we note that in this final rule, we are finalizing all reporting requirements in § 441.311, albeit some with modifications, as discussed in this section.

a. Compliance Reporting

(1) Incident Management System Assessment (§ 441.311(b)(1) and (2))

As noted earlier in section II.B.3. of this rule, there have been notable and high-profile instances of abuse and neglect in recent years that highlight the risks associated with poor quality care and with inadequate oversight of HCBS in Medicaid. This is despite State efforts to implement statutory and regulatory requirements to protect the health and welfare of individuals receiving section 1915(c) waiver program services, and State adoption of related subregulatory guidance. In addition, a July 2019 survey of States that operate section 1915(c) waivers found that:

- Definitions of critical incidents vary across States and, in some cases, within States for different HCBS programs or populations;
- Some States do not use standardized forms for reporting incidents, thereby impeding the consistent collection of information on critical incidents;
- Some States do not have electronic incident management systems, and, among those that do, many use systems with outdated electronic platforms that are not linked with other State systems, leading to the systems operating in silos and the need to consolidate information across disparate systems; and
- Many States cited the lack of communication within and across State agencies, including with investigative agencies, as a barrier to incident resolution.

Based on these findings and reports, as well as feedback obtained during various public engagement activities conducted with interested parties over the past several years to standardize and strengthen health and welfare reporting requirements, we proposed new requirements for States' incident management systems at § 441.302(a)(6), as discussed in section II.B.3. of this preamble. We also proposed new reporting requirements that will allow us to better assess State compliance with the requirements at § 441.302(a)(6).

Relying on our authority at section 1902(a)(6) of the Act, at § 441.311(b), we proposed to establish new compliance reporting requirements. Specifically, at § 441.311(b)(1)(i), we proposed to require that States report every 24 months on the results of an incident management system assessment to demonstrate that they meet the requirements at § 441.302(a)(6) that the State operate and maintain an incident management system that identifies, reports, triages, investigates, resolves, tracks, and trends critical incidents, including that:

- The State define critical incidents to meet the proposed minimum standard definition at § 441.302(a)(6)(i)(A);
- The State have an electronic critical incident system that, at a minimum, enables electronic collection, tracking (including of the status and resolution of investigations), and trending of data on critical incidents as proposed at § 441.302(a)(6)(i)(B);
- The State require that providers report any critical incidents that occur during the delivery of section 1915(c) waiver program services as specified in a waiver participant's person-centered service plan, or are a result of the failure to deliver authorized services, as proposed at § 441.302(a)(6)(i)(C);
- The State use claims data, Medicaid Fraud Control Unit data, and data from other State agencies such as Adult Protective Services or Child Protective Services to the extent permissible under applicable State law to identify critical incidents that are unreported by providers and occur during the delivery of section 1915(c) waiver program services, or as a result of the failure to deliver authorized services, as proposed at § 441.302(a)(6)(i)(D);
- The State ensure records being used as part of the incident management system are handled in compliance with 45 CFR 164.510(b), and records with protected health information are obtained and used with beneficiary consent at § 441.302(a)(6)(i)(E);
- The State share information on reported incidents, the status and resolution of investigations, such as through the use of information sharing agreements, with other entities in the State responsible for investigating critical incidents, if the State refers critical incidents to other entities for investigation, as proposed at § 441.302(a)(6)(i)(E); and
- The State separately investigate critical incidents if the investigative agency fails to report the resolution of an investigation within State-specified timeframes as proposed at § 441.302(a)(6)(i)(F).

Given the risk of preventable and intentional harm to beneficiaries when effective incident management systems are not in place, documented instances of abuse and neglect among people receiving HCBS, and identified shortcomings and weaknesses of States' incident management systems discussed earlier, we believed the proposed requirement for States to report every other year on the results of an incident management system assessment is in the best interest of and necessary for protecting the health and welfare of individuals receiving section 1915(c) waiver program services. In the absence of such a reporting requirement, we believed that we are unable to determine whether States have effective systems in place to identify and address incidents of abuse, neglect, exploitation, or other harm during the course of service delivery; ensure that States are protecting the health and welfare of individuals receiving section 1915(c) waiver program services; and safeguard people receiving section 1915(c) waiver program services from preventable or intentional harm.

In proposing an every 24-month timeframe for reporting, we were attempting to take into account the

likely frequency of State changes to policies, procedures, and information systems, while also balancing State reporting burden and the potential risk to beneficiaries if States have incident management systems that are not compliant with the proposed requirements at § 441.302(a)(6). We believed an every 24-month timeframe for reporting is sufficient to detect substantial changes to policies, procedures, and information systems and ensure that we have accurate information on States' incident management systems. We also proposed, at § 441.311(b)(1)(ii), to allow States to reduce the frequency of reporting to up to once every 60 months for States with incident management systems that are determined to meet the requirements at proposed § 441.302(a)(6). We invited comments on whether the timeframe for States to report on the results of the incident management system assessment is sufficient or if we should require reporting more frequently (every year) or less frequently (every 3 years). We also invited comment on whether we should require reporting more frequently (every 3 years or every 4 years) for States that are determined to have an incident management system that meets the requirements at § 441.302(a)(6). If an alternate timeframe is recommended, we requested that commenters provide the rationale for that alternate timeframe.

We received public comments on this proposal. The following is a summary of the comments we received and our responses. We also received comments on the incident management system requirements. Those comments and our responses are in section II.B.3. of this final rule.

Comment: A few commenters generally supported the proposed incident management requirements being finalized at § 441.302(a)(6), which are the subject of the reporting requirement at § 441.311(b)(1). One commenter questioned how these reporting requirements would interact with current State reporting requirements related to critical incidents or other waiver reporting requirements.

Response: We thank commenters for their support. We expect to implement new reporting forms for the new reporting requirements that we are finalizing in this final rule, including the critical incident reporting requirements. We also expect to modify existing reporting forms, particularly to remove the reporting requirements in the 2014 guidance [120] that are being superseded and fully replaced by the requirements in this final rule. We note that some components of the existing reporting forms may remain in effect to the extent that they cover other requirements that remain unchanged by the requirements that we are finalizing in this final rule. States and interested parties will have an opportunity to comment on the new reporting forms and the revised forms through the Paperwork Reduction Act notice and comment process. Further, we expect that States will be able to build on existing systems to comply with the requirements being finalized in this rule at §§ 441.302(a)(6) and 441.311(b)(1) (discussed in sections II.B.3. and II.B.7. of this rule, respectively.) We plan to provide technical assistance to specific State questions, as needed, about how these requirements can align and interact with current practices.

Comment: A few commenters requested clarification on the assessment that is mentioned in § 441.311(b)(1)(i). Commenters requested more information on the contents of the assessment States must perform of their incident management systems and how States should report the results of the assessment. A few commenters requested more detail on the reporting template and when the report would need to be submitted. A few commenters expressed the hope that the reporting timing could be aligned with waiver years or other administrative deadlines. One commenter inquired if States were expected to pay for the assessment. One commenter requested clarification on the deadline for when this assessment must be completed. A few commenters noted that the assessment was required to be performed annually.

Response: The assessment that States perform of their systems will include review of the elements being finalized at § 441.302(a)(6). The requirements we are finalizing in § 441.302(a)(6) is discussed in detail in section II.B.3. of this final rule. The assessment results will be collected as part of the overall data collection activities associated with the reporting requirements in § 441.311. Per § 441.311(f), as finalized herein (and discussed below in this section II.B.7.), States will be required to comply with the reporting requirement for § 441.311(b)(1) beginning 3 years after the effective date of this final rule. This means that States will be required to submit the assessment results to CMS in three years; thus, assessments should be performed in time for States to meet this timeframe. We will be making the required assessment and reporting template available for public comment through the Paperwork Reduction Act notice and comment process. Specific reporting due dates will be determined through subregulatory guidance.

We anticipate that the costs that States incur to conduct and report on the results of the assessment will be eligible for Federal match as an administrative activity. Current Medicaid Federal matching funds are available for State expenditures on the design, development, and installation (including enhancements), and for operation, of mechanized claims processing and information retrieval systems. Under section 1903(a)(7) of the Act, Federal matching funds are available for administrative activities necessary for the proper and efficient administration of the Medicaid State plan. This may include the costs that States incur to conduct and report on the results of the incident management assessment.

We also clarify that there is not a requirement that the incident management assessment be performed annually. As discussed in greater detail below, §§ 441.311(b)(1)(i) and (ii) require that States must submit an incident management assessment every 24 months unless CMS determines the system meets the requirements at § 441.302(a)(6), at which point the assessment must be made every 60 months. Assessments of the incident management system need to be performed as part of this assurance schedule. However, States are welcome to perform assessments more frequently than this schedule requires.

Comment: A few commenters requested that we require States to assess whether the State system tracks the reporting of critical incidents to the designated State Protection and Advocacy system at the same time the incident was reported to the State.

Response: We are declining to make modifications to requirements for States system assessments. We note that commenters made a similar request to add this requirement to the system requirements proposed at § 441.302(a)(6). We also declined to add the requirement to § 441.302(a)(6). We refer readers to section II.B.3. of this rule for the related discussion. However, States are welcome to add other factors to their system assessment beyond the requirements we are finalizing in this rule.

[120] We note that, although States will no longer be expected to meet the reporting requirements and 86 percent minimum performance level in the 2014 guidance, the six assurances and related subassurances in the 2014 guidance continue to apply.

Comment: One commenter requested clarification on the consequences of a State's incident management system being found to be non-compliant with § 441.302(a)(6).

Response: Corrective actions or other enforcement actions will be determined on a case-by-case basis, using our standard enforcement authority, for States with incident management systems that are determined by the assessment to not be compliant with the requirements at § 441.302(a)(6). Additionally, States that do not have compliant systems will be required to perform assessments every 24 months, as required by § 441.311(b)(1)(i) until CMS determines that the system meets the requirements of § 441.302(a)(6) and the State can reduce reporting frequency to every 60 months, as provided by § 441.311(b)(1)(ii). We are not making any changes in this final rule based on this comment.

Comment: A few commenters supported the proposals at § 441.311(b)(1)(i) and (ii) that States must provide the required assessment every 24 months and, if the system is determined to be compliant, every 60 months. One commenter encouraged us to reduce the frequency in § 441.311(b)(1)(i) to one year. One commenter suggested that States should provide assessments on their systems every 1 to 2 years, and if the State's system has been deemed to be in compliance, the assessment should be provided every 3 to 4 years.

A few commenters, however, believed that the reporting frequency should be increased. One commenter recommended this reporting should occur every three years. A few commenters worried that 24 months would not be sufficient time for States to submit the assessment to CMS, and implement any system changes, which might require IT systems updates and acquiring additional funding from State legislatures. One commenter suggested that the assessment should be submitted every 5 years to align with the waiver renewal cycle.

One commenter noted that requiring an assessment every 24 months will create an unnecessary duplication of work. The commenter agreed with the need for an initial assessment but contended that the ongoing assessments were unnecessary, as States could independently monitor ongoing operations and make quality improvements and system updates as needed.

Response: We continue to believe that 24 months (and, for compliant systems, 60 months) is an appropriate frequency that ensures accountability without being overly burdensome. We refer readers to our prior response regarding situations in which we determine, based on the State's assessment, that its system does not meet the requirements finalized at § 441.302(a)(6).

We do not agree that requiring a regular schedule of system review is duplicative. If a State is already conducting regular system reviews as part of a quality improvement process, that review can form the basis for the every 24-month or, as appropriate, every 60-month assessment. We believe that for States that may not already have such processes in place, some regular schedule of review is necessary to ensure that over time, systems do not fall out of compliance. We also would encourage States to use these assessments as opportunities to conduct more comprehensive audits or reviews to identify opportunities for system improvements.

After consideration of the comments received, we are finalizing the reporting frequency in § 441.311(b)(1)(i) with a technical modification for clarity that the State must report on the results of an incident management system assessment, every 24 months, in the form and manner, and at a time, specified by CMS, rather than according to the format and specifications provided by CMS. We are finalizing § 441.311(b)(1)(ii) as proposed.

(2) Critical Incidents (§ 441.311(b)(2))

As discussed earlier in section II.B.4. of the proposed rule, at § 441.302(a)(6)(i)(A), we proposed to require States to define critical incidents at a minimum as verbal, physical, sexual, psychological, or emotional abuse; neglect; exploitation including financial exploitation; misuse or unauthorized use of restrictive interventions or seclusion; a medication error resulting in a telephone call to or a consultation with a poison control center, an emergency department visit, an urgent care visit, a hospitalization, or death; or an unexplained or unanticipated death, including but not limited to a death caused by abuse or neglect.

Based on the same rationale as discussed previously in section II.B.7.a.(1) of this preamble related to the proposed incident management system assessment reporting requirement, at § 441.311(b)(2), relying on our authority under section 1902(a)(6) of the Act, we proposed to require that States report annually on the number and percent of critical incidents for which an investigation was initiated within State-specified timeframes; number and percent of critical incidents that are investigated and for which the State determines the resolution within State-specified timeframes; and number and percent of critical incidents requiring corrective action, as determined by the State, for which the required corrective action has been completed within State-specified timeframes. We intended to use the information generated from the proposed reporting requirements at § 441.311(b)(2)(i) through (iii) to determine if States meet the requirements at § 441.302(a)(6)(ii).[121] Given the risk of harm to beneficiaries when effective incident management systems are not in place, documented instances of abuse and neglect among people receiving HCBS, and identified shortcomings and weaknesses of States' incident management systems discussed earlier, we believed the proposed requirement at § 441.311(b)(2) for States to report annually on critical incidents is in the best interest of and necessary for protecting the health and welfare of individuals receiving section 1915(c) waiver program services. We invited comments on the timeframe for States to report on the critical incidents, whether we should require reporting less frequently (every 2 years), and if an alternate timeframe is recommended, the rationale for the alternate timeframe.

We received public comments on this proposal. The following is a summary of the comments we received and our responses. We also received comments on the minimum performance requirements for critical incident investigations proposed in § 441.302(a)(6), which form the basis of the reporting requirement at § 441.311(b)(2). These comments and our responses are in section II.B.3. of this final rule.

Comment: A few commenters generally supported our proposal at § 441.311(b)(2). One commenter observed that the current lack of standardized incident management systems across all States puts beneficiaries at risk and believed that the critical incident reporting requirements will help to prevent adverse experiences, increase accountability for States, and provide beneficiaries with an avenue of redress when they experience harm.

Response: We thank commenters for their support.

Comment: A few commenters opposed the reporting requirement at § 441.311(b)(2). One commenter

[121] We note that there was a typographical error in the NPRM at 88 FR 27987, incorrectly identifying the proposed reporting requirements at § 441.311(b)(2)(ii) through (iv), rather § 441.311(b)(2)(i) through (iii).

believed that building the necessary IT systems to complete the reporting will impose an extraordinary cost to States and take years to develop, test, and implement. Another commenter expressed concerns that the reporting requirements would necessitate a restructuring of some States' critical incident management, including revising policies, procedures, trainings, and processes.

Response: As discussed in the proposed rule (88 FR 27978), since 2014, States operating section 1915(c) waiver programs have been expected to demonstrate on an ongoing basis that they identify, address, and seek to prevent instances of abuse, neglect, exploitation, and unexplained death, and demonstrate that an incident management system is in place that effectively resolves incidents and prevents further similar incidents to the extent possible. While we acknowledge that some States may have to make some adjustments to their systems, we expect that most will be able to build on existing systems to achieve this reporting. We plan to offer States technical assistance as needed to support questions they may have about adjustments they need to make to existing policies, tracking, and reporting systems. We decline to make any changes in this final rule based on these comments.

Comment: A few commenters requested that we share more details about the reporting template and when the report would need to be submitted. A few commenters expressed the hope that the reporting timing could be aligned with waiver years or other administrative deadlines.

Response: The reporting requirement at § 441.311(b)(2) will be collected as part of the overall data collection activities associated with the reporting requirements in § 441.311. Per § 441.311(f), as finalized herein and discussed in this section II.B.7. of the rule, States must comply with the reporting requirement at § 441.311(b)(2) beginning 3 years from the effective date of this final rule]. Prior to that applicability date, we will be making the reporting template available for public comment through the Paperwork Reduction Act notice and comment process. Specific reporting due dates will be determined through subregulatory guidance.

Comment: One commenter requested clarification on whether the reporting was statewide or could be submitted for each program. The commenter noted that for States operating multiple critical incident systems, or tracking critical incidents at the program level, reporting of data at an aggregate statewide level will not only prove operationally challenging, but it could also limit the ability to identify and address program-specific issues.

Response: States are expected to report aggregated statewide data for this requirement. We believe that a State could track critical incidents by program at the State level and then aggregate this data for the purposes of the reporting requirement at § 441.311(b)(2). We plan to offer technical assistance to States, as needed, that have decentralized critical incident systems to facilitate the aggregated statewide reporting. We also note that States will be able to provide input into the reporting instrument when it is shared for public comment during the Paperwork Reduction Act notice and public comment process.

Comment: One commenter was critical of the proposed reporting metrics at § 441.311(b)(2), believing that the focus of the metrics was too much on timeliness: timely initiation of investigations, timely resolutions, and timely corrective action. The commenter did not believe that there was sufficient focus on the substance of the incidents. A few commenters recommended that we add the following metrics to § 441.311(b)(2): the number of critical incidents in each year, categorized by type of incident and extent of injury or by severity; whether corrective action was needed; whether corrective action was performed; whether any corrective action addressed the needs of current participants or future participants (or both); and whether corrective action adequately addressed participants' needs.

One commenter stated that the information should be reported to the public, although in a format that protects the anonymity of the beneficiary and filer. The commenter also suggested that a separate section of the public report should provide information on substantiated critical incidents by provider, including the service provider's owner and the name under which they are doing business.

Response: We disagree that the metrics in § 441.311(b)(2) focus only on timeliness. Inherent in these metrics is the expectation that States will promptly investigate and resolve critical incidents, which we believe is the essential purpose of the critical incident system. We developed the reporting requirement at § 441.311(b)(2) to strike a balance between collecting enough information to enable Federal oversight of the States' system designed to investigate and resolve critical incidents and imposing as minimal an administrative burden on States and providers as possible. We believe it is important for States to have flexibility in how they design their system to identify, report, triage, investigate, resolve, track, and trend critical incidents as set forth in the proposed requirements at § 441.302(a)(6), which we are finalizing as discussed in section II.B.3. We also believe that requiring a broad, national reporting requirement for States to report critical incident timeliness data will provide a mechanism to assess whether States are complying with their own timeframes for investigating, resolving, and implementing corrective actions, and to ensure States are complying with their own established processes for reviewing and addressing critical incidents.

We did not propose, and are not finalizing, specific requirements for how States must use this data. We will likely include promising practices related to data collection and analysis, including methods of capturing qualitative data from the records, in technical assistance for States to aid in implementation.

We note that the data required in § 441.311(b)(2) is included in the public posting requirement we are finalizing at § 441.313 (discussed in greater detail in II.B.9. of this final rule). We are not requiring that States publicly report specific information about critical incidents, including the names of providers involved in critical incidents. We believe that some public disclosures may not be suitable or appropriate in every instance, and it would be difficult to tailor a meaningful requirement to anticipate all of these circumstances. We are concerned that, for example, in States with smaller HCBS populations, it may be difficult to truly anonymize information about critical incidents. While we agree that, over time, qualitative data about trends in critical incidents could be useful to both States and other interested parties in promoting systemic improvements in their HCBS programs, we defer to States to determine when and how to make this information public, in accordance with applicable laws governing confidentiality of such information, and for what purpose.

Comment: A few commenters supported the proposal that this data should be reported on an annual basis. A few commenters recommended less frequent reporting, such as every two years, to reduce burden.

One commenter, while not necessarily recommending a different reporting frequency, noted that reporting requirements must take into account the unique factors that impact the length of time it could take to complete an

investigation or conduct corrective action. The commenter noted that depending on the nature of the corrective action and when the corrective action process begins in a reporting year, annual reporting may result in misleading data about the number of resolved critical incidents or completed corrective actions.

Response: Given the importance and time-sensitive nature of critical incident investigations, resolutions, and corrective actions, we believe it is necessary to collect this data on an annual basis so we may monitor these systems. We also clarify that the reporting is not intended to track how many critical incidents were investigated, resolved, or resulted in completed corrective actions in a reporting year; the requirement is to report how many critical incidents were investigated, resolved, or resulted in completed corrective actions within State-specified timeframes during the reporting period. Thus, even if the reporting period falls in the middle of a critical incident resolution or corrective action, these incidents would not be reported as ''non-compliant'' if they were still within the State-specified timeframes for completion.

After consideration of these comments, we are finalizing the introductory text at § 441.311(b)(2), with a technical modification for clarity that the State must report to CMS annually in the form and manner, and at a time, specified by CMS, rather than according to the format and specifications provided by CMS. We are also simplifying the title and moving the reference to § 441.302(a)(6)(i)(A) from the title of § 441.311(b)(2) to the introductory text. As finalized, the introductory text at § 441.311(b)(2) will specify that the State must report to CMS annually on the following information regarding critical incidents as defined in § 441.302(a)(6)(i)(A), in the form and manner, and at a time, specified by CMS. We are finalizing § 441.311(b)(2)(i) through (iii) as proposed.

(3) Person-Centered Planning (§ 441.311(b)(3))

Under the authority of section 1902(a)(6) of the Act, we proposed at § 441.311(b)(3) to require that States report annually to demonstrate that they meet the requirements at § 441.301(c)(3)(ii). Specifically, at § 441.311(b)(3)(i), we proposed to require that States report on the percent of beneficiaries continuously enrolled for at least 365 days for whom a reassessment of functional need was completed within the past 12 months. At § 441.311(b)(3)(ii), we proposed to require that States report on the percent of beneficiaries continuously enrolled for at least 365 days who had a service plan updated as a result of a reassessment of functional need within the past 12 months. These proposed requirements were based on feedback obtained during various interested parties' engagement activities conducted with States and other interested parties over the past several years about the reporting discussed in the 2014 guidance. As discussed in section II.B.7. of the preamble for the proposed rule, this feedback indicated that we should strengthen person-centered planning reporting requirements and eliminate annual performance measure reporting requirements that provide limited useful data for assessing State compliance with statutory and regulatory requirements. These proposed requirements were also based on feedback received through the RFI [122] discussed earlier about the need to standardize reporting and set minimum standards for HCBS.

As discussed in section II.B.1. of the preamble for the proposed rule, we proposed a revision to the regulatory text so that it is clear that changes to the person-centered service plan are not required if the re-assessment does not indicate a need for changes. As such, for the purpose of the reporting requirement at § 441.311(b)(3)(ii), beneficiaries would be considered to have had a person-centered service plan updated as a result of the re-assessment if it is documented that the required re-assessment did not indicate a need for changes.

For both of the metrics at § 441.301(c)(3)(ii), we proposed to allow States to report a statistically valid random sample of beneficiaries, rather than for all individuals continuously enrolled in the waiver program for at least 365 days.

We invited comments on whether there are other specific compliance metrics related to person-centered planning that we should require States to report, either in place of or in addition to the metrics we proposed. We also invited comments on the timeframe for States to report on person-centered planning, whether we should require reporting less frequently (every 2 years), and if an alternate timeframe is recommended, the rationale for the alternate timeframe.

We received public comments on this proposal. The following is a summary of the comments we received and our responses. We also received comments on the person-centered service plans minimum performance requirements proposed in § 441.301(c)(3)(ii), which form the basis of the reporting requirement at § 441.311(b)(3). These comments and our responses are in section II.B.1. of this final rule.

Comment: A few commenters expressed support for the requirement that States report annually on the specified performance metrics for person-centered planning. Commenters echoed sentiments that are reflected in section II.B.1. of this final rule, that many States are already regularly performing the assessment and reassessment activities in compliance with the minimum performance standards being finalized in § 441.301(c)(3)(ii) and, thus, reporting on these activities is reasonable.

We did not receive feedback in response to our request for comment on additional or alternative metrics that should be included in the reporting requirement at § 441.311(b)(3).

Response: We thank commenters for their support. We note that the metrics in § 441.311(b)(3) are based on the minimum performance requirements being finalized at § 441.301(c)(3)(ii); comments on these minimum performance standards are discussed in section II.B.1. of this final rule.

Comment: A few commenters expressed reservations about the proposal to allow States to report data on a statistically valid sample of beneficiaries, suggesting instead that we require complete reporting on all relevant beneficiary data.

Response: We intended that the proposed requirement allow States to report data and information for the person-centered service planning reporting metrics at § 441.311(b)(3) using a statistically valid random sampling of beneficiaries would reduce State burden, while still providing valuable data for strengthening States' person-centered service planning processes. We will consider expanding the reporting to capture the full population of beneficiaries receiving HCBS in future rulemaking if it is determined that such an approach gives a more complete picture of person-centered service planning. We note that States may choose to report on the total population for this measure as opposed to a sample, for instance, if doing so better aligns with their data collection process or needs.

We note that, as proposed, we stated in § 441.311(b)(3)(i) and (ii) that the State may report these metrics for a statistically valid random sample of

[122] CMS Request for Information: Access to Coverage and Care in Medicaid & CHIP. February 2022. For a full list of question from the RFI, see *https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-questions.pdf.*

beneficiaries. We are finalizing the requirements at § 441.311(b)(3)(i) and (ii) with a technical modification to specify that the State may report this metric **using statistically valid random sampling** of beneficiaries. (Revised language identified in bold.) We make this technical correction to better align the language with standard terminology for the sampling methodology we intended in these requirements.

Comment: One commenter specifically noted that the frequency of annual reporting was feasible. One commenter noted that while the reporting frequency is reasonable, it is important to align with other reporting requirements already placed on States and managed care plans to minimize State and managed care plan reporting burdens.

A few commenters requested clarification on when the report required in § 441.311(b)(3) would be due to CMS and whether we would provide a template for the reporting. One commenter requested clarification on how this aggregated data should be reported, noting that current mechanisms for reporting similar data are waiver specific.

Response: We will be releasing subregulatory guidance, including technical specifications for the new reporting requirements in this final rule, and making the required reporting templates available for public comment through the Paperwork Reduction Act notice and comment process. Per § 441.311(f) below, States must comply with the reporting requirement for § 441.311(b)(3) beginning 3 years from the effective date of this final rule]. Specific reporting due dates will be determined through subregulatory guidance; we will work with States to align these due dates with other obligations to minimize administrative burden to the greatest extent possible.

After consideration of the public comments received, we are finalizing the reporting requirement at § 441.311(b)(3)(i) and (ii), with the technical modification noted above to specify that the State may report this metric using statistically valid random sampling of beneficiaries. We are also finalizing a technical correction to the regulation text at § 441.311(b)(3). In the proposed rule (88 FR 27988), we indicated that we were proposing at § 441.311(b)(3) to require that States report annually to demonstrate that they meet the requirements at § 441.301(c)(3)(ii). In the publication of the proposed rule, this language was omitted from the regulatory text in error. We are finalizing § 441.311(b)(3) with technical modifications to specify that, to demonstrate that the State meets the requirements at § 441.301(c)(3)(ii) regarding person-centered planning (as described in § 441.301(c)(1) through (3)), the State must report to CMS annually. We are also making a technical modification to indicate that the reporting must be in the form and manner, and at a time, specified by CMS. We believe, based on the language included in the proposed rule (88 FR 27988) and the comments received, that commenters understood the intent of this regulation even with language omitted.

(4) Type, Amount, and Cost of Services (§ 441.311(b)(4))

As discussed previously in section II.B.4. of this preamble, we proposed to amend § 441.302(h) to avoid duplicative or conflicting reporting requirements with the new Reporting Requirements section at proposed § 441.311. In particular, at § 441.302(h), we proposed to remove paragraphs (1) and (2). At § 441.311(b)(4), we proposed to add the language previously at § 441.302(h)(1). In doing so, we proposed to retain the current requirement that States report on the type, amount, and cost of services and to include the reporting requirement in the new consolidated reporting section at § 441.311.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: One commenter supported this proposal.

Response: We thank the commenter for their support.

Comment: One commenter requested clarification on whether the reporting requirement at § 441.311(b)(4) will apply to managed care plans.

Response: The requirement at § 441.311(b)(4) replicates the current requirement at § 441.302(h), which applies to section 1915(c) programs, regardless of whether they are part of a FFS or managed care delivery system.

As stated in the proposed rule (88 FR 27988), it was our intent to consolidate the current reporting requirement at § 441.302(h)(1) with the new requirements being finalized at § 441.311. We note that as this requirement was presented in the proposed rule, we inadvertently struck part of the language from § 441.302(h) that we intended to retain in § 441.311(b)(4) that clarified the reporting frequency (annually) and the object (the 1915(c) waiver's impact on the State plan) of the requirement currently at § 441.302(h)(1). We are concerned that without this omitted language, § 441.311(b)(4) does not include information needed to implement this requirement. We believe that, as we expressed our intent in the proposed rule (88 FR 27988) to retain the reporting requirement at § 441.302(h)(1), readers would have understood that we intended to preserve the essential elements of the reporting.

To ensure that this requirement can be implemented as intended, we are finalizing § 441.311(b)(4) with language from § 441.302(h) to specify that, **annually,** the **State will provide CMS with information on the waiver's impact on** the type, amount, and cost of services provided under the State plan. (Restored language is noted in bold.)

We also specify here that, as the requirement at § 441.302(h) specifies certain reporting for programs authorized under section 1915(c), this new requirement at § 441.311(b)(4) will similarly apply only to section 1915(c) waiver programs. We discuss the impact of this clarification on references to section 1915(j), (k), and (i) services (at §§ 441.474(c), 441.580(i), and 441.745(a)(1)(vii)) later in this section.

After consideration of the comments received, and in light of the clarification outlined above, we are finalizing the provision at § 441.311(b)(4) to specify that annually, the State will provide CMS with information on the waiver's impact on the type, amount, and cost of services provided under the State plan. Further, we are finalizing § 441.311(b)(4) with a technical modification to specify that the information is to be reported in the form and manner, and at a time, specified by CMS.

b. Reporting on the Home and Community-Based Services (HCBS) Quality Measure Set (§ 441.311(c))

At § 441.311(c), relying on our authority under section 1902(a)(6) of the Act, we proposed to require that States report every other year on the HCBS Quality Measure Set, which is described later in section II.B.8. of the preamble. Specifically, we proposed, at § 441.311(c)(1)(i), to require that States report every other year, according to the format and schedule prescribed by the Secretary through the process for developing and updating the HCBS Quality Measure Set described in section II.B.8. of the final rule, on measures identified in the HCBS Quality Measure Set as mandatory measures for States to report or are identified as measures for which the Secretary will report on behalf of States, and, at § 441.311(c)(1)(ii), to allow States to report on measures in the HCBS Quality Measure Set that are not

identified as mandatory, as described later in this section of the rule.

We proposed every other year for State reporting in recognition of the fact that the current, voluntary HCBS Quality Measure Set is heavily comprised of survey-based measures, which are more burdensome, including for beneficiaries who would be the respondents for the surveys, and costlier to implement than other types of quality measures. Further, we believed that requiring reporting every other year, rather than annually, would better allow States to use the data that they report for quality improvement purposes, as it would provide States with sufficient time to implement interventions that would result in meaningful improvement in performance scores from one reporting period to another. We also proposed this frequency in recognition of the overall burden of the proposed requirement.

Because the delivery of high quality services is in the best interest of Medicaid beneficiaries, we proposed at § 441.311(c)(1)(iii), under our authority at section 1902(a)(19) of the Act, to require States to establish performance targets, subject to our review and approval, for each of the measures in the HCBS Quality Measure Set that are identified as mandatory for States to report or are identified as measures for which we will report on behalf of States, as well as to describe the quality improvement strategies that they will pursue to achieve the performance targets for those measures.[123]

At § 441.311(c)(1)(iv), we proposed to allow States to establish State performance targets for other measures in the HCBS Quality Measure Set that are not identified as mandatory for States to report or as measures for which the Secretary will report on behalf of States as well as to describe the quality improvement strategies that they will pursue to achieve the performance targets for those targets.

At § 441.311(c)(2), we proposed to report on behalf of the States, on a subset of measures in the HCBS Quality Measure Set that are identified as measures for which we will report on behalf of States. Further, at § 441.311(c)(3), we proposed to allow, but not require, States to report on measures that are not yet required but will be, and on populations for whom reporting is not yet required but will be phased-in in the future.

We solicited comments on whether there should be a threshold of compliance that would exempt the State from developing improvement strategies, and if so, what that threshold should be. We also invited comments on whether the timeframe for States to report on the measures in HCBS Quality Measure Set is sufficient, whether we should require reporting more frequently (every year) or less frequently (every 3 years), and, if an alternate timeframe is recommended, the rationale for that alternate timeframe. We welcomed comments on any additional changes we should consider in this section.

We received public comments on this proposal. The following is a summary of the comments we received and our responses. We also received comments on the HCBS Quality Measure Set requirements proposed at § 441.312. These comments and our responses are in section II.B.8. of this final rule.

Comment: Regarding whether there should be a threshold of compliance that would exempt the State from developing improvement strategies, one commenter recommended exemptions for States to develop improvement strategies if they are performing within the top 5th to 10th percentile of performance targets for the quality measures in the HCBS Quality Measure Set, to alleviate administrative burden. Another commenter discouraged CMS from permitting a compliance threshold exemption for States from developing improvement strategies, emphasizing that all States should be held accountable for providing high-quality care and services to beneficiaries receiving HCBS regardless of performance.

Response: We continue to believe that, for each of the measures in the HCBS Quality Measure Set that are identified as mandatory for States to report, or are identified as measures for which we will report on behalf of States, States should establish and describe the quality improvement strategies to achieve the performance targets for those measures.[124] We reiterate our belief that the HCBS Quality Measure Set will promote more common and consistent use within and across States of nationally standardized quality measures in HCBS programs, and will allow CMS and States to have comparative quality data on HCBS programs. As such, exempting States from developing improvement strategies for quality measures in the HCBS Quality Measure Set does not align with this intent.

Comment: Several commenters recommended either faster or slower implementation for reporting of the measures in the HCBS Quality Measure Set. A few commenters recommended we change the timeframe requirement for States to report on the quality measures in the HCBS Quality Measure Set to every year. In this same vein, one commenter suggested we align the reporting timelines required for reporting measures in the HCBS Quality Measure Set to other Medicaid, CHIP, Medicare, and Marketplace measure sets, expressing that reporting biennially (every other year) could lock in data lags that could hinder State progress in improving HCBS for beneficiaries. A few commenters recommended alternatives to the HCBS Quality Measure Set biennial reporting time frame. These alternatives included the following: initiating reporting based on State choice; reporting on odd- or even-numbered years; and beginning State reporting upon renewal of their section 1915(c) waiver or based on the State reporting years for their waiver program.

A few commenters expressed concern that the timeframe for reporting measures in the HCBS Quality Measure Set should be longer than every other year, emphasizing the significant amount of systems work, contracting, and survey data needed to capture the necessary data and implement reporting on HCBS measures. Commenters recommended we consider that the implementation of the HCBS Quality Measure Set reporting requirements as proposed at § 441.311(c)(1)(iii) could require State statutory and regulatory amendments, lead time for securing additional technology resources, and operational and workflow changes. Commenters requested CMS consider alternative dates for States beginning reporting on the measures in the HCBS Quality Measure Set, ranging from an additional 3 to 5 years to address these concerns.

Response: We continue to believe that a biennial timeframe requirement for States to report on the measures in HCBS Quality Measure Set is an appropriate frequency that ensures accountability without being overly burdensome and are finalizing the frequency of reporting as proposed. We determined that a shorter annual reporting timeframe would not likely be operationally feasible because of the potential systems and contracting changes (to existing contracts or the establishment of new contracts) that States may be required to make. For

[123] We note that compliance with CMS regulations and reporting requirements does not imply that a State has complied with the integration mandate of Title II of the ADA, as interpreted by the Supreme Court in the Olmstead Decision.

[124] We note that compliance with CMS regulations and reporting requirements does not imply that a State has complied with the integration mandate of Title II of the ADA, as interpreted by the Supreme Court in the Olmstead Decision.

example, additional reporting requirements may need to be added to State contracts, changes may be needed to data sharing agreements with managed care plans, and modifications of databases or systems might be required to record new variables.

However, to provide States sufficient time to comply with the requirements finalized at § 441.311(c), we are finalizing at § 441.311(f)(2) an applicability date beginning 4 years, rather than 3 years, from the effective date of this final rule for the HCBS Quality Measure Set reporting at § 441.311(c). Our primary purpose in extending the effective date is to ensure States have sufficient time for interested parties to provide input into the measures, as required by § 441.312(g), which we are finalizing in section II.B.8. of this rule.

In general, we anticipate that States will not need more than 4 years after the effective date of the final rule, to implement systems and contracting changes, or acquire any additional support needed to report on the quality measures in the HCBS Quality Measure Set.

We plan to work collaboratively with States to provide the technical assistance and reporting guidance through the Paperwork Reduction Act process necessary to support reporting.

Comment: A few commenters requested confirmation of whether States with section 1115 demonstrations are expected to comply with the HCBS Quality Measures Set requirements in this final rule.

Response: Yes, consistent with the applicability of other HCBS regulatory requirements to such demonstration projects, the reporting requirements for section 1915(c) waiver programs and section 1915(i), (j), and (k) State plan services included in this rule, including the requirements at § 441.311 (and the related quality measure requirements at § 441.312), would apply to such services included in approved section 1115 demonstration projects, unless we explicitly waive or exclude one or more of the requirements as part of the approval of the demonstration project.

Comment: A couple of commenters recommended that we offer States financial assistance to develop and deploy the ability to report the quality measures in the HCBS Quality Measure Set.

Response: We note that Medicaid Federal matching funds are available for State expenditures on the design, development, and installation (including of enhancements), and for operation, of mechanized claims processing and information retrieval systems. We also note that under section 1903(a)(7) of the Act, Federal matching funds are available for administrative activities necessary for the proper and efficient administration of the Medicaid State plan. This may include developing and deploying the ability to report the quality measures in the HCBS Quality Measure Set.

Comment: A few commenters expressed that instructions related to the reporting requirements for the quality measures in the HCBS Quality Measures Set, and how they are related to the section 1915(c) waiver reporting requirements, would be helpful for implementing the reporting of the measure set.

Response: We thank commenters for the feedback. We plan to work collaboratively with States to provide the technical assistance and reporting guidance through the Paperwork Reduction Act process necessary to support reporting and help facilitate compliance with this requirement.

After consideration of public comments received, we are finalizing the HCBS Quality Measure Set reporting requirements at § 441.311(c) with modifications. At § 441.311(f)(2), we are finalizing that States must comply with the reporting requirements at § 441.311(c) beginning 4 years, rather than 3 years, from the effective date of this final rule for the HCBS Quality Measure Set. Our primary purpose in extending the applicability date is to ensure States have sufficient time for interested parties to provide input into the measures, as required by § 441.312(g), which we are finalizing in section II.B.8. of this rule.

c. Access Reporting (§ 441.311(d))

As noted earlier in section II.B.6. of this preamble, feedback obtained during various public engagement activities conducted with States and other interested parties over the past several years about reporting requirements for HCBS, as well as feedback received through the RFI [125] discussed earlier, indicated that there is a need to improve public transparency and processes related to States' HCBS waiting lists and for standardized reporting on HCBS access, including timeliness of HCBS and the comparability to services received to eligibility for services. At § 441.311(d) we proposed that the State must report to CMS annually on the following, according to the format and specifications provided by CMS. We are finalizing in this rule § 441.311(d) with a technical modification for clarity that requires that the State must report to CMS annually on the following, **in the form and manner, and at a time,** specified by CMS. (New language identified in bold.)

(i) Waiver Waiting Lists (§ 441.311(d)(1)(i))

At § 441.311(d)(1)(i), relying on our authority under section 1902(a)(6) of the Act, we proposed to require that States provide a description annually, according to the format and specifications provided by CMS, on how they maintain the list of individuals who are waiting to enroll in a section 1915(c) waiver program, if they have a limit on the size of the waiver program and maintain a list of individuals who are waiting to enroll in the waiver program, as described in § 441.303(f)(6). We further proposed to require that this description must include, but be not limited to, information on whether the State screens individuals on the waiting list for eligibility for the waiver program, whether the State periodically re-screens individuals on the waiver list for eligibility, and the frequency of re-screening if applicable. We also proposed to require States to report, at § 441.311(d)(1)(ii), the number of people on the waiting list, if applicable, and, at § 441.311(d)(1)(iii), the average amount of time that individuals newly enrolled in the waiver program in the past 12 months were on the waiting list, if applicable. We invited comments on whether there are other specific metrics or reporting requirements related to waiting lists that we should require States to report, either in place of or in addition to the requirements we proposed. We also invited comments on the timeframe for States to report on their waiting lists, whether we should require reporting less frequently (every 2 or 3 years), and if an alternate timeframe was recommended, the rationale for that alternate timeframe.

We received public comments on this proposal. The following is a summary of the comments we received and our responses. We also received comments on the related requirement at § 441.303(f). Those comments are addressed in section II.B.6. of this rule.

Comment: Many commenters supported the proposal at § 441.311(d)(1) to require States to report on waiting lists, including whether the State screens individuals on the list for eligibility, frequency of re-screening, number of individuals waiting to enroll, and average amount of time newly enrolled individuals were on the waiting list. Commenters

[125] CMS Request for Information: Access to Coverage and Care in Medicaid & CHIP. February 2022. For a full list of question from the RFI, see *https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-questions.pdf.*

believed that this reporting would promote consistency, transparency, oversight, and accountability of waiting list practices and help States identify unmet needs among their Medicaid beneficiaries. Commenters noted that this additional information will better allow interested parties to advocate for policy changes to address underlying causes of waiting lists and expand HCBS programs; one commenter described this requirement as a good ''first step'' to understanding access issues for HCBS waivers.

A few commenters stated this requirement, with its potential to support policies that reduce waiting lists, would help beneficiaries avoid having to turn to institutional care for their LTSS needs. Commenters also noted transparent, understandable data about waiting lists may help individuals and families to make more informed decisions about accessing coverage as they plan for their future.

A few commenters noted that nationally comparable data and information-sharing among States will encourage standardization of waiting list processes and help States identify best practices for reducing waiting lists. Commenters noted that inconsistencies in the way States report data about their waiting lists and the current lack of standardized reporting requirements makes it difficult to form a clear picture of how many people are waiting to receive services, as well as how many of these individuals on the waiting list are actually eligible for services. One commenter suggested that making the waiting list public may lead to needed administrative updates to waiting lists, such as removing duplicate applications or applications from beneficiaries who have moved out of State or passed away.

Response: We agree that this critical data is not currently available in a way that allows for monitoring or comparison on a national level. We believe that this reporting requirement is an important first step in making data publicly available that can be used to identify unmet needs among Medicaid beneficiaries, support policymaking, and improve administrative efficiency.

Comment: A few commenters expressed opposition to, or concerns about, the waiting list reporting requirement at § 441.311(d)(1). A few commenters expressed concerns that the reporting requirement did not align with current State waiting list practices and would require significant change in data collection and IT systems. One commenter was concerned that due to differences in States' HCBS programs, infrastructure, and waiting list practices, attempting to collect and compare data on a national level could be misleading. A few commenters requested clarification on how CMS would use this data to drive meaningful policy changes and improvement in HCBS access. A few commenters stated that the proposed requirements would not address the underlying causes of waiting lists, which they attributed to limited funding for HCBS waiver slots, low Medicaid reimbursement rates, delays or barriers within States' Medicaid eligibility determination processes, or shortages of HCBS direct care workers. A few commenters, while not necessarily opposing the requirement at § 441.311(d)(1), suggested that we focus on gathering information about why States have caps on the number of beneficiaries who may be served by HCBS waivers and why States have waiting lists when they have not met their waiver caps.

One commenter raised a concern that the reporting requirement would cause States to redirect or prioritize resources for waivers with waiting lists at the expense of waivers that currently do not have waiting lists.

Response: We are not currently collecting States' data on their waiting lists and understand that States may have to update data collection systems to comply with this new requirement. We proposed the reporting requirement at § 441.311(d) to strike a balance between collecting enough information to enable Federal oversight of States' waiting list practices and imposing as minimal an administrative burden on States and providers as possible. We plan to offer States technical assistance as needed to help align their current data collection practices with what will be needed to comply with this reporting requirement. The reporting requirement at § 441.311(d)(1) is a first step in what will be an evolving process to promote transparency, oversight, and data-driven improvements in States' waiting list practices. We acknowledge that differences in States' HCBS programs may initially make comparing States' data challenging, but we believe that collecting this data will help highlight such differences and draw connections between different States' policies and the impact on their beneficiaries' access to HCBS. As noted by other commenters, States may be able to use this data to learn from the experiences of other States.

We acknowledge that there are many underlying causes for States to have long waiting lists, but we believe that the first step toward addressing these challenges, where possible, is to quantify the scope of these waiting lists through data collection. This data will not only help identify situations in which a State appears to be maintaining a waiting list when not all of the waiver's slots are taken but can also facilitate conversations with States about reasons for limitations on waiver enrollment.

We clarify that the purpose of this requirement is to document unmet needs for individuals who are seeking enrollment in HCBS waivers and to identify resources or practices that could be used to improve waiting list processes. As such, our goal is not to require that States shift needed resources away from other areas of their Medicaid programs.

Comment: One commenter requested that we provide reporting tools to help States track the required data. One commenter requested that the data needed for this reporting requirement be derived from the State's own eligibility and service authorization processes, not from providers and beneficiaries, particularly for self-directed services.

Response: We plan to release subregulatory guidance and other tools to assist States with implementation of this reporting requirement. We will also be making the reporting template available for public comment through the Paperwork Reduction Act notice and comment process.

While States have flexibility as to how they will gather the data needed to complete this reporting, we encourage States to find ways to rely on administrative data rather than gathering data directly from beneficiaries to meet the reporting requirements.

Comment: A few commenters requested that the information about waiting lists be made available to the public in a consumer-friendly and accessible format in order to facilitate program accountability and potentially improve beneficiary understanding of waiting list information. One commenter suggested that publishing data about the waiting list may help publicize the need for more direct care workers.

Response: As discussed in more detail later in section II.B.9 of this rule, we are finalizing a requirement at § 441.313(a) to require States to operate a website that meets the availability and accessibility requirements at § 435.905(b) of this chapter and that provides the results of the reporting requirements at § 441.311 (including this access reporting requirement at § 441.311(d), as well as the incident management, critical incident, person-centered planning, and service provision compliance data; data on the HCBS Quality Measure Set; and

payment adequacy data, discussed in this section) and the reporting requirements at § 441.302(k)(6). Please refer to the discussion of the website posting requirements in section II.B.9. of this rule.

Comment: One commenter suggested that we consider offering incentives for States to reduce or end waiting lists through a higher FMAP rate for a limited time period. One commenter requested that States be given a grace period and allowed to update their section 1915(c) waivers prior to any punitive action.

Response: We note that the requirement at § 441.311(d)(1) is a reporting requirement intended to encourage transparency and does not include any specific performance measures with which States must comply. To the extent that States are in compliance with existing requirements for section 1915(c) waiver programs, it is also not intended to require that States make changes to their waiver programs or processes. We intend to use our standard enforcement discretion to require State compliance with the reporting requirement, which (as discussed under § 441.311(f) below) will go into effect three years after the effective date of this final rule. In addition, we note that CMS does not have authority to provide States with a higher FMAP rate for any expenditures than has been authorized by statute.

Comment: A number of commenters noted that waiting list terminology, definitions, and processes vary widely among States and even among individual State programs. Commenters observed that some States operate what they refer to as interest lists, preauthorization lists, or similarly named lists, rather than waiting lists. In some cases, individuals can sign up to express interest in a waiver program but may not have yet been assessed for eligibility at the time they joined the interest list. Commenters questioned whether these individuals would be considered ''waiting to enroll'' as described in the proposed rule, as they are waiting to be determined eligible to enroll. Commenters requested clarification as to what data would be collected from States that maintain interest lists or similarly named lists of individuals who have not yet been determined to be eligible for the waiver.

A few commenters expressed concerns that if interest lists are not included in this requirement, States may be encouraged to stop maintaining waiting lists. One commenter noted that if the requirement does apply to interest lists, States that use an interest list approach would have to make significant changes to their processes to meet the waiting list reporting requirement. One commenter observed that in their State, the State maintains a single waiting list for all waivers, which could complicate reporting.

Several commenters requested that we create a definition of a waiting list. One commenter supported what they believed to be our proposed standardized definition of a waiting list (but did not specify what they thought that definition to be). A few commenters requested that we require States to have waiting lists for their waiver programs and that States screen individuals for eligibility prior to placing the individuals on the waiting list.

Response: We intended for the reporting requirement to apply to all States that maintain a list of individuals interested in enrolling in a section 1915(c) waiver program, whether or not the individual has been assessed for eligibility. As we stated in the proposed rule (88 FR 27986), many States maintain waiting lists of individuals interested in receiving waiver services once a spot becomes available. While some States require individuals to first be determined eligible for waiver services to join the waiting list, other States permit individuals to join a waiting list after an expression of interest in receiving waiver services.

We note that the requirement at § 441.311(d)(1) requires States to submit a description of their waiting list that includes information on whether the State screens individuals on the waiting list for eligibility for the waiver program, whether the State periodically re-screens individuals on the waiver list for eligibility, and the frequency of re-screening if applicable. This requirement indicates that § 441.311(d)(1) applies to States even if they do not screen the individuals on their list for eligibility. We believe that for the purposes of this requirement individuals who are waiting to be screened for eligibility for the waiver are considered ''waiting to enroll.''

We believe that States that maintain an interest list (or a similarly named list of individuals who have expressed interest in the waiver and are waiting to be assessed for eligibility) can report the same information required in § 441.311(d)(1) as States that maintain lists of individuals who have been screened for eligibility. We expect, for instance, that States typically would have information about the number of individuals who are on an interest list and how long those individuals have been on those lists. If a State maintains two separate lists for a waiver—a list of individuals who have been screened for eligibility for the waiver and a list of individuals who have expressed interest in enrolling in the waiver but have not yet been screened—the State should report on both to meet the reporting requirements at § 441.311(d)(1).

As we did not propose a formal definition of waiting list, nor a requirement for States to maintain a waiting list of individuals who have been screened for eligibility, we will not add these components to the finalized § 441.311(d). States retain flexibility in determining whether or not to maintain a list of individuals who are interested in enrolling in the waiver (whether or not the individual has been screened for eligibility). We will take commenters' recommendations into consideration for future policymaking if, after monitoring reporting generated by § 441.311(d), we identify the need for further standardization of these processes.

Comment: We received responses to our comment solicitation on additional metrics that could be collected regarding the waiting list. One commenter recommended that we not add more metrics to § 441.311(d)(1). Several commenters did suggest additional metrics. Many of these commenters believed that more detailed data would allow for a better assessment of overall unmet needs and disparities within the waiting lists. Additional metrics suggested by commenters included:

- Disaggregated data about beneficiaries, by demographic categories, including race, ethnicity, Tribal status, language status, sex or gender identification, sexual orientation, age, and geographic location;
- Disaggregated data on beneficiaries' dual eligible status, disability, diagnosis, functional status, level of care, and risk of institutionalization;
- Whether States maintain separate waiting lists or registries for beneficiaries who are eligible for HCBS but have been determined by the State to not have a need prioritized by the State for enrollment in the waiver;
- The criteria used to determine beneficiaries' placement and movement within a waiting list;
- How much time individuals spend waiting for an eligibility assessment and how much time elapses between an assessment and service authorization;
- The number of eligibility screens performed on each beneficiary on the waiting list in the past year, and why a rescreen was performed;
- The number of beneficiaries removed from the waiting list due to death, admission to an institutional

setting, or having been rescreened and deemed ineligible;

- The number of beneficiaries on the waiting list who are receiving care through another State Medicaid program, reasons why beneficiaries prefer to remain on the waiting list rather than enroll in other services, and what beneficiary needs remain unmet by other Medicaid programs while a beneficiary is on a waiting list; and
- Whether a participant who has been approved for HCBS waiver services is able to find a provider, how long it took for them to find that provider, and what services they wanted, but could not access because no provider was available.

Response: We thank commenters for their feedback. We will take these recommendations under consideration for future policymaking, but at this time decline to make modifications to the requirements based on these comments.

We believe it is important to strike a balance between collecting enough information to promote transparency around waiting lists and imposing as minimal an administrative burden on States and providers as possible. We also believe that information on whether States screen individuals on their waiting lists, the number of beneficiaries on the waiting list, and the average amount of time beneficiaries enrolled in HCBS waivers spent on the waiting list provides important preliminary data on the States' waiting list practices. As we gather and review this data, we will consider what additional information may be needed to further improve our oversight of HCBS programs and improve beneficiaries' access to services.

However, we agree that some of the granular data elements suggested by commenters could provide States with valuable insight into their own programs and beneficiary needs. We encourage States to consider what information they have the capacity to collect and would find useful for developing local policies to support beneficiaries' access to section 1915(c) HCBS waiver programs in their State.

Comment: One commenter recommended requiring that States report duplicated and unduplicated counts of individuals across waiver program waiting lists.

Response: We have not identified a compelling reason to require that States report unduplicated counts of beneficiaries for all waiver programs. We clarify that the reporting required for § 441.331(d)(1) is for each waiting list; if an individual is on multiple waiting lists, we believe that person should be counted among individuals on each of those waiting lists.

Comment: A few commenters recommended additional metrics that fall outside the scope of reporting on waiting list practices or waiver enrollment, including:

- Whether individuals on waiting lists are also being screened for eligibility for other programs that they may be able to benefit from (for example, Supplemental Nutrition Assistance Program);
- How long it takes a State to approve enrollment in any program that provides Medicaid LTSS, from the date that it receives an application until the date of the approval letter; and
- Additional measures to assess the needs of populations that face barriers to navigating the HCBS programs, applying, and getting on a waiting list.

Response: While these metrics lie outside the scope of the proposed reporting requirements, we will add these to other comments regarding broader HCBS access and equity issues that we will consider for future policymaking.

Comment: A few commenters suggested that we collect data on reasons for long waiting times, such as challenges with workforce availability or provider capacity. Some commenters, particularly those representing States or providers, were concerned that without this information, States and providers would be held responsible for long waiting lists or long waiting times for services that are due to reasons beyond States' or providers' control. One commenter recommended adding a requirement that States describe any conditions, such as State funding priorities, that serve to limit access to the HCBS described in the waiver application. A few commenters recommended adding a requirement to the interested parties' advisory group being finalized at § 447.203 that would require States, through their interested parties' advisory groups, to examine reasons for gaps in services that are revealed by the reporting on waiting lists.

Response: We do not believe it would be feasible at this stage to standardize the collection of qualitative data regarding the causes of waiting lists; this data would also be difficult to validate. As noted in prior responses, the purpose of the requirement at § 441.311(d)(1) is to encourage transparency; the requirement does not include any specific performance measures with which States or providers must comply. We believe that collecting the number of individuals on the waiting list and the length of time individuals spend on waiting list will present quantifiable and comparable baseline data that can facilitate more nuanced conversations with States about potential unmet beneficiary needs and the underlying causes of these unmet needs.

We note that, regarding the interested parties' advisory group being finalized at § 447.203, the requirements at § 447.203 already include an expectation that access reporting that is required by 441.311(d) would be appropriate data for the Interested Parties Advisory Group (IPAG) to consider when making recommendations regarding the sufficiency of rates. We decline to add a specific requirement as suggested by the commenter, as we wish to allow both States and the IPAGs some discretion in determining their approach to examining the impact on payments rates in their State.

Comment: A few commenters supported annual reporting for § 441.311(d)(1). One commenter observed that one of their State agencies had already identified annual reporting on the waiting list as a best practice and was publishing an annual report. One commenter recommended quarterly reporting to encourage States to take more aggressive steps to reduce the size of their waiting lists. A few commenters believed that biennial (every other year) reporting would reduce burden on States and better account for fluctuations in waiting list size that are beyond the State Medicaid agency's control.

One commenter highlighted that waiting list volumes may vary at certain times of year or from year to year, depending on how States structure the release of new waiver slots and the timing of the State legislative sessions where new funding for waiver slots may be approved. The commenter stated that it is important to take these factors into account when considering reporting frequency and when evaluating reported data from year to year.

Response: We are finalizing the annual reporting frequency as proposed at § 441.311(d)(1). We continue to believe that annual reporting on waiting lists strikes the right balance between collecting current data on waiting lists and minimizing burden on States to the greatest extent possible. We believe reporting more frequently than annually may represent an undue burden on States, although States are encouraged to share information with interested parties within their State on a more frequent basis if they are able to do so. We are concerned that if we extend the reporting to a biennial frequency, the information will become outdated prior

to the next public report. We also note that States will likely have to develop or maintain the same data tracking systems regardless of whether the reporting itself is done annually or biennially; we believe the potential reduction in administrative burden by biennial reporting is outweighed by the need for more timely information on waiting lists.

Comment: One commenter requested clarification that the reporting requirement at § 441.311(d)(1) is limited to the section 1915(c) authority and to the section 1915(j) authority, where it is used as the State's authority for self-direction in a section 1915(c) waiver. This commenter recommended limiting this requirement to these authorities.

Response: We agree that, because section 1915(i) and section 1915(k) State plan services cannot have capped enrollment, the reporting requirements at § 441.311(d)(1) would not apply to these authorities. We also agree that the reporting requirements at § 441.311(d)(1) would also apply to section 1915(j) authority only where section 1915(j) is used as the State's authority for self-direction in a section 1915(c) waiver. We note that the reporting requirements at § 441.311(d)(1) would apply to section 1115(a) demonstration projects that include HCBS if the State caps enrollment for the HCBS under the section 1115(a) demonstration project. As discussed later in this section, section II.B.7. of this final rule, we are finalizing the application of the reporting requirements at § 441.311 to section 1915(j), (k), and (i) authorities with modifications to specify that States must only comply with the reporting requirements applicable to the services under these authorities.

After consideration of the commenters received, we are finalizing § 441.311(d)(1) as proposed.

(ii) Reporting on Wait Times for Services and Authorized Service Hours Provided (§ 441.311(d)(2))

At § 441.311(d)(2)(i), based on our authority under section 1902(a)(6) of the Act, we proposed to require States report annually on the average amount of time from when homemaker services, home health aide services, or personal care services, as listed in § 440.180(b)(2) through (4), are initially approved to when services began, for individuals newly approved to begin receiving services within the past 12 months. We proposed to focus on these specific services for this reporting requirement because of feedback from States, consumer advocates, managed care plans, providers, and other HCBS interested parties that timely access to these services is especially challenging and because the failure of States to ensure timely access to these services poses substantial risk to the health, safety, and quality of care of individuals residing independently and in other community-based residences. We believed that having States report this information will assist us in our oversight of State HCBS programs by helping us target our technical assistance and monitoring efforts. We requested comment on whether this requirement should apply to additional services authorized under section 1915(c) of the Act.

For this metric, we proposed to allow States to report on a statistically valid random sample of individuals newly approved to begin receiving these services within the past 12 months, rather than for all individuals newly approved to begin receiving these services within the past 12 months. We invited comments on the timeframe for States to report on this metric, whether we should require reporting less frequently (every 2 or 3 years), and if an alternate timeframe is recommended, the rationale for that alternate timeframe. We also invited comments on whether there are other specific metrics related to the amount of time that it takes for eligible individuals to begin receiving homemaker services, home health aide services, or personal care services that we should require States to report, either in place of or in addition to the metric we proposed.

At § 441.311(d)(2)(ii), also based on our authority under section 1902(a)(6) of the Act, we proposed to require States to report annually on the percent of authorized hours for homemaker services, home health aide services, or personal care services, as listed in § 440.180(b)(2) through (4), that are provided within the past 12 months. For this metric, we further proposed to allow States to report on a statistically valid random sample of individuals authorized to receive these services within the past 12 months, rather than all individuals authorized to receive these services within the past 12 months. We invited comments on the timeframe for States to report on this metric, whether we should require reporting less frequently (every 2 or 3 years), and if an alternate timeframe is recommended, the rationale for that alternate timeframe. We also invited comments on whether there are other specific metrics related to individuals' use of authorized homemaker services, home health aide services, or personal care services that we should require States to report, either in place of or in addition to the metric we proposed. We further requested comment on whether this requirement should apply to additional services authorized under section 1915(c) of the Act.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported our proposals at § 441.311(d)(2) that States report on the time it takes between service authorization and service delivery and the number of authorized hours compared to the number of hours provided. A few commenters, while characterizing these as imperfect measures, nevertheless noted that the data measurements can help assess systematic issues with provider enrollment and access to care. One commenter observed that similar data is not currently available from their State, and believed this type of data would be useful.

Commenters noted that in their experience, beneficiaries might wait months after being authorized to receive services for the services to actually begin, or do not receive all of the services indicated in their person-centered care plan; these delays and underutilization of services cause a wide array of issues for the beneficiary and their families.

Commenters also noted these proposals complemented the waiver waiting list requirement at § 441.311(d)(1), noting that even when individuals are enrolled in a waiver, this does not always mean that their services start immediately. A few commenters also stated that in their experience, even in States that do not have waiting lists for their waiver programs, beneficiaries may wait long periods of time for the waiver services to begin.

Response: As we discuss further in responses below, we recognize that the reasons for service delays and underutilization are nuanced. The reporting requirements at § 441.311(d)(2) are a first step in what will be an evolving process to promote transparency, oversight, and data-driven improvements in States' waiting list practices.

Comment: A few commenters cited factors that may contribute to delays or underutilization of services, some of which are beyond the control of State Medicaid agencies, managed care plans, or providers. Commenters cited challenges including administrative inefficiency, shortages of direct care workers or available providers, and geographic constraints. Other

commenters cited specific obstacles, such as: difficulty in obtaining complete medical information from the beneficiary, delays in the care planning process, additional training requirements for self-directed service workers, lags in providers submitting claims or other delays in claims processing, or unavailability of the beneficiary due to travel, hospitalization, changes in provider, withdrawal from the program, or loss of Medicaid eligibility. A few commenters suggested that in some cases, beneficiaries decline services or are already receiving a different service that meets their needs prior to the new services being authorized.

One commenter noted that there are service delivery delays in care provided under private payers and wondered how these delays compare to those in Medicaid HCBS and whether they may be attributable to the adequacy of the provider network or to reimbursement rates.

A few commenters believed that the requirements at § 441.311(d)(2) would not address these underlying causes of service delays or underutilization and, thus, would not improve access to services. One commenter requested clarification on how this data would be used to promote meaningful change.

On the other hand, some commenters believed that the requirements at § 441.311(d)(2) can help identify unmet needs and uncover some of the causes of these challenges, which in turn can focus efforts on efficient solutions.

Response: We acknowledge that there are many underlying causes for service delays or service underutilization. We believe that the first step toward addressing these challenges, where possible, is to quantify the scope of these delays or underutilization through data collection. Additionally, some of the challenges commenters cited are within the purview of States, managed care plans, or providers to address. If the data demonstrates what appears to be significant delays or underutilization, we believe this information can help facilitate conversations with States, managed care plans, and providers about the reasons for these reporting results.

We also note that the purpose of the data is to track trends in service delivery times and utilization, not to track the outcomes for each beneficiary. The reporting will be the average amount of time a random sample of beneficiaries waited between service authorization and the start of services, and the total percent of authorized services that were provided. Thus, some of the factors that commenters cited, particularly those involving the behavior of specific beneficiaries, such as failure to provide timely medical data, declining services, or traveling, we believe should not significantly impact the reported numbers unless these obstacles are particularly prevalent (in which case, this may also be an area to identify for policy or program improvement).

Comment: A few commenters opposed the requirements at § 441.311(d)(2). A few commenters suggested that some States or managed care plans are not currently tracking the time between service authorization and the start of services and that it would take significant resources to develop, test, and deploy changes to the State's documentation management system. One commenter noted that it may be difficult to track this data because services are authorized, and claims are paid using different systems or are overseen by different parts of State government. One commenter noted that, while their State does track service utilization data, it would take additional staff resources to comply with the reporting requirements.

Response: We are not currently collecting States' data on the times between service authorization and when services begin, or the number of authorized hours that are being utilized and understand that States may not be tracking all of this data; the absence of this data is what has prompted us to propose the requirement at § 441.311(d)(2). We recognize that, because this data has not previously been tracked by all States, some States may have to update their data collection systems to comply with this new requirement. As discussed elsewhere in this rule, in Medicaid, enhanced FFP is available at a 90 percent FMAP for the design, development, or installation of improvements of mechanized claims processing and information retrieval systems, in accordance with applicable Federal requirements. Enhanced FFP at a 75 percent FMAP is also available for operations of such systems, in accordance with applicable Federal requirements. We reiterate that receipt of these enhanced funds is conditioned upon States meeting a series of standards and conditions to ensure investments are efficient and effective. We also note that, under section 1903(a)(7) of the Act, Federal matching funds are available for administrative activities necessary for the proper and efficient administration of the Medicaid State plan.

We developed the reporting requirement at § 441.311(d)(2) to strike a balance between collecting enough information to enable Federal oversight of service delivery and utilization and imposing as minimal an administrative burden on States and providers as possible. We believe the long-term benefits of collecting this data outweigh the initial burden of implementation. Accordingly, we decline to make any changes in this final rule based on these comments.

We are finalizing § 441.311(d)(2)(i) with a modification that we believe will further reduce administrative burden on States. As noted in an earlier comment summary, some commenters noted that in some instances beneficiaries may wait long periods of time to receive services. Upon further consideration, we have determined that the requirement at § 441.311(d)(2) as written may present some data collection challenges in situations in which the beneficiary's date of approval of service and the date when services actually begin are separated by enough time that they fall in two different reporting periods. For instance, if the reporting period aligned with the calendar year, if an individual was approved for services on November 1, 2028, but did not start receiving services until February 1, 2029, it is not clear how that beneficiary's wait time for services would be captured in the reporting period for January 1, 2028, through December 31, 2028. (We note that we are using the calendar year as the reporting period only for the purposes of this example. As discussed later in this section, we will work with States and other interested parties through the Paperwork Reduction Act process to determine the actual reporting period.) It appears that in this circumstance, the State would have to first indicate that the beneficiary had waited 2 months (November 1, 2028, through the end of the reporting period on December 31, 2028); then the State would need to submit updated information for this beneficiary to report the beneficiary's total wait time. This process would need to be repeated on a rolling basis for other beneficiaries whose approval date and service start date fell in different reporting periods. Repeated updates to States' data would be burdensome, make it difficult for States to share meaningful data with CMS and the public, and lead to delays in State reporting of complete data for each reporting period.

To avoid this type of confusion in reporting, we are amending the requirement at § 441.311(d)(2)(i) to specify that the reporting is for individuals **newly** receiving **services,** rather than for individuals newly approved to begin receiving services. (Revised language is noted in bold.) As applied to the example above, this

modification to § 441.311(d)(2)(i) means that the beneficiary whose services began on February 1, 2029 would be included in the January 1, 2029, through December 31, 2029, reporting period; the State would be able to ''look back'' to identify when the services were approved (in the example, services were approved November 1, 2028) and the State would report the beneficiary's total wait time between November 1, 2028 and February 1, 2029. We believe this modification preserves the intention of what we proposed in § 441.311(d)(2)(i)—to measure the time between when a beneficiary was approved to receive services and when the services actually begin—but clarifies and streamlines the reporting process.

Comment: A few commenters expressed concerns that States would use information about unfilled service hours to infer whether or not authorized services are necessary for the beneficiary. These commenters noted that many reasons exist as to why an individual would be unable to receive authorized care on a particular day but still need the care, such as the service provider was unavailable or there was confusion around when and what services were to be delivered on that day. One commenter requested reassurance that the reporting requirement at § 441.311(d)(2)(ii) to report on the average number of hours authorized that are provided would not be used to reduce or limit beneficiaries' access to services. One commenter suggested that we monitor services to ensure that States are not reducing services in response to this data.

Response: The purpose of this reporting requirement at § 441.311(d)(2)(ii) is not to audit individual beneficiaries' service utilization or to use the information as a reason to reduce their authorized service hours. The purpose and intent of the requirement is to identify barriers to beneficiaries' access to services. Accordingly, we decline to make any changes in this final rule based on these comments. However, we note that the State is required at § 441.301(c)(2) to ensure that the person-centered service plan reflects the services and supports that are important for the individual to meet the needs identified through an assessment of functional need, as well as what is important to the individual with regard to preferences for the delivery of such services and supports, and this requirement remains unchanged. States and managed care plans should not use the data collected to meet the reporting requirement at § 441.311(d)(2)(ii) to reduce authorized hours.

Comment: One commenter requested clarification on when the approval of services occurs, such as at the time of enrollment or when a physician signs the plan of treatment. The commenter also observed that it will be critical to standardize the data elements that must be captured in this reporting.

Response: Given the variable nature of States' processes, we defer to States to determine when services are considered to have been approved and how this approval date can be tracked consistently for the reported services. We intend to provide States with technical assistance, including technical specifications and sampling guidance, for the new reporting requirements in this final rule, which will aid in consistent data reporting. We will also be making the reporting template available for public comment through the Paperwork Reduction Act notice and comment process.

Comment: A couple of commenters recommended requiring States to set a target for timeliness (such as 7 days) and measure the percentage of all cases in which the wait time exceeded that target.

Response: At this time, we are focusing on creating baseline data-reporting standards. We will take these recommendations for setting or requiring benchmarks under consideration should we pursue future rulemaking in this area.

Comment: We received responses to our comment solicitation on whether § 441.311(d)(2) should apply to other section 1915(c) services aside from homemaker, home health aide, and personal care services as set forth at § 440.180(b)(2) through (4).

One commenter recommended narrowing the scope of this requirement to personal care services only and removing homemaker and home health aide services from the requirement. The commenter contended that homemaker services do not cover activities of daily living which are typically associated with direct care to HCBS beneficiaries. The commenter also noted that home health aide services are typically offered under the Medicaid State plan rather than a section 1915(c) waiver. The commenter concluded that limiting the requirement to personal care services would allow CMS and States to concentrate on highly utilized personal care services and would make the requirement more operationally feasible for States.

On the other hand, a few commenters advocated for extending the reporting requirements to all HCBS. One of these commenters suggested that applying the requirement to only a few services would create an unintended consequence of focusing more attention on certain services and the populations receiving those services, at the expense of other beneficiaries. A few of these commenters also pointed out that other services are experiencing direct care worker shortages that could be contributing to service delays or underutilization that need to be identified.

One commenter suggested that we add services offered by specialty providers, such as occupational therapists, physical therapists, or speech-language pathologists, to the requirement.

A couple of commenters recommended extending the requirement to include services typically delivered to people with intellectual or developmental disabilities, such as habilitation services. Similar to the reasons cited by commenters for extending the requirement to all HCBS, commenters in favor of extending the requirements to include habilitation noted that these services are critical and beneficiaries who receive them are experiencing delays in services or other access issues. However, one commenter requested that we not extend these requirements to habilitation services, citing concerns that some States' information systems are not equipped to track this information for habilitation services. The commenter also noted that differences between habilitation services and other types of HCBS require additional study and consideration prior to applying these reporting requirements for habilitation services.

Response: We believe that the services proposed for inclusion in this requirement include activities of daily living that are critical to beneficiaries' health, safety, and ability to live successfully in the community. Additionally, as identified in an analysis performed by CMS, the three services fall within the taxonomy of home-based services, which are both high-volume and high cost.[126] Thus, we believe that targeting these services will maximize the impact of this requirement by addressing the needs of many beneficiaries and promoting better oversight of frequently used services. Given the similarities among homemaker, home health aide, and personal care services, we cannot find a justification for removing homemaker

[126] Centers for Medicare & Medicaid Services. ''Trends in Rate Methodologies for High-Cost, High Volume Taxonomies.'' *https://www.medicaid.gov/sites/default/files/2019-12/trends-in-rate-august-2017.pdf.* Last access October 2, 2023.

and home health aide services from this requirement.

Because we want to start by focusing on a selection of high-volume, high-cost services, we do not at this time intend to expand the reporting requirement to all HCBS. We do agree with commenters that services in addition to homemaker, home health aide, and personal care services may be particularly vulnerable to delays due to shortages in the direct care workforce. For that reason, we are extending the requirement to habilitation services in this final rule which, like homemaker, home health aide, and personal care services, tend to be hands-on services that are delivered by direct care workers who often earn lower wages. We believe that expanding the reporting to include habilitation services will ensure that beneficiary populations, namely individuals with intellectual or developmental disabilities who commonly receive personal care services as part of their habilitation services, are not excluded from our efforts to support the direct care workforce.

We acknowledge the comment that habilitation services are unique from other services, but also cannot identify reasons why these differences should exclude them from this reporting requirement.

After consideration of these comments and the benefits of aligning reporting requirements across services, we are finalizing the reporting requirements at § 441.311(d)(2)(i) and (ii) with a modification to include homemaker, home health aide, personal care, and habilitation services, as set forth at § 440.180(b)(2) through (4) and (6).

Comment: One commenter requested clarification on whether § 441.311(d)(2) would apply to services in both managed care and FFS delivery systems. One commenter requested that we require reporting on managed care plans' prior authorization practices, including differing lengths of authorizations and untimely authorizations that were not in place or renewed prior to the date of expected services. The commenter noted that missing authorizations may cause disruptions in payments to providers and threaten the continuity of beneficiaries' access to the services.

Response: The reporting requirements apply to services delivered under both FFS and managed care delivery systems. For additional information, we refer readers to the discussion of §§ 441.311(f) and 438.72(b) below. We note that a State may consider requiring reporting on specific managed care processes through its contracts with managed care plans.

Comment: A few commenters requested clarification as to whether the requirements at § 441.311(d)(2) would apply to self-directed services. A few commenters raised specific questions or concerns about the application of the reporting requirements at § 441.311(d)(2) to self-directed services, particularly self-directed service models with individual budget authority. Commenters noted that the inherent flexibility of these services might make reporting on the utilization of service hours particularly misleading. One commenter noted that, when an individual selects an independent worker to provide services, that worker might have to go through background checks and training that would make it appear that the service delivery is delayed. One commenter worried that States would become concerned with the appearance of delays in the delivery of self-directed services and discourage beneficiaries from seeking self-directed services. Another commenter pointed out that since beneficiaries might use their budget authority to purchase equipment or devices that replace some hands-on services, or may choose to adjust their service schedules, service utilization data on these services might inaccurately suggest that the beneficiary is being underserved. On the other hand, one commenter recommended that self-directed services be included in this reporting. Another commenter stated that from their personal experience as a provider, beneficiaries receiving self-directed services tend to have higher service utilization rates than beneficiaries in agency-directed services. One commenter suggested that data on all models of self-directed services be tailored to the unique needs of the model, such as by requiring reporting on the percent of the budget used rather than the number of service hours. Another commenter suggested that additional guidance would be needed to apply the reporting requirements to self-directed models.

Response: As discussed in section II.B.7.e. of this final rule, these reporting requirements will apply to self-directed services. We thank commenters for raising these concerns. As noted earlier, we intend to provide States with technical assistance, including technical specifications and sampling guidance, for the new reporting requirements in this final rule, which should aid in reporting on self-directed services. As noted in a prior response, the purpose of the data is to track trends in service delivery times and utilization, not to track the outcomes for each beneficiary. The reporting will be the average amount of time a random sample of beneficiaries waited between service authorization and the start of services, and the total percent of authorized services that are provided. Thus, some of the factors that commenters cited, such as additional training for self-directed service workers or individual beneficiaries' changes in schedules, should not significantly impact the reported numbers. However, we will work with States to monitor this issue.

Comment: A few commenters raised concerns about the proposal to allow States to report data on a statistically valid sample of beneficiaries, suggesting instead that we require complete reporting on all relevant beneficiary data. Commenters were concerned that using a sample could mask disparities or fail to identify individuals with particularly acute unmet needs. One commenter suggested that if we permit reporting on a random sample, we add a requirement that the data must include information on race, ethnicity, and population (such as older adults, people with intellectual and developmental disabilities, and people with physical disabilities) in order to identify disparities in service delivery.

Response: To minimize State reporting burden, we are finalizing the requirement to allow States to report data for § 441.311(d)(2) using statistically valid random sampling. We believe that due to variety in States' current tracking systems, some States might find reporting using statistically valid random sampling to be more manageable and auditable than attempting to report on all beneficiaries. We will consider expanding reporting to the full population in future rulemaking if it is determined that such an approach gives a more complete picture of service delivery. We note that States may choose to report on the full population, as opposed to sampling their beneficiaries, if for instance, doing so better aligns with their data collection process or needs.

We are finalizing the requirements at § 441.311(d)(2)(i) and (ii) with a technical modification to specify that the State may report this metric using **statistically valid random sampling of beneficiaries.** (Revised language identified in bold.) We make this technical correction to better align the language with standard terminology for the sampling methodology we intended in these requirements.

Comment: We received responses to our comment solicitation on additional metrics that could be collected regarding service delivery and utilization. One commenter

recommended that we not add more metrics to § 441.311(d)(2). Several commenters did suggest additional metrics. Many of these commenters noted that more detailed data would allow for a better assessment of overall unmet needs and disparities within service delivery. Additional metrics suggested by commenters included:

- Disaggregated data about beneficiaries, by demographic categories, including race, ethnicity, language status, sex or gender identification, sexual orientation, age, and geographic location;
- Tracking the total number of beneficiaries who received service authorizations versus the number of beneficiaries who received services;
- Tracking why services are not provided or why a beneficiary declines a service;
- Disaggregated data by HCBS authority and population (including dual eligibility), delivery system, provider type, and managed care plan; and
- Tracking beneficiaries' long-term access to services or other metrics to measure continuity of care and how the care contributes to beneficiaries' goals and outcomes.

One commenter, while not recommending that we require the measure for all States, shared a State's experience of including a measure to assess missed visits in its managed LTSS program. The commenter observed that this required a significant amount of time to identify legitimate reasons for services to not have been provided and to build the system mechanisms to capture that data, which was primarily identified through case management record review.

Response: We thank commenters for their thoughtful feedback. We will take these recommendations under consideration for future policymaking, but at this time, we decline to modify the metrics required at § 441.311(d)(2) based on these comments.

As noted in previous responses, we do not believe it would be feasible at this stage to standardize the collection of certain types of qualitative data, such as reasons for delayed or undelivered services, or how the services contribute to beneficiaries' outcomes; this data would also be difficult to validate and, as noted by one commenter, time-consuming to implement.

We believe it is important to strike a balance between collecting information to promote transparency around service times and utilization and imposing as minimal an administrative burden on States and providers as possible. We also believe that the reporting requirements at § 441.311(d)(2) are straightforward metrics on which to begin reporting. As we gather and review this data, we will consider what additional information may be needed to further improve our oversight of HCBS programs and improve beneficiaries' access to services and may consider additional reporting requirements in the future.

However, we agree that some of the granular data elements suggested by commenters could provide States with valuable insight into their own programs and beneficiary needs. We encourage States to consider what information they have the capacity to collect and would find useful for developing local policies to support beneficiaries' access to HCBS waivers in their State.

Comment: A few commenters recommended additional metrics that fall outside the scope of the reporting in § 441.311(d)(2). One commenter recommended collecting data on case manager or service coordinator caseloads. A few commenters recommended measuring time between an individual's date of application and their eligibility determination, and the time between an individual's eligibility determination and the plan of care development or authorization for services.

Another commenter noted that a cause of delay in receiving HCBS may be due to delays in the development of care plans that are required for HCBS delivery to begin. The commenter noted that a potential solution to this specific barrier is the use of provisional plans of care, which are discussed in Olmstead Letter #3.[127] The commenter recommend that we affirm that HCBS provisional plans of care are an available option and require States to report on usage of such plans.

Response: We thank commenters and note these comments are not directly related to the proposed requirements in § 441.311(d), and thus we decline to make modifications to § 441.311(d) based on these suggestions. We plan to consider the comments as we regard broader HCBS access and equity issues for future policymaking. We also note that while requiring use of provisional care plans would be outside the of scope of this requirement, we agree with the commenter that the use of provisional care plans as described in Olmstead Letter #3 may help avoid the delay of services pending the development of the care plan.[128] In this letter, we explain that we will accept, as meeting requirements, a provisional written plan of care which identifies the essential Medicaid services that will be provided in the person's first 60 days of waiver eligibility, while a fuller plan of care is being developed and implemented. During this time, the relevant agencies work with the beneficiary to develop and finalize a ''comprehensive plan of care,'' which goes into effect as soon as practically possible, and at least within 60 days.

Comment: One commenter recommended that we allow States the option to choose one of the proposed criteria in § 441.311(d)(2) on which to report or to propose a different metric on which to report. The commenter believed this would permit flexibility in reporting on and context for data related to timeliness of initiation of service planning and service delivery. The commenter believed that this could serve as the first stage in a phased approach for access reporting.

Response: We thank the commenter for their suggestion. However, we believe it is important to take steps to establish nationally comparable data, which would require States to report on the same metrics. As discussed in previous responses, we are not finalizing any additional metrics for § 441.311(d)(2) and believe that the two metrics included in this requirement are a reasonable first step in data collection.

Comment: A few commenters supported annual reporting for § 441.311(d)(2). One commenter noted that annual reporting will better monitor service interruptions due to shortages of direct care workers. One commenter noted that a beneficiary's service utilization can fluctuate significantly even from month to month. One commenter believed that biennial (every other year) reporting would reduce burden on States.

Response: We are finalizing the annual reporting frequency as proposed

[127] Refer to Centers for Medicare and Medicaid Services, ''Olmstead Letter #3, Attachment 3–a.'' July 25, 2000. Available at *https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/downloads/smd072500b.pdf;*. The commenter notes that in Olmstead Letter #3, Attachment 3–a (*https://www.medicaid.gov/Federal-Policy-Guidance/downloads/smd072500b.pdf*), CMS explains that it ''will accept as meeting the requirements of the law a provisional written plan of care which identifies the essential Medicaid services that will be provided in the person's first 60 days of waiver eligibility, while a fuller plan of care is being developed and implemented.'' During this time, the relevant agencies work with the beneficiary to develop and finalize a ''comprehensive plan of care,'' which goes into effect as soon as practically possible, and at least within 60 days.

[128] Centers for Medicare and Medicaid Services, ''Olmstead Letter #3, Attachment 3–a.'' July 25, 2000, which is available at *https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/downloads/smd072500b.pdf.*

in § 441.311(d)(2). We continue to believe that annual reporting strikes the right balance between collecting current data and minimizing burden on States to the greatest extent possible. We are concerned that if we extend the reporting to a biennial frequency, the information will become outdated prior to the next public report.

After consideration of the comments received, we are finalizing the requirements at § 441.311(d)(2), with modifications. We are finalizing § 441.311(d)(2)(i) with a modification to specify that the reporting is for individuals newly receiving services within the past 12 months, rather than for individuals newly approved to begin receiving services. We are also finalizing a modification so that both reporting requirements at § 441.311(d)(2)(i) and (ii) require reporting on homemaker services, home health aide services, personal care, or habilitation services, as set forth in § 440.180(b)(2) through (4) and (6), and allow States to report using statistically valid random sampling of beneficiaries.

We note that we are finalizing § 441.311(d)(2) with technical corrections. As a result of modifying § 441.311(d)(2) to include habilitation services, we are modifying the title of this provision to specify *Access to homemaker, home health aide, personal care, and habilitation services.* We are also finalizing a technical modification in both § 441.311(d)(2)(i) and (ii) to indicate that the services are as ''set forth'' in § 440.180(b)(2) through (4) and (6), rather than as ''listed'' in.

d. Payment Adequacy (§ 441.311(e))

At § 441.311(e), we proposed new reporting requirements for section 1915(c) waivers, under our authority at section 1902(a)(6) of the Act, requiring that States report annually on the percent of payments for homemaker, home health aide, and personal care services, as listed at § 440.180(b)(2) through (4), spent on compensation for direct care workers. For the same reasoning discussed in section II.B.5. of this preamble, we have focused this requirement on homemaker services, home health aide services, and personal care services because they are services for which we expect that the vast majority of payment should be comprised of compensation for direct care workers and for which there would be low facility or other indirect costs. These are services that would most commonly be conducted in individuals' homes and general community settings. As such, there should be low facility or other indirect costs associated with the services. We also believed that this reporting requirement could serve as the mechanism by which States demonstrated that they meet the proposed HCBS Payment Adequacy requirements at § 441.302(k).

We considered whether the proposed reporting requirements at § 441.311(e) related to the percent of payments going to the direct care workforce should apply to other services, such as adult day health, habilitation, day treatment or other partial hospitalization services, psychosocial rehabilitation services and clinic services for individuals with chronic mental illness. We had selected homemaker, home health aide, and personal care services (as defined at § 440.180(b)(2) through (4)) for this reporting requirement to align with the payment adequacy minimum performance requirement at § 441.302(k)(3), which is discussed in section II.B.5. of this preamble. However, we requested comment on whether States should be required to report annually on the percent of payments for other services listed at § 440.180(b) spent on compensation for direct care workers and, in particular, on the percent of payments for residential habilitation services, day habilitation services, and home-based habilitation services spent on compensation for direct care workers.

We further proposed that States separately report for each service subject to the reporting requirement and, within each service, separately report on payments for services that are self-directed. We considered whether other reporting requirements such as a State assurance or attestation or an alternative frequency of reporting could be used to determine State compliance with the requirement at § 441.302(k) and decided that the proposed requirement would be most effective to demonstrate State compliance. We requested comment on whether we should allow States to provide an assurance or attestation, subject to audit, that they meet the requirement in place of reporting on the percent of payments, and whether we should reduce the frequency of reporting to every other year.

To minimize burden on States and providers, we proposed that States report in the aggregate for each service across all of their services across all programs as opposed to separately report for each waiver or HCBS program. However, we requested comment on whether we should require States to report on the percent of payments for certain HCBS spent on compensation for direct care workers at the delivery system, HCBS waiver program, or population level. We also requested comment on whether we should require States to report on median hourly wage and on compensation by category.

In consideration of additional burden reduction for certain providers, we requested comment on whether we should allow States the option to exclude, from their reporting to us, payments to providers of agency directed services that have low Medicaid revenues or serve a small number of Medicaid beneficiaries, based on Medicaid revenues for the service, number of direct care workers serving Medicaid beneficiaries, or the number of Medicaid beneficiaries receiving the service. We also requested comment on whether we should establish a specific limit on this exclusion and, if so, the specific limit we should establish, such as to limit the exclusion to providers in the lowest 5th, 10th, 15th, or 20th percentile of providers in terms of Medicaid revenues for the service, number of Medicaid beneficiaries served, or number of direct care workers serving Medicaid beneficiaries.

We proposed that payments for self-directed services by States should be included in these reporting requirements, although we noted feedback from interested parties indicating that compensation for direct care workers in self-directed models tends to be higher and may comprise a higher percentage of the payments for services than other HCBS. This decision not to exclude them was based on the importance of ensuring a sufficient direct care workforce for self-directed services. We requested comment on whether we should allow States to exclude payments for self-directed services from these reporting requirements.

We note that, for clarity, we are aligning the definitions of compensation, direct care worker, and excluded costs at § 441.311(e)(1) with those we are finalizing in § 441.302(k)(1). As a result, the reporting requirement we proposed at § 441.311(e) is finalized at § 441.311(e)(2)(i), as discussed below. While we consider the reporting requirement at § 441.311(e) to be distinct and severable from the payment adequacy requirements in § 441.302(k), we believe that the reverse is not the case—that § 441.302(k) does rely on the reporting mechanism at § 441.311(e) to establish compliance with the minimum performance requirement at § 441.302(k)(3). As such, we believe it is advantageous to have aligned definitions.

We received public comments on this proposal. The following is a summary of

the comments we received and our responses.

Comment: Several commenters expressed general support for our proposed requirement at § 441.311(e) that States report annually on the percent of payments for homemaker, home health aide, and personal care services, as listed at § 440.180(b)(2) through (4), spent on compensation for direct care workers. Commenters believed that this requirement would provide data about how Medicaid payments are being spent, which would improve oversight and enable meaningful comparisons across programs. One commenter requested clarification on the intent of the reporting requirement.

Commenters also believed that this requirement would ensure compliance with the payment adequacy minimum performance requirement at § 441.302(k)(3). Several commenters, however, expressed support for finalizing this reporting requirement, but not for finalizing the minimum performance requirement at § 441.302(k)(3). These commenters noted that the reporting requirement by itself would yield useful data that would support payment transparency in HCBS programs.

Response: This requirement is intended to help track the percent of Medicaid payments for certain HCBS that is spent on compensation for direct care workers. As we discussed extensively in section II.B.5. of this rule, we believe that ensuring that a significant portion of payments for these hands-on services is spent on compensation for direct care workers aligns with our responsibility under section 1902(a)(30)(A) of the Act to require assurance that payments are consistent with efficiency, economy, and quality of care. We do note that this reporting requirement also is a mechanism by which States demonstrate compliance with the payment adequacy requirements at § 441.302(k), which is discussed in detail in section II.B.5. of this rule.

While we are finalizing the payment adequacy requirements at § 441.302(k), we agree that the value provided by this reporting requirement is distinct and severable from the minimum performance requirement and serves as a standalone requirement. To clarify the distinction between this reporting requirement and the payment adequacy requirement at § 411.302(k), we are revising the language at § 411.311(e)(2) to remove the reference to the minimum performance requirement at § 411.302(k)(3). We believe this will better demonstrate that the reporting requirement has a function aside from demonstrating compliance with § 411.302(k). We also believe this to be necessary because, as discussed further below, we are finalizing the reporting requirement at § 411.311(e)(2) to include reporting of data related to habilitation services, which are not subject to the minimum performance requirement at § 411.302(k)(3). Thus, we believe retaining the reference to § 411.302(k)(3) would cause some confusion.

Comment: A few commenters opposed the reporting requirement proposed at § 441.311(e) (which we are finalizing at § 411.311(e)(2)). These commenters noted that the reporting requirement would increase administrative burden and administrative costs for providers; a few commenters believed the increase in administrative tasks would undermine the goal of the minimum performance requirement at § 441.302(k)(3) to reduce providers' spending on administrative activities.

Other commenters expressed concern that this requirement would create a burden for States. One commenter, although recognizing the need for more data about compensation to direct care workers, believed that most States do not currently collect this type of data and would require significant time, administrative effort, and expense to collect, compile, report, and analyze the data in a meaningful way. A few commenters stated that States would need to make significant changes to current billing and reporting practices and IT in order to isolate the use of reimbursements for the three specified services from the larger menu of services a provider typically offers. A couple of commenters expressed concerns about the time and resources it would take to educate providers about the requirements and their reporting responsibilities.

Additionally, a few commenters expressed concerns about whether States have the capacity to validate the accuracy of providers' reports and conduct audits, especially in States with a large number of providers. One commenter expressed concern about the cost associated with hiring and training independent auditors to audit providers' reported compensation of direct care workers. One commenter shared first-hand experience with implementing a wage pass-through requirement as part of the State's spending plan under ARP section 9817; the commenter regarded the process of monitoring and validating the percentage of payments going to direct care workers as administratively burdensome.

Response: We acknowledge that complying with this reporting requirement will necessitate certain expenditures of resources and time on the part of providers and States. As noted by commenters, we believe that the value of the data collected through their efforts makes these expenditures of resources worthwhile. As discussed further below, we are finalizing the redesignated § 441.311(e)(2)(i) to require only aggregated data by service, as proposed, which we believe will reduce burden on both providers and States.

We believe that, generally speaking, States and providers should already have information about the amount of Medicaid payments providers receive for specific services, and that providers likely already track expenditures on wages and benefits for their workers. We also believe that the simpler, aggregated reporting will be easier for States to validate and include in their existing auditing processes.

However, to ensure that States are prepared to comply with this reporting, we are adding a requirement at § 441.311(e)(3) to require that States must report, one year prior to the applicability date for (e)(2)(i) of this section, on their readiness to comply with the reporting requirement in (e)(2)(i) of this section. This will allow us to identify States in need of additional support to come into compliance with § 441.311(e)(2)(i) and provide targeted technical assistance to States as needed.

Comment: A couple of commenters requested that CMS issue subregulatory guidance or share best practices to assist with strategies for collecting data and ensuring compliance with the requirement. One commenter recommended that we work with States to determine the most efficient way to gather comparable, useful data to inform future rate policies, including exploring whether existing State tools could meet the requirement or could do so with modification.

A few commenters raised particular concerns about cost reports, which they believed would be necessary for implementing the reporting requirement. Commenters stated that without standardized cost reports, it will be difficult to ensure consistent and comparable data reporting across programs. Some of these commenters noted that, in States that do not currently require cost reports, this will present a new burden for both providers and States. A couple of commenters worried that providers may lack both the familiarity and the resources to complete cost reports. A few commenters requested that CMS

develop a standard cost reporting template to ensure accurate data collection and assessment of compliance across all States.

A couple of commenters, noting the language proposed in § 441.311(e) (which we are finalizing at § 441.311(e)(2)(i)) that the reporting will be at the time and in the form and matter specified by CMS, requested additional information regarding the method of submission and the methodology that will be required for the calculations used in the report.

Response: We intend to release subregulatory guidance to assist States with implementation of this requirement, and we plan to also provide technical assistance and best practices to help States identify ways to use existing infrastructure or tools to gather and report. Further, as noted earlier, we intend to provide States with technical specifications for the new reporting requirements in this final rule, which will aid in consistent data reporting. In addition, we will be making the reporting template available for public comment through the Paperwork Reduction Act notice and comment process. Through that process, the public will have the opportunity to review and provide feedback on the elements of the required State reports, including the methodology of the calculations, as well as the timing and format of the report to us.

As discussed further below, we are finalizing the requirement at § 441.311(e)(2)(i) (originally proposed at § 441.311(e)) that States need only report aggregated data by service. We believe this will reduce the overall burden on States and providers and reduce the need for complex cost reporting.

Comment: One commenter requested enhanced FMAP for costs associated with the reporting requirement.

Response: Enhanced FFP is available at a 90 percent FMAP for the design, development, or installation of improvements of mechanized claims processing and information retrieval systems, in accordance with applicable Federal requirements.[129] Enhanced FFP at a 75 percent FMAP is also available for operations of such systems, in accordance with applicable Federal requirements.[130] We reiterate that receipt of these enhanced funds is conditioned upon States meeting a series of standards and conditions to ensure investments are efficient and effective.[131] We decline to make any changes in this final rule based on this comment.

Comment: One commenter suggested that, instead of requiring reporting on the percentage of Medicaid payments going to compensation for direct care workers, we should require States to report annually on how their rates are determined and if the State's rate review included factors such as current wage rates, inflation, required costs of business, and increasing health insurance rates. Another commenter recommended that CMS consider implementing a regular review and assessment to determine if State Medicaid rates provide competitive wages for the direct care workforce and review how these wages are funded in the various payment models.

Response: We focused this particular proposal on the allocation of Medicaid payments, not on rate setting or rate methodology. Such considerations are outside the scope of this proposal. However, we direct readers to the discussion in Documentation of Access to Care and Service Payment Rates (section II.C. of this final rule) which may speak to readers' interests in rate transparency and analysis. We decline to make any changes in this final rule based on this comment.

Comment: A few commenters requested clarification of the enforcement mechanisms for the reporting requirement.

Response: In terms of enforcing compliance of the States' obligation to submit reports as required at § 441.311(e), we intend to use our standard enforcement discretion. In terms of providers' cooperation with States in submitting the data States need to make their reports, we note that States already have broad authority to take enforcement action and create penalties, whether monetary or non-monetary, for providers that have violated their obligations as set forth by the State Medicaid program. We decline to make any changes in this final rule based on this comment.

Comment: A few commenters requested that we clarify managed care plans' responsibility for tracking and reporting expenditures. A few commenters expressed concern that this proposal would pose particular reporting or accounting burdens for providers that participate in multiple Medicaid managed care plans, serve non-Medicaid clients, or receive bundled payments.

Response: We plan to provide technical assistance to States to address the role of managed care plans in adhering to this reporting requirement, as well as to assist with strategies for addressing bundled payments that include the services affected by this requirement. Also, as discussed in greater detail below, we are not proposing granular reporting (such as requiring data be disaggregated by managed care plan or by HCBS waiver program). Additionally, we would like to emphasize that our intention is that the State requires providers share information about the percent of all of their Medicaid FFS payments and the payment they receive from managed care plans that is being spent on compensation for the direct care workforce; we do not intend that the State should expect providers to provide a separate percent of Medicaid payments from each managed care plan in which they are enrolled, or provide separate calculations based on payment from services provided to non-Medicaid beneficiaries that is separate and distinct from their participation in the Medicaid managed care program. We therefore decline to make any changes in this final rule based on this comment.

Comment: A couple of commenters suggested that we expand reporting to include more HCBS than the three services specified, or even to apply this requirement to all HCBS. One of the commenters noted that, while more work, it would be administratively simpler to report on a broader array of services, rather than trying to isolate data for a few HCBS. One of the commenters recommended that we could phase in these expanded reporting requirements, beginning with homemaker, home health aide, and personal care services.

Response: As discussed below, we are expanding this reporting requirement in this final rule to include habilitation services. We tailored this requirement to address the services that are most likely to be delivered by direct care workers who predominantly earn lower wages. At this time, we do not intend to expand the requirement beyond homemaker, home health aide, personal care, and habilitation services. However, we note that States are free to collect additional information for State use if the States believe this would simplify administration or they would like to track allocations of Medicaid payments to direct care workers providing other types of HCBS.

[129] See section 1903(a)(3)(A)(i) and § 433.15(b)(3), 80 FR 75817–75843; *https://www.medicaid.gov/state-resourcecenter/faq-medicaid-and-chip-affordable-care-act-implementation/downloads/affordable-care-act-faq-enhancedfunding-for-medicaid.pdf; https://www.medicaid.gov/federal-policy-guidance/downloads/SMD16004.pdf.*

[130] See section 1903(a)(3)(B) and § 433.15(b)(4).

[131] See § 433.112 (b, 80 FR 75841; *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-433/subpart-C.*

Comment: In response to our request for comments, a few commenters recommended expanding the reporting requirement to include the percent of payments for residential habilitation services, day habilitation services, and home-based habilitation services that is spent on compensation for direct care workers. One commenter believed that it was important to include habilitation because, in the absence of such data, individuals with developmental disabilities will be disadvantaged since habilitation is a primary vehicle for the delivery of support services to people with intellectual and developmental disabilities in most States. Another commenter believed this information would be critical for determining any future minimum performance level for compensation to direct care workers that was applied to habilitation services.

A few commenters, on the other hand, did not support including habilitation services, but did not specify reasons why these services should be excluded.

Response: We agree with commenters that collecting information about habilitation services would yield useful data about the allocation of Medicaid payments in support of the direct care workforce. Like homemaker, home health aide, and personal care services, habilitation services also tend to be hands-on services that are delivered by direct care workers who often earn lower wages. However, a key difference between habilitation services and the services that were initially selected for this reporting requirement is that they may include facility costs if the service includes residential habilitation or day habilitation. Reporting on habilitation could be useful in better understanding these costs as well, as it will allow for a comparison between the facility-based habilitation services and in-home services. We also agree with commenters that, as habilitation services are more often delivered to people with intellectual and developmental disabilities, excluding habilitation services will disproportionately impact beneficiaries with intellectual and developmental disabilities.

While we agree with commenters that it is important to collect data on habilitation services, we also acknowledge that, as noted above, some services include facility costs that may impact the percent of Medicaid payments being spent on compensation for direct care workers. Similar to our proposed requirement at § 441.311(e), that self-directed services be reported separately, we also are requiring that services that include facility costs in the Medicaid rate be reported separately; this way, we can observe the differences between the allocation of payments in facility-based services versus services that are provided solely in the beneficiary's home or in community settings that are not facilities.

After consideration of the comments, we are adding habilitation services to this reporting requirement being finalized at § 441.311(e)(2)(i). We are modifying the requirement at § 441.311(e)(2)(i) to specify that the services included in this requirement are those set forth at § 440.180(b)(2) through (4) and (6). We note that § 440.180(b)(6) refers to habilitation services, without distinguishing between residential habilitation services, day habilitation services, and home-based habilitation services. Thus, we are also specifying that services with facility costs included in the Medicaid rate must be reported separately. These categories will be further described in subregulatory guidance. We approximate this distinction in this reporting requirement through the separate depiction of services with facility costs.

Comment: One commenter recommended that we exclude nurses and direct care workers who provide nursing assistance from this reporting requirement. Another commenter suggested that we should require data to be stratified by workforce. This commenter worried that without this disaggregation, workers who typically earn lower wages (such as personal care assistants) will be ''overshadowed'' in the data by workers who typically earn higher wages (such as nurses). The commenter believed this lack of transparency within the data would limit targeted interventions and advocacy for the lowest-paid positions within HCBS.

Response: Nurses and staff who provide nursing assistance are included in the definition of direct care worker we are finalizing at § 441.311(e)(1)(ii), as discussed previously. While some of the underlying rationale of this reporting requirement is related to concerns about low wages earned by some direct care workers, our broader concern is the health of the HCBS workforce as a whole. The HCBS workforce is experiencing a shortage of workers in all categories, including clinicians and nursing assistants. These workers provide direct, hands-on services to beneficiaries and may in some cases be required to provide or supervise the services. We do not believe excluding them from the reporting serves our larger interests in supporting the direct care workforce overall. For that reason, we also do not believe that it is necessary to include a Federal reporting requirement that compensation to nurses should be reported separately, as our primary interest is in tracking the allocation of Medicaid payments to the direct care workers who are delivering the services. As noted above, States may choose to disaggregate data (for State use) for different categories of direct care workers in order to examine workforce issues at the State level.

Comment: Several commenters responded to our request for comment on whether we should allow States to provide an assurance or attestation, subject to audit, that they meet the requirement in place of reporting on the percent of payments. A few commenters opposed an attestation rather than a reporting requirement. These commenters agreed that the reporting requirement is the most effective means of verifying States' compliance with the payment adequacy minimum performance requirement at § 441.302(k)(3). Commenters also noted that the reporting requirement, rather than an attestation only, will yield granular data that will allow for comparison across States and, within States, across providers and service categories; such data, commenters believe, will enable States to better understand the impact of payment levels on access and adjust their rates accordingly, as well as prove useful for CMS's Federal oversight of beneficiaries' access.

A few commenters, on the other hand, supported requiring an attestation in lieu of a reporting requirement. Commenters, who mostly represented State agencies, preferred the option as being less burdensome and allowing for more flexibility. One commenter suggested that such an attestation could still be a means of limited data collection and proposed that, as part of an attestation, we provide States with a standardized reporting tool to assess whether their rates are sufficient to ensure a livable wage for direct care workers.

A couple of commenters noted that, while an attestation would be helpful to Medicaid programs, some Medicaid agencies noted that they would still need to collect at least some provider-level data to ensure compliance.

Response: We agree with commenters that a reporting requirement will be more effective and useful at monitoring and understanding the allocation of Medicaid payments to compensation for direct care workers, especially as this reporting requirement is intended to do more than simply demonstrate compliance with the payment adequacy requirements at § 441.302(k). We also

are persuaded by commenters' observations that, even with an attestation, States would still need to collect data from providers to ascertain the accuracy of their attestation. In light of the fact that an attestation would only slightly reduce burden and would not result in data collection that would allow for national comparisons, we are moving forward with the reporting requirement rather than replacing it with an attestation.

Comment: Several commenters responded to our proposal at § 441.311(e) (which we are finalizing at § 441.311(e)(2)(i)) that reporting would be required annually as well as our request for comment on whether we should reduce the frequency of reporting to every other year. A few commenters supported our proposal that this reporting would be collected annually. One commenter believed that reporting less frequently than every year would result in the reporting of out-of-date data and would delay identification of problems in the HCBS system that could cause access issues for beneficiaries. Another commenter noted that the value of the data for rate-setting and the work of the interested party advisory group (discussed in section II.C.2. of this final rule, specifically in the discussion of § 447.203(b)(6)) outweighs any potential burden of annual reporting.

A few commenters supported reporting every two years, rather than an annual reporting period. One commenter made the specific suggestion that the reporting should be every two years with a 12-month lag to better ensure accurate reporting. Commenters who supported reporting every 2 years stated that this would allow States sufficient time to collect data, conduct necessary follow-up activities, and publish data while also helping them better balance this requirement with other compliance and reporting activities. One commenter opposed an annual reporting period because it misaligned with their State's cycle of rate methodology review, which occurs every three to five years.

One commenter proposed an alternative reporting frequency of 3 years, but with the expectation that States would be collecting the data quarterly and analyzing the data annually. The commenter noted this frequency would also give the MAC and BAG (discussed in section II.A. of this rule) time to react to the data prior to its being reported to CMS.

Response: We agree that if too much time lapses between each reporting period, the reports, when released, will become quickly out of date. We also appreciate commenters' observations that interested parties, including advisory groups, might rely on this data when making recommendations for Medicaid rates or examining HCBS workforce issues; this places even greater importance on timely data. We also note that, as discussed further below, we are finalizing the requirement that only aggregated data must be reported, which should reduce burden on States and providers and make annual reporting manageable. We note that while annual reporting may be more frequent than States' rate review process, collecting this data annually will allow States to track trends in workforce compensation that they could include in their rate reviews.

We decline to add a requirement specifying how frequently States should review the data they collect. The purpose of this requirement is, in part, to establish the frequency with which States must submit a report to CMS, which we proposed as being on an annual basis. We do not intend to require that States collect and internally review their data quarterly; however, States may choose to do so if feasible and useful. We expect that, at minimum, States will review and analyze the data they receive on an annual basis as part of their submission of the report required by § 441.311(e)(2)(i).

Comment: One commenter specifically noted support for the requirement at § 441.311(e) that States report separately for each service subject to the reporting requirement. A few commenters requested that we finalize the requirement to allow States to report aggregated data to minimize burden. A few commenters suggested that aggregate reporting would be preferable to a more granular approach (such as reporting on the percent of payments for certain HCBS spent on compensation for direct care workers at the delivery system, HCBS waiver program, or population level; reporting on median hourly wage and on compensation by category).

Response: As noted in our background discussion of this provision, we believe that reporting on aggregated data by service strikes the best balance between monitoring the proportion of Medicaid payments that are being spent on compensation for direct care workers and avoiding unnecessary data collection and burden on States and providers.

Comment: We received responses to our request for comment on whether we should require States to report on the percent of payments for certain HCBS that is spent on compensation for direct care workers at the delivery system, HCBS waiver program, or population level. A number of commenters supported more granular reporting, which they believed would yield more valuable data and support transparency. Several commenters supported reporting at the delivery system level, which commenters believed would help capture differences between managed care and FFS. A few of these commenters also suggested that for managed care delivery systems, reporting should also be disaggregated by plan. One commenter also suggested that within managed care reporting, States should report separately for services delivered to dually eligible beneficiaries.

A few commenters supported breaking down the reporting by HCBS program.

One commenter noted that both provider payments and direct care worker compensation can have considerable variations across all of a State's programs and having this information would be useful for State policymakers as they develop payment rates. This commenter believed that States and providers must already be tracking which services are provided under each program.

A few commenters supported reporting at the population level. Suggestions for what would be included in the population level reporting included race, ethnicity, and geographic location. One commenter believed that demographic information about beneficiaries and their geographic regions would help address barriers to access that are unique to certain populations and areas (such as access issues in rural regions). One commenter, however, believed that collecting data at the population level was not feasible.

Commenters made suggestions for additional details to add to the reporting requirement, including reporting on:

- Direct care worker turnover;
- Compensation to workers by setting (services delivered at home, residential, or facility-based day settings); and
- The number of direct care workers who are considered W–2 employees versus independent contractors.

Response: We thank commenters for their thoughtful feedback. We will take these recommendations under consideration for future policymaking, but at this time are moving forward with finalizing the language in the requirement at § 441.311(e)(2)(i) specifying that States must report the percent of total Medicaid payments spent on compensation to direct care workers by service. We note that a few of the suggestions are outside of the

scope of this proposal, which is intended for States to report data about the percent of payments for certain HCBS that is spent on compensation for direct care workers, not for providers to report on the demographics or employment status of each of their workers, nor on granular beneficiary-level data. We direct readers who are interested to data collection about beneficiaries, including demographic data, to the discussion of the HCBS Quality Measure Set in section II.B.8. of this rule.

As noted in previous responses, we believe it is important to strike a balance between collecting enough information to enable Federal oversight of how Medicaid payments are being allocated and imposing as minimum an administrative burden on States and providers as possible. We believe that the data on the percent of Medicaid payments going to compensation for direct care workers is sufficient to help us ensure that a significant portion of Medicaid payments for these hands-on services goes to the direct care workforce, which in turn supports our responsibility under section 1902(a)(30)(A) of the Act to require assurance that payments are consistent with efficiency, economy, and quality of care.

However, we agree that some of the granular data elements suggested by commenters could provide States with valuable insight into their own programs and workforce needs. We encourage States to consider what information they have the capacity to collect and would find useful for developing local policies to support direct care workers in their State.

Comment: One commenter also recommended collecting data specifically designed to measure the impact of the payment adequacy minimum performance requirement (which we are finalizing at § 441.302(k)) on the HCBS provider network. The commenter suggested we collect data on:

- The number of providers employing direct care workers that opened or closed before and after the effective date of the minimum performance requirement;
- The number of beneficiaries (particularly those with higher needs) for whom providers started or discontinued service provision before and after the effective date of the minimum performance requirement;
- The number of health and safety waiver requests that were received before and after the effective date of the minimum performance requirement; and
- The causal factors service providers cite when closing their business before and after the rule becomes effective.

Response: As the reporting requirement proposed at § 441.311(e) was intended only to measure the percent of Medicaid rates going to direct care worker compensation, recommendations for data collection regarding provider behavior are outside of the scope of our proposal.

However, we note that there are already data collection requirements for some HCBS regarding the number of beneficiaries served through a section 1915(k) program (as required at § 441.580) or annual reporting on the projected number of beneficiaries who will be served under section 1915(i) (as required at § 441.745(a)(1)).

Additionally, we are finalizing other reporting requirements in this final rule that may speak to some of the commenter's concerns. Specifically, we note that we are finalizing a rate disclosure process (discussed in section II.C., particularly under § 447.203(c)), which will include identification of the number of Medicaid-paid claims and the number of Medicaid enrolled beneficiaries who received a service within a calendar year for certain services, including homemaker, home health aide, personal care, and habilitation services defined at § 440.180(b)(2) through (4) and (6). We also note that the reporting requirement finalized in the previous section of this rule (under § 441.311(d)) will require reporting on the following metrics related to beneficiary access to homemaker, home health aide, personal care, and habilitation services: the average amount of time from when services are initially approved to when services began, for individuals newly approved to begin receiving services within the past 12 months; and the percent of authorized hours for the services that are provided within the past 12 months. We note that these other reporting requirements, as finalized, will go into effect prior to the finalized effective date for the payment adequacy minimum performance requirement. This means that there will be data collected for these metrics both before and after the implementation of the payment adequacy requirement at § 441.302(k). Finally, we note that we do not know what the commenter is referring to by using the term, health and safety waiver requests.

Comment: Commenters responded to our request for comment on whether we should require States to report on median hourly wage and on compensation by category. A number of commenters supported adding this level of detail to the reporting requirement. Commenters noted that this level of reporting would help monitor workforce compensation generally, including identifying whether there were compensation disparities across service types. A few commenters also suggested this data would help track the impact of the payment adequacy minimum performance requirement (required at § 441.302(k)(3)) on workforce compensation. One commenter also suggested that this data could be helpful to the interested parties advisory group (discussed further in section II.C.2. of this rule, under § 447.203(b)(6)). A few commenters also recommended that we require collection of specific details on other provider expenditures, such as for travel, training, administrative expenses, or other non-compensation program expenses.

One commenter, however, noted that median hourly wage and compensation by category reporting could be duplicative of other measures and required reporting.

Response: We thank commenters for their thoughtful feedback. In the proposed rule, in addition to requesting comment on whether we should require reporting on median hourly wages, in a separate proposal (under § 447.203(b)(3)) we had proposed a payment rate disclosure process for HCBS that included providing information about the hourly Medicaid rates paid for homemaker, home health aide, and personal care services. The proposals under § 447.203(b)(3) were standalone reporting requirements unrelated to the reporting requirement at § 441.311(e). As discussed in section II.C. of this final rule, the payment rate disclosure process at § 447.203(b)(3) is being finalized with modifications to include habilitation services in the reporting requirement. We do not see a need to finalize an additional reporting process that may be duplicative of both data and burden.

Additionally, upon consideration of the comments, we have identified no compelling reason to require a Federal requirement for disaggregating the data by compensation category. We believe that employee benefits, in addition to wages, are also integral to direct care workers. (We refer readers to the discussion in section II.B.5. of this rule, which includes concerns raised by public commenters about the lack of benefits for direct care workers.) Additionally, the third component of compensation—employers' share of payroll taxes—is a fixed cost. While States may want to collect this disaggregated data from providers to observe local compensation trends or to

share with the interested parties advisory group, we are not adding a requirement for this disaggregation as part of the required State reporting at § 441.311(e).

Comment: In response to our request for comment, a few commenters recommended that we allow States to exclude from their reporting to CMS payments to providers of agency-directed services that have low Medicaid revenues or serve a small number of beneficiaries. We did not receive feedback on metrics for determining which providers would be eligible for such an exclusion, nor on possible caps or limits for an exclusion.

One commenter noted that excluding certain providers due to size, revenue, or geography would create further inequities in the HCBS field and be administratively infeasible to implement. A couple of commenters worried that excluding small providers would create perverse incentives for providers to remain small by failing to hire additional workers or declining to serve additional beneficiaries.

Response: We are concerned that excluding certain providers from the reporting requirement at § 441.311(e) would not support the goals of this requirement to promote transparency about how Medicaid payments are being allocated.

For clarity, we also note that the reporting requirement we proposed at § 441.311(e), and are finalizing at § 441.311(e)(2)(i), requires each State to report to CMS annually on the percentage of Medicaid payments for certain services that is spent on compensation for direct care workers. We intend that each State collect and report this data regardless of whether the State establishes, and their providers meet, the hardship exemption we are finalizing at § 441.302(k)(5) or the small provider requirements at § 441.302(k)(3)(ii) and (4). We do note that, under the requirements we are finalizing at § 441.302(k)(6), the State must report additional information regarding any small provider requirements or hardship exemptions the State develops and implements.

However, we are finalizing the reporting requirement at § 441.311(e) with modification, adding § 441.311(e)(4) to exclude data from Indian Health Service and Tribal health programs subject to the requirements at 25 U.S.C. 1641 from the required reporting. As discussed in section II.B.5.b. of this final rule, the requirements being finalized at § 441.302(k) conflict with statutory requirements at 25 U.S.C. 1641, and we are finalizing, at § 441.302(k)(7), an exemption to the payment adequacy requirement at § 441.302(k) for IHS and Tribal health programs subject to 25 U.S.C. 1641. Given the conflict between § 441.302(k) and the statutory requirements at 25 U.S.C. 1641, we would likely be unable to use HCBS payment adequacy data from IHS and the Tribal health programs subject to 25 U.S.C. 1641 to inform future policymaking related to how IHS or Tribal health programs spend Medicaid payments they receive, including on direct care worker compensation. Further, we do not want data from the exempted IHS and Tribal health programs to skew the other data States would collect and report to CMS under § 441.311(e), which CMS intends to use to evaluate direct care worker compensation nationally and inform policymaking to address the workforce shortage.

Comment: A few commenters suggested other metrics that could be used as the basis for an exception to the reporting requirement. One commenter suggested that an exception could be made for providers in areas (defined as a city, county, or grouping of zip codes) with a documented deficit of service providers accepting new clients. One commenter recommended that any provider who pays a full-time direct care worker at an hourly rate that exceeds 200 percent of the Federal poverty level be exempted from reporting. Another commenter suggested that if a provider can demonstrate they spend more than 85 percent of Medicaid payments on compensation should be exempted from any detailed cost reporting.

Response: As noted above, we are finalizing the reporting requirement without exceptions for providers. However, we appreciate the recommendations for possible exceptions criteria and will take these into consideration for future policymaking.

Comment: One commenter requested that we exclude self-directed services from reporting. However, we received a number of comments encouraging us to include self-directed services in the reporting as proposed and agreeing that these services should be reported separately. A few of these commenters stated that self-directed services should be reported separately from agency-provided services, due to the differences in these service models.

A few commenters, however, believed that the reporting for self-directed services should be further broken down by whether the service is provided by an independent worker or by a worker who is employed by an agency. One commenter noted that our rationale for separating out self-directed services was that compensation for workers in self-directed models tends to be higher and to comprise a greater percentage of Medicaid payment for services, which the commenter believed to be true of services delivered by independent providers, but not necessarily of self-directed services delivered through agency models.

One commenter noted that some States might have challenges in distinguishing payments for self-directed services delivered via agency models, as these payments may appear in claims processing as traditional HCBS agency payments, rather than as self-directed services.

Response: We agree with commenters that, in terms of the percent of the payment going to compensation for direct care workers, there will be significant differences between the percent for services delivered by independent workers hired by the beneficiary for whom the beneficiary sets the payment rate under a self-directed services delivery model versus those delivered by a worker employed by a provider. In particular, we are concerned that this reporting requirement might not yield meaningful data if applied to the self-directed services delivery models in which the individual beneficiary determines the wage paid directly to the direct care worker out of the beneficiary's service budget (such as models meeting the definition at § 441.545(b) for section 1915(k) services, self-directed services typically authorized under section 1915(j)). We believe the reporting requirement on the percentage of payments going to compensation for direct care workers is only appropriate when applied to a Medicaid rate that includes both compensation to direct care workers and administrative activities. In the former scenario, we expect that all or nearly all of that payment rate routinely is spent on the direct care worker's compensation; in the latter scenario, we expect the payment rate to a provider includes both the direct care worker's compensation and administrative costs for the provider.

Based on the comments received, and to ensure we are collecting only meaningful data that demonstrates the percent of Medicaid payments that are going to direct care worker compensation, we are finalizing a new requirement at § 441.311(e)(2)(ii) that specifies, if the State provides that homemaker, home health aide, personal care services, or habilitation services, as set forth at § 440.180(b)(2) through (4)

and (6), may be furnished under a self-directed services delivery model in which the beneficiary directing the services sets the direct care worker's payment rate, then the State must exclude such payment data from the reporting required in paragraph (e) of this section. We note that self-directed homemaker, home health aide, personal care, or habilitation services delivered through self-directed services models not described in § 441.311(e)(2)(ii) would still be part of the reporting requirements finalized at § 441.311(e)(2)(i).

After consideration of the comments received, we are finalizing § 441.311(e) with modifications. As discussed in section II.B.5. of this final rule, we are replicating at § 441.311(e)(1)(i), (1)(ii), and (1)(iii) the finalized definitions at § 441.302(k)(1)(i), (k)(1)(ii), and (k)(1)(iii), respectively.

At § 441.311, we are redesignating paragraph (e) as paragraph (e)(2)(i). At finalized § 441.311(e)(2)(i), we are making a technical modification to remove the reference to the definition of direct care workers at § 441.302(k)(1). As we are also adding the definition of direct care workers at § 441.311(e)(1)(ii), the reference to § 441.302(k)(1) is unnecessary. We are finalizing § 441.311(e)(2)(i) with substantive modifications to specify that the State must report to CMS annually on the percentage of total payments **(not including excluded costs)**, to include habilitation services (as set forth in § 440.180(b)(6)) in the reporting, and to specify that States must report separately **for** services **delivered in a provider-operated physical location for which** facility-**related costs are included in the payment rate**. (Revised text in bold font). We are also finalizing § 441.311(e)(2)(i) with technical modifications to: include references to § 441.311(e)(2)(ii) and (4); clarify that the provision applies to services as **set forth** in § 440.180(b)(2) through (4) and (6) (as opposed to services at § 440.180(b)(2) through (4) that are authorized under section 1915(c) of the Act); and clarify that reporting is at the time and in the form and manner specified by CMS.

We are finalizing a new requirement at § 441.311(e)(2)(ii) that specifies if the State provides that homemaker, home health aide, personal care services, or habilitation services, as set forth at § 440.180(b)(2) through (4) and (6), may be furnished under a self-directed services delivery model in which the beneficiary directing the services sets the direct care worker's payment rate, then the State must exclude such payment data from the reporting required in paragraph (e) of this section.

We are finalizing a new § 441.311(e)(3), requiring that the State must report, one year prior to the applicability date for paragraph (e)(2)(i) of this section, on its readiness to comply with the reporting requirement in paragraph (e)(2)(i) of this section.

We are finalizing a new § 441.311(e)(4) to require States to exclude data from the Indian Health Service and Tribal health programs subject to the requirements at 25 U.S.C. 1641 from the required reporting at § 441.311(e), as well as to require that States not require submission of data by, or include any data from, the Indian Health Service or Tribal health programs subject to the requirements at 25 U.S.C. 1641 for the State's reporting required under § 441.311(e)(2).

e. Applicability Date (§ 441.311(f))

We proposed at § 441.311(f)(1) to provide States with 3 years to implement the compliance reporting requirements at § 441.311(b), the HCBS Quality Measure Set reporting requirements at § 441.311(c), and the access reporting requirements at § 441.311(d) in FFS delivery systems following the effective date of the final rule. For States that implement a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and include HCBS in the MCO's, PIHP's, or PAHP's contract, we proposed to provide States until the first rating period for contracts with the MCO, PIHP, or PAHP, beginning on or after 3 years after the effective date of the final rule to implement these requirements. This time period was based on feedback from States and other interested parties that it could take 2 to 3 years to amend State regulations and work with their State legislatures, if needed, as well as to revise policies, operational processes, information systems, and contracts to support implementation of these proposed reporting requirements. We also considered all of the HCBS proposals outlined in the proposed rule as whole. We invited comments on whether this timeframe was sufficient, whether we should require a shorter timeframe (2 years) or longer timeframe (4 years) to implement these provisions, and if an alternate timeframe was recommended, the rationale for that alternate timeframe.

In addition, we proposed at § 441.311(f)(2) to provide States with 4 years to implement the payment adequacy reporting requirements at § 441.311(e) in FFS delivery systems following the effective date of the final rule. For States that implement a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and include HCBS in the MCO's, PIHP's, or PAHP's contract, we proposed to provide States until the first rating period for contracts with the MCO, PIHP, or PAHP beginning on or after 4 years after the effective date of the final rule to implement these requirements. This time period was intended to align with the effective date for the HCBS payment adequacy requirements at § 441.302(k), which are discussed in section II.B.5. of this preamble. It was also based on feedback from States and other interested parties that it could take 3 to 4 years to amend State regulations and work with their State legislatures, if needed, as well as to revise policies, operational processes, information systems, and contracts to support implementation of these reporting requirements. We also considered all of the HCBS proposals outlined in the proposed rule as a whole. We solicited comments on whether this timeframe was sufficient, whether we should require a shorter timeframe (3 years) or longer timeframe (5 years) to implement these provisions, and if an alternate timeframe is recommended, the rationale for that alternate timeframe.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the effective dates in § 441.311(f). One commenter noted that the effective dates appear to be appropriate and necessary to ensure that data is reported accurately and uniformly. One commenter suggested that States should begin to report on person-centered planning within 2 years. One commenter noted particular support for the longer four-year timeframe for the payment adequacy reporting requirements at § 441.311(e), which the commenter noted recognized the additional complexity of this provision. A few commenters stated that they support the 4-year effective date for § 441.311(e) but would advocate for a 6-year effective date if the payment adequacy minimum performance level in § 441.302(k) is also being finalized.

A number of commenters noted that while they are supportive of each of these proposals individually, they were nevertheless concerned that the number of new requirements will be difficult to implement cost-effectively and accurately in the proposed timeframes. Several commenters noted that proposed data elements required in § 441.311 are beyond what the States

currently collect and—even if the States are able to expand on existing systems—will require policy and process changes and system updates and will place strain on existing staff resources; some commenters stated these changes may require seeking appropriations from State legislatures for additional staff or system upgrades, as well as acquiring vendor support, which could take additional time. A few commenters noted their States would face challenges in coordinating data collection across multiple systems, which may be administered by different agencies or contracted entities. A few commenters noted the feasibility of compliance with § 441.311 will depend on how quickly CMS can provide subregulatory guidance on the reporting requirements; these commenters requested that we set an effective date of 3 or 4 years after the release of subregulatory guidance.

While commenters requested that we extend the timeframes in § 441.311(f), we received few suggestions for how much additional time would be needed. A few commenters suggested alternative timeframes of 4 to 6 years for the provisions in § 441.311. One commenter suggested that timeframes should be specifically waived for self-directed services and that States should be required to submit transition plans for implementing the requirements for self-directed services.

Response: We are finalizing the substance of § 441.311(f) as proposed, but with minor modifications to correct erroneous uses of the word ''effective.'' We are retitling the requirement at § 441.311(f) as Applicability dates (rather than Effective dates). We are also modifying the language at § 441.311(f) to specify the dates when States must comply with the requirements in § 441.311(f), rather than stating the dates when the requirements in § 441.311(f) are effective, beginning a specified number of years after the effective date of the final rule.

As noted above in section II.B.7.b. of the rule, we have determined it is necessary to provide States with an additional year for compliance with the quality measure set reporting requirement at § 441.311(c). Our primary purpose in extending the date for States to comply is to ensure States have sufficient time for interested parties to provide input into the measures, as required by § 441.312(g), which we are finalizing in section II.B.8. of this rule.

Regarding the dates for States to comply with the other requirements in § 441.311, as discussed throughout this section, we continue to believe that many of these requirements build on activities that States have already been doing as part of the administration of their HCBS programs and will work with States to identify ways to leverage existing data collection tools and update their current systems as efficiently as possible.

We also acknowledge that complying with these reporting requirements will necessitate expenditures of resources and time on the part of States, managed care plans, and (in some cases) providers. We believe that the value of the data collected through their efforts makes this expenditure of resources worthwhile. This data captures information related to beneficiaries' health and safety (addressed by the incident management system and critical incident reporting in § 441.311(b)(1) and (2)) and beneficiaries' long-standing concerns about access to HCBS waivers and services (addressed by the person-centered planning and access reporting requirements in § 441.311(b)(3) and (d)). These data are urgently needed, and we do not want to postpone implementation of this reporting further than proposed.

Additionally, the data collected as part of the payment adequacy reporting requirement in § 441.311(e) not only addresses the current workforce shortages that are impacting service delivery, but the data are also going to be relied on by the interested parties advisory group (discussed further in section II.C.2. of this rule, under § 447.203(b)(6)) to develop recommendations to the State on Medicaid rates for certain HCBS. We do not believe the interests of beneficiaries, providers, workers, or States are served by delaying the collection and publication of this information. As a result, we are declining to make changes in this final rule based on these comments. We plan to provide technical assistance to States experiencing challenges implementing specific reporting requirements.

Comment: A few commenters, while not opposing the proposed dates that the reporting requirements become effective, noted that it is important to align these reporting requirements with other reporting requirements in States and for managed care plans to minimize State and managed care plan reporting burdens. Commenters also believed that streamlining reporting requirements across programs could help to ensure that States and CMS do not analyze similar data that report on the same populations and same or similar programs across different timeframes, which would complicate findings.

Response: We will be releasing subregulatory guidance, including technical specifications for the new reporting requirements in this final rule, and making the required reporting templates available for public comment through the Paperwork Reduction Act notice and comment process. Specific reporting due dates will be determined through subregulatory guidance; we plan to work with States to align these due dates with other obligations to minimize administrative burden to the greatest extent possible.

After consideration of public comments, we are finalizing § 441.311(f) with minor modifications to correct erroneous uses of the word ''effective.'' We are removing from § 441.311(f)(1) the date for States to comply with the quality measure set reporting requirements date and adding it to § 441.311(f)(2) so that States will have 4 years from the effective date of this final rule to comply with those requirements.

We are also finalizing in § 441.311(f)(1) and (2) a modification to the language pertaining to managed care delivery systems to improve accuracy and alignment with common phrasing in managed care contracting policy. We are specifying at § 441.311(f)(1) that States must comply with the reporting requirements at paragraphs (b) and (d) of this section beginning 3 years after the effective date of this final rule; and in the case of a State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes HCBS in the MCO's, PIHP's, or PAHP's contract, the first rating period for contracts with the MCO, PIHP, or PAHP beginning on or after the date that is 3 years after the effective date of this final rule.

We are specifying at § 441.311(f)(2) that States must comply with the reporting requirements at paragraphs (c) and (e) of this section beginning 4 years after the effective date of this final rule; and in the case of a State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes HCBS in the MCO's, PIHP's, or PAHP's contract, the first rating period for contracts with the MCO, PIHP or PAHP beginning on or after the date that is 4 years after the effective date of this final rule.

f. Application to Other Authorities (§§ 441.311(f), 441.474(c), 441.580(i), and 441.745(a)(1)(iii))

At § 441.311(f), we proposed to apply all of the reporting requirements described in § 441.311 to services delivered under FFS and managed care

delivery systems. As discussed earlier in section II.B.1. of this preamble, section 2402(a)(3)(A) of the Affordable Care Act requires States to improve coordination among, and the regulation of, all providers of Federally and State-funded HCBS programs to achieve a more consistent administration of policies and procedures across HCBS programs, and as noted in the Medicaid context this would include consistent administration between FFS and managed care programs. We accordingly proposed to specify that a State must ensure compliance with the requirements in § 441.302(a)(6) with respect to HCBS delivered both under FFS and managed care delivery systems.

As discussed earlier in section II.B.1. of this preamble, the proposed requirements at § 441.311, in combination with other proposed requirements identified throughout the proposed rule, are intended to supersede and fully replace the reporting expectations and the minimum 86 percent performance level for State's performance measures described in the 2014 guidance, also discussed earlier in section II.B.1. of this preamble. We expect that States may implement some of the requirements proposed in the proposed rule in advance of any effective date. We will work with States to phase out the 2014 guidance as they implement the requirements in this final rule to reduce unnecessary burden and to avoid duplicative or conflicting reporting requirements.

In accordance with the requirement of section 2402(a)(3)(A) of the Affordable Care Act for States to achieve a more consistent administration of policies and procedures across HCBS programs, and because these reporting requirements are relevant to other HCBS authorities, we proposed to include these requirements within the applicable regulatory sections for other HCBS authorities. Specifically, we proposed to apply the requirements at § 441.311 to section 1915(j), (k), and (i) State plan services at §§ 441.474(c), 441.580(i), and 441.745(a)(1)(vii), respectively. Consistent with our proposal for section 1915(c) waivers, we proposed these requirements based on our authority under section 1902(a)(6) of the Act, which requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports. We believed the same arguments for these requirements for section 1915(c) waivers are equally applicable for these other HCBS authorities. We requested comment on the application of these provisions across section 1915(i), (j), and (k) authorities. To accommodate the addition of new language at § 441.580(i), we proposed to renumber existing § 441.580(i) as § 441.580(j).

We considered whether to also apply these reporting requirements to section 1905(a) ''medical assistance'' State plan personal care, home health, and case management services. However, we proposed that these requirements not apply to any section 1905(a) State plan services based on State feedback that they do not have the same data collection and reporting capabilities in place for section 1905(a) services as they do for sections 1915(c), (i), (j), and (k) services and because the person-centered planning, service plan, and waiting list requirements that comprise a significant portion of these reporting requirements have little to no relevance for section 1905(a) services, in comparison to section 1915(c), (i), (j), and (k) services. Further, the vast majority of HCBS is delivered under section 1915(c), (i), (j), and (k) authorities, while only a small percentage of HCBS nationally is delivered under section 1905(a) State plan authority. We requested comment on whether we should establish similar reporting requirements for section 1905(a) ''medical assistance'' State plan personal care, home health, and case management services.

We noted that we expected that we would establish new processes and forms for States to meet the reporting requirements, provide additional technical information on how States can meet the reporting requirements including related to sampling requirements (where States are permitted to report on a sample of beneficiaries rather than on all individuals who meet the inclusion criteria for the reporting requirement), and amend existing templates and establish new templates under the Paperwork Reduction Act.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported applying the proposed reporting requirements at § 441.311 to services delivered under managed care, noting that it is important to gather data on services across delivery systems. A few commenters requested clarification on whether, or how, the reporting requirements applied to services delivered under managed care.

Response: The reporting requirements in this section apply to services in both FFS and managed care delivery systems. We note that comments about the application of specific provisions to managed care are addressed in the sections above. As needed, we plan to provide technical assistance to States that have additional questions.

Comment: A few commenters expressed support for applying reporting requirements at § 441.311 to services delivered through other section 1915 authorities. A few commenters, while not necessarily recommending that we exclude self-directed services authorized under section 1915(j), noted that because of differences in self-directed services, we should consider extending timeframes for implementation in self-directed services or release additional guidance specific to self-directed services.

Response: We are finalizing our proposal to extend the reporting requirements in this section to services offered under sections 1915(i), (j), and (k). We note that comments about the application of specific provisions to self-directed care are addressed in the sections above. While we do not believe it is necessary to extend timeframes for the implementation of the reporting requirements in section 1915(j) self-directed services, we plan to provide technical assistance to States that have additional questions.

Comment: One commenter requested clarification that the waiver reporting requirement at § 441.311(d)(1) is limited to the section 1915(c) authority and to the section 1915(j) authority, where it is used as the State's authority for self-direction in a section 1915(c) waiver. This commenter recommended limiting this requirement to these authorities.

Response: We agree that, because section 1915(i) and section 1915(k) State plan services cannot have capped enrollment, the reporting requirements at § 441.311(d)(1) would not apply to these authorities. We also agree that the reporting requirements at § 441.311(d)(1) would also apply to section 1915(j) authority only where section 1915(j) is used as the State's authority for self-direction in a section 1915(c) waiver. We note that the reporting requirements at § 441.311(d)(1) would apply to section 1115(a) demonstration projects that include HCBS if the State caps enrollment for the HCBS under the section 1115(a) demonstration project.

We also note that, similar to the concern raised by commenters about the applicability of § 441.311(d)(1), as discussed in section II.B.7.a.4. of this

rule, § 441.311(b)(4) also applies only to section 1915(c) programs.

Comment: A few commenters requested that we extend the reporting requirements at § 441.311 to section 1905(a) services. Commenters noted that, in some States, many people receive services through section 1905(a). A few commenters also raised concerns that there would be a disparate impact on certain populations or less oversight of certain services if reporting requirements were not extended to services under section 1905(a), such as personal care, home health, or rehabilitative services. A few commenters recommended not extending the reporting requirements to section 1905(a) services at this time, citing concerns about additional burden.

Response: At this time, we are not mandating inclusion of section 1905(a) services in the reporting requirements at § 441.311. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider these comments provided on the proposed rule to help inform any future rulemaking in this area, as appropriate. We are not persuaded by the argument that including section 1905(a) services would simply be too much work, as we do agree that transparency, accountability, and oversight are critical for all HCBS. However, we are continuing to review statutory and regulatory differences between services authorized under sections 1905(a) and 1915 of the Act that could impact how these requirements would apply to section 1905(a) services. We also note that we have not extended the minimum performance requirements for incident management, person-centered planning, or payment adequacy to section 1905(a) services (refer to discussions in sections II.B.1., II.B.3, and II.B.5. of this final rule, respectively, for more detail on those discussions). Furthermore, as section 1905(a) service do not have waiting lists, the requirement at § 441.311(d)(1) would not be applicable to these services.

After consideration of the comments received, we are finalizing application of § 441.311 to section 1915(j), (k), and (i) authorities. We are making modifications at §§ 441.474(c), 441.580(i) and 441.745(a)(1)(vii) with modifications to clarify that the references to section 1915(c) of the Act are instead references to section 1915(j), (k) and (i) of the Act, respectively.

g. Summary of Finalized Requirements

After consideration of the public comments, we are finalizing the requirements at § 441.311 as follows:

- We are finalizing § 441.311(a) with a modification for clarity to remove ''simplification'' and make a minor formatting change to ensure § 441.311(a) aligns directly with the statutory requirement at section 1902(a)(19) of the Act .
- We are finalizing the incident management system compliance requirement at § 441.311(b) with a technical modification for clarity in § 441.311(b)(1)(i) that the State must report on the results of an incident management system assessment, every 24 months, in the form and manner, and at a time, specified by CMS, rather than according to the format and specifications provided by CMS.
- We are finalizing the critical incident compliance requirement at § 441.311(b)(2) with a technical modification for clarity that the State must report to CMS annually in the form and manner, and at a time, specified by CMS, rather than according to the format and specifications provided by CMS. For consistency, we are also simplifying the title and removing the reference to § 441.302(a)(6)(i)(A) from the title of § 441.311(b)(2).
- We are finalizing the person-centered planning reporting requirement at § 441.311(b)(3) with a technical modification to specify at § 441.311(b)(3), to demonstrate that the State meets the requirements at § 441.301(c)(3)(ii) regarding person-centered planning (as described in § 441.301(c)(1) through (3)), the State must report to CMS annually on the following, in the form and manner, and at a time, specified by CMS, rather than according to the format and specifications provided by CMS. We are also finalizing the reporting requirement at § 441.311(b)(3)(i) and (ii), with the technical modification noted previously, to specify that the State may report this metric using statistically valid random sampling of beneficiaries.
- We are finalizing the reporting requirement at § 441.311(b)(4) with a modification to restore language that was erroneously omitted, and with additional technical modifications so that § 441.311(b)(4) specifies that annually, the State will provide CMS with information on the waiver's impact on the type, amount, and cost of services provided under the State plan, in the form and manner, and at a time, specified by CMS.
- We are finalizing the HCBS Quality Measure Set reporting requirements at § 441.311(c) with modifications. At § 441.311(c), we are finalizing a date of 4 years, rather than 3 years, for States to comply with the HCBS Quality Measure Set reporting requirements at § 441.311(c).
- We are finalizing the access reporting requirement at § 441.311(d) with a technical modification to specify that reporting will be in the form and manner, and at a time, specified by CMS. We are finalizing § 441.311(d)(1) as proposed. We are finalizing § 441.311(d)(2)(i) with a modification to specify that the reporting is for individuals newly receiving services within the past 12 months, rather than for individuals newly approved to begin receiving services. We are finalizing the requirements at § 441.311(d)(2), with modifications so that both reporting requirements at § 441.311(d)(2)(i) and (ii) require reporting on homemaker services, home health aide services, personal care, or habilitation services, as set forth in § 440.180(b)(2) through (4) and (6), and allow States to report using statistically valid random sampling of beneficiaries. We are modifying the title of this provision at § 441.311(d)(2) to specify *Access to homemaker, home health aide, personal care, and habilitation services.* We are also finalizing a technical modification in both § 441.311(d)(2)(i) and (ii) to indicate that the services are, as set forth in § 440.180(b)(2) through (4) and (6), rather than, as listed in, as noted in the proposed rule.
- We are replicating at § 441.311(e)(1)(i) through (iii) the finalized definitions at § 441.302(k)(1)(i), through (iii), respectively.
- We are redesignating § 441.311(e) as § 441.311(e)(2)(i) and finalizing § 441.311(e)(2)(i) with modifications to specify that, except as provided at (e)(2)(ii) and (4), the State must report to CMS annually on the total percentage of payments (not including excluded costs) for furnishing homemaker services, home health aide services, personal care, and habilitation services, as set forth in § 440.180(b)(2) through (4) and (6), that is spent on compensation for direct care workers, at the time and in the form and manner specified by CMS. The State must report separately for each service and, within each service, must separately report services that are self-directed and services delivered in a provider-operated physical location for which facility-related costs are included in the payment rate.

• We are finalizing a new requirement at § 441.311(e)(2)(ii) that specifies if the State provides that homemaker, home health aide, personal care services, or habilitation services, as set forth at § 440.180(b)(2) through (4) and (6), may be furnished under a self-directed services delivery model in which the beneficiary directing the services sets the direct care worker's payment rate, then the State must exclude such payment data from the reporting required in paragraph (e) of this section.

• We are finalizing a new § 441.311(e)(3), requiring that the State must report, 1 year prior to the applicability date for paragraph (e)(2)(i) of this section, on its readiness to comply with the reporting requirement in paragraph (e)(2)(i) of this section.

• We are finalizing a new § 441.311(e)(4) to require States to exclude the Indian Health Service and Tribal health programs subject to the requirements at 25 U.S.C. 1641 from the reporting required in paragraph (e) of this section, and not require submission of data by, or include any data from, the Indian Health Service or Tribal health programs subject to the requirements at 25 U.S.C. 1641 for the State's reporting required under paragraph (e)(2).

• We are finalizing § 441.311(f) with modification to move the date that States are required to comply with the quality measure reporting at § 441.311(c) from § 441.311(f)(1) to § 441.311(f)(2), and to clarify the language regarding applicability dates in the case of a State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes HCBS in the MCO's, PIHP's, or PAHP's contract.

• We are finalizing §§ 441.474(c), 441.580(i), and 441.745(a)(1)(vii) with modifications to clarify that the references to section 1915(c) of the Act are instead references to section 1915(j), (k), and (i) of the Act, respectively.

8. Home and Community-Based Services (HCBS) Quality Measure Set (§§ 441.312, 441.474(c), 441.585(d), and 441.745(b)(1)(v)).

On July 21, 2022, we issued State Medicaid Director Letter #22–003 [132] to release the first official version of the HCBS Quality Measure Set. The HCBS Quality Measure Set is a set of nationally standardized quality measures for Medicaid-covered HCBS. It is intended to promote more common and consistent use within and across States of nationally standardized quality measures in HCBS programs, create opportunities for CMS and States to have comparative quality data on HCBS programs, drive improvement in quality of care and outcomes for people receiving HCBS, and support States' efforts to promote equity in their HCBS programs. It is also intended to reduce some of the burden that States and other interested parties may experience in identifying and using HCBS quality measures. By providing States and other interested parties with a set of nationally standardized measures to assess HCBS quality and outcomes and by facilitating access to information on those measures, we believe that we can reduce the time and resources that States and other interested parties expend on identifying, assessing, and implementing measures for use in HCBS programs.

a. Basis and Scope (§ 441.312(a))

Section 1102(a) of the Act provides the Secretary of HHS with authority to make and publish rules and regulations that are necessary for the efficient administration of the Medicaid program. Section 1902(a)(6) of the Act requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports. Under our authority at sections 1102(a) and 1902(a)(6) of the Act, we proposed a new section, at § 441.312, Home and Community-Based Services Quality Measure Set, to require use of the HCBS Quality Measure Set in section 1915(c) waiver programs and promote public transparency related to the administration of Medicaid-covered HCBS. We proposed to describe the basis and scope for this requirement at § 441.312(a).

In proposing this requirement, we believed that quality is a critical component of efficiency, and as such, having a standardized set of measures used to assess the quality of Medicaid HCBS programs supports the efficient operation of the Medicaid program. Further, we believed that it is necessary for the efficient administration of Medicaid-covered HCBS authorized under section 1915(c) of the Act, consistent with section 1902(a)(4) of the Act, as it would establish a process through which we regularly update and maintain the required set of measures at § 441.311(c) in consultation with States and other interested parties (as described later in this section of the rule). The process, as proposed, would ensure that the priorities of interested parties are reflected in the selection of the measures included in the HCBS Quality Measure Set. The process, as proposed, also would ensure that the required set of HCBS quality measures is updated to address gaps in the HCBS Quality Measure Set as new measures are developed and to remove measures that are less relevant or add less value than other available measures, and the HCBS quality measures meets scientific and other standards for quality measures. Due to the constantly evolving field of HCBS quality measurement, we proposed these requirements based on our belief that the failure to establish such a process would result in ongoing reporting by States of measures that do not reflect the priorities of interested parties, measures that offer limited value compared to other measures, and measures that do not meet strong scientific and other standards. It would also result in a lack of reporting on key measurement priority areas, which could be addressed by updating the HCBS Quality Measure Set as new measures are developed. The failure to establish such a process would lead to inefficiency in States' HCBS quality measurement activities through the continued reporting on an outdated set of measures. In other words, we believed that such a process is necessary for the efficient administration of Medicaid-covered HCBS by ensuring that quality measure reporting requirements are focused on the most valuable, useful, and scientifically supported areas of quality measurement, and that quality measures with limited value are removed timely from quality measure reporting requirements.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposed basis and scope at § 441.312(a). Several commenters supported the requirements at § 441.312 (a) in its entirety.

Response: We thank the commenters for their support for our proposal.

Comment: A few commenters raised concerns that the HCBS Quality Measure Set is overly prescriptive from a Federal perspective and sets a one-size-fits-all approach, expressing that the responsibility for safeguarding quality in HCBS belong to each State.

Response: We disagree with commenters that the proposed requirement for States to use the HCBS Quality Measure Set is overly

[132] CMS State Medicaid Director Letter. SMD# 22–003 Home and Community-Based Services Quality Measure Set. July 2022. Accessed at *https://www.medicaid.gov/federal-policy-guidance/downloads/smd22003.pdf.*

prescriptive. CMS and States have worked for decades to support the increased availability and provision of high-quality HCBS for Medicaid beneficiaries. While there are quality and reporting requirements for Medicaid HCBS, the requirements vary across authorities and are often inadequate to provide the necessary information for ensuring that HCBS are provided in a high-quality manner that best protects the health and welfare of beneficiaries. Consequently, quality measurement and reporting expectations are not consistent across services, and instead vary depending on the authorities under which States are delivering services. While we support State flexibility, the lack of standardized measures has resulted in thousands of metrics and measures currently in use across States, with different metrics and measures often used for different HCBS programs within the same State. As a result, CMS and States are limited in the ability to compare HCBS quality and outcomes within and across States or to compare the performance of HCBS programs for different Medicaid beneficiary populations. We underscore our belief that use of the HCBS Quality Measure Set will promote more common and consistent use within and across States of nationally standardized quality measures in HCBS programs, create opportunities for CMS and States to have comparative quality data on HCBS programs, drive improvement in quality of care and outcomes for people receiving HCBS, and support States' efforts to promote equity in their HCBS programs. As discussed further in this section II.B.8. of this rule, we are finalizing the requirements at § 441.312(a) as proposed and plan to provide technical assistance to States as needed to address the concerns raised by commenters.

Comment: Several commenters requested that CMS align the HCBS quality measures universally across Medicaid programs, recommending streamlining measures across the HCBS Quality Measure Set, the Medicaid and CHIP (MAC) Quality Rating System (QRS), and the Adult Core Set. Further, commenters recommended we consider a minimum set of mandatory quality measures and limit them to a small set, similar to the MAC QRS, and allow States the flexibility to utilize voluntary measures in addition to the minimum mandatory measures, as appropriate. Commenters further noted that States already have implemented measures that may not be included in the quality measures identified in the HCBS Quality Measure Set, and this approach for a small set of mandatory measures could minimize disruption to the quality-related work that is currently being undertaken by States in their Medicaid programs.

One commenter observed that creating a unified reporting structure on mandatory measures would bring a level of discipline and consistency that would foster more reliable data across the Medicaid program, noting that it is imperative to create alignment for data collection across States.

Response: We thank the commenters for this feedback. We will take these comments into consideration when developing and updating the HCBS Quality Measure Set and developing subregulatory guidance on the required use of the HCBS Quality Measure Set. We agree with the commenters on the importance of parsimony, alignment, and harmonization in quality measurement across the Medicaid program, to the extent possible. While we aim to align measures across programs as much as possible, the HCBS Quality Measure Set is designed to promote more common and consistent use of nationally standardized quality measures in HCBS programs and to support States with improving quality and outcomes specifically for beneficiaries receiving HCBS. As a result, we expect the HCBS Quality Measure Set to be in alignment with the MAC QRS and the Child and Adult Core Sets.

We also acknowledge that States are already using quality measures to assess quality in their HCBS programs, and it is not our intent for States to abandon this quality-related work. The measure set is intended to reduce some of the burden that States and other interested parties may experience in identifying and using HCBS quality measures. However, States may continue to utilize existing measures not found in the HCBS Quality Measure Set if the States believe they generate valuable information, as long as the measures in the HCBS Quality Measures Set are implemented in accordance with § 441.312, which we are finalizing as discussed further in this section II.B.8. of this rule.

After consideration of the comments received, we are finalizing § 441.312(a) with a minor formatting change to correct punctuation.

b. Definitions (§ 441.312(b))

We proposed a definition at § 441.312(b)(1) for ''Attribution rules,'' to mean the process States use to assign beneficiaries to a specific health care program or delivery system for the purpose of calculating the measures in the HCBS Quality Measure Set as described at § 441.312(d)(6). We also proposed a definition at § 441.312(b)(2) for ''Home and Community-Based Services Quality Measure Set'' to mean the Home and Community-Based Services Quality Measures for Medicaid established and updated at least every other year by the Secretary through a process that allows for public input and comments, including through the **Federal Register**.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters generally supported the proposed definitions at § 441.312(b).

Response: We thank these commenters for their support.

After consideration of the comments received, we are finalizing at § 441.312(b)(1) the definition of attribution rules as proposed. As discussed in more detail in our discussion of § 441.312(c) in the next section below (section B.8.c. of this rule), we are making several changes related to the frequency of updates to the HCBS Quality Measure Set. To accommodate those changes, we are striking the words, at least every other year, from the definition of the Home and Community-Based Services Quality Measure Set we proposed at § 441.312(b)(2).

As finalized at § 441.312(b)(2) the definition of Home and Community-Based Services Quality Measure Set means the Home and Community-Based Services Quality Measures for Medicaid established and updated by the Secretary through a process that allows for public input and comment, including through the **Federal Register**, as described in paragraph (d) of this section. We note that the measure updates are specified in § 441.312(c) as finalized, and thus the frequency of updates do not need to be set forth in the definition of the HCBS Quality Measure Set. *Additionally, we are finalizing* § 441.312(b) with a minor technical modification to correct an inadvertent omission in the regulatory text in the proposed rule and are finalizing the addition of the numbers (1) and (2) in front of each definition.

c. Responsibilities of the Secretary (§ 441.312(c))

At § 441.312(c), we described the proposed general process for the HCBS Quality Measure Set that the Secretary will follow to update and maintain the HCBS Quality Measure Set. Specifically, at § 441.312(c)(1), we proposed that the Secretary will identify, and update at

least every other year, through a process that allows for public input and comment, the quality measures to be included in the HCBS Quality Measure Set. At § 441.312(c)(2), we proposed that the Secretary will solicit comment at least every other year with States and other interested parties, which we identified later in this section of the preamble of the proposed rule, to:

- Establish priorities for the development and advancement of the HCBS Quality Measure Set.
- Identify newly developed or other measures that should be added, including to address gaps in the measures included in the HCBS Quality Measure Set.
- Identify measures that should be removed as they no longer strengthen the HCBS Quality Measure Set.
- Ensure that all measures included in the HCBS Quality Measure Set are evidence-based, are meaningful for States, and are feasible for State-level and program-level reporting as appropriate.

The proposed frequency for updating the quality measures included in the HCBS Quality Measure Set was aligned with the proposed frequency at § 441.311(c)(1) for States' reporting of the measures in the HCBS Quality Measure Set. We based other aspects of the proposed process that the Secretary will follow to update and maintain the HCBS Quality Measure Set in part on the processes for the Secretary to update and maintain the Child, Adult, and Health Home Core Sets as described in the Medicaid Program and CHIP; Mandatory Medicaid and Children's Health Insurance Program (CHIP) Core Set Reporting final rule (88 FR 60278); (hereinafter the ''Mandatory Medicaid and CHIP Core Set Reporting final rule''). We believed that such alignment in processes will ensure consistency and promote efficiency for both CMS and States across Medicaid quality measurement and reporting activities.

At § 441.312(c)(3), we proposed that the Secretary will, in consultation with States and other interested parties, develop and update the measures in the HCBS Quality Measure Set, at least every other year, through a process that allows for public input and comment. We solicited comments on whether the timeframes for updating the measures in the HCBS Quality Measure Set and conducting the process for developing and updating the HCBS Quality Measure Set is sufficient, whether we should conduct these activities more frequently (every year) or less frequently (every 3 years), and if an alternate timeframe was recommended, the rationale for that alternate timeframe.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed support for our proposal at § 441.312(c)(1) to identify and update the quality measures included in the HCBS Quality Measure Set at least every other year, through a process that allows for public input and comment. One commenter noted that identifying and updating the measures annually, instead of every other year, could maximize the effectiveness of the HCBS Quality Measure Set, especially with a new and rapidly evolving field of HCBS measures, suggesting that an every other year frequency might impact the use of innovative approaches to inform quality improvement in HCBS. Alternatively, several commenters expressed concern and recommended less frequent updates to the HCBS Quality Measure Set, questioning the usefulness of the measures that change every other year and suggesting that taking a longer time between updates to the HCBS Quality Measure Set will minimize financial burden and allow States to more accurately measure improvement over time. In the same vein, one commenter expressed that every other year updates to the measure set might have an effect and impact the usefulness of longitudinal data. These commenters suggested alternative timeframes ranging from 3 to 5 years, with 3 years being the most frequently suggested frequency for updates to the HCBS Quality Measure Set.

Response: We thank commenters for their feedback. In consideration of comments received, we agree that clarification of the frequency in updates to the HCBS Quality Measure Set is required. We note that the proposed process for updating the quality measures included in the Quality Measure Set differs in frequency from, though is based in part on, the processes for the Secretary to update and maintain the Child, Adult, and Health Home Core Sets as described in the final rule, ''Medicaid Program and CHIP; Mandatory Medicaid and Children's Health Insurance Program (CHIP) Core Set Reporting'' (88 FR 60278) (hereinafter the ''Mandatory Medicaid and CHIP Core Set Reporting final rule''). We proposed a frequency for updating the quality measures included in the HCBS Quality Measure Set, which is different from the mandatory annual State reporting of the Core Set measures in the Mandatory Medicaid and CHIP Core Set Reporting final rule, because the HCBS Quality Measure Set was only first released for voluntary use by States in July 2022, while Child, Adult, and Health Home Core Sets voluntary reporting has been in place for a number of years. Further, a substantial portion of the measures included in the HCBS Quality Measure Set, particularly compared to the Child, Adult, and Health Home Core Sets, is derived from beneficiary experience of care surveys, which are costlier to implement than other types of measures. We recognize that States may need to make enhancements to their data and information systems or incur other costs in implementing the HCBS Quality Measure Set. Upon further consideration, we assure States that CMS will not update the measure set to add new measures or retire existing measures more frequently than every other year, and are modifying the beginning date as no later than December 31, 2026, instead of 2025. We note that, while the finalized requirement will allow CMS to add new measures or retire existing measures every other year, CMS intends to retain each of the measures in the measure set for at least 5 years to ensure the availability of longitudinal data, unless there are serious issues associated with the measures (such as related to measure reliability or validity) or States' use of the measures (such as excessive cost of State data collection and reporting or insurmountable technical issues with State reporting on the measures).

After consideration of the comments received about the frequency of updating the quality measures in § 441.312(c)(1), we are finalizing § 441.312(c)(1) with modifications to require that the Secretary shall identify and update **quality measures no more frequently than** every other year, beginning no later than December 31, 202**6,** the quality measures to be included in the Home and Community-Based Services Quality Measure Set as defined in paragraph (b) of this section). (New language identified in bold.)

We are also finalizing a new requirement at § 441.312(c)(2) to require the Secretary to **make** technical updates and corrections to the Home and Community-Based Services Quality Measure Set annually as appropriate. This addition is intended to ensure that the measures included in the measure set are accurate and up to date, and that we may correct errors, clarify information related to the measures, and align with updated technical specifications of measure stewards, particularly given the revision to § 441.312(c)(2) to indicate that CMS will not update the HCBS Quality Measure Set more frequently than every other

year. To accommodate the new requirement at § 441.312(c)(2), we have renumbered the provisions proposed at §§ 441.312(c)(2) and (3) to §§ 441.312(c)(3) and (4), respectively.

We are finalizing redesignated § 441.312(c)(3)(iv) with a minor technical modification for clarity to specify that the Secretary shall ensure that all measures included in the Home and Community-Based Services Quality Measure Set reflect an evidence-based process including testing, validation, and consensus among interested parties; are meaningful for States; and are feasible for State-level, program-level, or provider-level reporting as appropriate. We are also finalizing the redesignated requirement at § 441.312(c)(4) with a modification to replace the words, at least, with the words, no more frequently than, to require that the Secretary, in consultation with States, develop and update, no more frequently than every other year, the Home and Community-Based Services Quality Measure Set using a process that allows for public input and comment as described in paragraph (d) of this section.

As noted in the proposed rule, in Medicaid, enhanced FFP is available at a 90 percent FMAP for the design, development, or installation of improvements of mechanized claims processing and information retrieval systems, in accordance with applicable Federal requirements.[133] Enhanced FFP at a 75 percent FMAP is also available for operations of such systems, in accordance with applicable Federal requirements.[134] However, we reiterate that receipt of these enhanced funds is conditioned upon States meeting a series of standards and conditions to ensure investments are efficient and effective.[135] We clarify, to receive enhanced FMAP funds, the State Medicaid agency is required at § 433.112(b)(12) to ensure the alignment with, and incorporation of, standards and implementation specifications for health information technology adopted by the Office of the National Coordinator for Health IT in 45 CFR part 170, subpart B, among other requirements set forth in § 433.112(b)(12). States should also consider adopting relevant standards identified in the Interoperability Standards Advisory (ISA) [136] to bolster improvements in the identification and reporting on the prevalence of critical incidents for HCBS beneficiaries and present opportunities for the State to develop improved information systems that can support quality improvement activities that can help promote the health and safety of HCBS beneficiaries.

We plan to provide States with technical assistance and subregulatory guidance to support implementation of the HCBS Quality Measure Set.

After consideration of the comments received, we are finalizing § 441.312(c) with modifications. We are finalizing § 441.312(c)(1) with modifications to require that the Secretary shall identify, and update no more frequently than every other year, beginning no later than **December 31, 2026**, the quality measures to be included in the Home and Community-Based Services Quality Measure Set as defined in paragraph (b) of this section. (New language identified in bold.)

We are finalizing § 441.312(c)(2) without substantive changes, but we are redesignating the requirement as § 441.312(c)(3). We are finalizing a new requirement at § 441.312(c)(2) that the Secretary shall make technical updates and corrections to the Home and Community-Based Services Quality Measure Set annually as appropriate. We are also redesignating what had been proposed as § 441.312(c)(3) as (c)(4) and finalizing the redesignated § 441.312(c)(4) with a modification to replace the word at least with no more frequently than.

d. Process for Developing and Updating the HCBS Quality Measure Set (§ 441.311(d))

At proposed § 441.312(d), we described the proposed process for developing and updating the HCBS Quality Measure Set. Specifically, we proposed that the Secretary will address the following through a process to:

- Identify all measures in the HCBS Quality Measure Set, including newly added measures, measures that have been removed, mandatory measures, measures that the Secretary will report on States' behalf, measures that States can elect to have the Secretary report on their behalf, as well as the measures that the Secretary will provide States with additional time to report and the amount of additional time.
- Inform States how to collect and calculate data on the measures.
- Provide a standardized format and reporting schedule for reporting the measures.
- Provide procedures that States must follow in reporting the measure data.
- Identify specific populations for which States must report the measures, including people enrolled in a specific delivery system type such as those enrolled in a managed care plan or receiving services on a fee-for-service basis, people who are dually eligible for Medicare and Medicaid, older adults, people with physical disabilities, people with intellectual or developmental disabilities, people who have serious mental illness, and people who have other health conditions; and provide attribution rules for determining how States must report on measures for beneficiaries who are included in more than one population.
- Identify the measures that must be stratified by race, ethnicity, Tribal status, sex, age, rural/urban status, disability, language, or such other factors as may be specified by the Secretary.
- Describe how to establish State performance targets for each of the measures.

As discussed in section II.B.8. of the proposed rule (88 FR 27992 through 27993), we anticipated that, for State reporting on the measures in the HCBS Quality Measure Set, as outlined in the reporting requirements we proposed at § 441.311, the technical information on attribution rules described at proposed § 441.312(d)(6), would call for inclusion in quality reporting based on a beneficiary's continuous enrollment in the Medicaid waiver. This ensures the State has enough time to furnish services during the measurement period. In the technical information, we anticipated we would set attribution rules to address transitions in Medicaid eligibility, enrollment in Medicare, or transitions between different delivery systems or managed care plans, within a reporting year, for example, based on the length of time beneficiaries was enrolled in each. We invited comment on other considerations we should address in the attribution rules or other topics we should address in the technical information.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters provided input on the proposed process

[133] See section 1903(a)(3)(A)(i) and § 433.15(b)(3), 80 FR 75817–75843; *https://www.medicaid.gov/state-resourcecenter/faq-medicaid-and-chip-affordable-care-act-implementation/downloads/affordable-care-act-faq-enhancedfunding-for-medicaid.pdf; https://www.medicaid.gov/federal-policy-guidance/downloads/SMD16004.pdf.*

[134] See section 1903(a)(3)(B) and § 433.15(b)(4).

[135] See § 433.112 (b, 80 FR 75841; *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-433/subpart-C.*

[136] Relevant standards adopted by HHS and identified in the ISA include the USCDI (*https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi*), eLTSS (*https://www.healthit.gov/isa/documenting-care-plans-person-centered-services*), and Functional Assessment Standardized Items (*https://www.healthit.gov/isa/representing-patient-functional-status-andor-disability*).

that the Secretary will follow to update and maintain the HCBS Quality Measure Set. A few commenters recommended that, to advance meaningful quality improvement and measurement, we should prioritize the importance of a measure and a measure's usability and use for measure selection and suggested an additional evaluative category of advancing equity. A couple of commenters suggested that we should consider implementing a process to determine if quality measures are based on person-centered planning principles, emphasizing that many of the measures in the HCBS Quality Measure Set are more system and process-oriented, rather than focused on assessing and improving person-centered experiences and preferences. One commenter recommended we conduct a broad-based public review of possible quality measures and domains for individuals with intellectual and developmental disabilities to inform the quality measures process. Another commenter suggested that we include an oral health measure for beneficiaries receiving HCBS in the selection of measures for the HCBS Quality Measure Set. A few commenters recommended we prioritize the development and inclusion of culturally and linguistically appropriate measures within the HCBS Quality Measure Set, prioritizing reporting of the most feasible measures, aligning the CMS Core Sets, to capture the experiences and outcomes of diverse populations and ensure that HCBS programs address the unique needs and preferences of beneficiaries from different cultural backgrounds.

Response: At § 441.312(d), we described the general process that the Secretary will follow to update and maintain the HCBS Quality Measure Set.

We underscore the importance of alignment in quality measurement across the Medicaid program, to the extent possible. We proposed at § 441.312(d)(7), that the process for developing and updating the HCBS Quality Measure Set will address the subset of measures that must be stratified by race, ethnicity, Tribal status, sex, age, rural/urban status, disability, language, or such other factors as may be specified by the Secretary and informed by consultation every other year with States and interested parties.

After further consideration, we have identified that including Tribal status as a measure stratification factor is misaligned, as it is not included as a measure stratification factor for the Adult Core Set as defined in the Mandatory Medicaid and CHIP Core Set Reporting final rule. We are also concerned that this additional measure stratification factor will create additional burden for States. After further consideration, to ensure alignment in Medicaid quality measurement and alignment of the HCBS Quality Measure Set with the Adult Core Set, we are removing Tribal status as a measure stratification factor at § 441.312(d)(7). We note that Tribal status could be included as a measure stratification factor under such other factors as may be specified by the Secretary and informed by consultation every other year with States and interested parties in accordance with § 441.312(b)(2) and (g).

At § 441.312(d), we proposed and are finalizing the process for developing and updating the HCBS Quality Measure Set. At § 441.312(d)(5) the process for developing and updating the HCBS Quality Measure Set includes the identification of the beneficiary populations for which States are required to report the HCBS quality measures identified by the Secretary. We are finalizing § 441.312(d)(5)(i) with a technical modification, including the identification of the beneficiaries receiving services through specified delivery systems for which States are required to report the HCBS quality measures identified by the Secretary, replacing managed care plan with **MCO, PIHP, or PAHP as defined in § 438.2.** (New language identified in bold.)

Comment: A few commenters requested we clarify how the HCBS Quality Measure Set would relate to measurement for beneficiaries who are dually eligible for Medicare and Medicaid. One commenter further expressed strong support for disaggregation of data for dually eligible beneficiaries, but also questioned whether partial benefit dually eligible beneficiaries were required to be included in the population for quality measurement, as most do not receive HCBS or any other Medicaid benefits.

Response: We plan to provide States with guidance and technical assistance to help address issues specific to dually eligible beneficiaries. Further, inclusion and exclusion criteria for each measure will be addressed through the technical specifications for the measure. We note that, to the extent that dual-eligible beneficiaries are receiving services authorized under section 1915(c), (i), (j), or (k) Medicaid programs and delivered through managed care plans, and meet the inclusion criteria for the measure, they are required to be included in the reporting on that measure. We will provide technical assistance regarding the application of these requirements to beneficiaries in different categories of dual eligibility.

Comment: One commenter requested that CMS clarify the requirement at § 441.312(d)(7) referencing the subset of measures in the HCBS Quality Measure Set that must be stratified by health equity characteristics, noting that the proposed § 441.312(f) would require States to stratify 100 percent of measures by 7 years after the effective date of the final rule. They emphasized a disconnect between the two provisions, as a subset of measures is not the same as 100 percent of measures and suggest removing the word subset to avoid confusion in implementation.

Response: Reporting of stratified data is a cornerstone of our approach to advancing health equity. We note reporting stratified data helps identify and eliminate health disparities across HCBS populations. As we noted in the proposed rule (88 FR 27993), measuring health disparities, reporting these results, and driving improvements in quality are cornerstones of the CMS approach to advancing health equity through data reporting and stratification aligns with E.O. 13985.[137]

At § 441.312(f), in specifying which measures, and by which factors, States must report stratified measures consistent with § 441.312(d)(7), the Secretary will take into account whether stratification can be accomplished based on valid statistical methods and without risking a violation of beneficiary privacy and, for measures obtained from surveys, whether the original survey instrument collects the variables necessary to stratify the measures, and such other factors as the Secretary determines appropriate. We reiterate that we considered giving States the flexibility to choose which measures they would stratify and by what factors. However, as discussed in the Mandatory Medicaid and CHIP Core Set Reporting rule (87 FR 51313), consistent measurement of differences in health and quality of life outcomes between different groups of beneficiaries is essential to identifying areas for intervention and evaluation of those interventions.[138] This consistency could not be achieved if each State made its own decisions about which data it

[137] Exec. Order No. 13985 (2021), Accessed at *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/*.

[138] Schlotthauer AE, Badler A, Cook SC, Perez DJ, Chin MH. Evaluating Interventions to Reduce Health Care Disparities: An RWJF Program. Health Aff (Millwood). 2008;27(2):568–573.

would stratify and by what factors.[139] [140] We also recognize that States may be constrained in their ability to stratify measures in the HCBS Quality Measure Set and that data stratification would require additional State resources. We also may face constraints in stratifying measures for which we are able to report on behalf of States, as our ability to stratify will be dependent on whether the original dataset or survey instrument: (1) collects the demographic information or other variables needed and (2) has a large enough sample size. preserved and model accuracy is improved. In consideration of these factors we are finalizing at § 441.312(d)(7) that the subset of measures among the measures in the HCBS Quality Measure Set that must be stratified by health equity characteristics as proposed.

In response to the commenter's observation regarding when 100 percent of the measures must be stratified, we note that, for reasons discussed in greater detail in section II.B.7. and II.B.8.e. of this final rule, we are modifying the requirement at § 441.311(f) to change the timing by which measures must be stratified. As finalized, § 441.311(f) requires that stratification of 25 percent of the measures in the Home and Community-Based Services Quality Measure Set for which the Secretary has specified that reporting should be stratified by 4 years after the effective date of these regulations, 50 percent of such measures by 6 years after the effective date of these regulations, and 100 percent of measures by 8 years after the effective date of these regulations.

After consideration of the comments received, we are finalizing § 441.312(d)(1) through (6) and (8) as proposed. We are finalizing § 441.312(d)(7) with modification to remove Tribal status as a stratification factor. As finalized, § 441.312(d)(7) provides that the process for developing and updating the HCBS Quality Measure Set will address the subset of measures among the measures in the HCBS Quality Measure Set that must be stratified by race, ethnicity, sex, age, rural/urban status, disability, language, or such other factors as may be specified by the Secretary and informed by consultation every other year with States and interested parties.

e. Phasing In of Certain Reporting (§ 441.311(e) and (f))

At § 441.312(e), we proposed, in the process for developing and updating the HCBS Quality Measure Set described at proposed § 441.312(d), that the Secretary consider the complexity of State reporting and allow for the phase-in over a specified period of time of mandatory State reporting for some measures and of reporting for certain populations, such as older adults or people with intellectual and developmental disabilities. At § 441.312(f), we proposed that, in specifying the measures and the factors by which States must report stratified measures, the Secretary will consider whether such stratified sampling can be accomplished based on valid statistical methods, without risking a violation of beneficiary privacy, and, for measures obtained from surveys, whether the original survey instrument collects the variables or factors necessary to stratify the measures.

We considered giving States the flexibility to choose which measures they would stratify and by what factors. However, as we noted was discussed in the Mandatory Medicaid and CHIP Core Set Reporting final rule (88 FR 60278), consistent measurement of differences in health and quality of life outcomes between different groups of beneficiaries is essential to identifying areas for intervention and evaluation of those interventions.[141] This consistency could not be achieved if each State made its own decisions about which data it would stratify and by what factors.[142] [143]

In the proposed rule, we recognized that States may be constrained in their ability to stratify measures in the HCBS Quality Measure Set and that data stratification would require additional State resources. We also noted that there are several challenges to stratification of measure reporting. First, the validity of stratification is threatened when the demographic data are incomplete. Complete demographic information is often unavailable to us and to States due to several factors, including the fact that Medicaid applicants and beneficiaries are not required to provide race and ethnicity data. Second, when States with smaller populations and less diversity stratify data, it may be possible to identify individual data, raising privacy concerns. Therefore, if the sample sizes are too small, the data would be suppressed, in accordance with the CMS Cell Size Suppression Policy and the data suppression policies for associated measure stewards and therefore not publicly reported to avoid a potential violation of privacy.[144]

We also acknowledged that we may face constraints in stratifying measures for which we are able to report on behalf of States, as our ability to stratify would be dependent on whether the original dataset or survey instrument: (1) collects the demographic information or other variables needed and (2) has a large enough sample size. The Transformed Medicaid Statistical Information System (T–MSIS), for example, currently has the capability to stratify some HCBS Quality Measure Set measures by sex and urban/rural status, but not by race, ethnicity, or disability status. This is because applicants provide information on sex and urban/rural address, which is reported to T–MSIS by States, whereas applicants are not required to provide information on their race and ethnicity or disability status, and often do not do so. However, we have developed the capacity to impute race and ethnicity using a version of the Bayesian Improved Surname Geocoding (BISG) method [145] that includes Medicaid-specific enhancements to optimize accuracy, and are able to stratify by race and ethnicity, urban/rural status, and sex.

With these challenges in mind, we proposed that stratification by States in reporting of HCBS Quality Measure Set data would be implemented through a phased-in approach in which the Secretary would specify which measures and by which factors States must stratify reported measures. At § 441.312(f), we proposed that States would be required to provide stratified data for 25 percent of the measures in the HCBS Quality Measure Set for

[139] Centers for Medicare & Medicaid Services (CMS) Office of Minority Health (OMH). Stratified Reporting. 2022; *https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting.*

[140] National Quality Forum. A Roadmap for Promoting Health Equity and Eliminating Disparities. Sep 2017. Accessed at *https://www.qualityforum.org/Publications/2017/09/A_Roadmap_for_Promoting_Health_Equity_and_Eliminating_Disparities__The_Four_I_s_for_Health_Equity.aspx.*

[141] Schlotthauer AE, Badler A, Cook SC, Perez DJ, Chin MH. Evaluating Interventions to Reduce Health Care Disparities: An RWJF Program. Health Aff (Millwood). 2008;27(2):568–573.

[142] Centers for Medicare & Medicaid Services (CMS) Office of Minority Health (OMH). Stratified Reporting. 2022; *https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting.*

[143] National Quality Forum. A Roadmap for Promoting Health Equity and Eliminating Disparities. Sep 2017. Accessed at *https://www.qualityforum.org/Publications/2017/09/A_Roadmap_for_Promoting_Health_Equity_and_Eliminating_Disparities__The_Four_I_s_for_Health_Equity.aspx.*

[144] CMS Cell Size Suppression Policy, Issued 2020: *https://www.hhs.gov/guidance/document/cms-cell-suppression-policy* or the cell suppression standards of the associated measure stewards.

[145] Elliott, Marc N., et al. ''Using the Census Bureau's surname list to improve estimates of race/ethnicity and associated disparities.'' *Health Services and Outcomes Research Methodology* 9.2 (2009): 69–83.

which the Secretary has specified that reporting should be stratified by 3 years after the effective date of these regulations, 50 percent of such measures by 5 years after the effective date of these regulations, and 100 percent of measures by 7 years after the effective date of these regulations. We noted that the percentages listed here aligned with the proposed phase-in of equity reporting in the Mandatory Medicaid and CHIP Core Set Reporting final rule (88 FR 60278). However, the timeframe associated with each percentage of measures to phase-in equity reporting that we proposed in this rule is different with a slower phase-in, in large part because when compared to the Child, Adult, and Health Home Core Sets, the HCBS Measure Set in its current form includes a substantial number of measures that are derived from beneficiary experience of care surveys, which are costlier to implement than other types of measures. In addition, the slower phase-in was also intended to take into consideration the overall burden of the reporting requirements and that States have less experience with the HCBS Quality Measure Set. Specifically, the Mandatory Medicaid and CHIP Core Set Reporting final rule (88 FR 60278) requires States to provide stratified data for 25 percent of measures within 2 years after the effective date of the final rule, 50 percent of measures within 3 years after the effective date of the final rule, and 100 percent of measures within 5 years after the effective date of the final rule.

In our proposed rule, we determined that our proposed phased-in approach to data stratification would be reasonable and minimally burdensome, and thus consistent with E.O. 13985 on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (January 20, 2021),[146] because we were balancing the importance of being able to identify differences in outcomes between populations under these measures with the potential operational challenges that States may face in implementing these proposed requirements.

We recognized that States may need to make enhancements to their data and information systems or incur other costs in implementing the HCBS Quality Measure Set. We reminded States that enhanced FFP is available at a 90 percent match rate for the design, development, or installation of improvements of mechanized claims processing and information retrieval systems, in accordance with applicable Federal requirements.[147] Enhanced FFP at a 75 percent match rate is also available for operations of such systems, in accordance with applicable Federal requirements.[148] We also encouraged States to advance the interoperable exchange of HCBS data and support quality improvement activities by adopting standards in 45 CFR part 170 and other relevant standards identified in the ISA.[149]

We invited comments on the proposed schedule for phasing in reporting of HCBS Quality Measure Set data. We also solicited comment on whether we should phase-in reporting on all of the measures in the HCBS Quality Measure Set.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported our proposal at § 441.312(f) in its entirety.

Response: We thank the commenters for their support of our proposed requirements.

Comment: Several commenters submitted recommendations and requests related to the details of stratified reporting, such as definitions of specific categories of populations, data suppression policies, how to handle missing data, and different measures of delivery systems.

Response: We believe that stratified data would enable us and States to identify the health and quality of life outcomes of underserved populations and potential differences in outcomes based on race, ethnicity, sex, age, rural/urban status, disability, language, and other such factors on measures contained in the HCBS Quality Measure Set. We refer readers to section II.B.8. of the proposed rule (88 FR 27993) for a detailed discussion of stratified data and sampling.

We expect to align with Department of Health and Human Services (HHS) data standards for stratification, based on the disaggregation of the 1997 Office of Management and Budget (OMB) Statistical Policy Directive No 15.[150] We expect to update HCBS Quality Measure Set reporting stratification categories if there are any changes to OMB or HHS Data Standards. We will take this feedback into account as we plan technical assistance and develop guidance for States.

Comment: Several commenters supported all the proposed requirements for stratification but recommended either faster or slower implementation. A couple of commenters suggested that States be required to report stratified data by 3 years after the effective date of this final rule rather than phase in this requirement. Multiple commenters provided alternate phase-in schedules for stratification of the HCBS Quality Measure Set, with the most frequent suggestions to add two to five years to the phase-in timeline for data stratification requirements for the measures in the HCBS Quality Measure Set. Some commenters expressed that they supported a staggered implementation timeline of the data stratification requirements and noted that additional time and flexibility for States could make compliance more attainable because of State legislative, budgeting, procurement, and contracting requirements. Another commenter, who represents State agencies, emphasized that many States have long-standing challenges with collecting complete demographic data on Medicaid beneficiaries, and they expressed concerns with small samples, staffing capacity, survey fatigue, and problems identifying baseline demographics. One commenter recommended that the initial implementation of stratification occur with a rolling start date by State, based on waiver renewal date.

Response: We continue to believe that the time frame for States to implement stratification of data on quality measures in the HCBS Quality Measure Set is an appropriate frequency that ensures accountability without being overly burdensome. We determined that a shorter phase timeframe would not likely be operationally feasible because of the potential systems and contracting changes (to existing contracts or the establishment of new contracts) that

[146] Exec. Order No. 13985 (2021), Accessed at *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/*.

[147] See section 1903(a)(3)(A)(i) of the Act and § 433.15(b)(3), 80 FR 75817 through 75843; *https://www.medicaid.gov/state-resourcecenter/faq-medicaid-and-chip-affordable-care-act-implementation/downloads/affordable-care-act-faq-enhancedfunding-for-medicaid.pdf; https://www.medicaid.gov/federal-policy-guidance/downloads/SMD16004.pdf.*

[148] See section 1903(a)(3)(B) and § 433.15(b)(4).

[149] Relevant standards adopted by HHS and identified in the ISA include the USCDI (*https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi*), eLTSS (*https://www.healthit.gov/isa/documenting-care-plans-person-centered-services), and Functional Assessment Standardized Items (https://www.healthit.gov/isa/representing-patient-functional-status-andor-disability*).

[150] The categories for HHS data standards for race and ethnicity are based on the disaggregation of the OMB standard: *https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=3&lvlid=53*.

States may be required to make, in order to collect these data for reporting. For example, additional reporting requirements may need to be added to State contracts, changes may be needed to data sharing agreements with managed care plans, and modifications of databases or systems might be required to record new variables.

As discussed in section II.B.7. of this final rule, we are finalizing at § 441.311(f)(2) that States must comply with the HCBS Quality Measure Set reporting requirement at § 441.311(c) beginning 4 years after the effective date of this final rule, rather than 3 years. We are making this modification in order to allow for sufficient time for interested parties to provide input into the measures, as required by § 441.312(g), which we are finalizing as described in this section II.B.8. of this rule. To align with this modification, we are finalizing the phase-in requirement at § 441.312(f). As finalized, § 441.312(f) requires that stratification of 25 percent of the measures in the Home and Community-Based Services Quality Measure Set for which the Secretary has specified that reporting should be stratified by 4 years after the effective date of these regulations, 50 percent of such measures by 6 years after the effective date of these regulations, and 100 percent of measures by 8 years after the effective date of these regulations.

We anticipate that States will not need more than 4 years after the effective date of the final rule, to implement systems and contracting changes, or any additional support needed to report on the quality measures in HCBS Quality Measure Set. However, as described at finalized § 441.312(e), we will consider the complexity of State reporting and allow for the phase in over a specified period of time of mandatory State reporting for some measures and of reporting for certain populations, such as older adults or people with intellectual and disabilities. Further, we plan to work collaboratively with States to provide technical assistance and reporting guidance through the Paperwork Reduction Act process necessary to support reporting.

Comment: A couple of commenters recommended that we offer States financial assistance to develop and deploy health equity efforts, including funding support in addressing the capture of self-reported data.

Response: As discussed above, in Medicaid, enhanced FFP is available at a 90 percent FMAP for the design, development, or installation of improvements of mechanized claims processing and information retrieval systems, in accordance with applicable Federal requirements. Enhanced FFP at a 75 percent FMAP is also available for operations of such systems, in accordance with applicable Federal requirements. We reiterate that receipt of these enhanced funds is conditioned upon States meeting a series of standards and conditions to ensure investments are efficient and effective.[151] This may include improving data reporting, which could promote greater health equity.

We clarify, to receive enhanced FMAP funds, the State Medicaid agency is required at § 433.112(b)(12) to ensure the alignment with, and incorporation of, standards and implementation specifications for health information technology adopted by the Office of the National Coordinator for Health IT in 45 CFR part 170, subpart B, among other requirements set forth in § 433.112(b)(12). States should also consider adopting relevant standards identified in the ISA [152] to bolster improvements in the identification and reporting on the prevalence of critical incidents for HCBS beneficiaries and present opportunities for the State to develop improved information systems that can support quality improvement activities. We further clarify that States are responsible for ensuring compliance with the requirements of HIPAA and its implementing regulations, as well as any other applicable Federal or State privacy laws governing confidentiality of a beneficiary's records.

After consideration of the comments we received, we are finalizing § 441.312(e) as proposed.

We are finalizing § 441.312(f) with a modification to require that stratification of 25 percent of the measures in the Home and Community-Based Services Quality Measure Set for which the Secretary has specified that reporting should be stratified by 4 years after the effective date of these regulations, 50 percent of such measures by 6 years after the effective date of these regulations, and 100 percent of measures by 8 years after the effective date of these regulations.

[151] See § 433.112 (b, 80 FR 75841; *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-433/subpart-C.*

[152] Relevant standards adopted by HHS and identified in the ISA include the USCDI (*https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi*), eLTSS (*https://www.healthit.gov/isa/documenting-care-plans-person-centered-services*), and Functional Assessment Standardized Items (*https://www.healthit.gov/isa/representing-patient-functional-status-andor-disability*).

e. Consultation With Interested Parties (§ 441.312(g))

At § 441.312(g), we proposed the list of interested parties with whom the Secretary must consult to specify and update the quality measures established in the HCBS Quality Measure Set. The proposed list of interested parties included: State Medicaid Agencies and agencies that administer Medicaid-covered HCBS; health care and HCBS professionals who specialize in the care and treatment of older adults, children and adults with disabilities, and individuals with complex medical needs; health care and HCBS professionals, providers, and direct care workers who provide services to older adults, children and adults with disabilities and complex medical and behavioral health care needs who live in urban and rural areas or who are members of groups at increased risk for poor outcomes; HCBS providers; direct care workers and organizations representing direct care workers; consumers and national organizations representing consumers; organizations and individuals with expertise in HCBS quality measurement; voluntary consensus standards setting organizations and other organizations involved in the advancement of evidence-based measures of health care; measure development experts; and other interested parties the Secretary may determine appropriate.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters commended our proposal at § 441.312(g) to consult and receive input from interested parties. These commenters expressed they are encouraged by the continued collaboration with CMS in identifying and updating the HCBS Quality Measure Set. A few commenters shared suggestions for others to include as interested parties, mentioning managed care plans, community representatives from underserved communities, family members, and caregivers.

Response: We appreciate the submission of these comments and will take them into consideration as the Secretary carries out the responsibilities at § 441.312(g).

Comment: One commenter recommended we establish an ongoing process of consultation with States and interested parties to make updates to the quality measures in the HCBS Quality Measure Set in a longer cycle between updates based on consensus, such as 5 years. This commenter emphasized this

approach can assure interested parties that the measure set will continue to be developed over time based on new information and priorities and help avoid making changes too rapidly to be sustained by States.

Response: We appreciate the submission of these comments. As noted previously, we are finalizing § 441.312(c)(1) and (2) with modifications to indicate that we will identify, and update no more frequently than every other year, beginning no later than December 31, 2026, the quality measures to be included in the HCBS Quality Measure Set as defined in paragraph (b) of this section.

We will make technical updates and corrections to the HCBS Quality Measure Set annually as appropriate. Additionally, as discussed in greater detail in section II.B.7. of this final rule, we are giving States more time to engage with interested parties by finalizing an applicability date of 4 years, rather than 3 years, for the requirement that States must comply with the HCBS Quality Measure Set reporting at § 441.311(c). We are making this revision in order to allow for sufficient time for interested parties to provide input into the measures, as required by § 441.312(g).

After consideration of the comments received, we are finalizing § 441.312(g) as proposed.

f. Application to Other Authorities (§§ 441.474(c), 441.585(d), and 441.745(b)(1)(v))

Because these quality measurement requirements are relevant to other HCBS authorities, we proposed to include these requirements within the applicable regulatory sections for other HCBS authorities. Specifically, we proposed to apply the proposed requirements at § 441.312 to section 1915(j), (k), and (i) State plan services at §§ 441.474(c), 441.585(d), and 441.745(b)(1)(v), respectively. Consistent with our proposal for section 1915(c) waivers, we proposed these requirements based on our authority under section 1902(a)(6) of the Act, which requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports. We believed the same arguments for proposing these requirements for section 1915(c) waivers are equally applicable for these other HCBS authorities. We requested comment on the application of these provisions across sections 1915(i), (j), and (k) authorities.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposal to apply the HCBS Quality Measure Set requirements at § 441.312 to sections 1915(i), (j) and (k) authorities, stating there should be equally applicable requirements for States across authorities to ensure consistency, coordination, and alignment across quality improvement activities for these HCBS beneficiaries.

Alternatively, a few commenters expressed that applying the HCBS Quality Measure Set requirements across sections 1915(i), (j) and (k) authorities could pose challenges for States since the application of quality measure data collection and reporting for these HCBS authorities is mixed among States. One commenter requested an exemption for the section 1915(i) authority, noting that implementing the HCBS Quality Measure Set requirements for this authority is onerous, since the service array for section 1915(i) programs is more limited than in section 1915(c) programs.

Response: We thank commenters for their support. We note that States can cover the same services under section 1915(i) as they can cover under section 1915(c) of the Act. As such, exempting States from implementing the HCBS Quality Measure Set requirements under section 1915(i) does not align with our intent, which is to ensure consistency and alignment in reporting requirements across HCBS authorities. We are finalizing our proposal to apply the HCBS Quality Measure Set requirements to sections 1915(c), (i), (j) and (k) authorities and plan to provide technical assistance to States as needed to address the concerns raised by commenters.

After consideration of the comments received, we are finalizing the application of § 441.312 to section 1915(j) services by finalizing a reference to § 441.312 at § 441.474(c). (Note that we also discuss finalization of §§ 441.474(c) in section II.B.7. of this final rule.) We are finalizing the application of § 441.312 to sections 1915(k) and 1915(i) services at §§ 441.585(d) and 441.745(b)(1)(v) with modifications to clarify that the references to section 1915(c) of the Act are instead references to section 1915(k) and 1915(i) of the Act, respectively.

g. Summary of Finalized Requirements

After consideration of the public comments, we are finalizing the requirements at § 441.312 as follows:

- We are finalizing § 441.312(a) with a minor technical change.
- We are finalizing the definition of attribution rules and Home and Community-Based Services Quality Measure Set at § 441.312(b)(1) with a minor formatting change.
- We are finalizing the responsibilities of the Secretary at § 441.312(c)(1) with technical modifications to revise the frequency for updating the measure set to no more frequently than every other year and replace December 31, 2025 with December 31, 2026.
- We are finalizing a new requirement at § 441.312(c)(2) that the Secretary shall make technical updates and corrections to the Home and Community-Based Services Quality Measure Set annually as appropriate.
- We are redesignating § 441.312(c)(2) as paragraphs (c)(3) and finalizing with minor technical modification.
- We are redesignating § 441.312(c)(3) as § 441.312(c)(4) and finalizing § 441.312(c)(4) with a minor technical modification to replace ''at least'' with ''no more frequently than.''
- We are finalizing § 441.312(d)(i) as proposed with a modification for clarity to replace managed care plan with MCO, PIHP or PAHP as defined in § 438.2.
- We are finalizing § 441.312(e) as proposed.
- We are finalizing the requirement at § 441.312(f) with a technical modification in the dates by when a certain percent of measures are to be stratified, delaying each deadline by one year.
- We are finalizing § 441.312(g) as proposed.
- We are finalizing the reference to § 441.312 in § 441.474(c) as proposed.
- We are finalizing the requirements at §§ 441.585(d) and 441.745(b)(1)(v) with modification to clarify that the references to section 1915(c) of the Act are instead references to section 1915(k) and 1915(i) of the Act, respectively.

9. Website Transparency (§§ 441.313, 441.486, 441.595, and 441.750)

Section 1102(a) of the Act provides the Secretary of HHS with authority to make and publish rules and regulations that are necessary for the efficient administration of the Medicaid program. Under our authority at section 1102(a) of the Act, we proposed a new section, at § 441.313, titled Website Transparency, to promote public transparency related to the administration of Medicaid-covered HCBS. As noted in the proposed rule, we believe quality is a critical component of efficiency, as payments

for services that are low quality do not produce their desired effects and, as such, are more wasteful than payments for services that are high quality. The proposed approach was based on feedback we obtained during various public engagement activities conducted with States and other interested parties over the past several years that it is difficult to find information on HCBS access, quality, and outcomes in many States. As a result, it is not possible for beneficiaries, consumer advocates, oversight entities, or other interested parties to hold States accountable for ensuring that services are accessible and high quality for people who need Medicaid HCBS. We believe that the website transparency requirements support the efficient administration of Medicaid-covered HCBS authorized under section 1915(c) of the Act by promoting public transparency and the accountability of the quality and performance of Medicaid HCBS systems, as the availability of such information improves the ability of interested parties to hold States accountable for the quality and performance of their HCBS systems.

a. Website Availability and Accessibility (§ 441.313(a))

At § 441.313(a), we proposed to require States to operate a website that meets the availability and accessibility requirements at § 435.905(b) of this chapter and provides the results of the reporting requirements under § 441.311 (specifically, incident management, critical incident, person-centered planning, and service provision compliance data; data on the HCBS Quality Measure Set; access data; and payment adequacy data). We solicited comment on whether the requirements at § 435.905(b) are sufficient to ensure the availability and accessibility of the information for people receiving HCBS and other HCBS interested parties and for specific requirements to ensure the availability and accessibility of the information.

We received public comment on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the website transparency provisions at § 441.313(a), emphasizing that advancing the collection of information and data by States is important to enable the ability of the public, including beneficiaries, to be able to access and compare performance results across States for the reporting requirements proposed at § 441.311.

Response: We appreciate the support for our proposal and thank commenters for their feedback. We note that consistent with statements we made in the introduction of sections II. and II.B. of this final rule regarding severability, while the intent of § 441.313 is for States to post all information collected under §§ 441.302(k)(6) and 441.311 as required, we believe that the website posting requirements being finalized herein at § 441.313 would provide critical data to the public even in a circumstance where individual provisions at §§ 441.302(k)(6) and 441.311 were not finalized or implemented. We do acknowledge that § 441.313 is interrelated with §§ 441.302(k)(6) and 441.311 to the extent that if one of the reporting requirements was not finalized or implemented, posting of the data collected under that particular requirement would not be available to post on the website as required at § 441.313. However, if one or more of the reporting requirements at §§ 441.302(k)(6) and 441.311 is finalized and implemented, then States must post this data on the website as required in § 441.313, as finalized. We note that in this final rule, we are finalizing the reporting requirement at § 441.302(k)(6) (as discussed in section II.B.5. of this final rule) and the reporting requirements proposed in § 441.311 (with modifications, as discussed in section II.B.7. of this final rule.)

Comment: One commenter requested we consider providing additional FMAP for the website creation and support needed to conduct the public posting of information and data required under § 441.311 on the State web page, including to address increased staff time and effort to answer questions regarding the public information required to be reported.

Response: We note we do not have authority to permit States to claim Medicaid expenditures at enhanced FMAP rates that are not specified in statute. As noted in the proposed rule, in Medicaid, enhanced FFP is available at a 90 percent FMAP for the design, development, or installation of improvements of mechanized claims processing and information retrieval systems, in accordance with applicable Federal requirements.[153] Enhanced FFP at a 75 percent FMAP is also available for operations of such systems, in accordance with applicable Federal requirements.[154] However, receipt of these enhanced funds is conditioned upon States meeting a series of standards and conditions to ensure investments are efficient and effective.[155] We plan to provide States with technical assistance related to the availability of enhanced FMAP to support the implementation of the requirements in this final rule.

After consideration of the comments received, we are finalizing the introductory paragraph at § 441.313(a) as proposed with one modification to include the additional reporting requirements to specify that the State must operate a website consistent with § 435.905(b) of this chapter that provides the results of the reporting requirements specified at §§ 441.302(k)(6) and 441.311.

b. Website Data and Information (§ 441.313(a)(1))

We proposed at § 441.313(a)(1) to require that the data and information States are required to report under § 441.311 be provided on one web page, either directly or by linking to the web pages of the MCO, PAHP, PIHP, or primary care case management entity that is authorized to provide services. We solicited comment on whether States should be permitted to link to web pages of these managed care plans and whether we should limit the number of separate web pages that a State could link to, in place of directly reporting the information on its own web page.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported and noted that the States should have one central web page operated and housed solely by the State to ensure data and information is reported consistently across their HCBS programs. One of the commenters suggested a State could, in their centralized State web page, give users the opportunity to filter by provider, managed care plan, or locality and include contact information for managed care plans. A few commenters generally supported permitting States to link to web pages of managed care plans to meet the proposed requirement.

Another commenter identified that beneficiaries may rely on their managed care plan's website for information instead of the State website and

[153] See section 1903(a)(3)(A)(i) and § 433.15(b)(3), 80 FR 75817–75843; *https://www.medicaid.gov/state-resourcecenter/faq-medicaid-and-chip-affordable-care-act-implementation/downloads/affordable-care-act-faq-enhancedfunding-for-medicaid.pdf; https://www.medicaid.gov/federal-policy-guidance/downloads/SMD16004.pdf.*

[154] See section 1903(a)(3)(B) and § 433.15(b)(4).

[155] See § 433.112 (b, 80 FR 75841; *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-433/subpart-C.*

recommended limiting web page links to managed care plans' websites, raising concern that requiring States to post the data and information from the managed care plans could be duplicative and lead to user confusion if website updates between the State and managed care plans were not synched. A few commenters emphasized that having multiple managed care plan web page links to access the data and information that States are required to report under § 441.311 could place a burden on beneficiaries, consumers, and the public, to find and navigate the unique displays of managed care plan websites.

Response: We thank commenters for their suggestions. We have attempted to provide States with as much flexibility as possible in reporting of data and information required at § 441.311. State and managed care plan reporting of required data and information must be available and accessible for HCBS beneficiaries and other interested parties, without placing undue burden on them. Upon further consideration, we agree that it adds a undue level of complexity and the potential for duplicate sources of the data and information by requiring the State to link to individual web pages of managed care plans.

After consideration of these public comments, we are finalizing the requirements at § 441.313(a)(1) with a modification to remove the word, web page, and replace with the word, website, and made minor formatting changes. We plan to provide technical assistance to States as needed to address the concerns raised by commenters.

Comment: One commenter agreed that the State should link to managed care plan web pages to report on the results of the reporting requirements at § 441.311, rather than have the managed care plans forward these results to the State to report on their State website. This commenter also recommended requiring the same language and format requirements in § 438.10(d) apply to § 441.33 and noted that many States serve Medicaid HCBS participants who receive services under managed LTSS and FFS, and that misalignment could occur between the regulations for managed care and FFS.

Response: Managed care plan websites required at § 438.10(c)(3) are already subject to the requirements at § 438.10(d), and we have not identified a compelling reason to make a similar reference in § 441.311. We decline to add mention of § 438.10(d) and are finalizing the requirements at § 441.311 as proposed.

After consideration of public comments, we are finalizing the requirements at § 441.313(a)(1) with a modification to require the State to include all content on one website, either directly or by linking to websites of individual MCO's, PIHP's, or PAHP's, as defined in § 438.2. We also are finalizing the requirements at § 441.313(a)(1) with a modification to remove the word, web page, and replace with the word, website, and make minor formatting changes.

c. Accessibility of Information (§ 441.313(a)(2))

At § 441.313(a)(2), we proposed to require that the website include clear and easy to understand labels on documents and links. We requested comments on whether these requirements are sufficient to ensure the accessibility of the information for people receiving HCBS and other HCBS interested parties and for specific requirements to ensure the accessibility of the information.

We received public comment on this proposal. The following is a summary of the comments we received and our responses.

Comment: Two commenters recommended we recognize the communication needs of deaf, hard of hearing, deaf-blind, and blind individuals, including those who have low vision, emphasizing that these beneficiaries should have access to culturally and linguistically competent services, as well as services and auxiliary aids pursuant to Title II of the Americans with Disabilities Act (ADA) of 1990 and section 504 of the Rehabilitation Act of 1973 (section 504). They also recommended that we reference the Twenty-First Century Communications and Video Accessibility Act of 2010 (Pub. L. 111–260), which includes the use of clear language, icons, captioned videos, American Sign Language, and suitable color contrast. The commenters emphasized that any website materials and reports should be written with accommodations, including large print and braille, to ensure beneficiaries have equal, effective, and meaningful website communication. One commenter recommend that we also consider that due to the ''digital divide'' many HCBS beneficiaries do not have easy access to the internet and recommended we require States and managed care plans to share the information posted on their websites in an alternative format at the beneficiary's request.

Response: We confirm that our proposal requires States to operate a website that meets the availability and accessibility requirements at § 435.905(b) of this chapter, which requires the provision of auxiliary aids and services at no cost to individuals with disabilities in accordance with the ADA and section 504. We have attempted to provide the State with as much flexibility as possible in the design of their website. We agree that State and managed care plan websites must be available and accessible for people receiving HCBS and other HCBS interested parties. Further, we note that States' websites are subject to State or local laws regarding accessibility, and States must comply with other applicable laws independent of the requirements at § 441.313(a).

We encourage States to identify inequities for HCBS beneficiaries who have insufficient internet access and develop mechanisms to communicate website information that is available and accessible.

After consideration of comments received, we are finalizing § 441.313(a)(2) as proposed.

d. Website Operation Verification (§ 441.313(a)(3))

At § 441.313(a)(3), we proposed to require that States verify the accurate function of the website and the timeliness of the information and links at least quarterly. We requested comment on whether this timeframe is sufficient or if we should require a shorter timeframe (monthly) or a longer timeframe (semi-annually or annually).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters responded to our comment solicitation, expressing alternative timeframes related to the requirements at § 441.313(a)(3). Two commenters suggested websites should be updated on a more frequent monthly basis to ensure accuracy and functionality. A few other commenters suggested that websites should be updated semi-annually. Alternatively, another commenter requested that the verification of web content be completed annually to minimize administrative burden on States with significant web content to review and verify.

Response: We agree that accurate function of the website and the timeliness of the information is important. We note in section II.B.9. of the proposed rule (88 FR 27995 through 27996), and reiterate here, that we believe promoting public transparency and accountability of the quality and performance of Medicaid HCBS systems, and the availability of such information will improve the ability of

beneficiaries, consumer advocates, oversight entities, or other interested parties to hold States accountable for ensuring that services are accessible and high quality for people who need Medicaid. We believe that verification quarterly, is reasonable taking into account the level of complexity required for such State reporting. We decline to make any changes to § 441.313(a)(3) in this final rule.

After consideration of the comments received, we are finalizing § 441.313(a)(3) as proposed.

e. Oral and Written Translation Requirements (§ 441.313(a)(4))

At § 441.313(a)(4), we proposed to require that States include prominent language on the website explaining that assistance in accessing the required information on the website is available at no cost and include information on the availability of oral interpretation in all languages and written translation available in each non-English language, how to request auxiliary aids and services, and a toll free and TTY/TDY telephone number.

We received public comment on this proposal. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposed requirements at § 441.313(a)(4), One commenter further stated that, to ensure best quality, instructions to States on expectations for conducting translation in non-English languages to support the availability of oral interpretation in all languages and to assure uniformity across State policies to implement this component of the provision would be helpful. A few commenters opposed the proposed requirements at § 441.313(a)(4), expressing concern about the State financial and administrative burden that could occur due to the necessity to hire vendors to meet the expectations to conduct translation in non-English languages as required.

Response: We believe that the proposed requirements at § 441.313(a)(4) are important for ensuring that the required information on the website is accessible to people receiving HCBS and other interested parties. We reiterate, as noted in the proposed rule (88 FR 27979 and 27995), in Medicaid, enhanced FFP is available at a 90 percent FMAP for the design, development, or installation of improvements of mechanized claims processing and information retrieval systems, in accordance with applicable Federal requirements.[156] Enhanced FFP at a 75 percent FMAP is also available for operations of such systems, in accordance with applicable Federal requirements.[157] However, receipt of these enhanced funds is conditioned upon States meeting a series of standards and conditions to ensure investments are efficient and effective.[158]

After consideration of comments received, we are finalizing the requirements at § 441.313(a)(4) as proposed.

f. CMS Website Reporting (§ 441.313(b))

We proposed at § 441.313(b) that CMS report on its website the information reported by States to us under § 441.311. For example, we envisioned that we will update CMS's website to provide HCBS comparative information reported by States that can be compared to HCBS information shared by other States. We also envisioned using data from State reporting in future iterations of the CMS Medicaid and CHIP Scorecard.[159]

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposal that CMS would report on its own website the results of the data and information required to be reported under § 441.311, noting this enables easier comparison of results across States and serve as a single information source for users. One commenter suggested we consider a source, such as an HCBS hub, as defined by the commenter, on the CMS website, where users can quickly be directed to State HCBS programs and contracted managed care plan website pages.

One commenter suggested we initiate a best practice using the CMS website as an example for States to follow and share input with States on developing their websites to meet the requirements at § 441.313(a). Another commenter recommended we convene a technical expert panel of relevant interested parties to create a set of guidelines and best practices that States could leverage to meet the proposed website transparency requirements at § 441.313(a) to offset States' time and resource investments in building the website, and to assist with minimizing the State's risk of updating websites that do not meet requirements.

Response: We appreciate the submission of these comments and will take this feedback into consideration as CMS updates its website to report on the results of the data and information required to be reported under § 441.311.

After consideration of the comments received, we decline to make any changes to § 441.313(b) in this final rule and are finalizing as proposed.

g. Applicability Dates (§ 441.313(c))

We proposed at § 441.313(c) to provide States with 3 years to implement these requirements in FFS delivery systems. For States with managed care delivery systems under the authority of sections 1915(a), 1915(b), 1932(a), or section 1115(a) of the Act and that include HCBS in the MCO's, PIHP's, or PAHP's contract, we proposed to provide States until the first managed care plan contract rating period that begins on or after 3 years after the effective date of the final rule to implement these requirements. We based this proposed time period primarily on the effective date for State reporting at § 441.311.

We solicited comments on whether this timeframe is sufficient, whether we should require a longer timeframe (4 years) to implement these provisions, and if a longer timeframe is recommended, the rationale for that longer timeframe.

We received comments on this proposal. Below is a summary of the comments and our responses.

Comment: Most commenters supported the timeframe of 3 years following the effective date of the final rule to implement the website transparency requirements at § 441.313, emphasizing that these requirements facilitate the process of comparing results across States and create a single source where beneficiaries, providers, advocates, and policymakers can find a ''wealth of information about HCBS access.'' One commenter expressed support for the proposed section regarding transparency related to the administration of Medicaid-covered HCBS but did not believe it should take 3 years to implement. A few commenters also expressed concerns about the challenges they believe will be associated with the website transparency requirements at § 441.313, due to administrative burden States may face with significant web content to

[156] See section 1903(a)(3)(A)(i) and § 433.15(b)(3), 80 FR 75817–75843; *https://www.medicaid.gov/state-resourcecenter/faq-medicaid-and-chip-affordable-care-act-implementation/downloads/affordable-care-act-faq-enhancedfunding-for-medicaid.pdf; https://www.medicaid.gov/federal-policy-guidance/downloads/SMD16004.pdf.*

[157] See section 1903(a)(3)(B) and § 433.15(b)(4).

[158] See § 433.112 (b, 80 FR 75841; *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-433/subpart-C.*

[159] CMS's Medicaid and CHIP Scorecard. Accessed at *https://www.medicaid.gov/state-overviews/scorecard/index.html.*

review and verify to implement the provision.

Response: We believe that 3 years is a realistic and achievable timeframe for States to comply with the website transparency requirements, and we have not identified a compelling reason make changes to this date. We are finalizing the requirement at § 441.3131(c) as proposed with modifications as described later in this section. We reiterate, as noted in the proposed rule, in Medicaid, enhanced FFP is available at a 90 percent FMAP for the design, development, or installation of improvements of mechanized claims processing and information retrieval systems, in accordance with applicable Federal requirements.[160] Enhanced FFP at a 75 percent FMAP is also available for operations of such systems, in accordance with applicable Federal requirements.[161] However, receipt of these enhanced funds is conditioned upon States meeting a series of standards and conditions to ensure investments are efficient and effective.[162]

After consideration of public comments, we are finalizing the substance of § 441.313(c) as proposed, but with minor modifications to correct erroneous uses of the word ''effective'' and to make technical modifications at § 441.313(c) to the language pertaining to managed care delivery systems to improve accuracy and alignment with common phrasing in managed care contracting policy. We are retitling the requirement at § 441.313(c) as Applicability date (rather than Effective date). We are also modifying the language at § 441.313(c) to specify that States must comply *with the* requirements in § 441.313(c) *beginning* 3 years from the effective date of this final rule.

h. Application to Managed Care and Fee-for Service (§§ 441.486, 441.595, and 441.750)

As discussed in section II.B.1. of the proposed rule, section 2402(a)(3)(A) of the Affordable Care Act requires States to improve coordination among, and the regulation of, all providers of Federally and State-funded HCBS programs to achieve a more consistent administration of policies and procedures across HCBS programs. In the context of Medicaid coverage of HCBS, it should not matter whether the services are covered directly on a FFS basis or by a managed care plan to its enrollees. The requirement for consistent administration should require consistency between these two modes of service delivery. We accordingly proposed to specify that a State must ensure compliance with the requirements in § 441.313, with respect to HCBS delivered both under FFS and managed care delivery systems.

Similarly, because we proposed to apply the reporting requirements at § 441.311 to other HCBS State plan options, we also proposed to include these website transparency requirements within the applicable regulatory sections. Specifically, we proposed to apply the requirements of § 441.313 to section 1915(j), (k), and (i) State plan services at §§ 441.486, 441.595, and 441.750, respectively. Consistent with our proposal for section 1915(c) waivers, we proposed these requirements based on our authority under section 1102(a) of the Act to make and publish rules and regulations that are necessary for the efficient administration of the Medicaid program. We believe the same reasons for these requirements for section 1915(c) waivers are equally applicable for these other HCBS authorities.

We solicited comment on the application of these provisions across section 1915(i), (j), and (k) authorities.

We did not receive public comments on this provision.

After consideration of public comments received on this rule, we are finalizing the application of the website transparency requirements at § 441.313 to section 1915(j), (k), and (i) State plan services. We are finalizing our proposed requirements at §§ 441.486, 441.595, and 441.750 with minor modifications to clarify that the references to section 1915(c) of the Act are instead references to section 1915(j), 1915(k), and 1915(i) of the Act, respectively.

i. Summary of Finalized Requirements

After consideration of the public comments, we are finalizing the requirements at § 441.313 as follows:

- We are finalizing the requirement at § 441.313(c), with a technical modification to the language to improve accuracy and alignment with common phrasing in managed care contracting policy. We also are finalizing § 441.313(c) to specify that States must comply with the requirements as described in § 441.313(c) of this section beginning 3 years after the effective date of this final rule; and in the case of the State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes HCBS in the MCO's, PIHP's, or PAHP's contract, the first rating period for contracts with the MCO, PIHP, or PAHP beginning on or after the date that is 3 years after the effective date of this final rule.
- We are finalizing at §§ 441.313(a) and (b) with minor technical modifications to include the additional requirements at § 441.302(k)(6).
- We are finalizing the requirements at § 441.313(c) with minor formatting changes.
- We are finalizing §§ 441.486, 441.595, and 441.750 with minor modifications to clarify that the references to section 1915(c) of the Act are instead references to section 1915(j), 1915(k), and 1915(i) of the Act, respectively.

10. Applicability of Proposed Requirements to Managed Care Delivery Systems

As discussed earlier in sections II.B.1., II.B.4., II.B.5., II.B.7., and II.J. of this rule, we proposed to apply the requirements we proposed at §§ 441.301(c)(3), 441.302(a)(6), 441.302(k), 441.311, and 441.313 to both FFS and managed care delivery systems. Although the proposed provisions at §§ 441.301(c)(3), 441.302(a)(6) and (k), 441.311, and 441.313 would apply to LTSS programs that use a managed care delivery system to deliver services authorized under section 1915(c) waivers and section 1915(i), (j), and (k) State plan authorities, we believe incorporating a reference in 42 CFR part 438 would be helpful to States and managed care plans. Therefore, we proposed to add a cross reference to the requirements in proposed § 438.72 to be explicit that States that include HCBS in their MCO's, PIHP's, or PAHP's contracts would have to comply with the requirements at §§ 441.301(c)(1) through (3), 441.302(a)(6) and (k), 441.311, and 441.313. We believed this would make the obligations of States that implement LTSS programs through a managed care delivery system clear, consistent, and easy to locate. While we believed the list proposed in § 438.72 would help States easily identify the provisions related to LTSS, we identified that a provision specified in any other section of 42 CFR part 438 or any other Federal regulation but omitted from § 438.72, is still in full force and effect. We also noted that § 438.208(c)(3)(ii) currently references § 441.301(c)(1) and (2). We did not propose any changes to the regulatory

[160] See section 1903(a)(3)(A)(i) and § 433.15(b)(3), 80 FR 75817–75843; *https://www.medicaid.gov/state-resourcecenter/faq-medicaid-and-chip-affordable-care-act-implementation/downloads/affordable-care-act-faq-enhancedfunding-for-medicaid.pdf; https://www.medicaid.gov/federal-policy-guidance/downloads/SMD16004.pdf.*

[161] See section 1903(a)(3)(B) and § 433.15(b)(4).

[162] See § 433.112 (b, 80 FR 75841; *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-433/subpart-C.*

language at § 441.301(c)(1) or (2) or to § 438.208(c)(3)(ii) in the proposed rule. We included § 441.301(c)(1) and (2) in the proposed regulatory language at § 438.72 so that it would be clear that the requirements at § 441.301(c)(1) and (2) continue to apply.

We received various comments and questions about how specific provisions would be implemented in managed care contexts; these comments and our responses are addressed in the sections pertaining to those provisions. We did not receive other comments specifically on this proposal at § 438.72.

Upon further review, we have determined it necessary to make a clarifying correction to § 438.72, which we are finalizing with modifications. We proposed that § 438.72(b) would read that the State must comply with the review of the person-centered service plan requirements at § 441.301(c)(1) through (3), the incident management system requirements at § 441.302(a)(6), the payment adequacy requirements at § 441.302(k), the reporting requirements at § 441.311, and the website transparency requirements at § 441.313 for services authorized under section 1915(c) waivers and section 1915(i), (j), and (k) State plan authorities. We noted that in some cases, our description of the references in the regulations did not align with the titles of those regulations (such as at § 441.302(a)(6), in which only § 441.302(a)(6)(i) is specifically titled requirements, although our intent was for States to comply with § 441.302(a)(6)(i) through (iii). To avoid confusion due to any misaligned language, we are removing the narrative descriptions of the requirements and retaining just the references to the regulatory text.

After consideration of public comments, we are finalizing § 438.72(b) with this modification, which will read that the State must comply with requirements at §§ 441.301(c)(1) through (3), 441.302(a)(6), 441.302(k), 441.311, and 441.313 for services authorized under section 1915(c) waivers and section 1915(i), (j), and (k) State plan authorities.

C. Documentation of Access to Care and Service Payment Rates (§ 447.203)

Section 1902(a)(30)(A) of the Act requires that State plans ''assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.'' Through the provisions we are finalizing in § 447.203, we are establishing an updated process through which States will be required to document, and we will ensure, compliance with the requirements of section 1902(a)(30)(A) of the Act.

In the 2015 final rule with comment period, we codified a process that requires States to complete and make public AMRPs that analyze and inform determinations of the sufficiency of access to care (which may vary by geographic location in the State) and are used to inform State policies affecting access to Medicaid services, including provider payment rates. The AMRP must specify data elements that support the State's analysis of whether beneficiaries have sufficient access to care, based on data, trends, and factors that measure beneficiary needs, availability of care through enrolled providers, and utilization of services. States are required to update their AMRPs at regular intervals and whenever the State proposes to reduce FFS provider payment rates or restructure them in circumstances when the changes could result in diminished access. Specifically, the AMRP process at § 447.203 before this final rule (which we refer to in this final rule preamble as the previous AMRP process) required States to consider the extent to which beneficiary needs are fully met; the availability of care through enrolled providers to beneficiaries in each geographic area, by provider type and site of service; changes in beneficiary utilization of covered services in each geographic area; the characteristics of the beneficiary population (including considerations for care, service and payment variations for pediatric and adult populations and for individuals with disabilities); and actual or estimated levels of provider payment available from other payers, including other public and private payers, by provider type and site of service. The analysis further required consideration of beneficiary and provider input, and an analysis of the percentage comparison of Medicaid payment rates to other public and private health insurer payment rates within geographic areas of the State, for each of the services reviewed, by the provider types and sites of service. While the previous regulations included broad requirements for what an acceptable methodology used to conduct this analysis must include, States retained discretion in establishing their processes, including but not limited to the specification of data sources and analytical methodologies to be used. For example, States were broadly required to include actual or estimated levels of provider payments available from other payers; however, States retained discretion on which payers they reported on, including where the payment data was sourced from. The result has been a large analytical burden on States without a standardization that allows us and other interested parties to compare data between States to understand whether the Federal access standards are successfully achieving access consistent with section 1902(a)(30)(A) of the Act for beneficiaries nationwide.

Through the previous AMRP process, we aimed to create a transparent and data-driven process through which to ensure State compliance with section 1902(a)(30)(A) of the Act. Following publication of the 2011 proposed rule and as discussed in both the 2015 final rule with comment period and the 2016 final rule, as we worked with States to implement the previous AMRP requirements, many States expressed concerns about the rule.[163] [164] [165] States were concerned about the administrative burden of completing the previous AMRPs and questioned whether the previous AMRP process is the most effective way to establish that access to care in a State's Medicaid program meets statutory requirements. States with high managed care enrollment were also concerned about the previous AMRP process because the few remaining FFS populations in their State often reside in long-term care facilities or require only specialized care that is ''carved out'' of managed care (that is, not covered under the State's contract with managed care plans), but long-term care and specialized care services were not required to be analyzed under the previous AMRP process. We have also heard concerns from other interested parties, including medical associations and non-profit organizations, that the 2015 final rule with comment period afforded States too much discretion in developing access measures which could lead to ineffective monitoring and enforcement, as well as challenges comparing access across States. One commenter on the 2015 final rule was concerned that States had too much discretion in ''. . . setting standards and access measure . . .'' and ''. . . whether they have met their chosen standards'' as this process relies on self-regulation rather than ''an independent, objective third party as the primary arbiter of a State's compliance

[163] 76 FR 26341.

[164] 80 FR 67576 at 67583 and 67584.

[165] 81 FR 21479 at 21479.

. . .'' [166] Another commenter stated that ''CMS should designate a limited and standardized set of data measures that would be collected rather than leaving the decision of which data measures to use to State discretion'' as this would ''enable the development of key, valid, and uniform measures; more effective monitoring and enforcement; and will ensure comparability of objective measures across the States.'' [167] At the time of publication of the 2011 proposed rule and 2015 final rule with comment period, we noted our belief that a uniform approach to meeting the statutory requirement under section 1902(a)(30)(A) of the Act, including setting standardized access to care data measures, could prove difficult given then-current limitations on data, local variations in service delivery, beneficiary needs, and provider practice roles.[168] [169]

Separately, the Supreme Court, in *Armstrong* v. *Exceptional Child Center, Inc.,* 575 U.S. 320 (2015), ruled that Medicaid providers and beneficiaries do not have a direct private right of action against States to challenge Medicaid payment rates in Federal courts. This decision means provider and beneficiary legal challenges against States are unavailable in Federal court to supplement our oversight as a means of ensuring compliance with section 1902(a)(30)(A) of the Act. The Armstrong decision also underscored HHS' and CMS' unique responsibility for resolving issues concerning the interpretation and implementation of section 1902(a)(30)(A) of the Act. The Supreme Court's Armstrong decision placed added importance on CMS' administrative review of SPAs proposing to reduce or restructure FFS payment rates. Accordingly, the 2015 final rule with comment period was an effort to establish a more robust oversight and enforcement strategy with respect to section 1902(a)(30)(A) of the Act.

In consideration of State agencies' and other interested parties' feedback on the previous AMRP process, as well as CMS' obligation to ensure continued compliance with section 1902(a)(30)(A) of the Act, we are updating the requirements in § 447.203. We are rescinding and replacing the AMRP requirements previously in § 447.203(b)(1) through (8) with a streamlined and standardized process, described in § 447.203(b) and (c). This change is informed by a center-wide review of our policy and processes regarding access to care for all facets of the Medicaid program. The 2015 final rule with comment period acknowledged our need to better understand FFS rate actions and their potential impact on State programs, and the requirements we finalized require a considerable amount of data from States. To ensure States were meeting the statutory requirement under section 1902(a)(30)(A) of the Act, the previous AMRP process was originally intended to establish a transparent data-driven process for States to measure the current status of access to services within the State and utilize this process for monitoring access when proposing rate reductions and restructurings.[170] As the rule took effect and as we reviewed States' previous AMRPs, we found that some rate reductions and restructurings had much smaller impacts than others. The 2017 SMDL reflected the experience that certain payment rate changes would not likely result in diminished access to care and do not require the substantial review of access data that generally is required under the 2015 final rule with comment period. Since publication of the 2019 CMCS Informational Bulletin stating the agency's intention to establish a new access strategy, we have developed the new process we are finalizing in this final rule that considers the lessons learned under the previous AMRP process, and emphasizes transparency and data analysis, with specific requirements varying depending on the State's current payment levels relative to Medicare, the magnitude of the proposed rate reduction or restructuring, and any access to care concerns raised to State Medicaid agency by interested parties. With these provisions, we aim to balance Federal and State administrative burden with our shared obligation to ensure compliance with section 1902(a)(30)(A) of the Act (and our obligation to oversee State compliance with the same).

We received public comments on our overall approach to a new access strategy as well as broad comments about multiple provisions in the rule. We received some comments that were outside of the scope of the proposed rule entirely (for example, related to access in managed care and coverage of services), and therefore, are not addressed in this final rule. We also note that some commenters expressed general support for all of the provisions in section II.C. of this rule, as well as for this rule in its entirety. In response to commenters who supported some, but not all, of the policies and regulations we proposed in the proposed rule (particularly in section II.C related to FFS access), we are clarifying and emphasizing our intent that each final policy and regulation is distinct and severable to the extent it does not rely on another final policy or regulation that we proposed.

While the provisions in section II.C. of this final rule are intended to present a comprehensive approach to ensuring that FFS payment rates are adequate to ensure statutorily sufficient access for beneficiaries, and these provisions complement the goals expressed and policies and regulations being finalized in sections II.A. (MAC and BAC) and II.B. (HCBS) of this final rule, we intend that each of them is a distinct, severable provision, as finalized. Unless otherwise noted in this rule, each policy and regulation being finalized under this section II.C is distinct and severable from other final policies and regulations being finalized in this section or in sections II.A. or II.B of this final rule, as well as from rules and regulations currently in effect.

Consistent with our previous discussion earlier in section II. of this final rule regarding severability, we are clarifying and emphasizing our intent that if any provision of this final rule is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further State action, it shall be severable from this final rule, and from rules and regulations currently in effect, and not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances. For example, we intend that the policies and regulations we are finalizing related to the payment rate transparency publication requirement (section II.C.2.a. of this final rule) are distinct and severable from the policies and regulations we are finalizing related to the comparative payment rate analysis requirement and the payment rate disclosure publication requirement (sections II.C.2.b. of this final rule, which we further intend are severable from each other). These provisions are in turn also severable from the interested parties advisory group provision in section II.C.2.c. of this final rule, the State analysis procedures for rate reduction and restructuring SPAs in section II.C.3. of this final rule, and from the Medicaid provider participation and

[166] American Medical Association, Comment Letter on 2015 Final Rule with Comment Period (January 4, 2016), *https://www.regulations.gov/comment/CMS-2011-0062-0328.*

[167] American Association of Retired Persons, Comment Letter on 2011 Propose Rule (July 5, 2011), *https://www.regulations.gov/comment/CMS-2011-0062-0121.*

[168] 76 FR 26341 at 26349.

[169] 80 FR 67576 at 67577, 67579, 67590.

[170] 80 FR 67576 at 67577.

public process to inform access to care policies in section II.C.4. of this final rule, and each of these in turn is intended to be severable from each other.

The following is a summary of the general comments we received on our proposal to rescind the previous AMRP requirements in § 447.203(b)(1) through (8) and replace them with a streamlined and standardized process in § 447.203(b) and (c), and our responses.

Comment: We received general support from most commenters for our proposal to rescind the AMRP process finalized in the 2015 final rule with comment period in its entirety and replace it with new requirements for payment rate transparency and State analysis procedures for rate reductions and restructuring as described in the proposed rule to ensure compliance with section 1902(a)(30)(A) of the Act. We also received commenter feedback encouraging CMS to ensure the process replacing the AMRPs is robust and public, and that it ensures access to critical services is measured adequately.

Response: We thank the commenters for their support and are finalizing the rescission of the previous AMRP process in its entirety and its replacement with the new requirements as proposed, apart from some minor revisions to the proposed regulatory language, which we address in detail later in this final rule. As of the effective date of this final rule, States are no longer required to submit AMRPs to CMS as previously required in § 447.203(b)(1) through (8). We believe our new policies are robust and that they ensure public transparency and that access to critical services is measured adequately.

Comment: While most commenters generally supported the proposal to rescind § 447.203(b) in its entirety and replace it with new requirements to ensure FFS Medicaid payment rate adequacy, a couple of commenters recommended that CMS maintain some or all of the AMRP process for certain providers (that is, FQHCs, clinics, dental care providers, and community mental health providers), in addition to the newly proposed payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements. Additionally, these commenters raised concerns that the newly proposed requirements focused exclusively on fee schedule payment rate transparency and comparison to Medicare payment rates; therefore, FQHCs, clinics, dental care providers, and community mental health providers would be excluded from the proposed payment rate transparency and comparative payment rate analysis provisions because these providers generally are not paid fee schedule payment rates (within the meaning of this final rule) and/or lack corresponding Medicare payment rates. One commenter recommended keeping the AMRP requirements in place as a separate process for analyzing access to primary care services provided by FQHCs, clinics, or dental providers if these providers are excluded from the payment rate transparency and comparative payment rate disclosure as a way to assess access to care to these services and providers as they were previously included in the AMRP requirements. Another commenter stated that, in comparison to the AMRPs, the provisions in the proposed rule are an oversimplified approach to evaluating Medicaid FFS payment rates and do not sufficiently focus on payment levels for a comprehensive continuum of behavioral health services.

Response: We acknowledge these commenters' support for the previous AMRP process and suggestion to continue to subject payment rates for FQHCs, clinics (as defined in § 440.90), dental care providers, and community mental health providers to the previous AMRP process. However, we are not incorporating this suggestion, to ensure a consistent approach to evaluating access to care within FFS and across delivery systems that more appropriately balances administrative burden on States and us with the usefulness of the process for ensuring that payment rates comply with section 1902(a)(30)(A) of the Act.

To address commenters' concerns about services being excluded from the payment rate transparency provision in § 447.203(b)(1), we will briefly address which payment rates are and are not subject to the payment rate transparency provisions, but this issue is discussed in greater detail in a later comment response. For purposes of the payment rate transparency provision in § 447.203(b)(1), Medicaid FFS fee schedule payment rates are payment amounts made to a provider and known in advance of a provider delivering a service to a beneficiary by reference to a fee schedule. To the extent a State pays fee schedule payment rates for clinic services (as defined in § 440.90), dental services, and community mental health services that meet the previously stated description, those payment rates are subject to the payment rate transparency provisions in § 447.203(b)(1). As for the comparative payment rate analysis requirements in § 447.203(b)(2)–(3), as discussed in greater detail later in this final rule, only codes included on the CMS-published list of evaluation and management (E/M) Current Procedural Terminology or Healthcare Common Procedure Coding System (HCPCS) CPT/HCPCS codes are subject to the analysis.

Additionally, as further discussed in a later comment response, States use provider-specific cost and visit data for a particular benefit category to set the prospective payment system (PPS) rates that are paid to FQHCs or rural health clinics (RHCs) in a process governed by section 1902(bb) of the Act. Because States utilize these data rather than fee schedule payment rates within the meaning of this final rule, those rates paid to FQHCs and RHCs are not subject to the new payment rate transparency provisions in § 447.203(b)(1) or the comparative payment rate analysis requirements in § 447.203(b)(2) through (3). Lastly, like all State plan services for which the State proposes a rate reduction or restructuring in circumstances where the changes could result in reduced access, FQHC, RHC, clinic (as defined in § 440.90), dental, and community mental health services are subject to access analyses in § 447.203(c) for proposed rate reductions and restructuring.

While we recognize that there may be multiple approaches to evaluating access to care for Medicaid beneficiaries, we respectfully disagree with the commenter that the payment rate transparency and State analysis procedures for rate reductions and restructuring are an oversimplified approach for evaluating Medicaid FFS payment rates. As part of a comprehensive review of our policy and processes regarding access to care for all facets of the Medicaid program, we proposed a more streamlined approach, as compared to previous AMRP process, that we intended better to balance Federal and State administrative burden with our shared obligation to ensure compliance with section 1902(a)(30)(A) of the Act.

Additionally, we disagree with the commenter that, in comparison to the previous AMRP process, the provisions in the proposed rule do not sufficiently focus on payment levels for a comprehensive continuum of behavioral health services. The provisions of this final rule serve as one part of our comprehensive efforts to ensure that payment levels across the continuum of behavioral health services are economic and efficient, as well as consistent with quality and access consistent with the statute. As we discussed in the proposed rule, we limited the scope of behavioral health services subject to

comparative payment rate analysis to include only outpatient services.[171] For this final rule, we have revised the outpatient behavioral health services category of service in § 447.203(b)(2)(iii), which we are finalizing as ''Outpatient mental health and substance use disorder services.'' This revision will ensure this final rule is consistent with the services in the Managed Care final rule (as published elsewhere in this **Federal Register**) and reflects a more granular level of service description. As this category of service remains outpatient, this allows us to focus on ambulatory care provided by practitioners in an office-based setting without duplicating existing Federal requirements for demonstrating compliance with applicable upper payment limits (UPLs) and the supplemental payment reporting requirements under section 1903(bb) of the Act. Therefore, between the comparative payment rate analysis requirements that we are finalizing in this rule (including outpatient mental health and substance use disorder services) and existing UPL and supplemental payment reporting requirements (including requirements specific to inpatient services furnished in psychiatric residential treatment facilities, institutions for mental diseases, and psychiatric hospitals), we believe that States and CMS will have available sufficient information about inpatient and outpatient mental health and substance use disorder services payment rates to appropriately monitor payment levels across the continuum of mental health and substance use disorder services.

Comment: Several commenters raised concerns about administrative burden on States to comply with the payment rate transparency publication, comparative payment rate analysis, and payment rate disclosure requirements. Commenters were generally concerned about the compounding effect on already overburdened State resources that would be required to meet these provisions, the other HCBS and MAC and BAG provisions of the proposed rule, and the provisions of the Managed Care proposed rule. Specifically for the payment rate transparency provisions under § 447.203(b), commenters were generally concerned about the significant amount of State resources (including number of staff, staff time, and financial expense) that would be required to collect, prepare, analyze, and publish the data and information required.

[171] 88 FR 27960 at 28006.

Additionally, a few commenters expressed concerns about the burden associated with the proposed rule and stated that they did not believe the requirement to publish Medicaid payment rates through the payment rate transparency publication would benefit the Medicaid program by providing States and CMS with an effective and meaningful way of ensuring access to care is sufficient. One commenter stated that they expect their State Medicaid program to limit future program enhancements and improvements because they would need to redirect resources to complying with the provisions of the proposed rule, if finalized.

Response: We appreciate the commenters' concerns, and we would like to note that the FFS provisions, including the payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements (§ 447.203(b)(1) through (5)), interested parties' advisory group requirements (§ 447.203(b)(6)), and State analysis procedures for payment rate reductions or payment restructuring (§ 447.203(c)), finalized in this rule are expected to result in a net burden reduction on States compared to the previous AMRP requirements, as discussed in the proposed rule and in section III. of this final rule. We are also providing States with a full 2-year compliance period between the effective date of this final rule and the initial applicability date of July 1, 2026, rather than 6 or 9 months as finalized with the previous AMRP process.[172] Given that the previously referenced requirements of this final rule should be less burdensome for States than the rescinded, previous AMRP requirements, and the length of time States have to prepare to implement these new requirements, we expect that States will be able to meet the payment rate transparency, interested parties' advisory group, and State analysis procedures for payment rate reductions or payment restructuring requirements, if a rate reduction or restructuring is proposed through a SPA, without needing to limit future program enhancements or increase the level of State resources dedicated to ensuring compliance with the access requirement in section 1902(a)(30)(A) of the Act.

We would also like to reassure States that the provisions of § 447.203(b)(1) in this final rule include flexibilities that could further ease the burden on States. For example, the payment rate transparency publication requirements described in paragraph (b)(1) and paragraph (b)(1)(ii) have limited formatting requirements, and therefore we expect many States that already publish at least some of their Medicaid FFS fee schedule payment rates directly on fee schedules posted on the State agency's website would only need to make minor revisions or updates (if any) to comply with the new requirements with respect to these already-published payment rates. States are not required to create new fee schedules if their published payment rate information is already organized in such a way that a member of the public can readily determine the amount that Medicaid would pay for each covered service, consistent with § 447.203(b)(1). Additionally, because commenters informed us that some States use a contractor to maintain their fee schedules on the contractor's website, we have revised the language in § 447.203(b)(1) to permit the State to ''publish all Medicaid fee-for-service payment rates on a website that is accessible to the general public'' by removing the proposed requirement that the payment rates be published on a website that is ''developed and maintained by the single State agency.'' This flexibility is being provided for States to continue utilizing a contractor to develop fee schedules as well as utilizing a contractor's (or other third party's) website to publish the payment rate transparency publication so long as the State publishes a readily accessible link on its State-maintained website to the required content and ensures on an ongoing basis that the linked content meets all applicable requirements of this final rule. We continue to require that ''[t]he website where the State agency publishes its Medicaid fee-for-service payment rates must be easily reached from a hyperlink on the State Medicaid agency's website'' in § 447.203(b)(1)(ii). We acknowledge that States utilization of contractors to meet certain programmatic responsibilities is a common occurrence, and with this modification, we are ensuring flexibility for States to rely on these relationships to meet the payment rate transparency publication requirement.

With respect to the comparative payment rate analysis in § 447.203(b)(2) and (3), as discussed in the proposed

[172] In the 2015 final rule with comment period (80 FR 67576), the previous AMRPs were originally due on July 1 providing States with approximately 6 months between the final rule effective date of January 4, 2016, and due date of July 1, 2016. Based on comments received on the 2015 final rule with comment period, the 2016 final rule (81 FR 21479) extended the due date to October 1, 2016, providing States with an additional 3 months to submit their first AMRPs for a total of approximately 9 months from the effective date of the 2015 final rule when States were first notified they would be required to submit AMRPs.

rule, States have the flexibility to map their geographical areas to those used for Medicare payment for purposes of meeting the requirement that States break down their payment rates by geographical location, as applicable.[173] We will provide States with a list of the CPT/HCPCS codes to be used for comparison in subregulatory guidance, including an example list, that will be issued prior to the effective date of this final rule.[174] While the first published list will be an example list of codes that would have been subject to the comparative payment rate analysis if it were in effect for CY 2023, we will publish the initial list of E/M CPT/HCPCS codes subject to the comparative payment rate analysis no later than June 30, 2025, to provide States 1 full calendar year between the issuance of the CMS-published list of E/M CPT/HCPCS codes and the due date of the comparative payment rate analysis, as described in the proposed rule.[175]

For the payment rate disclosure in § 447.203(b)(2) and (3), which requires States to publish the average hourly Medicaid FFS fee schedule payment rate for personal care, home health aide, homemaker, and habilitation services, as discussed in detail in a later response to comments in this section, there is no Medicare comparison component. Because the disclosure will reflect only the State's payment rate data, we chose not to specify codes; this will provide States more flexibility in meeting the requirements in line with each State's unique circumstances. For example, the payment rate disclosure requirements can accommodate the flexibility States have in setting their payment rates and methodologies for personal care, home health aide, homemaker, and habilitation services, as well as the provider types licensed to deliver these services to beneficiaries.

We disagree with commenters that the requirement to publish Medicaid payment rates through the payment rate transparency publication would not benefit the Medicaid program by providing States and CMS with an effective and meaningful way of ensuring access to care is sufficient. As discussed in the proposed rule, payment rate transparency is a critical component of assessing compliance with section 1902(a)(30)(A) of the Act. By publishing their Medicaid payment rates publicly, States will be providing the necessary information to evaluate if State payment rates are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area and interested parties have basic information available to them to understand Medicaid payment levels and the associated effects of payment rates on access to care so that they may raise concerns to State Medicaid agencies via the various forms of public processes available to interested parties.[176] Also as discussed in section V.D. of the proposed rule, we considered, but did not propose, to require Medicaid payment information be directly submitted to CMS, rather than publicly published, because this requirement to publicly display payment rate information is methodologically similar to the previous regulation at § 447.203, which required previous AMRPs be submitted to us and publicly published by the State and CMS. We found this aspect of the rule to be an effective method of publicly sharing access to care information, as well as ensuring State compliance, and are carrying it forward into the provisions finalized in this rule.[177] Additionally, the Supreme Court's *Armstrong* decision underscored the importance of CMS' determinations, as the responsible Federal agency, regarding the sufficiency of Medicaid payment rates.

Comment: A couple of commenters requested clarification regarding CMS exempting States that deliver all of their Medicaid services through managed care from all of the payment rate transparency provisions under § 447.203(b).

Response: All States are required to comply with the payment rate transparency publication, comparative payment rate analysis, and payment rate disclosure provisions finalized in this rule under § 447.203(b), regardless of the quantity of services covered or delivered or beneficiaries enrolled in managed care. Due to coverage transition periods, such as where an individual is Medicaid eligible but not yet enrolled in a managed care plan or benefits are covered retroactively,[178] even States that generally enroll all beneficiaries into managed care plans pay for some services on a FFS basis that are carved out of the managed care plan contracts, and therefore, are expected to have Medicaid FFS fee schedule payment rates in effect. Such Medicaid FFS fee schedule payment rates are subject to the provisions finalized in this rule under § 447.203(b).

Comment: Several commenters requested CMS clearly define the services considered to be categories of services subject to all provisions under § 447.203(b). One commenter requested CMS publish information regarding the timing of when States can expect the CMS published list of E/M CPT/HCPCS codes subject to the comparative payment rate analysis.

Response: For the payment rate transparency requirements in § 447.203(b)(1), as further discussed in a later response to comments in this section, services for which providers are paid Medicaid FFS fee schedule payment rates within the meaning of this final rule, which generally are payment amounts made to a provider and known in advance of a provider delivering a service to a beneficiary, are subject to the requirements of § 447.203(b)(1)(i) through (vi).

For the comparative payment rate analysis described in § 447.203(b)(3)(i), the list of the E/M CPT/HCPCS codes that specifies the services subject to the analysis will be published in subregulatory guidance. Prior to the effective date of this final rule, we will issue subregulatory guidance, including a hypothetical example list of the E/M CPT/HCPCS codes that would be subject to the comparative payment rate analysis, if the comparative rate analysis requirements were applicable with respect to payment rates in effect for CY 2023. This example list defines the services that would be subject to the comparative payment rate analysis through the identification of specific E/M CPT/HCPCS codes that are in effect for CY 2023. In other words, the example list of E/M CPT/HCPCS codes includes codes that meet the following criteria: the code is effective for CY 2023; the code is classified as an E/M CPT/HCPCS code by the American Medical Association (AMA) CPT Editorial Panel; the code is included on the Berenson-Eggers Type of Service (BETOS) code list effective for the same time period as the hypothetical comparative payment rate analysis (CY 2023) and falls into the E/M family grouping and families and subfamilies for primary care services, obstetrics and gynecological services, and outpatient behavioral services (now called

[173] 88 FR 27960 at 28013.

[174] 88 FR 27960 at 28008.

[175] 88 FR 27960 at 28008 through 28009.

[176] 88 FR 27960 at 27967.

[177] 88 FR 27960 at 28075.

[178] Once an individual is enrolled in Medicaid, coverage is effective either on the date of application or the first day of the month of application. Benefits also may be covered retroactively for up to three months prior to the month of application if the individual would have been eligible during that period had he or she applied. Coverage generally stops at the end of the month in which a person no longer meets the requirements for eligibility. *https://www.medicaid.gov/medicaid/eligibility/index.html.*

outpatient mental health and substance use disorder services in this final rule); and the code has an A (Active), N (Non-Covered), R (Restricted), or T (Injections) code status on the Medicare Physician Fee Schedule (PFS) with a Medicare established relative value unit (RVU) and payment amount for CY 2023. As discussed in the proposed rule, we expect to provide States with approximately 1 full calendar year of access to the CMS-published list of E/M CPT/HCPCS codes and Medicare non-facility payment rates as established in the annual Medicare PFS rule for a calendar year to provide States with sufficient time to develop and publish their comparative payment rate analyses as described in § 447.203(b)(4).[179] Therefore, we expect that the first CMS-published list of the E/M CPT/HCPCS codes that actually will be subject to the comparative payment rate analysis requirements will be published by July 1, 2025 for CY 2025, to facilitate States' publication of their comparative payment rate analyses by the applicability date of July 1, 2026.

The categories of services subject to the payment rate disclosure requirements described in § 447.203(b)(3)(ii), as discussed later in this preamble, are personal care, home health aide, homemaker, and habilitation services provided under FFS State plan authority, including sections 1915(i), 1915(j), 1915(k) State plan services; section 1915(c) waiver authority; and under section 1115 demonstration authority. We are not identifying codes for these categories of services because States may use a wide variety of codes to bill and pay for these services, and because the payment rate disclosure does not have a comparison element that would necessitate uniformity with another payer. While we encourage States to organize their payment rate disclosure on a code basis, when possible, for clarity and formatting consistency with the comparative payment rate analysis, States have flexibility in meeting the payment rate disclosure requirements to ensure each State's unique circumstances can be accounted for in the disclosure.

Comment: Several commenters urged CMS to delay the proposed applicability date of the § 447.203(b) provisions, including the compliance actions described in § 447.203(b)(5), to allow States sufficient time for compliance. Commenters stated that the amount of recently proposed Federal changes, including this rulemaking and the Managed Care proposed rule, raised concerns about State resources necessary to comply with all new Federal regulations. Some commenters expressed concern that withholding administrative FFP would further hinder States' ability to meet the requirements and CMS should only act after exhausting all other efforts to ensure States are compliant (including adopting a tiered approach to enforcement and directly engaging with non-compliant States to create a corrective action plan).

Commenters suggested the following alternative applicability dates: approximately 3 years from the effective date of a final rule (that is, January 1, 2027), 4 years (that is, January 1, 2028), or 5 years (that is, January 1, 2029). Alternatively, a few commenters urged CMS to accelerate the proposed applicability date of the § 447.203(b) provisions by one year from January 1, 2026, to January 1, 2025, to ensure payment rate information is published timely to help address questions about access, particularly for HCBS. In addition to the proposed compliance procedures described in § 447.203(b)(5), a couple of commenters suggested CMS publish an annual calendar for States to follow and CMS should also report on the timeliness of each State's compliance with the payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements.

Response: We are finalizing the payment rate transparency requirements in § 447.203(b) with an applicability date of July 1, 2026, which is 6 months later than we proposed. This date is an alternative applicability date that was described in the proposed rule to allow for States to have a period of at least 2 years between the effective date of the final rule and the applicability date for the § 447.203(b) provisions. The July 1, 2026, applicability date applies to the payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements. For payment rate transparency, the initial publication of the Medicaid FFS payment rates shall occur no later than July 1, 2026, and include approved Medicaid FFS payment rates in effect as of July 1, 2026. For the comparative payment rate analysis and payment rate disclosure, the initial comparative payment rate analysis and payment rate disclosure must include Medicaid payment rates in effect as of July 1, 2025, and be published no later than July 1, 2026. As finalized in this rule, the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year included in the comparative payment rate analysis must be effective for the same time period for the same set of E/M CPT/HCPCS codes used for the base Medicaid FFS fee schedule payment rate. The Medicare PFS is published through annual notice and comment rulemaking, and takes effect January 1 of the upcoming calendar year. As discussed in the proposed rule, we acknowledged that Medicare may issue a correction to the Medicare PFS after the final rule is in effect, and this correction may impact our published list of E/M CPT/HCPCS codes and we would like to reemphasize that we expect States to rely on the CMS published list of E/M CPT/HCPCS codes subject to the comparative payment rate analysis for complying with the requirements in paragraphs (b)(2) through (4).[180] States are required to use the Medicare non-facility payment rates as established in the Medicare PFS final rule for calendar year 2025 for purposes of the initial comparative payment rate analysis to be published by July 1, 2026. In accordance with paragraph (b)(4), the comparative payment rate analysis is required to be updated no less than every 2 years and by no later than July 1 of the second year following the most recent update, therefore, the second comparative payment rate analysis would be for calendar year 2027, the third analysis would be for calendar year 2029, so on and so forth. Each comparative payment rate analysis would use the respective year's CMS published list of E/M CPT/HCPCS codes which will be updated by CMS approximately one full calendar year before the due date of the next comparative payment rate analysis and the list will include changes made to the AMA CPT Editorial Panel and the Medicare PFS based on the most recent Medicare PFS final rule, as described in the proposed rule.[181]

We are not finalizing the alternative applicability dates, including dates sooner and later than the July 1, 2026, due date finalized in this rule, as suggested by commenters. We are not accelerating the date as we are mindful of the numerous new regulatory requirements established in this final rule, the Managed Care final rule (as published elsewhere in this **Federal Register**), and the Streamlining Eligibility & Enrollment final rule. We want to ensure States have adequate time to implement all newly finalized provisions, with at least 2 years between the effective date and applicability date as described in the proposed rule.[182] We

[179] 88 FR 27960 at 28008–28009.

[180] 88 FR 27960 at 28009.

[181] 88 FR 27960 at 28008.

[182] 88 FR 27960 at 28008.

are also not delaying the applicability date as we believe the applicability date for the provisions finalized in section II.C. of this final rule are reasonable given that States should have their Medicaid FFS fee schedule payment rates data readily available, Medicare payment rate data are publicly available, and we are making available supportive guidance and templates with this final rule. In the beginning of section II. of this final rule, we include a table with the provisions and relevant timing information and applicability dates of all provisions in the rule. We believe this table delivers the information the commenter was seeking. We expect the information published in this final rule is sufficient for States to comply in a timely manner and we currently do not intend to publish a calendar in any other format. We are finalizing the compliance provisions at § 447.203(b)(5) as proposed. While we currently do not intend to publish a report of the timeliness of each State's compliance with the payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements, as suggested by a couple of commenters, given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

Comment: A number of commenters suggested CMS conduct the proposed payment rate transparency publication, comparative payment rate analysis, and payment rate disclosure on behalf of States to ensure a consistent, national approach to analyzing and publishing payment rate information. These commenters stated CMS could do this by requiring States to submit their fee schedules to CMS or CMS could collect fee schedule rate information during the SPA approval process. Specifically for the payment rate disclosure, two commenters suggested using existing data collection tools, specifically the State of the Workforce Survey, to source the information required for the disclosure to ease burden on States.[183] Additionally, a couple of commenters suggested CMS create a centralized data repository of all States' payment rate transparency, comparative payment rate analysis, and payment rate disclosure publications for public use, including data analysis, if the proposed requirements are applied to States.

Response: As described in section V.D.3 of this final rule, prior to the issuance of the 2023 proposed rule, we specifically considered ways for CMS to produce and publish the comparative payment rate analysis proposed in § 447.203(b)(2) through (3) whereby we would develop reports for all States demonstrating Medicaid payment rates for all services or a subset for Medicaid services as a percentage of Medicare payment rates.[184] We decided not to propose this approach because it would rely on T–MSIS data, which would increase the lag in available data due to the need for CMS to prepare it and then validate the data with States to ensure the publication is accurate, in addition to introducing uncertainty into the results due to ongoing variation in State T–MSIS data quality and completeness. Given the increased lag time associated with T–MSIS data and uncertainty in results that would diminish the utility of the comparative payment rate analysis, we decided producing and publishing the analysis would likely result in inaccuracies, resulting in burden on States to correspond with CMS to provide missing information and correct other information. After considering, and ultimately not proposing, CMS complete a comparative payment rate analysis on behalf of States, we did not further consider conducting the payment rate transparency publication or payment rate disclosure on behalf of States due to the previously stated reasons (that is, lagging data from T–MSIS and the need that would remain to validate data with States).

We are not creating a centralized data repository of all States' payment rate transparency, comparative payment rate analysis, and payment rate disclosure publications for public use as suggested by commenters because we are striving to balance Federal and State administrative burden with our shared obligation to ensure compliance with section 1902(a)(30)(A) of the Act. Requiring States to submit the information they already published on their State or contractor's website would be duplicative and create additional burden on States. We acknowledge that we could also pull data from State or contractor websites to create a central Federal repository; however, we intend our initial focus to be on establishing the new payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements; providing States with support during the compliance period; and ensuring these data are available to beneficiaries, providers, CMS, and other interested parties for the purposes of assessing access to care issues. Additionally, we believe that the States, as stewards of Medicaid payment rate information in each of their Medicaid programs, are the party in the best position to publish and analyze their own payment rate information. States' ownership of payment rate information will ensure accurate payment rate transparency publications, comparative payment rate analyses, and payment rate disclosures. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

While we appreciate the suggestion to utilize existing data collection tools, specifically the State of the Workforce Survey, we will not be relying on the State of the Workforce Survey because the data do not include all States, the District of Columbia, and the Territories (2021 Survey only sourced data from 28 States and the District of Columbia);), account for payment rate variation by population (pediatric and adult), provider type, and geographical location (2021 Survey only includes mean starting wage, the median starting wage, as well as the minimum and maximum starting hourly wages); or include individual providers (2021 Survey only sourced data from provider agencies). Accordingly, it would not be a sufficient data source to meet the requirements for the payment rate disclosure as finalized in this final rule.

Comment: We received some comments about CMS requiring States to change their payment rates. A couple of commenters requested CMS require States to change their payment rates when deficiencies are identified through the payment rate transparency publication, comparative payment rate analysis, or payment rate disclosure; when provider shortages are documented; and when reimbursement or payment rates fall below a certain threshold, such as 50 percent of the corresponding Medicare payment rate; however, most commenters who suggested CMS set a threshold did not

[183] The State of the Workforce Survey collects comprehensive data on provider agencies and the Direct Support Professional (DSP) workforce providing direct supports to adults (age 18 and over) with intellectual and developmental disabilities (IDD). The goal of the survey and the resulting data is to help States examine workforce challenges, identify areas for further investigation, benchmark their workforce data, measure improvements made through policy or programmatic changes, and compare their State data to those of other States and the NCI–IDD average. *https://idd.nationalcoreindicators.org/staff-providers/.*

[184] 88 FR 27960 at 28075.

suggest a specific number for the threshold. One commenter specifically asked if CMS would require States to increase institutional service payment rates. The commenter was concerned that an increase in a direct care worker's Medicaid hourly rate, without a corresponding increase in a Medicaid payment rate for institutional services, would result in fewer hours of care able to be delivered. We received one comment requesting CMS to expressly permit States to pay more than Medicare for services furnished through the FFS system. Additionally, one commenter expressed caution that increasing payment rate transparency does not necessarily ensure access to care or coverage of services in Medicaid.

Response: To clarify, the provisions in this final rule do not require States to change their payment rates. Although we intend for States to consider the information produced for the payment rate transparency publication, comparative payment rate analysis, and payment rate disclosure in an ongoing process of evaluating the State's payment rate sufficiency and when considering changing payment rates or methodologies (and we intend to make similar use of the information in performing our oversight activities and in making payment SPA approval decisions), we did not propose and are not finalizing that any payment rate changes necessarily would be triggered by the proposed requirements.

Specifically, we did not propose, nor are we finalizing, a requirement that States must increase their institutional or non-institutional service payment rates through this final rule. Based on the information provided by the commenter (and without additional information about providers, such as, number of providers in a State or number of provider accepting new patients or accepting Medicaid), we understand the concerns raised to generally be an issue with a State's limitations on service coverage (that is, a coverage limit of $1,000/month limit on institutional services is insufficient for the amount of care required). While we do not have the authority to require States to change their Medicaid payment rates, we remind States that the Medicaid program is a Federal-State partnership and States have the flexibility and responsibility to set payment rates that are consistent with efficiency, economy, quality of care, and access as required by section 1902(a)(30)(A) of the Act and a coverage limit could be inconsistent with this standard. We encourage the commenter to utilize the public process procedures described in § 447.204 to raise these concerns with their State. We also did not propose and are not finalizing a regulatory change that explicitly permits States to pay more than Medicare for services furnished through the FFS system. We acknowledge that existing UPL requirements limit Medicaid payments to a reasonable estimate of what Medicare would have paid.[185] However, outside of the services subject to UPL requirements limiting aggregate State Medicaid payment amounts, as the Medicaid program is a Federal-State partnership, States have the flexibility and responsibility to set payment rates that are consistent with efficiency, economy, and quality of care as required by section 1902(a)(30)(A) of the Act. Currently, States can set FFS payment rates that are more than Medicare for numerous services, provided any applicable aggregate UPL is satisfied, and creating an explicit permission in regulation would not change the existing flexibilities States have in setting their payment rates.

We understand the commenter's concerns that increasing payment rate transparency does not necessarily ensure access to care or coverage of services in Medicaid. We acknowledged in the proposed rule that there may be other causes of access to care issues outside of provider payment rates, such as beneficiaries experiencing difficulty scheduling behavioral health care appointments due to a provider shortage where the overall number of behavioral health providers within a State is not sufficient to meet the demands of the general population.[186] However, we believe it is important to address one of the potential causes of access to care issues: payment rates that are not sufficient to enlist an adequate supply of providers as required by section 1902(a)(30)(A) of the Act. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider additional areas of access to care outside of payment rates to help inform any future rulemaking to promote improved access to care, as appropriate.

Comment: A number of commenters requested CMS provide States with guidance, templates, tools, examples, or descriptions of acceptable forms for publishing the payment rates, comparative payment rate analysis, and payment rate disclosure to ensure States understand how to comply with these provisions. A few commenters requested guidance on specific aspects of provisions of the proposed rule: accessible web pages and accounting for additional ways payment rates can vary (such as site of service and patient acuity). Those commenters also noted that some States use value-based payment (VBP) methodologies and requested guidance on how the various provisions of the proposed rule has accounted for these payment methodologies. Additionally, a couple of commenters suggested CMS provide guidance to the public to ensure the newly published data are understandable.

Response: Prior to the effective date of this final rule, we will issue subregulatory guidance including a hypothetical example list of the E/M CPT/HCPCS codes that would be subject to the comparative payment rate analysis, if the comparative rate analysis requirements were applicable with respect to payment rates in effect for CY 2023; illustrative examples of compliant payment rate transparency, comparative payment rate analysis, and payment rate disclosure publications (including to meet accessibility standards); and a template to support completion of the additional State rate analysis under § 447.203(c)(2). We encourage States to review the subregulatory guidance to be issued prior to the effective date of this final rule and reach out to CMS for technical guidance regarding compliance with the comparative payment rate analysis and any other requirement of this final rule.

We are only requiring the payment rate transparency publication, comparative payment rate analysis, and payment rate disclosure include payment rate breakdowns by population (pediatric and adult), provider type, and geographical location, as applicable. Payment rate variations by site of service are not required, but States have flexibility to include this optional payment rate break down in the payment rate transparency publication. While not required in this final rule, should a State opt to breakdown their payment rates by site of service, the State should use the minimum payment amount for purposes of the requirements of § 447.203(b), because a provider is assured to receive at least this amount for furnishing the service at any site of service. At State option, the State could also include additional payment rate breakdowns a provider might receive at other sites of service in the State (for example: office, inpatient hospital, school, mobile unit, urgent

[185] § 447.272 for inpatient hospitals, § 447.321 for outpatient hospitals and clinic services, § 447.325 for other inpatient and outpatient facilities (nursing facilities, intermediate care facilities for the developmentally disabled (ICF/DD), psychiatric residential treatment facilities (PRTF), and institutions for mental disease (IMDs).

[186] 88 FR 27960 at 28016.

care facility, nursing facility). We did not propose or finalize in this rule a requirement for States to include a payment rate breakdown for site of services because we want our initial focus to be on establishing the new payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements, providing States with support during the compliance period, and ensuring the data required under this final rule are available to beneficiaries, providers, CMS, and other interested parties for the purpose of assessing access to care issues. We believe that payment rate breakdowns by population (pediatric and adult), provider type, and geographical location will provide a sufficient amount of transparency to ensure that interested parties have basic information available to them to understand Medicaid payment levels and the associated effects of payment rates on access to care so that they may raise concerns to State Medicaid agencies via the various forms of public processes available to interested parties.

Additionally, payment rate variations based on patient acuity are also not explicitly required in the payment rate transparency publication. Payment adjustments for patient acuity generally are limited to institutional settings (for example, inpatient hospitals and nursing facilities). Should a State opt to breakdown their payment rates by patient acuity, to the State should use the minimum payment amount for purposes of the requirements of § 447.203(b), because a provider is assured to receive at least this amount for furnishing the service to any patient. At State option, the State could also include additional payment rate breakdowns the provider might receive for other levels of patient acuity. We also acknowledge that prospective payment system rates, such as Medicare's Patient Driven Payment Model (PDPM) for nursing facilities and inpatient prospective payment system (IPPS) for inpatient hospitals, typically account for patient acuity. As further discussed in a later response to comments in this section, PPS rates for inpatient hospital, outpatient hospital, and nursing facility services that are paid to most hospitals and nursing facilities and are payments based on a predetermined, fixed amount are subject to the payment rate transparency provision in this final rule. This is because these PPS rates are typically known in advance of a provider delivering a service to a beneficiary and fall into the scope of a Medicaid FFS fee schedule payment rate within the meaning of this final rule, as discussed in a later response to comments in this section.

We understand the commenters' concerns about ensuring the various payment rate transparency publications of this final rule are understandable to the public. We expect State publications of Medicaid payment rate transparency information, comparative payment rate analysis, and payment rate disclosures that comply with the requirements of this final rule to be transparent and clearly understandable to beneficiaries, providers, CMS, and other interested parties. Therefore, we do not anticipate a need for guidance for the public at this time, but we will continue to assess once the requirements are in effect.

Comment: A couple of commenters suggested CMS conduct provider shortage assessments and engage providers, beneficiary advocacy organizations, direct service workers, caregivers, and other relevant interested parties in the data collection and analysis processes in the proposed rule and create a Federal-level public comment process within the CMS review of SPAs and HCBS waiver applications or renewals.

Response: We appreciate the commenters' suggestions; however, we did not propose to conduct provider shortage assessments, or to engage with interested parties in the data collection and analysis processes outside of the work of the interested parties' advisory group in § 447.203(b)(6). After obtaining implementation experience of these new policies, we will keep these suggestions in mind as we consider whether additional requirements may be appropriate to propose through future rulemaking.

Comment: One commenter suggested CMS consider future rulemaking to require States survey HCBS participants and their support systems to identify additional access issues and perceived causes, with a particular focus on assessing access related to unpaid and paid support. The commenter provided an example of a parent of an adult child providing a significant number of hours, both paid and unpaid, which the commenter suggested could be an indicator that the family cannot find a qualified provider for the services.

Response: We appreciate the commenter's suggestion. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

Comment: One commenter questioned the relationship between higher payment rates in FFS and higher rates of accepting new Medicaid patients, as well as the potential for affecting rates across payers and delivery systems, noting that even if the State raise the rates for the Medicaid FFS that does not mean that Medicaid or Medicare managed care plans, including managed care plans for individuals dually eligible for both Medicare and Medicaid, also will raise their provider payment rates. The commenter noted that raising the rates for Medicaid FFS does not mean that the State will ensure that the managed care plans operating in the State also pay higher rates, noting that practitioners are less likely to accept Medicaid if the managed care plans do not raise payment rates to align when FFS rates have been increased.

Response: We appreciate the views of the commenter. The provisions of § 447.203(c) only apply to Medicaid FFS, and do not apply to Medicaid managed care plans. Requirements for Medicaid managed care are discussed in the Medicaid Managed Care final rule (as published elsewhere in this **Federal Register**). Payment rates that managed care plans pay to providers are not required to be set at the Medicaid FFS rate levels as managed care is a risk-based arrangement whereby States pay managed care plans prospective capitation rates, and plans contract with network providers and negotiate provider payment rates. Managed care plans have their own access to care requirements, including the network adequacy requirements in 42 CFR 438.68. Managed care plan capitation rates are subject to actuarial soundness requirements at § 438.4.

1. Fully Fee-For-Service States

We solicited comments on whether additional access standards for States with a fully FFS delivery system may be appropriate. Because the timeliness standards of the proposed Medicaid and Children's Health Insurance Program Managed Care Access, Finance, and Quality proposed rule (Managed Care proposed rule) at § 438.68 would not apply to any care delivery in such States, we stated that we were considering whether a narrow application of timeliness standards to fully FFS States that closely mirrored the proposed appointment wait time standards, secret shopper survey requirements, and publication requirements (as applied to outpatient mental health and substance use disorder, adult and pediatric; primary care, adult and pediatric; obstetrics and gynecology; and an additional type of

service determined by the State) in that rule might be appropriate. Given that timeliness standards would apply directly to States, we also solicited comments on a potentially appropriate method for CMS to collect data demonstrating that States meet the established standards at least 90 percent of the time.

In developing the proposed rule, with respect to FFS, our intent and focus was on replacing the previous AMRP process. While we saw value in discussing and seeking public input on timeliness standards for fully FFS States that would mirror those proposed in the Managed Care proposed rule, creating additional alignment between the delivery systems, we were mindful of the volume of proposed changes that would require State resources for implementation. Therefore, we chose to maintain our goal with the FFS provisions of this access rule to replace the previous AMRP process, and we believed that timeliness standards were better suited to a larger, ongoing access strategy, to be considered and proposed in future rulemaking. Nevertheless, we saw value in gauging the appetite for CMS to adopt timeliness standards in fully FFS States, and as such included a short section about the possibility of those standards in the fully FFS context in the proposed rule. Although we are not finalizing any FFS timeliness standards in this final rule, we intend to propose them in future rulemaking, informed by the comments received on this discussion in the proposed rule. Additionally, by keeping this current rulemaking focused on replacing the previous AMRP process and not implementing FFS timeliness standards at this time, we afford ourselves an opportunity to observe and learn from those standards being established in managed care (and in the marketplace). Those experiences will provide greater insights into how to best propose these standards in FFS and provide time to engage with interested parties on how we might best include newly proposed FFS timeliness standards in existing requirements, including those we are finalizing in this rule, mitigating unnecessary burden on States.

We received public comments in response to this request for comment. The following is a summary of the comments we received and our responses.

Comment: Several commenters noted general support for timeliness standards for fully FFS States. Generally, these commenters agreed that there is value in aligning access monitoring strategies across delivery systems so that all Medicaid beneficiaries would benefit from a new policy, and that these standards could improve access by confirming whether beneficiaries are actually able to access care in a timely manner. Some commenters had suggestions if CMS were to adopt timeliness standards in FFS, such as phasing in the requirements over time or by service, collecting information on geographic variations in wait times, and either applying the standards to all FFS programs or allowing exception for States with minimal covered services delivered through FFS. Others cited concerns that they would want a future proposal to address, such as establishing protections for providers who do not have direct control over their scheduling. Commenters varied on whether they believed providers should have to perform any additional work to meet new standards, with one requesting that providers, not just States, be held accountable for outcomes based on these standards, while another commenter wanted to ensure these requirements would not add any burden on providers. One commenter suggested including provider surveys in addition to participant surveys.

Response: We appreciate the support expressed by a number of commenters for the concept of applying timeliness standards in fully FFS delivery systems as a further means to ensure beneficiary access to covered services. We are also grateful for the suggestions that will allow us to formulate future proposed rulemaking that considers various needs and concerns. We note that the request for comment was with respect to fully FFS States (that deliver no services through managed care), but we will consider for future rulemaking whether to expand on that limit, for example, applying standards to States that cover only a small number of services through managed care delivery, to apply them to FFS generally, or to maintain the focus on fully FFS States. We intend to use the experience of the managed care plans and the States implementing timeliness requirements to assess things like a phased-in approach, or whether such standards should be proposed for FFS delivery systems in non-fully FFS States.

Comment: We received a number of comments expressing general opposition to establishing timeliness standards for services delivered on a FFS basis, particularly in the context of implementing them simultaneously with the other access provisions in the proposed rule. These commenters expressed concern about the burden, both in time and cost, of establishing the necessary administrative infrastructure to meet timeliness requirements as well as the requirements proposed in the proposed rule. One commenter suggested CMS explore how these areas could be better monitored using existing data collections and processes. Another pointed out the differences in available resources between managed care and FFS, such as increased matching rates associated with managed care External Quality Review that does not exist with respect to FFS Medicaid, making FFS timeliness standards more cost prohibitive to implement. Another commenter pointed out that in FFS delivery systems, States would not know whether wait time issues identified through monitoring were specific to Medicaid or whether similar wait time issues were encountered by other patients with other payers.

Response: We understand the concerns about burden on States, and for that reason we limited the proposed rule and are only finalizing provisions that, generally, serve to replace the previous AMRP process. We see value in the oversight and positive program outcomes that could be achieved through proposing and implementing FFS timeliness standards in the future, and also understand there will be differences between managed care and FFS that create unique issues to address in any future proposal. For example, there are differences in how providers interact with plans in a managed care system versus how they interact with the State Medicaid agency in a FFS system. There are also differences in the idea of a ''network'' between these delivery models that may impact how we would assess network adequacy. We will explore how we can best support States with the administrative burden, and how we can establish standards that identify problems unique to providing services to Medicaid beneficiaries.

Comment: Many commenters expressed support for specific aspects of our request, such as for establishing wait time standards in a FFS delivery system or utilizing secret shopper surveys for oversight. These commenters generally pointed to the access improvements such standards can provide, as they would highlight where there are deficiencies in finding available providers. One commenter shared personal experience of longer wait times as a Medicaid beneficiary than those experienced by non-Medicaid enrollees. One commenter shared suggestions regarding which benefit categories needed more focus, both for oversight and in length of wait times, and this commenter along with a couple others encouraged CMS to align with the Health Insurance

Marketplace®.[187] Another commenter cautioned that provider shortages must be addressed as part of the overall access strategy.

Response: We appreciate hearing from commenters on the specifics of the timeliness standards request for comments, as we hope to use this feedback to inform and enhance a future set of proposals. We also fully intend to include lessons from the experience of the marketplace and Medicaid managed care in proposing these future standards for the FFS delivery system and will continue to engage with interested parties between now and when we undertake future rulemaking on this topic. We agree that provider shortages present a challenge to access and the efficacy of wait time standards, and we will examine how best to acknowledge that reality while holding States and providers to appropriate standards.

Comment: Several commenters opposed the specific standards listed in our request for comment. One encouraged CMS to achieve its access goals through a focus on payment adequacy rather than wait times. Similarly, another requested CMS allow States to provide verification and assurances of sufficient access through other, existing data collection mechanisms. Another stated wait time standards that do not account for differences in provider availability, as in whether there are sufficient providers in a geographic area to meet the standards based on the beneficiary population in that area, would not achieve the desired effect of increasing access. One commenter expressed that a secret survey process would be duplicative of existing directory review processes already undertaken by States and would also force States to switch vendors from an existing outside entity performing the role, and stated CMS should instead allow States to continue with current practices that achieve a similar purpose. Another questioned the data integrity of a secret survey approach to oversight, stating there are inherent challenges in collecting consistent information.

Response: We intend to make every effort to utilize existing processes and to mitigate duplication wherever possible when we propose FFS timeliness standards in the future. However, we are exploring proposing these standards because, in our view, appointment wait time maximums and secret shopper surveys may provide for unique and valuable oversight of access that we may wish to propose in the future. As stated previously, in this rule we prioritized a replacement for an existing rate-based process, but our evaluation and enhancement of means to ensure beneficiary access will be ongoing. We will utilize lessons learned from the implementation of timeliness standards under managed care to inform our future FFS proposals.

Comment: Some commenters were unclear as to whether CMS was proposing to implement the timeliness standards for fully FFS States as proposed in the Managed Care proposed rule. One commenter was concerned how and when CMS would communicate to States that these requirements had taken effect. Another pointed out specifically that CMS had included preamble language without including proposed regulatory text or burden estimates, which they noted would be significant. The commenter was concerned that the public had not been afforded a meaningful opportunity for notice and comment.

Response: We apologize for the confusion experienced by some as to whether this section of the rule was intended as a proposed policy. This discussion in the proposed rule was a request for comment, not a proposed policy. We intend to propose these timeliness standards under FFS in future rulemaking, affording States and other interested parties the ability to examine a complete proposal and provide comments that we would consider in a subsequent finalization decision. We are not finalizing any timeliness standards for FFS delivery systems in this final rule.

2. Documentation of Access to Care and Service Payment Rates (§ 447.203(b))

We proposed to rescind § 447.203(b) in its entirety and replace it with new requirements to ensure FFS Medicaid payment rate adequacy, including a new process to promote payment rate transparency. This new proposed process would require States to publish their FFS Medicaid payment rates in a clearly accessible, public location on the State's website, as described later in this section. Then, for certain services, States would be required to conduct a comparative payment rate analysis between the States' Medicaid payment rates and Medicare rates or provide a payment rate disclosure for certain HCBS that would permit CMS to develop and publish HCBS payment benchmark data.

a. Payment Rate Transparency § 447.203(b)(1)

In paragraph (b)(1), we proposed to require the State agency to publish all Medicaid FFS payment rates on a website developed and maintained by the single State agency that is accessible to the general public. We proposed that published Medicaid FFS payment rates would include fee schedule payment rates made to providers delivering Medicaid services to Medicaid beneficiaries through a FFS delivery system. We also proposed to require that the website be easily reached from a hyperlink on the State Medicaid agency's website.

Within this payment rate publication, we proposed that FFS Medicaid payment rates must be organized in such a way that a member of the public can readily determine the amount that Medicaid would pay for the service and, in the case of a bundled or similar payment methodology, identify each constituent service included within the rate and how much of the bundled payment is allocated to each constituent service under the State's methodology. We also proposed that, if the rates vary, the State must separately identify the Medicaid FFS payment rates by population (pediatric and adult), provider type, and geographical location, as applicable.

We noted that longstanding legal requirements to provide effective communication with individuals with disabilities and the obligation to take reasonable steps to provide meaningful access to individuals with limited English proficiency also apply to the State's website containing Medicaid FFS payment rate information. Under Title II of the Americans with Disabilities Act of 1990, section 504 of the Rehabilitation Act, section 1557 of the Affordable Care Act, and implementing regulations, qualified individuals with disabilities may not be excluded from participation in, or denied the benefits of any programs or activities of the covered entity, or otherwise be subjected to discrimination by any covered entity, on the basis of disability, and programs must be accessible to people with disabilities.[188] Individuals with disabilities are entitled to communication that is as effective as communication for people without disabilities, including through the provision of auxiliary aids and services.[189] Section 1557 of the Affordable Care Act requires recipients of Federal financial assistance, including State Medicaid programs, to take reasonable steps to provide

[187] Health Insurance Marketplace® is a registered service mark of the US Department of Health & Human Services.

[188] 29 U.S.C. 794; 42 U.S.C. 18116(a); 42 U.S.C. 12132; 28 CFR 35.130(a); 45 CFR 84.4 (a); 45 CFR 92.2(b).

[189] 28 CFR 35.160; 45 CFR 92.102; *see also* 45 CFR 84.52(d).

meaningful access to their health programs or activities for individuals with limited English proficiency, which may include the provision of interpreting services and translations when reasonable.[190]

We proposed that for States that pay varying Medicaid FFS payment rates by population (pediatric and adult), provider type, and geographical location, as applicable, those States would need to separately identify their Medicaid FFS payment rates in the payment rate transparency publication by each grouping or multiple groupings, when applicable to a State's program. In the event rates vary according to these factors, as later discussed in this final rule, our intent is that a member of the public be readily able to determine the payment amount that will be made, accounting for all relevant circumstances. For example, a State that varies their Medicaid FFS payment rates by population may pay for a service identified by code 99202 when provided to a child at a rate of $110.00 and when provided to an adult at a rate of $80.00. Because the Medicaid FFS payment rates vary based on population, both of these Medicaid FFS payment rates would need to be included separately as Medicaid FFS payment rates for 99202 in the State's payment rate transparency publication. As another example, a State that varies their Medicaid FFS payment rates by provider type may pay for 99202 when delivered by a physician at a rate of $50.00, and when delivered by a nurse practitioner or physician assistant at a rate of $45.00.

In the proposed rule, we acknowledged that we are aware that some State plans include language that non-physician practitioners (NPPs), such as a nurse practitioner or physician assistant, are paid a percentage of the State's fee schedule rate. Because the Medicaid FFS payment rates vary by provider type, both of the Medicaid FFS payment rates in both situations (fee schedule rates of $50.00 and $45.00) would need to be separately identified as Medicaid FFS payment rates for 99202 in the State's payment rate transparency publication, regardless of whether the State has individually specified each amount certain in its approved payment schedule or has State plan language specifying the nurse practitioner or physician assistant rate as a percentage of the physician rate. Additionally, for example, a State that varies their Medicaid FFS payment rates by geographical location may pay for 99202 delivered in a rural area at a rate of $70, in an urban or non-rural area as a rate of $60, and in a major metropolitan area as a rate of $50. We are also aware that States may vary their Medicaid FFS payment rates by geographical location by zip code, by metropolitan or micropolitan areas, or other geographical location breakdowns determined by the State. Because the Medicaid FFS payment rates vary based on geographical location, all Medicaid FFS payment rates based on geographical location would need to be included separately as Medicaid FFS payment rates for 99202 in the State's payment rate transparency publication.

For a State that varies its Medicaid FFS payment rates by any combination of these groupings, then the payment rate transparency publication would be required to reflect these multiple groupings. For example, the State would be required to separately identify the rate for a physician billing 99202 provided to a child in a rural area, the rate for a nurse practitioner billing 99202 provided to a child in a rural area, the rate for a physician billing 99202 provided to an adult in a rural area, the rate for a nurse practitioner billing 99202 provided to an adult in a rural area, the rate for a physician billing 99202 provided to a child in an urban area, the rate for a nurse practitioner billing 99202 provided to a child in an urban area, and so on. We proposed that this information would be required to be presented clearly so that a member of the public can readily determine the payment rate for a service that would be paid for each grouping or combination of groupings (population (pediatric and adult), provider type, and geographical location), as applicable. We acknowledged that States may also pay a single Statewide rate regardless of population (pediatric and adult), provider type, and geographical location, and as such would only need to list the single Statewide rate in their payment rate transparency publication.

We acknowledged that there may be additional burden associated with our proposal that the payment rate transparency publication include a payment rate breakdown by population (pediatric and adult), provider type, and geographical location, as applicable, when States' Medicaid FFS payment rates vary based on these groupings. Despite the additional burden, we noted our belief that the additional level of granularity in the payment rate transparency publication is important for ensuring compliance with section 1902(a)(30)(A) of the Act, given State Medicaid programs rely on multiple provider types to deliver similar services to Medicaid beneficiaries of all ages, across multiple Medicaid benefit categories, throughout each area of each State.

We further proposed that Medicaid FFS payment rates published under the proposed payment rate transparency requirement would only include fee schedule payment rates made to providers delivering Medicaid services to Medicaid beneficiaries through a FFS delivery system. To ensure maximum transparency in the case of a bundled fee schedule payment rate or rate determined by a similar payment methodology where a single payment rate is used to pay for multiple services, we proposed that the State must identify each constituent service included in the bundled fee schedule payment rate or rate determined by a similar payment methodology. We also proposed that the State must identify how much of the bundled fee schedule payment rate or rate determined by a similar payment methodology is allocated to each constituent service under the State's payment methodology. For example, if a State's fee schedule lists a bundled fee schedule rate that pays for day treatment under the rehabilitation benefit and the following services are included in the day treatment bundle: community based psychiatric rehabilitation and support services, individual therapy, and group therapy, then the State would need to identify community based psychiatric rehabilitation and support services, individual therapy, and group therapy separately and each portion of the bundled fee schedule payment rate for day treatment that is allocated to community based psychiatric rehabilitation and support services, individual therapy, and group therapy. We proposed to require States identify the portion of the bundled fee that is allocable to each constituent service included in the bundled fee schedule payment rate, which would add an additional level of granularity to the payment rate transparency publication to enable a member of the public to readily be able to determine the payment amount that would be made for a service, accounting for all relevant circumstances, including the payment rates for each constituent service within a bundle and as a standalone service. We also proposed to require that the website be easily reached from a hyperlink to ensure transparency of payment rate information is available to beneficiaries, providers, CMS, and other interested parties.

In the proposed rule, we proposed the initial publication of Medicaid FFS

[190] 45 CFR 92.101; *see also https://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/guidance-federal-financial-assistance-title-vi/index.html.*

payment rates would occur no later than January 1, 2026, and include approved Medicaid FFS payment rates in effect as of that date, January 1, 2026. We proposed this timeframe to provide States with at least 2 years from the possible effective date of the final rule, if this proposal were finalized, to comply with the payment rate transparency requirement. We explained that the proposed timeframe would initially set a consistent baseline for all States to first publish their payment rate transparency information and then set a clear schedule for States to update their payment rates based on the cadence of the individual States' payment rate changes.

We noted that the same initial publication due date for all States to publish their payment rates would promote comparability between States' payment rate transparency publications. In proposing an initial due date applicable to all States, we reasoned that, once States would begin making updates to their payment rate transparency publications, there would be a clear distinction between States that have recently updated their payment rates and States that have long maintained the same payment rates. For example, say two States initially publish their payment rates for E/M CPT code 99202 (office or outpatient visit for a new patient) at $50. One State annually increases its payment rate by 5 percent over the next 2 years, and would update its payment rate transparency publication accordingly in 2027 with a payment rate of $52.50, then in 2028 with a payment rate of $55.13, while the other State's payment rate for the same service remains at $50 in 2027 and 2028. The transparency of a State's recent payment rates including the date the payment rates were last updated on the State Medicaid agency's website, as discussed later, as well as the ability to compare payment rates between States on accessible and easily reachable websites, highlights how the proposed payment rate transparency would help to ensure that Medicaid payment rate information is available to beneficiaries, providers, CMS, and other interested parties for the purposes of assessing access to care issues to better ensure compliance with section 1902(a)(30)(A) of the Act.

We also proposed that the initial publication include approved Medicaid FFS payment rates in effect as of January 1, 2026. We proposed this language to narrow the scope of the publication to CMS-approved payment rates and methodologies, thereby excluding any rate changes for which a SPA or similar amendment request is pending CMS review or approval. SPAs are submitted throughout the year, can include retroactive effective dates, and are subject to a CMS review period that varies in duration.[191] [192]

As discussed later in this final rule regarding paragraph (b)(2) and (b)(3), we encouraged States to use the proposed payment rate transparency publication as a source of Medicaid payment rate data for compliance with the paragraph (b)(3)(i)(B) proposed comparative payment rate analysis and paragraph (b)(3)(ii)(B) proposed payment rate disclosure requirements. However, we noted that the comparative payment rate analysis and payment rate disclosure requirements would look to rates in effect one year before the publication of the required analysis or disclosure. We include a more in-depth discussion of the timeframes for publication of the comparative payment rate analysis and payment rate disclosure in paragraph (b)(4) later in this final rule, where we note that the 1-year shift in timeframe is necessitated by the timing of when Medicare publishes their payment rates in November and the rates taking effect on January 1, leaving insufficient time for CMS to publish the code list for States to use for the comparative payment rate analysis and for States develop and publish their comparative payment rate analysis by January 1. We noted that the ongoing payment transparency publication requirements would allow the public to view readily available, current Medicaid payment rates at all times, even if slightly older Medicaid payment rate information must be used for comparative payment rate analyses due to the cadence of Medicare payment rate changes as well as the payment rate disclosure. We are cognizant that the payment rate disclosure does not depend on the availability of Medicare payment rates; however, we proposed to provide States with the same amount of time to comply with both the proposed comparative payment rate analysis and payment rate disclosure requirements.

We stated that, if this proposal were finalized at a time that would not allow for States to have a period of at least 2 years between the effective date of the final rule and the proposed January 1, 2026, due date for the initial publication of Medicaid FFS payment rates, then we proposed an alternative date of July 1, 2026, for the initial publication of Medicaid FFS payment rates and for the initial publication to include approved Medicaid FFS payment rates as of that date, July 1, 2026. This shift would allow more than 2 years from the effective date of this final rule for States to comply with the payment rate transparency requirements.

We proposed to require the that the single State agency include the date the payment rates were last updated on the State Medicaid agency's website. We also proposed to require that the single State agency ensure that Medicaid FFS payment rates are kept current where any necessary updates to the State fee schedules made no later than 1 month following the date of CMS approval of the SPA, section 1915(c) HCBS waiver, or similar amendment revising the provider payment rate or methodology. Finally, in paragraph (b)(1), we proposed that, in the event of a payment rate change that occurs in accordance with a previously approved rate methodology, the State would be required to update its payment rate transparency publication no later than 1 month after the effective date of the most recent update to the payment rate. This provision is intended to capture Medicaid FFS payment rate changes that occur because of previously approved SPAs containing payment rate methodologies. For example, if a State sets its Medicaid payment rates for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) at a percentage of the most recent Medicare fee schedule rate, then the State's payment rate would change when Medicare adopts a new fee schedule rate through the quarterly publications of the Medicare DMEPOS fee schedule, unless otherwise specified in the approved State plan methodology that the State implements a specific quarterly publication, for example, the most recent April Medicare DMEPOS fee schedule. Therefore, the State's Medicaid FFS payment rate automatically updates when Medicare publishes a new fee schedule, without the submission of a SPA because the State's methodology pays a percentage of the most recent State plan-specified Medicare fee schedule rate. In this example, the State would need to

[191] In accordance with 42 CFR 430.20, an approved SPA can be effective no earlier than the first day of the calendar quarter in which an approvable amendment is submitted. For example, a SPA submitted on September 30th can be retroactively effective to July 1st.

[192] In accordance with 42 CFR 430.16, a SPA will be considered approved unless CMS, within 90 days after submission, requests additional information or disapproves the SPA. When additional information is requested by CMS and the State has respond to the request, CMS will then have another 90 days to either approve, disapprove, and request the State withdraw the SPA or the State's response to the request for additional information. This review period includes two 90-day review periods plus additional time when CMS has requested additional information which can result is a wide variety of approval timeframes.

update its Medicaid FFS payment rates in the payment rate transparency publication no later than 1 month after the effective date of the most recent update to the Medicare fee schedule payment rate made applicable under the approved State plan payment methodology.

While there is no current Federal requirement for States to consistently publish their rates in a publicly accessible manner, we noted our awareness that most States already publish at least some of their payment rates through FFS rate schedules on State agency websites. Currently, rate information may not be easily obtained from each State's website in its current publication form, making it difficult to understand the amounts that States pay providers for items and services furnished to Medicaid beneficiaries and to compare Medicaid payment rates to other health care payer rates or across States. However, through this proposal, we sought to ensure all States do so in a format that is publicly accessible and where all Medicaid FFS payment rates can be easily located and understood. The new transparency requirements under this final rule help to ensure that interested parties have access to updated payment rate schedules and can conduct analyses that would provide insights into how State Medicaid payment rates compare to, for example, Medicare payment rates and other States' Medicaid payment rates. The policy intends to help ensure that payments are transparent and clearly understandable to beneficiaries, providers, CMS, and other interested parties. We solicited comments on the proposed requirement for States to publish their Medicaid FFS payment rates for all services paid on a fee schedule, the proposed structure for Medicaid FFS payment rate transparency publication on the State's website, and the timing of the publication of and updates to the State's Medicaid FFS payment rates for the proposed payment rate transparency requirements in § 447.203(b)(1).

We received public comments on these provisions. The following is a summary of the comments we received and our responses.

Comment: Commenters overwhelmingly supported the proposed payment rate transparency provision at § 447.203(b)(1) in its entirety. A couple of commenters specifically expressed support for ensuring the State's website where the payment rate transparency is published is fully accessible and provides meaningful access for individuals with limited English proficiency. Additionally, a couple of commenters stated that their State already publishes their fee schedules as proposed by the payment rate transparency requirements.

However, a couple of commenters expressed opposition to the proposed payment rate transparency provision in its entirety. Commenters in opposition stated the proposed payment rate transparency requirements would be administratively burdensome for States and that the payment rate transparency publication would not result in a meaningful access analysis. One commenter questioned CMS' authority to require States to publish their payment rates because section 1902(a)(30) of the Act does not explicitly grant CMS this authority.

Response: We thank the commenters for their support of the proposed payment rate transparency provision at § 447.203(b)(1). We are finalizing the payment rate transparency provisions by adding and deleting regulatory language for clarification, making minor revisions to the organizational structure, updating the required timeframe for compliance and for updating payment rates after SPA or other payment authority approval, and incorporating a technical change to account for States submitting SPAs with prospective effective dates. We list and describe the specific revisions we made to the regulatory language for the payment rate transparency provision at § 447.203(b)(1) at the end of this section of responses to comments. The policies in this final rule allow flexibility that we believe will allow some States to use existing fee schedule publications for compliance, and we expect additional States will only need minor revisions. We encourage States that already publish their fee schedules to review the final regulatory language and reach out to CMS with any questions regarding compliance.

We disagree with the commenters regarding administrative burden of the payment rate transparency publication. As documented in section III. of this final rule, the FFS provisions, including the payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements (§ 447.203(b)(1) through (5)), interested parties' advisory group requirements (§ 447.203(b)(6)), and State analysis procedures for payment rate reductions or payment restructuring (§ 447.203(c)), finalized in this rule are expected to result in a net burden reduction on States compared to the previous AMRP requirements. Additionally, as addressed in another comment response generally discussing commenters' concerns about State burden, we have described numerous flexibilities States will have for compliance with this final rule. Specifically for the payment rate transparency publication, and as discussed in a later response to comments, States have flexibility to (1) organize and format their publication, so that they can use existing fee schedule publications for compliance (assuming all requirements in § 447.203(b)(1) are met); (2) utilize contractors or other third party websites to publish the payment rate transparency publication on (however, we remind States that they are still requiring to publish the hyperlink to the website where the publication is located on the State Medicaid agency's website as required in § 447.203(b)(1)(ii) of this final rule); and (3) for the initial publication, if necessary historical information about bundled payment rates is unavailable to the State, then the State does not need to include the bundled payment rate breakdown as required in § 447.203(b)(1)(iv) of this final rule (however, we remind States that upon approval of a SPA that revised the bundled payment rate, the State will be required to update the publication to comply with § 447.203(b)(1)(iv)). Additionally, we are providing examples of payment rates that are not subject to the payment rate transparency publication and an illustrative example of a compliant payment rate transparency (including to meet accessibility standards) through subregulatory guidance issued prior to the effective date of this final rule. We expect these flexibilities and clarifications to minimize the State administrative burden commenters expressed concern about, which potentially stemmed from an imprecise understanding of the Medicaid FFS fee schedule payment rates that are required to be published in the payment rate transparency publication. Finally, we would expect that States already have the data for the payment rate transparency publication readily available through existing fee schedules, SPAs, or other internal documentation, so the work to compile that data into a format that complies with this final rule should require minimal effort.

To clarify, the payment rate transparency publication is not an analysis requirement, but a transparency requirement for States to publish their Medicaid FFS fee schedule payment rates, as discussed in detail in a later response to comments in this section. However, an analysis component is being finalized in § 447.203(b)(2) and (3) called the comparative payment rate

analysis, which we believe will result in a meaningful access analysis because it requires States to compare certain of their Medicaid FFS payment rates to the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year. This access analysis will help States and CMS to assess compliance with section 1902(a)(30)(A) of the Act where Medicare payment rates serve as a benchmark for comparing Medicaid payment rates to another of the nation's large public health coverage programs. As described in the proposed rule and in greater detail later in this final rule, Medicare and Medicaid programs cover and pay for services provided to beneficiaries residing in every State and territory of the United States, Medicare payment rates are publicly available, and broad provider acceptance of Medicare makes Medicare non-facility payment rates as established on the Medicare PFS for a calendar year an available and reliable comparison point for States to use in the comparative payment rate analysis.[193]

We disagree that we do not have the authority to require States to publish their payment rates. As discussed in the proposed rule, payment rate transparency is a critical component of assessing compliance with section 1902(a)(30)(A) of the Act, which requires that State plans assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.[194] Transparency, particularly the requirement that States must publicly publish their payment rates, helps to ensure that interested parties have basic information available to them to understand Medicaid payment levels and the associated effects of payment rates on access to care so that they may raise concerns to State Medicaid agencies via the various forms of public process available to interested parties. As noted in the proposed rule, most States already published at least some of their payments through FFS rate schedule on State agency websites.[195] Our efforts finalized in this rule will help ensure all States publish their payment rates consistently and accessibly so interested parties have fundamental information about payment rates and can utilize existing public processes to raise concerns about access. Additionally, the Supreme Court's *Armstrong* decision placed added importance on CMS' determinations, as the responsible Federal agency, regarding the sufficiency of Medicaid payment rates. The payment rate transparency requirements included in this final rule reflect that statutory responsibility to ensure compliance with section 1902(a)(30)(A) of the Act. We also note that the previous AMRP process that was in effect prior to this final rule established a transparent data-driven process to measure access to care in States, including oversight of provider payment rates, actual or estimated levels of provider payment available from other payers, and the percentage comparison of Medicaid payment rates to other public and private health insurer payment rates. This final rule merely streamlines the approach under the same statutory authority and shared responsibility that applied for the previous AMRP process. We remind States of longstanding, general requirement for the State to maintain statistical, fiscal, and other records necessary for reporting and accountability under § 431.17(b)(2).

Comment: Some commenters expressed concerns about the burden associated with the payment rate transparency publication. They specifically cited concern about meeting strict State-level website accessibility requirements, extensive changes that could be needed to existing claims payment systems (that is, for a State that does not currently include beneficiary copayment information on their existing fee schedules, the State may need to make change requests of their contractor to modify their claims payment system to produce the Medicaid payment information required in the payment rate transparency publication to include the total payment amount a provider would receive inclusive of beneficiary cost sharing), conducting research on when payment rates were last updated, and monthly monitoring of Medicare rates to ensure State fee schedule rates set at a percentage of Medicare are updated timely.

Response: As described in the proposed rule, longstanding legal requirements to provide effective communication with individuals with disabilities and the obligation to take reasonable steps to provide meaningful access to individuals with limited English proficiency also apply to the websites containing Medicaid FFS payment rate information. These requirements apply to all State agency, contractor, or other third-party websites and any burden associated with meeting those Federal obligations is not created by policies finalized in this rule. With respect to any State-level accessibility requirements that might exceed Federal requirements, we refer the commenter to the State Medicaid agency or other agency responsible for compliance with State accessibility requirements for guidance or technical assistance concerning State-imposed accessibility requirements.

Regarding commenters' concerns that States would need to change existing claims payment systems (that is, the State may need to make change requests of their contractor to modify their claims payment system to produce the Medicaid payment information required for the payment rate transparency publication that includes beneficiary cost sharing in fee schedule amounts), we want to clarify State claiming and payment systems, and the output of these systems, generally are not subject to the payment rate transparency publication requirements as the provision only applies to Medicaid FFS fee schedule payment rates. We do not anticipate it would be unduly burdensome for a State to maintain its Medicaid FFS fee schedules in an appropriate format outside of its claiming and payment systems. States are not required to publish claims data or data about actual payments made to providers under the payment rate transparency publication provision.

Commenters were concerned about whether beneficiary cost sharing information should be included in the payment rate transparency publication. To clarify, the payment rates published under § 447.203(b)(1)(i) must be inclusive of the payment amount from the Medicaid agency plus any applicable coinsurance and deductibles to the extent that a beneficiary is expected to be liable for those payments. By requiring States to publish the payment amount the Medicaid agency would pay and any beneficiary cost sharing as a single payment amount, we focus on the total Medicaid payment amount a provider would expect to receive for furnishing a given service to a Medicaid beneficiary and which is therefore most relevant to a provider's decision to accept the Medicaid payment rate, thereby furthering our section 1902(a)(30)(A) access goals to ensure payment rates are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area. Furthermore, this representation of payment rates is consistent with the

[193] 88 FR 27960 at 28011.

[194] 88 FR 27960 at 27967.

[195] 88 FR 27960 at 28000.

comparative payment rate analysis,[196] which minimizes burden on States by requiring the Medicaid FFS fee schedule payment rate be displayed in the same way for both publications. Additionally, we recognize that beneficiary cost sharing amounts can vary depending on the State Medicaid program and the status of the Medicaid enrollee. Therefore, we expect States with cost-sharing requirements could experience additional burden in complying with the payment rate transparency publication, if States were required to remove variable cost sharing amount from the Medicaid FFS fee schedule payment rate for each service subject to the publication.

Regarding commenters' concerns about conducting research on when payment rates were last updated, we want to clarify that the requirement to include the date the rates were last updated refers to a date for the website publication. In other words, the date should provide assurance that the rates on the website are current as of the specified date. We do not expect, nor did we propose, States to examine historical records to find the dates every rate was last updated. However, if a State wishes to include that information for all or a subset of published rates, it can.

Regarding commenters' concerns about monthly monitoring of Medicare rates to ensure the payment rate transparency publication is up to date, firstly, to clarify, only States that set their Medicaid payment rates at a percentage of a Medicare payment rate would be affected by this consideration. For those States that set their Medicaid payments rates as a percentage of a Medicare payment rate, we expect the State to already be monitoring changes in Medicare rates in accordance with their approved payment methodology and §§ 430.10 and 430.20 and part 447, subpart B, which require States to pay the approved State plan payment rates in their State plan effective on or after the approved effective date of the State plan provision. Therefore, if a State's approved State plan pays a rate based on the most current Medicare payment rate for a particular service, then payment of any rate outside of the approved State plan methodology would result in a State plan compliance issue. We expect that States with such payment methodologies routinely are monitoring Medicare payment rates to ensure that their Medicaid payment rates are updated according to the approved methodology. Medicare fee schedule updates are well documented and accessible to States on cms.gov, even in the event of a change to a Medicare payment rate outside the usual cadence of Medicare updates for that rate (an off-cycle update) and keeping up with Medicare fee schedule updates is critical for ensuring a State's payment rate transparency publication is accurate and updated timely.[197]

Comment: A few commenters requested clarification on the format of the payment rate transparency publication, particularly if Medicaid FFS payment rates should be organized by CPT code.

Response: In this final rule, in regard to the payment rate transparency provision, we are not requiring States to publish their payment rates by CPT/HCPCS code, which is required in the comparative payment rate analysis discussed later in this section. However, we encourage States to consider organizing their publication by CPT/HCPCS code, due to the common use of CPT/HCPCS for billing for medical services across the country, including in State Medicaid programs. The goal of the payment rate transparency publication is to ensure all States publish their Medicaid FFS fee schedule payment rates in a format that is publicly accessible and where all these rates can be easily located and understood. States can determine what organizational and formatting structure is most suitable for organizing rates in a manner that will be easily understood by providers and beneficiaries.

Comment: A couple of commenters requested clarification on the requirement that States separately identify Medicaid FFS fee schedule payment rates by population, specifically inquiring if ''population'' referred to beneficiary demographics or waiver/program population.

Response: As indicated in the regulation text, population refers to beneficiary demographics, specifically adult and pediatric populations. Under this final rule, States will be required to publish their Medicaid FFS fee schedule payment rates separately identified by rates paid for the adult population and the pediatric population, if the rates differ in the State. As stated in the proposed rule, we acknowledge that a State may pay a single Statewide rate regardless of population, provider type, or geographical location, and such a State would only need to list the single Statewide rate in its payment rate transparency publication. We also acknowledge that States define pediatric differently (such as, 18 years old or younger, 19 years old or younger, and 21 years old or younger) and we encourage States to disclose the age range the State's Medicaid program uses in the payment rate transparency publication for transparency purposes.

Comment: Some commenters requested clarification regarding which payments are subject to the payment rate transparency requirements outlined in paragraph (b)(1). Multiple commenters questioned if the following payment methodologies would be subject to the payment rate transparency requirements under paragraph (b)(1): manually priced items (for example, physician administered drugs), provider-specific rates (for example, PPS rates typically paid to FQHCs or all-inclusive per-visit rates typically paid to clinics (we assume commenters meant clinics as defined in § 440.90)), per diem rates, cost and cost-based payment methodologies (including interim payments) typically paid to facility-based providers, and negotiated rates. Additionally, many commenters questioned if disproportionate share hospital (DSH) payments, FFS supplemental payments, or managed care State directed payments (SDPs) would be included in the payment rate transparency publication. A couple of commenters stated that only requiring States to publish base payment rates would not provide a member of the public with the ability to readily determine the amount Medicaid would pay for a service because excluding DSH payments and supplemental payments is an inaccurate, incomplete, and misleading representation of a Medicaid provider's actual, overall payments from the Medicaid program.

Response: In § 447.203(b)(1) of the proposed rule, we proposed that ''[t]h State agency is required to publish all Medicaid fee-for-service payment rates . . . . Published Medicaid [FFS] payment rates include fee schedule payment rates made to providers delivering Medicaid services to Medicaid beneficiaries through a [FFS] delivery system.'' We acknowledge that this language was not clear that we intended to require the publication requirement to include only Medicaid FFS fee schedule payment rates. Accordingly, in this final rule, we have made some revisions to the proposed regulatory language in § 447.203(b)(1) to change the organizational structure of (b)(1) by adding romanettes and clarify that only Medicaid FFS fee schedule payment rates are required to be published in the payment rate transparency publication. Throughout (b)(1), references to ''fee schedule payment'' were replaced with

[196] 88 FR 27960 at 28013.

[197] *https://www.cms.gov/medicare/payment/fee-schedules.*

''Medicaid fee-for-service fee schedule payment rates'' for clarity and consistency. Therefore, in (b)(1) we state that, the State agency is required to publish all Medicaid FFS fee schedule payment rates. Further, in § 447.203(b)(1)(i), we specify that, ''for purposes of paragraph (b)(1), the payment rates that the State agency is required to publish are Medicaid fee-for-service fee schedule payment rates made to providers delivering Medicaid services to Medicaid beneficiaries through a fee-for-service delivery system.''

We would like to clarify which Medicaid FFS fee schedule payment rates are subject to the payment rate transparency provisions in § 447.203(b). Medicaid FFS fee schedule payment rates are payment amounts made to a provider, known in advance of a provider delivering a service to a beneficiary by reference to a fee schedule. A fee schedule is a list, table, or similar presentation of covered services and associated payment amounts that are generally determined at the State's discretion. We also consider a State to use a fee schedule when the State has not yet organized its payment amounts into such a straightforward list, table, or similar presentation, but under the State's approved payment methodology, the State determines payment rates based on the application of a mathematical formula to another fee schedule or other reference rate stated as an amount certain. In other words, a fee schedule that utilizes a formula, but has not yet been organized into a list, table, or similar presentation of covered services and associated payment amounts, is included in the scope of fee schedules subject to the payment rate transparency provisions. For example, a Medicaid payment methodology that provides for payment at 80 percent of the corresponding Medicare PFS rate would constitute a Medicaid fee schedule payment methodology because it applies a formula to a fee schedule to produce a fee schedule payment rate that is known in advance of a provider delivering the service. This formula reflects that the State's fee schedule payment methodology starts with the Medicare PFS fee schedule, then reduces the fee schedule amount to 80 percent of the Medicare PFS amount to arrive at the Medicaid fee schedule payment rate. States that utilize the previously described formula-based methodology that may not currently publish these payment rates on a fee schedule will be required to publish the actual payment amounts as determined by their formula in the payment rate transparency publication under this final rule. This final rule focuses on ensuring transparency of Medicaid FFS fee schedule payment rates so that they are ''. . . organized in such a way that a member of the public can readily determine the amount that Medicaid would pay for the service,'' as stated in the proposed regulatory language in § 447.203(b)(1), which we are finalizing in § 447.203(b)(1)(iii) of this final rule with a slight modification to replace ''the service'' with ''a given service.'' Merely publishing the mathematical formula that a member of the public would need to use to calculate each payment rate the State has set for a particular service would not meet this requirement of this final rule. To summarize, fee schedule payment methodologies that utilize a formula applied to another fee schedule are included in the scope of fee schedules, and the payment rate transparency publication must reflect the actual fee schedule payment rate amounts.

Certain bundled payment rates (as discussed later in this comment response) and PPS rates for inpatient hospital, outpatient hospital, and nursing facility services are considered fee schedules payment rates subject to the payment rate transparency publication because these payment amounts are also known in advance of a provider delivering a service to a beneficiary and are stated (or can readily be stated) as a list, table, or similar presentation.

We recognize that PPS rates are utilized in different contexts in Medicaid to pay for various services (including for services of FQHCs, RHCs, inpatient hospitals, outpatient hospitals, inpatient psychiatric facilities, inpatient rehabilitation facilities, long-term care hospitals, and nursing facilities) and can be calculated differently, depending on the service. PPS rates in Medicaid used to pay for services provided by inpatient hospitals, outpatient hospitals, inpatient psychiatric facilities, inpatient rehabilitation facilities, long-term care hospitals, and nursing facilities would be included. In the context of payment rates to hospitals and nursing facilities, the term ''encounter rate'' or ''per diem rate'' can also be used to describe the PPS rate received by these providers. This term generally describes a daily payment rate that is paid to a hospital or nursing facility during a patient's admission to a hospital or nursing facility. In this situation, the PPS payment methodology typically makes payment based on a predetermined, fixed amount. States often use or model their payment methodologies after Medicare's prospective payment systems to pay for outpatient hospital, inpatient hospital, and nursing facility services. In these situations, under Medicare's prospective payment systems, Medicare typically pays providers for a particular service an amount derived based on the services expected to be received during a visit or course of treatment (for more complex conditions). For example, under the Medicare IPPS, payment is made based on the Diagnosis Related Group (DRG) to which the patient discharge is assigned. States also often use other grouping systems, such as Medicare's PDPM for nursing facilities, Ambulatory Payment Classifications under Medicare's hospital outpatient PPS for hospital outpatient services items, or Medicare's End Stage Renal Disease PPS for facilities or hospital-based providers that furnish dialysis services and supplies. These PPS rates for inpatient hospital, outpatient hospital, and nursing facility services are paid to most hospitals and nursing facilities and are typically known in advance of a health care provider delivering a service to a beneficiary. Therefore, these types of PPS rates would be subject to the payment rate transparency publication in this final rule.

In contrast, FQHCs and RHCs are paid PPS rates that are developed under a methodology that is statutorily mandated under section 1902(bb) of the Act, which generally requires that FQHCs and RHCs receive a per visit, or encounter, rate that is provider-specific and must be based on a health center's unique cost and visit data.[198] This requirement creates a payment rate floor where FQHC and RHCs cannot be paid less than the PPS rate developed under this statutorily mandated methodology. Because this statutory payment floor is set by Congress, FQHC and RHC payment rates are uniquely situated in a manner that does not exist for other Medicaid payment rates under State discretion.[199] Although States must comply with section 1902(a)(30)(A) of the Act, this statutory provision does

[198] In the context of payment rates to FQHCs and RHCs, the terms ''encounter rate,'' ''per visit rate,'' and ''provider-specific rate'' can also be used to describe the PPS payment rate.

[199] We acknowledge that Medicaid payment rates for hospice services also have a statutorily mandated payment floor: the Medicaid hospice payment rates are calculated based on the annual hospice rates established under Medicare. These rates are authorized by section 1814(i)(1)(C)(ii) of the Act, which also provides for an annual increase in payment rates for hospice care services. However, we do not believe these rates would be burdensome on States to include because they are paid to all Medicaid participating hospice providers and are therefore not carving them out of this requirement.

not set a specific payment rate floor. Therefore, because of the unique provider-specific payment floor mandated by Congress for FQHCs and RHCs, we believe access concerns related to payment rates for FQHCs and RHCs are attenuated and as such, we are not including FQHC and RHC PPS rates in the payment rate transparency publication requirement. Furthermore, because the FQHC and RHC PPS rates are provider-specific based on an individual provider's costs and scope of service and required to be paid by States as a floor set by Congress, we generally do not believe that publication of the individual providers' payment rates as part of the payment rate transparency provision finalized in this rule would not result in actionable information for CMS to consider in ensuring compliance with section 1902(a)(30)(A) of the Act as intended through this final rule at this time.

In addition, if we were to require States to also publish FQHC and RHC PPS rates, we would expect a significant increase in burden on States in meeting this requirement. FQHC and RHC PPS rates are unique to each FQHC and RHC in a State (rather than a single fee schedule rate that Medicaid would pay for a given service to any provider in a State) and, therefore, publicizing the FQHC and RHC rates would represent a sharp increase in States' efforts for rates that are less concerning to CMS due to the statutory payment floor in section 1902(bb) of the Act. We do not believe the increase in burden is justifiable given our aim to balance Federal and State administrative burden with our shared obligation to ensure compliance with section 1902(a)(30)(A) of the Act with this final rule. Finally, and as discussed in detail in an earlier response to comments in this section, like all State plan services for which the State proposes a rate reduction or restructuring in circumstances where the changes could result in reduced access, FQHC and RHC services are subject to the access analyses in § 447.203(c) for proposed rate reductions and restructuring.

Certain FFS VBP payment methodologies are also fee schedule payment methodologies, even if the exact dollar amount that a particular provider will receive for a given service is not known in advance because of the need to adjust for metric-based performance. In such a case, a State might have an approved FFS VBP payment methodology in the State plan that includes a 2 percent withhold of the fee schedule payment amount and the potential for an additional 3 percent bonus to the provider based on the provider's performance for the year on certain quality measures. Assuming the State's payment methodology starts with a base payment of 80 percent of the Medicare PFS payment amount, the provider's minimum payment for the service would be .98 * (PFS * .80), and the maximum payment (achieved through a retrospective true-up payment based on final quality performance for the year) would be 1.03 * (PFS * .80). The provider's minimum and maximum possible payment amounts are known in advance (2 percent less than the Medicaid fee schedule amount, and 3 percent more, respectively) and are based on the application of a formula to a fee schedule. We also consider this type of FFS VBP arrangement to constitute a fee schedule payment methodology, because although the State does not know in advance the final payment amount a given provider will receive for a particular service (since the provider's quality performance is not known in advance), the minimum payment amount is calculable in advance based on the application of a mathematical formula to a fee schedule amount. We expect the State to use the minimum payment amount for purposes of the requirements of § 447.203(b), because this is the amount that a provider is assured to receive for furnishing the service. At State option, the State could also include information on the maximum payment amount the provider might receive under the FFS VBP payment methodology.

We would also like to clarify what payments are not subject to the payment rate transparency publication provision. Payment rates that are not subject to the transparency provisions include those where the minimum fee schedule payment is not known in advance of a provider delivering a service to a beneficiary because certain variables required for the payment calculation are unknown until after the provider has delivered the service. For example, cost-based and reconciled cost payment methodologies (including those that involve interim payments) are not subject to the payment rate transparency provisions because actual cost is unknown until the end of the provider's reporting period. As another example, FFS supplemental payment methodologies are not subject to the payment rate transparency publication provision because these methodologies often utilize variables, such as claims volume or number of qualifying providers, for dividing up a pre-determined payment pool, and actual supplemental payment amounts are unknown until the end of the provider's (or providers') reporting period.

While a relatively simple FFS VBP payment methodology (such as the one discussed earlier in this response, with a bonus and withhold percentage added to or subtracted from a fee schedule rate based on provider performance) is considered to result in a fee schedule payment rate subject to the payment rate publication requirement, we acknowledge that some States already utilize more complex FFS VBP payment methodologies (including episodes of care [200] and integrated care models [201]) that utilize quality and cost measures to determine the provider's unique payment amount. Providers who participate in one of these complex VBP payment arrangements generally report quality and cost data to the State at the end of the provider's reporting period and then the State uses that data to determine the provider's payment amount after the provider has furnished services. Excluding complex VBP payment methodologies from the payment rate transparency publication balances burden on States to publish the required information with the ability of interested parties to understand key Medicaid payment levels so that they may raise concerns to State Medicaid agencies. If we were to require States to publish payment rates determined by complex FFS VBP payment methodologies, it would be burdensome on States, as these payment rates are

[200] We consider episodes of care to be a complex VBP because the payment methodology determines the total payment by comparing the provider's cost of care for an episode to the State determined thresholds for how much the State expects a provider to spend on an episode. The provider's cost of care is an unknown variable that can be higher, the same, or lower than the State's threshold and will vary from provider to provider and episode to episode. Therefore, the unknown amount of a provider's cost of care for an episode relative to the State's threshold affects the actual payment the provider will receive for delivering a service, creating a situation where the State is unable to reasonably know a provider's payment in advance.

[201] We consider integrated care models to be a complex VBP because the payment methodologies used in these models, for example, shared savings methodologies, determine the total payment by comparing the provider's cost of care to the State determined total cost of care benchmark for how much the State expects a provider to spend. The provider's cost of care is an unknown variable that can be higher, the same, or lower than the State's threshold and will vary from provider to provider. Additionally, States can apply risk and gain-sharing arrangements that decreases or increases provider's payment rate based on their performance in meeting specific quality goals. Therefore, the unknown amount of a provider's cost of care relative to the State's total cost of care benchmark and additional decreases or increases to payment rates based on performance meeting quality goals affects the actual payment the provider will receive for delivering a service, creating a situation where the State is unable to reasonably know a provider's payment in advance.

unique to the provider and are determined using variables (the provider's quality performance and cost of furnishing services) that are unknown until after a provider's reporting period has ended. As these measures are generally unknown until after the provider's reporting period has ended, the State does not know a provider's payment in advance. Therefore, complex VBP payment methodologies as previously described are not fee schedule payment methodologies within the meaning of this final rule that are subject to the payment rate transparency provision.

We also recognize that an advanced payment methodology, as described in SMDL 20–004, could utilize fee schedule payments within the meaning of this final rule.[202] For example, a State could calculate an advanced payment of $10,000 for a provider that is expected to furnish 1,000 services and each service is paid at a fee schedule payment rate of $10. The advanced payment amount was originally determined by a fee schedule payment rate, which is known in advance of a provider delivering a service to a beneficiary, and therefore these rates would appear to be covered by this requirement. However, there are also features of certain advanced payment methodologies that could place them outside the scope of this requirement. For example, an advanced payment methodology that permits States to include risk adjustments and quality performance adjustments to the advanced payment amount, and/or requires the State to perform a reconciliation to the actual number of claims, could mean that the Medicaid payment amount that the provider could expect to receive could not be known in advance. At the time of publication of this final rule, there are no approved SPAs that utilize an advanced payment methodology as discussed in SMDL 20–004, so we are unable to state definitively whether any advanced payment methodology that may be used in FFS Medicaid pursuant to a future SPA would be subject to the payment rate transparency publication requirement. Without implementation experience of advanced payment methodologies, we will review future advanced payment methodologies on a case-by-case basis to determine if the methodology uses a fee schedule payment methodology within the meaning of this final rule. We encourage States that propose advanced payment methodology after finalization of this rule to reach out to CMS for technical assistance on determining whether advanced payment amounts are subject to the payment rate transparency publication requirements.

We interpret the commenter's reference to ''manually priced items'' to mean a provider payment rate that the State determines after a service or item has been delivered to a beneficiary and the provider has billed for it. For example, certain durable medical equipment items that are infrequently furnished to beneficiaries may be paid at the manufacturer's suggested retail price minus a percentage. This is described in the approved State plan, and when such an item is furnished to a beneficiary, the State must manually adjust the amount paid for the claim to equal the manufacturer's suggested retail price minus the percentage listed in the State plan, rather than pay a particular Medicaid FFS fee schedule payment rate. Because these services and items are infrequently furnished and States manually price each service and item as they are delivered to the beneficiary, we understand that it would be impractical and burdensome on States to maintain current lists of the manufacturer's suggested retail price for all potential items or services a beneficiary might require and a provider may bill for, and that States often source these items and services from multiple manufacturers. Therefore, for the purposes of the payment rate transparency publication, we consider manually priced payment methodologies that utilize the manufacturer's suggested retail price to result in a payment amount that is not known in advance of a provider delivering a service or item to a beneficiary, and thus not to be a fee schedule payment methodology subject to the payment rate transparency publication requirements.

We interpret the commenter's reference to ''negotiated rates'' to mean a provider payment rate where the individual provider's final payment rate is agreed upon through negotiation with the State Medicaid agency. For example, negotiated rates may be offered by a State when a particular service has very low utilization, a custom item is required (for example, certain wheelchairs), or the State does not have information needed to establish a payment rate under an approved State plan payment methodology (for example, information from other payers, such as Medicare or the State's employee health insurance on how much they pay for the service or item) to establish a fixed payment rate. In these instances, generally, the State has not developed a rate prior to service delivery; payment for the service or item on a case-by-case-basis in the circumstances does not constitute a fee schedule payment methodology. Additionally, DSH payments and supplemental payments are not subject to the payment rate transparency publication requirement because they do not fall into the description of Medicaid FFS fee schedule payment rates for purposes of the payment rate transparency provision in § 447.203(b)(1). Finally, SDPs in Medicaid managed care delivery systems are outside the scope of § 447.203(b)(1)(i), which is specific to the FFS delivery system.

We invite States to reach out to CMS for technical assistance if they have a FFS payment rate or methodology that may not clearly align with the previous descriptions and examples of Medicaid FFS fee schedule payment rates that are subject to the payment rate transparency publication provision, and other payment methodologies that are not.

We disagree with commenters that that only requiring States to publish base payment rates would not provide a member of the public with the ability to readily determine the amount Medicaid would pay for a service. To clarify, we did not intend for the payment rate transparency publication to reflect the entire universe of payments a provider may receive. Setting the scope of the publication to Medicaid FFS fee schedule payment rates, as previously discussed in this response to commenters, balances burden on States to publish the required information with the ability of interested parties to understand key Medicaid payment levels so that they may raise concerns to State Medicaid agencies. If we were to require States to also include DSH payments and supplemental payments along with the Medicaid FFS fee schedule payment rates, it would significantly increase burden on States and might not result in the public clearly understanding the amount that any given provider could expect to receive for furnishing the service to a Medicaid beneficiary, as DSH payments and supplemental payments are generally paid on a provider-level basis rather than a service-level basis, and not all providers of a given service will qualify for these payments.

Comment: One commenter requested clarification regarding whether payment rates paid to the direct support workforce are subject to the payment rate transparency publication requirements. Another commenter questioned if self-directed service payment rates should be published

[202] *https://www.medicaid.gov/sites/default/files/2020-09/smd20004.pdf.*

separately from agency model personal care services.

Response: We interpret the commenter's reference to ''the direct support workforce'' to generally mean the direct support workers or direct support professionals that provide hands-on and in-person Medicaid services to beneficiaries. To the extent a State's payment rates to direct support workforce utilize Medicaid FFS fee schedule payment rates within the meaning of this final rule, as discussed in detail in an earlier response to comments in this section, those payment rates would be subject to payment rate transparency requirements under § 447.203(b)(1).

Regarding self-directed service payment rates being separately published from agency model personal care services, we assume the commenter was referring to self-directed models with service budget and agency-provider models authorized under 42 CFR 441.545. We would like to clarify that, to the extent a State pays an agency-provider a Medicaid FFS fee schedule payment rate as discussed in detail in an earlier response to comments in this section, then those payment rates are subject to the payment rate transparency requirements in § 447.203(b)(1). Self-directed models with service budget [203] are not subject to the payment rate transparency publication requirement in § 447.203(b)(1). As previously stated, payment rates that are not subject to the payment rate transparency publication requirement include those that that are not known in advance of a provider delivering a service to a beneficiary. Under the self-directed model with service budget, the State only sets the beneficiary's overall service budget, and the beneficiary negotiates the payment rate with the direct support worker; therefore, the State is not setting the payment rate and does not know in advance what rate the direct service worker will be paid for furnishing services to the beneficiary. This does not constitute a fee schedule payment methodology for purposes of the payment rate transparency publication requirement, and as such these types of payment rates are excluded from the publication requirement. We further clarify that we do not expect States to list each beneficiary's individual self-directed service budget in the payment rate transparency publication.

Comment: One commenter expressed concern that requiring States to publish all Medicaid FFS payment rates online could have unintended consequences, such as beneficiary confusion about how much their copayment amount would be if it was included on the State's fee schedule which typically lists the amount allowed for the service, as well as State burden from increased documentation on the State's website. The commenter recommended CMS permit States to provide easily accessible links where the fee schedules are located to copayment information already available to providers and clients in a clear and concise manner.

Response: We understand commenters' concerns about the effects of the payment rate transparency publication in practice. Regarding commenters' concerns about beneficiary confusion, we want to clarify that the payment rates published under § 447.203(b)(1)(i) must be inclusive of the payment amount from the Medicaid agency plus any applicable coinsurance and deductibles to the extent that a beneficiary is expected to be liable for those payments, as discussed earlier in a response to comments this section. We encourage States, as part of transparency efforts, to include in the payment rate transparency publication a link to the page on the website where existing beneficiary cost sharing information is located so beneficiaries and other interested parties will be able to easily access this existing source of information about beneficiary cost sharing obligations. Additionally, regarding commenters' concerns about burden from increased documentation on the State's website, as documented in section III. of this final rule, the FFS provisions, including the payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements (§ 447.203(b)(1) through (5)), interested parties' advisory group requirements (§ 447.203(b)(6)), and State analysis procedures for payment rate reductions or payment restructuring (§ 447.203(c)), are expected to result in a net burden reduction on States compared to the previous AMRP requirements. With the finalization of the provisions in this rule, we aim to balance Federal and State administrative burden with our shared obligation to ensure compliance with section 1902(a)(30)(A) of the Act (and our obligation to oversee State compliance with the same). As previously stated, States also have the flexibility to utilize contractors or other third-party websites to publish the payment rate transparency publication on (however, we remind States that they are still requiring to publish the hyperlink to the website where the publication is located on the State Medicaid agency's website as required in § 447.203(b)(1)(ii) of this final rule).

Comment: One commenter requested clarification on the 1-month update requirement for the payment rate transparency requirement. The commenter stated that there are instances where SPAs are submitted with prospective effective dates or where States may face a delayed operationalization in their claims system that includes approved rate changes. The commenter noted that, in both instances under the proposed regulatory language for the payment rate transparency requirement, a State would be expected to publish rates that are not yet in effect or not currently being paid to providers. The commenter suggested revising the regulatory language to require States update rate changes in the payment rate transparency publication within 1 month of CMS approval of a SPA, the effective date of payment rate changes, or the date system changes are operationalized by a State, whichever date occurs latest. Additionally, one commenter suggested extending the requirement for updates to the payment rate transparency publication to 2 months instead of 1 month as proposed.

Response: In response to comments, we have revised the regulatory language to account for SPAs with prospective effective dates. As finalized in this rule, § 447.203(b)(1)(vi) now states, ''[t]he agency is required to include the date the payment rates were last updated on the State Medicaid agency's website and to ensure these data are kept current where any necessary update must be made no later than 1 month following the latter of the date of CMS approval of the State plan amendment, section 1915(c) HCBS waiver amendment, or similar amendment revising the provider payment rate or methodology, or the effective date of the approved amendment.'' We are adding this language as a technical change to account for States submitting SPAs with prospective effective dates as the proposed regulatory language would have required State to publish payment rates in the payment rate transparency publication that were approved, but not yet effective. We thank the commenter for pointing out this possibility, and we believe this change will ensure a State's payment rate transparency publication is as current as possible, and accurate once published.

[203] Self-directed services are paid for using an individualized budget. States are required to describe the method for calculating the dollar values of individual budgets based on reliable costs and service utilization, define a process for making adjustments to the budget when changes in participants' person-centered service plans occur, and define a procedure to evaluate participants' expenditures. *https://www.medicaid.gov/medicaid/long-term-services-supports/self-directed-services/index.html.*

However, we have not included regulatory language to account for system changes with a delayed operationalization date as suggested by this commenter. In accordance with §§ 430.10 and 430.20 and part 447, subpart B, States are required to pay the approved State plan payment rates in their State plan effective on or after the approved effective date. Therefore, payment of any rate outside of the approved State plan would result in a State plan compliance issue, and non-compliance is not a circumstance we would accommodate in regulations. We have also not extended the timeframe from 1 month to 2 months for States to update their payment rate transparency publications after a payment rate change. States are aware that a payment rate change is forthcoming and its requested effective date when they submit a SPA, and as such, we believe 1 month is more than sufficient to update the payment rate transparency publication. We invite States to reach out to CMS for technical guidance regarding any technological or operational limitations that may impact a State's compliance with the payment rate transparency publication requirement.

Comment: We received a few comments expressing concern about which bundled payment rates would be subject to the payment rate transparency publication as well as concern about the burden imposed on States from operational challenges to break down bundled payment rates into constituent services and rates allocated to each constituent service in the bundle. These commenters also requested clarification on how States will be required to publish bundled payment rates in the payment rate transparency publication. Commenters requested clarification regarding the following instances where bundled payment rates are used by States: team-based services, provider-specific rates (for example, PPS rates typically paid for FQHC and RHC services or an encounter rate typically paid to clinics for clinic services (we assume commenters meant clinic services as defined in § 440.90) and CCBHC services), and per diem rates paid for facility or institutional (that is, hospital and nursing facility) services. These commenters stated that this requirement would be burdensome, operationally difficult, or not feasible because individual rates for constituent services within the bundle do not exist or bundled rates are established on a provider-specific basis using provider-specific historical cost data and inflationary adjustments. These commenters requested further clarification regarding a definition of constituent services, how States should unbundle rates and services from a bundled rate, as well as additional explanation of the value CMS believes this requirement will contribute to the Medicaid program. They encouraged CMS to explicitly exempt facility and institutional providers from the payment rate transparency publication requirements.

Response: Bundled payments are a versatile payment methodology that States can utilize within and across numerous Medicaid benefit categories. Bundled payments are generally developed using State-specific assumptions about the type, quantity, and intensity of services included in the bundle, and generally are based on the payment rates for the individual constituent services when they are furnished outside the bundled rate.

In this final rule, we clarify bundled payment rates that are subject to the requirement in the payment rate transparency publication provision that States identify how much of the bundled fee schedule payment rate is allocated to each constituent service under the State's payment methodology. In the case of a bundled payment methodology, the State must publish the Medicaid FFS bundled payment rate and, where the bundled payment rate is based on fee schedule payment rates for each constituent service, must identify each constituent service included within the rate and how much of the bundled payment rate is allocated to each constituent service under the State's methodology.

To explain further, the bundled payment rates that are subject to this requirement are State-developed payment rates that provide a single payment rate for furnishing a bundle of services, including multiple units of service, multiple services within a single benefit category, or multiple services across multiple benefit categories. In any of these instances, multiple providers and provider types could contribute to a bundle of services, which is what we interpret the comment about team-based services to mean. Bundled payment rates that are based on fee schedule payment rates for each constituent service are subject to the requirement to identify each constituent service included within the rate and how much of the bundled payment rate is allocated to each constituent service under the State's methodology.

States can develop bundled payment rates for multiple units of a single service, for example, by setting a daily rate for up to 4 hours of personal care services a day that includes multiple 15-minute units of personal care services for which there is a fee schedule payment rate. States can also develop a bundled payment rate for multiple services within a single benefit category. For example, within the rehabilitative services Medicaid benefit, a daily rate for assertive community treatment, which can include constituent services set at fee schedule payment rates for assessments, care coordination, crisis intervention, therapy, and medication management, is considered a bundled rate. Finally, States can also develop a bundled payment rate for one or more services across multiple benefit categories. For example, a daily rate that includes constituent services set at fee schedule payment rates for up to 2 hours of personal care services, up to 2 hours of targeted case management services, and 1 hour of physical therapy services is considered a bundled rate. As all of these examples describe bundled payment rates comprised of constituent services that are based on fee schedule payment rates, they are subject to the bundled rate breakdown requirement in the payment rate transparency provision. Later in this response, we will discuss how States are required to allocate the bundled payment rate to each constituent service under the State's methodology.

Within a bundled payment rate, a constituent service is a Medicaid-covered service included in a bundle of multiple units of service and/or multiple services. These constituent services within the bundled payment rate must correspond to service descriptions in section 3.1–A of the State plan, which describes covered services. When initially adding a bundled payment rate to the State plan, States are required to separately list out each constituent service included in the bundle to ensure that non-covered services are not included in the bundled rate.[204] For example, a bundle for assertive community treatment covered under the rehabilitative services State plan benefit should not include room and board, as rehabilitative services are not covered in institutional settings. Therefore, ''room and board'' is a non-covered service under the rehabilitative services benefit and would not be a constituent service in the bundled payment rate.

We also clarify payment rates that pay for various services and could be considered a bundled payment rate that

[204] *https://www.medicaid.gov/sites/default/files/state-resource-center/downloads/spa-and-1915-waiver-processing/bundled-rate-payment-methodology.pdf.*

are not subject to the requirement in the payment rate transparency publication provision. For purposes of the requirement of this final rule, this bundled payment rate breakdown requirement only applies to bundled payment rates that are based on fee schedule payment rates for each constituent service. Payment rate methodologies that do not utilize fee schedule payment rates for each constituent service to create a single State-developed bundled payment rate to pay for a combination of services, including multiple units of the same service, multiple services within a single benefit category, or multiple services across multiple benefit categories, are not subject to the bundled rate breakdown requirement in the payment rate transparency publication provision. For example, prospective payment system rates that States use to pay for services provided in inpatient hospitals, outpatient hospitals, inpatient psychiatric facilities, inpatient rehabilitation facilities, long-term care hospitals, and nursing facilities are not subject to the bundled rate breakdown requirement, because these PPS rates (as previously mentioned, in the context of payment rates to hospitals and nursing facilities, the terms ''encounter rate'' or ''per diem rate'' can also be used to describe the prospective payment system rate received by these providers) do not utilize fee schedule payment rates to create a single payment rate to pay for a bundle of services. These PPS payment methodologies generally pay providers an amount derived based on a formula that accounts for the resources required to treat a patient, such as the patient's condition (that is, illness severity or clinical diagnosis), the provider's operating costs (that is, labor, supplies, insurance), and adjustment factors (that is, cost of living, case-mix, State determined factors), such as when an individual has an inpatient hospital stay for knee replacement surgery. While these PPS rates generally are subject to the payment rate transparency publication requirement in this final rule because they are typically known in advance of a provider delivering a service to a beneficiary, they are not subject to the breakdown requirement to the extent they do not utilize exclusively fee schedule payment rates to create a single payment rate for the bundle of services. Therefore, if we were to require States to also break down PPS rates, it would significantly increase burden on States and might not result in the public clearly understanding the amount that any given provider could expect to receive for the furnishing the services to a Medicaid beneficiary, as PPS rates are generally not determined based only on payment rates for constituent services within the meaning of this final rule. We believe a fee schedule payment rate for each constituent service is needed to enable the State to perform a straightforward and reliable allocation of the bundled payment rate to each included service. Therefore, because PPS rates are not determined based on fee schedule payment rates for each constituent service within the meaning of this final rule, States do not need to identify each constituent service included within a PPS rate and how much of the PPS rate is allocated to each constituent service under the State's methodology. In response to the comment asking about FQHC and RHC PPS rates, please see the discussion earlier in this section explaining why these rates are carved out of this requirement due to the statutory floor for rates and consideration of potentially undue burden on States.

Regarding whether payment rates for CCBHC services are subject to the bundled payment rate breakdown requirement, PPS rates for CCBHC demonstration services authorized under section 223 of the Protecting Access to Medicare Act of 2014 are not subject to the payment rate transparency publication requirement, including the bundled rate breakdown requirement, because these payments rates are outside of Medicaid FFS State plan authority. For CCBHC services covered and paid for under Medicaid FFS State plan authority, States that use Medicaid FFS fee schedule rates within the meaning of this rule to pay for CCBHC services must include these payment rates in the payment rate transparency provisions. Additionally, Medicaid FFS fee schedule rates that are bundled payment rates within the meaning of this rule paid to clinics (as defined in § 440.90), are subject to the bundled rate breakdown requirement.

Based on this, if a State determines a bundled payment rate is subject to the bundled payment rate breakdown requirement, we will now discuss how to allocate the bundled payment rate to each constituent service under the State's methodology. States have flexibility in determining the assumptions regarding the type, quantity, intensity, and price of the constituent services that they factor into the initial development of a bundled rate.[205] When States establish the payment rate for a bundle, States may include the current fee schedule payment rates for the constituent services to determine the total bundled rate. For example, a State might pay a $480 bundled rate for assertive community treatment, based on the application of a small discount factor to the fee schedule payment rates for all of the constituent services (assessments, care coordination, crisis intervention, therapy, and medication management). In this scenario, the State's fee schedule payment rates might be $50 for an assessment, $30 for care coordination, $200 for crisis intervention, $200 for 2 hours of individual therapy, and $20 for medication management. Separately, the State would pay a total of $500 for all of these services; however, the State might determine that a provider likely would realize efficiencies from providing the services together in a coordinated fashion, and so might reduce the bundled payment rate by 4 percent to account for these expected savings. Thus, the State's bundled payment rate would be $480, which would be allocated as follows: $480 * ($50/$500) = $48 for assessment; $480 * ($30/$500) = $28.80 for care coordination; $480 * ($200/$500) = $192 for crisis intervention; $480 * ($200/$500) = $192 for 2 hours of individual therapy; and $480 * ($20/$500) = $19.20 for medication management. In this example, the State would identify each of these constituent services and use these allocation amounts to meet the requirements finalized in paragraph (b)(1)(iv).

In response to commenters' request for an explanation of the value CMS believes the bundled payment rate breakdown requirement will contribute to the Medicaid program, our rationale is the same as for this payment rate publication requirement generally. Bundled rates are not inherently transparent, and in order to achieve the same goal of transparency in service of ensuring adequate access to covered care and services, it is important for interested parties to know what is covered in a bundled rate and how much of the bundle is attributable to each constituent service, which provides information relevant to whether the bundled rate is adequate in relation to its constituent services and enables comparison to how the constituent services are paid when

[205] For new bundled rates, CMS requests information on how States developed the rates, including: assumptions regarding the type, quantity, intensity, and price of the component services typically provided to support the economy and efficiency of the rate. *https://www.medicaid.gov/sites/default/files/state-resource-center/downloads/spa-and-1915-waiver-processing/bundled-rate-payment-methodology.pdf.*

furnished outside the bundle. Our primary goal with the payment rate transparency publication is ensuring Medicaid payment rates are publicly available in such a way that a member of the public can readily determine the amount that Medicaid would pay for a given service. Transparency helps to ensure that interested parties have basic information available to them to understand Medicaid payment levels and the associated effects of payment rates on access to care so that they may raise concerns to State Medicaid agencies via the various forms of public process available to interested parties.

In response to commenters' concerns that the bundled payment rate breakdown provision would be burdensome, operationally difficult, or not feasible because individual rates for constituent services within the bundle do not exist, we are providing guidance on how States are expected to address these circumstances. We acknowledge there are instances where States may have bundled payment rates that have been in place for many years, even decades, and the State currently does not have available information about how the payment rates were developed. Therefore, the State may lack historical data to perform a reasonable allocation of the bundled payment rate to constituent services. We also recognize there are instances where States utilizing bundled payment rates do not permit providers to bill for the constituent services separately. In this instance, States may no longer regularly update the fee schedule amounts for the constituent services included in the bundled payment rate because the bundle is primarily how the services are delivered and billed by providers. Therefore, the current fee schedule payment rates for the constituent services do not reflect how the State would pay for the constituent services outside of the bundle.

States have flexibility in determining how best to allocate the bundled payment rate to each constituent service in these scenarios. Should a State not have certain historical data about the bundled payment rate available, we are offering a few solutions for the State to consider. If a State can reasonably calculate missing rates, we expect them to do so for the purposes of completing the bundled payment rate allocation. For example, a State may have a bundled payment rate that includes five constituent services, which the State knows was calculated by summing the undiscounted fee schedule payment rates for each of the five constituent services. Today, the State may be unable to locate the fee schedule amount for one of the constituent services. In this instance, we would expect the State to reasonably deduce the allocated rate for the fifth constituent service by summing the four known rates for the four constituent services and subtracting that amount from the total bundled payment rate. If a State cannot calculate a missing portion of a bundled payment rate, they may use current fee schedule rates. For example, a State may have a bundled payment rate, but it does not have historical information about how the bundled payment rate was originally calculated from the constituent services. In this instance, we would expect the State to use the current fee schedule rates for the constituent services included in the bundle to allocate the bundled payment rate for the payment rate transparency publication. Regardless of the approach States utilize to allocate the bundled payment rate to the constituent services, we expect States to include a description of how the bundled payment rate was allocated in the payment rate transparency publication to ensure that a member of the public can readily determine the amount that Medicaid would pay for the bundled service and understand how the State has accomplished a reasonable allocation of this amount to each constituent service included in the bundle, as required in § 447.203(b)(1)(iii).

In situations where the State cannot reasonably deduce how to allocate the bundled payment rate to the constituent services included in the bundle or the current fee schedule rates for the constituent services do not serve as a reasonable proxy to determine the allocation of the bundled payment rate to its constituent services, we invite States to reach out to us for technical assistance on how to comply with § 447.203(b)(1)(iv) on a case-by-case basis. We expect this guidance to provide States with relief from burden associated with allocating the bundled payment rate to constituent services when historical information is unavailable, including in certain situations raised by commenters where individual historical rates for constituent services within the bundle are no longer available. Regardless of how a State chooses to address a lack of data related to a bundled payment rate, we expect the State to update the payment rate transparency publication with an accurate allocation information following the effective date or CMS approval date of a SPA, a section 1915(c) HCBS waiver amendment, or similar amendment amending the bundled payment rate in question in accordance with § 447.203(b)(1)(vi). These processes require the State to provide information about the fee schedule payment rates for the constituent services included in the bundle, therefore making available the necessary data to perform an allocation for the payment rate transparency publication.

We also invite States to contact CMS for technical assistance if they have a bundled payment methodology that does not clearly align with the previous descriptions and examples of bundled payment rates that are and are not subject to the bundled payment rate breakdown requirement. We also encourage States to review our existing Bundled Rate Payment Methodology resource on Medicaid.gov for more information about bundled payment methodologies.[206]

Regarding commenters' concerns about burden on States to break down institutional services bundled payment rates into constituent services in the payment rate transparency publication, we understand these concerns were primarily about operational challenges States would face if rates paid to hospitals and nursing facilities, as well as cost-based rates generally, were subject to this provision. As previously discussed in this response, PPS rates that are not determined based on fee schedule payment rates for each constituent service within the meaning of this final rule are not subject to the bundled rate breakdown requirement in § 447.203(b)(1)(iv); however, PPS rates generally are considered Medicaid FFS fee schedule payment rates in the context of this rule and are required to be published in the payment rate transparency publication under § 447.203(b)(1) as finalized in this rule. Also previously discussed in this response, PPS rates for FQHCs and RHCs are not subject to the bundled rate breakdown requirement in § 447.203(b)(1)(iv) because these payment rates are not subject to the payment rate transparency publication requirement under § 447.203(b)(1).

In this final rule, we are revising the regulatory language to make clear what bundled payment rates are subject to the constituent service allocation, or breakdown, requirement. We proposed in § 447.203(b)(1) to provide that the State must, ''. . . in the case of a bundled or similar payment methodology, identify each constituent service included within the rate and

[206] *https://www.medicaid.gov/sites/default/files/state-resource-center/downloads/spa-and-1915-waiver-processing/bundled-rate-payment-methodology.pdf.*

how much of the bundled payment rate is allocated to each constituent service under the State's methodology.'' We are finalizing § 447.203(b)(1)(iv) to state, ''In the case of a bundled payment methodology, **the State must publish the Medicaid fee-for-service bundled payment rate and, where the bundled payment rate is based on fee schedule payment rates for each constituent service, must** identify each constituent service included within the rate and how much of the bundled payment is allocated to each constituent service under the State's methodology.'' (new language identified in bold). We also deleted ''or similar'' from ''In the case of a bundled payment methodology . . .'' because we determined that this language is unnecessary and potentially confusing; instead, in this final rule, we are clarifying specifically which bundled payment rates are subject to the requirement to identify each constituent service included within the rate and how much of the bundled payment is allocated to each constituent service under the State's methodology.

Comment: Several commenters offered suggestions and recommendations for the proposed payment rate transparency requirements. These suggestions and recommendations include linking together FFS and managed care plan web pages for full transparency, allowing State contractors to publish the State's payment rates, requiring the published format of the payment rates be ready for data analysis, requiring States to publish information about payment rate models and methodologies (that is, payment rate development information, potentially including cost factors and assumptions underlying a rate, such as wages, employee-related expenses, program-related expenses, and general and administrative expenses) as well as the frequency and processes for rate reviews, and requiring States publish additional granular data, particularly for dental services (for example, utilization, median payment rates, and service frequency).

Response: We appreciate commenters' suggestions and recommendations for the payment rate transparency publication requirement. While the transparency provisions in the Managed Care final rule (as published elsewhere in this **Federal Register**) and this final rule share a similar goal, we are not incorporating the suggestion to require States to link together FFS and managed care plan web pages for full transparency because there is often no relationship between FFS Medicaid payment rates and managed care plan provider rates, as the rates are determined through different processes, subject to different Federal requirements, and States, managed care plans, and CMS assess access to care differently for FFS and managed care. Therefore, we believe that requiring States link their FFS payment rate transparency publication websites with managed care plan web pages would not provide beneficiaries, providers, CMS, and other interested parties with relevant payment information for the purposes of assessing access to care issues to better ensure compliance of FFS payment rates with section 1902(a)(30)(A) of the Act.

As discussed in an earlier response to comments in this section, we have revised the regulatory language in § 447.203(b)(1) from what we originally proposed to permit States the flexibility to continue to utilize contractors and other third parties for developing and publishing their fee schedules on behalf of the State. Specifically, in § 447.203(b)(1), we deleted the language requiring that the website where Medicaid fee-for-service fee schedule payment rates be published be ''developed and maintained by the single State agency.'' As finalized, § 447.203(b)(1) requires the State ''. . . publish all Medicaid fee-for-service fee schedule payment rates on a website that is accessible to the general public.'' We continue to require that ''The website where the State agency publishes its Medicaid fee-for-service payment rates must be easily reached from a hyperlink on the State Medicaid agency's website.'' in § 447.203(b)(1)(ii).

We are not incorporating the suggestion to require the format of the payment rate transparency publication be ready for any particular form of data analysis. Our primary goal with the payment rate transparency publication is ensuring Medicaid payment rates are publicly available in such a way that a member of the public can readily determine the amount that Medicaid would pay for a given service. Transparency helps to ensure that interested parties have basic information available to them to understand Medicaid payment levels and the associated effects of payment rates on access to care so that they may raise concerns to State Medicaid agencies via the various forms of public process available to interested parties. Transparency will provide us and other interested parties with information necessary that is not currently available at all or not available in a clear and accessible format for us to ensure the payment rates for consistency with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area. The payment rate transparency publication is the first step in ensuring payment rate data is transparent, then the comparative payment rate analysis is the next step in analyzing the payment rate data relative to Medicare as a benchmark. Additionally, given the requirements that the payment rate transparency publications be publicly available, clear, and accessible, we anticipate that various interested parties will be able to adapt the published information manually or through technological means so that it is suited to any analysis they wish to perform.

We are not incorporating the suggestion to require States to publish information about payment rate models and methodologies (that is, payment rate development information, potentially including cost factors and assumptions underlying a rate, such as wages, employee-related expenses, program-related expenses, and general and administrative expenses), the frequency and processes for rate reviews, or additional granular data, particularly for dental services (for example, utilization, median payment rates, and service frequency), because we want our initial focus to be on establishing the new payment rate transparency publication, comparative payment rate analysis, and payment rate disclosure requirements, providing States with support during the compliance period, and ensuring these data are available to beneficiaries, providers, CMS, and other interested parties for the purposes of assessing access to care issues. While the payment rate transparency publication does not require additional granular data outside of payment rate variations by population (pediatric and adult), provider type, and geographical location, we would like to note that utilization in the form of the number of Medicaid-paid claims and the number of Medicaid enrolled beneficiaries who received a service is required to be included in the comparative payment rate analysis and payment rate disclosure; however, these requirements do not include dental services. We acknowledge that the commenters' suggestions would add relevant and beneficial context to the payment rate information required to be published by States in this final rule. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with

this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate. While we are not adopting all of these suggestions and recommendations, we note that States have the flexibility to add the elements described to their payment rate transparency publications if they so choose.

We believe that there are minimal qualities that the website containing the payment rate transparency publication necessarily must include, such as being able to function quickly and as an average user would expect; requiring minimal, logical navigation steps; taking reasonable steps to provide meaningful access to individuals with limited English proficiency; and ensuring accessibility for persons with disabilities in accordance with section 504 of the Rehabilitation Act and Title II of the ADA. An example of this includes a single web page clearly listing the names of the State's published fee schedules (such as Physician Fee Schedule, Rehabilitation Services Fee Schedule, etc.)) as links that transport the user to the relevant State fee schedule file, which file should be in a commonly accessible file format that generally can be viewed within a web browser without requiring the user to download a file for viewing in separate software. In this example, there is no unnecessary burden (including requiring payment (paywall)) creation of an account and/or password to view the web page, or need to install additional software to view the files) on the individual to trying to view the published fee schedules. We invite States to reach out to CMS for technical guidance regarding compliance with the payment rate transparency publication requirement. We also encourage States to review the subregulatory guidance, which includes an example of what a compliant payment rate transparency publication might look like, that we will issue prior to the effective date of this final rule.

Comment: A few commenters suggested narrowing the scope of the payment rate transparency requirement. Commenters recommended narrowing the scope by requiring publication of payment rate transparency information only about a representative subset of services, a State's most common provider types and covered services, or the same CMS-published list of E/M codes that we proposed for the comparative payment rate analysis requirement. A subset of these commenters suggested that, once States have acclimated to the requirements of payment rate transparency, then CMS could expand the requirement gradually to include all Medicaid FFS payment rates, to ease burden on States.

Response: We appreciate the commenters' suggestions on narrowing the scope of the payment rate transparency requirement; however, we are not changing the scope in this final rule. As previously discussed in detail in an earlier response to comments in this section, for purposes of the payment rate transparency provision in § 447.203(b)(1), Medicaid FFS fee schedule payment rates are FFS payment amounts made to a provider, and known in advance of a provider delivering a service to a beneficiary by reference to a fee schedule. While we understand the broad scope of included rates will require some work for many States to implement, we believe the time between the effective date of this final rule and the applicability date of July 1, 2026, for the first publication of payment rate transparency information is sufficient for these requirements. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

Comment: One commenter suggested requiring States identify an additional level of payment rate variation within the population (pediatric and adult) where, within the pediatric population, Medicaid and CHIP pay different rates, which should be disclosed separately in the payment rate transparency publication.

Response: We appreciate the commenter's suggestion; however, we are not including a requirement that States break down payment rates to include separate Medicaid and CHIP payment rate information within the pediatric population payment rate reporting. Regulations applicable to CHIP under 42 CFR part 457 and relevant guidance are beyond the scope of this rulemaking. After obtaining implementation experience with these new policies, we will consider proposing to require States to identify additional levels of payment rate variations in the Medicaid FFS payment rate transparency publication through future rulemaking.

Comment: One commenter suggested applying the payment rate transparency requirements to all Medicaid HCBS programs.

Response: To the extent a State's Medicaid HCBS program utilizes Medicaid FFS fee schedule payment rates within the meaning of this final rule, as discussed in detail earlier in this section, those payment rates would be subject to payment rate transparency publication requirements described in § 447.203(b)(1). Additionally, we are finalizing a similar provision to the Medicaid FFS fee schedule payment rate transparency requirement for HCBS direct care worker compensation elsewhere in this final rule. The HCBS Payment Adequacy and Reporting requirements in this final rule require that States report annually, in the aggregate for each service, on the percent of payments for homemaker, home health aide, personal care, and habilitation services that are spent on compensation for direct care workers, and separately report on payments for such services when they are self-directed and facility-based.

Comment: One commenter suggested collecting provider-level data on all payments, not just fee schedule payment rates, as well as the source(s) of non-Federal share for payments, to determine net Medicaid payments (total Medicaid provider payments received minus the provider's contributions to the non-Federal share through mechanisms including provider-related donations, health care-related taxes, intergovernmental transfers, and certified public expenditures) to each provider.

Response: Existing UPL and the supplemental payment reporting requirements under section 1903(bb) of the Act, as established by Division CC, Title II, Section 202 of the Consolidated Appropriations Act, 2021 (CAA) (Pub L. 116–260),) already require States to submit provider-level payment data for certain services to CMS. Therefore, we are not incorporating the suggestion to collect provider-level data on all payments because this would be duplicative of existing requirements and because that is not the intention of the payment rate transparency publication requirement. While we do collect information about the non-Federal share through SPA reviews, regulatory requirements regarding collection of non-Federal share data are beyond the scope of this rulemaking.

Comment: A couple of commenters stated that dually eligible beneficiaries and their providers face unique issues when accessing and delivering Medicaid services (such as beneficiaries facing worse outcomes and having complex needs that require providers to coordinate and deliver specialized care) and requested CMS include additional provisions in the payment rate transparency publication requirements specifically for this group. One commenter suggested CMS require the

payment rate transparency publication, comparative payment rate analysis, and payment rate disclosure address the experience of people who are dual-eligible and include factors related to Medicare coverage. Another commenter suggested requiring that the payment rates be disaggregated for the purposes of comparing providers serving dually eligible beneficiaries from those serving Medicare-only or Medicaid-only beneficiaries to ensure differences in access to care and payment rates are documented. The commenter also recommended the payment rate transparency publication identify when Medicaid is the primary or secondary payer in the context of a State's lesser-of payment policies (that is, for dually eligible Qualified Medicare Beneficiaries, States are obligated to pay Medicare providers for deductibles and co-insurance after Medicare has paid; however, States limit those payments to the lesser of the Medicaid rate for the service or the Medicare co-insurance amount).

Response: We appreciate the commenters' concern for and suggestions on how we might evaluate access to care for dually eligible beneficiaries. We are not incorporating the suggestion to require the payment rate transparency publication, comparative payment rate analysis, and payment rate disclosure address the experience of people who are dual-eligible and include factors related to Medicare coverage because these provisions focus on requiring States to publish and analyze quantitative data (such as, payment rates, claims volume, beneficiary counts) to assess access to care, rather than qualitive data (such as, surveys on beneficiary experience). We are also not incorporating the suggestion to identify when Medicaid is the primary or secondary payer in the context of a State's lesser-of payment policies in the payment rate transparency publication because we remain focused on the transparency of States' payment rates, rather than States' payment policies, as a method of assessing consistency with section 1902(a)(30)(A) of the Act. Additionally, we are not incorporating the suggestion to require States disaggregate their Medicaid FFS fee schedule payment rates for providers serving dually eligible beneficiaries from those serving Medicare-only or Medicaid-only beneficiaries because we want our initial focus to be on establishing the new payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements, providing States with support during the compliance period, and ensuring the data required under this final rule are to beneficiaries, providers, CMS, and other interested parties for the purpose of assessing access to care issues. We believe that payment rate breakdowns by population (pediatric and adult), provider type, and geographical location will provide a sufficient amount of transparency to ensure that interested parties have basic information available to them to understand Medicaid payment levels and the associated effects of payment rates on access to care so that they may raise concerns to State Medicaid agencies via the various forms of public processes available to interested parties.

Monitoring access to care is an ongoing priority of the agency and we will continue to work with States and other interested parties as we seek to expand access monitoring in the future, including potentially through future rulemaking. However, we remain focused on maintaining a balance in Federal and State administrative burden with our shared obligation to ensure compliance with section 1902(a)(30)(A) of the Act (and our obligation to oversee State compliance with the same).

Comment: A couple of commenters recommended that the payment rate transparency requirements under § 447.203(b) be applied to payment rates for services delivered to beneficiaries through managed care to ensure managed care plan rates are published publicly.

Response: While we appreciate the value in transparency of provider payment rates in managed care delivery systems, regulations applicable to managed care under 42 CFR parts 438 and 457 are beyond the scope of this rulemaking.

Comment: One commenter requested CMS work with States to correct deficient payment rates once identified by the transparency requirements.

Response: To clarify, the provisions in this final rule do not require States to change their provider payment rates. The goal of the payment rate transparency publication is to ensure all States publish their Medicaid FFS fee schedule payment rates in a format that is publicly accessible and where all Medicaid FFS fee schedule payment rates can be easily located and understood.

Transparency, particularly the requirement that States must publicly publish their Medicaid FFS fee schedule payment rates, helps to ensure that interested parties have basic information available to them to understand Medicaid payment levels and the associated effects of payment rates on access to care so that they may raise concerns to State Medicaid agencies via the various forms of public process available to interested parties. We will utilize the information in the payment rate transparency publication during SPA reviews and other situations when States are proposing provider payment rate changes for services included in the publication and when the public process in § 447.204 is used to raise access to care issues related to possible deficient payment rates for services included in the publication.

After consideration of public comments, we are finalizing all provisions under § 447.203(b)(1) as proposed, apart from the following changes:

- Updated the organizational structure of (b)(1) to add romanettes.
- Added clarifying language to the proposed language stating what Medicaid FFS payment rates need to be published.

++ In paragraph (b)(1), the proposed language was revised from ''The State agency is required to publish all Medicaid fee-for-service payment rates . . .'' to finalize the language as ''The State agency is required to publish all Medicaid fee-for-service **fee schedule** payment rates . . .'' (new language identified in bold)

++ In paragraph (b)(1)(i), the proposed language was revised from ''Published Medicaid fee-for-service payment rates include fee schedule payment rates . . .'' to finalize the language as ''**For purposes of paragraph (b)(1), the payment rates that the State agency is required to publish are** Medicaid fee-for-service payment rates . . .'' (new language identified in bold)

- Deleted the proposed language specifying that the payment rate transparency must be developed and maintained on the State Medicaid agency's website. The proposed language was revised from ''The State agency is required to publish all Medicaid fee-for-service payment rates on a website developed and maintained by the single State agency that is accessible to the general public'' to finalize the language as ''The State agency is required to publish all Medicaid fee-for-service payment rates on a website that is accessible to the general public.'' in paragraph (b)(1).
- Revised the proposed language about a member of the public being able to readily determine the payment amount for a service from ''Medicaid fee-for-service payment rates must be organized in such a way that a member of the public can readily determine the amount that Medicaid would pay for the service'' to finalize the language as

''Medicaid fee-for-service payment rates must be organized in such a way that a member of the public can readily determine the amount that Medicaid would pay for a given service.'' in paragraph (b)(1)(iii). (new language identified in bold)

- Revised the proposed language about bundled payment rates from ''. . . in the case of a bundled or similar payment methodology, identify each constituent service included within the rate and how much of the bundled payment is allocated to each constituent service under the State's methodology'' to:

++ Delete ''or similar'' from ''In the case of a bundled or similar payment methodology . . .''

++ Add ''the State must publish the Medicaid fee-for-service bundled payment rate and, where the bundled payment rate is based on fee schedule payment rates for each constituent service, must . . .''

The language is finalized as ''In the case of a bundled payment methodology, **the State must publish the Medicaid fee-for-service bundled payment rate and, where the bundled payment rate is based on fee schedule payment rates for each constituent service, must** identify each constituent service included within the rate and how much of the bundled payment is allocated to each constituent service under the State's methodology.'' in paragraph (b)(1)(iv). (new language identified in bold)

- Revised the applicability date for this section from the proposed January 1, 2026, to require that the initial publication of the Medicaid FFS payment rates shall occur no later than July 1, 2026, and include approved Medicaid FFS payment rates in effect as of July 1, 2026, in paragraph (b)(1)(vi).
- Revised the proposed language about updating the publication after SPA approval from ''The agency is required to include the date the payment rates were last updated on the State Medicaid agency's website and to ensure these data are kept current where any necessary update must be made no later than 1 month following the date of CMS approval of the State plan amendment, section 1915(c) HCBS waiver amendment, or similar amendment revising the provider payment rate or methodology.'' to finalize the language as ''The agency is required to include the date the payment rates were last updated on the State Medicaid agency's website and to ensure these data are kept current, where any necessary update must be made no later than 1 month following the latter of the date of CMS approval of the State plan amendment, section 1915(c) HCBS waiver amendment, or similar amendment revising the provider payment rate or methodology, or the effective date of the approved amendment.'' in paragraph (b)(1)(vi). (new language identified in bold)

b. Comparative Payment Rate Analysis and Payment Rate Disclosure § 447.203(b)(2) Through (5)

In paragraph (b)(2), we proposed to require States to develop and publish a comparative payment rate analysis of Medicaid payment rates for certain specified services, and a payment rate disclosure for certain HCBS. We specified the categories of services that States would be required to include in a comparative payment rate analysis and payment rate disclosure of Medicaid payment rates. Specifically, we proposed that for each of the categories of services in paragraphs (b)(2)(i) through (iii), each State agency would be required to develop and publish a comparative payment rate analysis of Medicaid payment rates as specified in proposed § 447.203(b)(3). We also proposed that for each of the categories of services in paragraph (b)(2)(iv), each State agency would be required to develop and publish a payment rate disclosure of Medicaid payment rates as specified in proposed § 447.203(b)(3). We proposed for both the comparative payment rate analysis and payment rate disclosure that, if the rates vary, the State must separately identify the payment rates by population (pediatric and adult), provider type, and geographical location, as applicable. The categories of services listed in paragraph (b)(2) include: primary care services; obstetrical and gynecological services; outpatient mental health and substance use disorder services; and personal care, home health aide, and homemaker services, as specified in § 440.180(b)(2) through (4), provided by individual providers and providers employed by an agency.

In paragraph (b)(2), we proposed to require States separately identify the payment rates in the comparative payment rate analysis and payment rate disclosure, if the rates vary, by population (pediatric and adult), provider type, and geographical location, as applicable. These proposed breakdowns of the Medicaid payment rates, similar to how we proposed payment rates would be broken down in the payment rate transparency publication under proposed § 447.203(b)(1), would apply to all proposed categories of services listed in paragraph (b)(2): primary care services, obstetrical and gynecological services, outpatient mental health and substance use disorder services, and personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency.

We acknowledged that not all States pay varied payment rates by population (pediatric and adult), provider type, and geographical location, which is why we have included language ''if the rates vary'' and ''as applicable'' in the proposed regulatory text. We included this language in the proposed regulatory text to ensure the comparative payment rate analysis and payment rate disclosure capture all Medicaid payment rates, including when States pay varied payment rates by population (pediatric and adult), provider type, and geographical location. We also included proposed regulatory text for the payment rate disclosure to ensure that the average hourly payment rates for personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency would be separately identified for payments made to individual providers and to providers employed by an agency, if the rates vary, as later discussed in connection with § 447.203(b)(3)(ii). For States that do not pay varied payment rates by population (pediatric and adult), provider type, and geographical location and pay a single Statewide payment rate for a single service, then the comparative payment rate analysis and payment rate disclosure would only need to include the State's single Statewide payment rate.

We proposed to include a breakdown of Medicaid payment rates by population (pediatric and adult), provider type, and geographical location, as applicable, on the Medicaid side of the comparative payment rate analysis in paragraph (b)(2) to align with the proposed payment rate transparency provision, to account for State Medicaid programs that pay variable Medicaid payment rates by population (pediatric and adult), provider type, and geographical location, and to help ensure the State's comparative payment rate analyses accurately align with Medicare. Following the initial year that the proposed provisions proposed would be in effect, these provisions would align with and build on the payment rate transparency requirements described in § 447.203(b)(1), because States could source the codes and their corresponding Medicaid payment rates that the State already would publish to meet the payment rate transparency requirements.

We explained that these proposed provisions are intended to help ensure that the State's comparative payment rate analysis contains the highest level of granularity in each proposed aspect by considering and accounting for any variation in Medicaid payment rates by population (pediatric and adult), provider type, and geographical location, as previously required in the AMRP process under § 447.203(b)(1)(iv) and (v), and (b)(3). Additionally, Medicare varies payment rates for certain NPPs (nurse practitioners, physician assistants, and clinical nurse specialists) by paying them 85 percent of the full Medicare PFS amount and varies their payment rates by geographical location through calculated adjustments to the pricing amounts to reflect the variation in practice costs from one geographical location to another; therefore, we explained that the comparative payment rate analysis accounting for these payment rate variations is crucial to ensuring the Medicaid FFS payment rates accurately align with FFS Medicare PFS rates.[207] Medicare payment variations for provider type and geographical location would be directly compared with State Medicaid payment rates that also apply the same payment variations, in addition to payment variation by population (pediatric and adult) which is unique to Medicaid, yet an important payment variation to take into consideration when striving for transparency of Medicaid payment rates. For States that do not pay varied payment rates by population (pediatric and adult), provider type, or geographical location and pay a single Statewide payment rate for a single service, Medicare payment variations for provider type and geographical location would be considered by calculating a Statewide average of Medicare PFS rates which is later discussed in this final rule.

Similar to the payment rate transparency publication, we acknowledged that there may be additional burden associated with our proposal that the payment rate transparency publication and the comparative payment rate analysis include a payment rate breakdown by population (pediatric and adult), provider type, and geographical location, as applicable, when States' payment rates vary based on these groupings. However, we believe that any approach to requiring a comparative payment rate analysis would involve some level of burden that is greater for States that choose to employ these payment rate differentials, since any comparison methodology would need to take account—through a separate comparison, weighted average, or other mathematically reasonable approach—of all rates paid under the Medicaid program for a given service. In all events, we believe this proposal would create an additional level of granularity in the analysis that is important for ensuring compliance with section 1902(a)(30)(A) of the Act. We noted that multiple types of providers, for example, physicians, physician assistants, and nurse practitioners, are delivering similar services to Medicaid beneficiaries of all ages, across multiple Medicaid benefit categories, throughout each State.

Section 1902(a)(30)(A) requires ''. . . that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area,'' and we noted our belief that having sufficient access to a variety of provider types is important to ensuring access for Medicaid beneficiaries meets this statutory standard. For example, a targeted payment rate reduction to nurse practitioners, who are often paid less than 100 percent of the State's physician fee schedule rate, could have a negative impact on access to care for services provided by nurse practitioners, but this reduction would not directly impact physicians or their willingness to participate in Medicaid and furnish services to beneficiaries. By proposing that the comparative payment rate analysis include a breakdown by provider type, where States distinguish payment rates for a service by provider type, we explained that the analysis would capture this payment rate variation among providers of the same services and provide us with a granular level of information to aid in determining if access to care is sufficient, particularly in cases where beneficiaries depend to a large extent on the particular provider type(s) that would be affected by the proposed rate change for the covered service(s).

We identified payment rate variation by population (pediatric and adult), provider type, and geographical location as the most commonly applied adjustments to payment rates that overlap between FFS Medicaid and Medicare and could be readily broken down into separately identified payment rates for comparison in the comparative payment rate analysis. For transparency purposes and to help to ensure the comparative payment rate analysis is conducted at a granular level of analysis, we explained our belief that it is important for the State to separately identify their rates, if the rates vary, by population (pediatric and adult), provider type, and geographical location, as applicable. We solicited comments on the proposal to require the comparative payment rate analysis to include, if the rates vary, separate identification of payment rates by population (pediatric and adult), provider type, and geographical location, as applicable, in the comparative payment rate analysis in proposed § 447.203(b)(2).

We acknowledged that States may apply additional payment adjustments or factors, for example, the Consumer Price Index, Medicare Economic Index, or State-determined inflationary factors or budget neutrality factors, to their Medicaid payment rates other than population (pediatric and adult), provider type, and geographical location. We stated that we expect any other additional payment adjustments and factors to already be included in the State's published Medicaid fee schedule rate or calculable from the State plan, because § 430.10 requires the State plan to be a ''comprehensive written statement . . . contain[ing] all information necessary for CMS to determine whether the plan can be approved to serve as a basis for . . . FFP . . .'' Therefore, for States paying for services with a fee schedule payment rate, the Medicaid fee schedule is the sole source of information for providers to locate their final payment rate for Medicaid services provided to Medicaid beneficiaries under a FFS delivery system. For States with a rate-setting methodology where the approved State plan describes how rates are set based upon a fee schedule (for example, payment for NPPs are set a percentage of a certain published Medicaid fee schedule), the Medicaid fee schedule would again be the source of information for providers to identify the relevant starting payment rate and apply the rate-setting methodology described in the State plan to ascertain their Medicaid payment.[208] We solicited comments on any additional types of payment adjustments or factors States make to their Medicaid payment rates as listed on their State fee schedules that should be identified in the comparative payment rate analysis that we have not

[207] *https://www.medpac.gov/wp-content/uploads/2021/11/MedPAC_Payment_Basics_22_Physician_FINAL_SEC.pdf.*

[208] *https://www.medicaid.gov/state-resource-center/downloads/spa-and-1915-waiver-processing/fed-req-pymt-methodologies.docx.*

already discussed in § 447.203(b)(i)(B) of this final rule, and how the inclusion of any such additional adjustments or factors should be considered in the development of the Medicare PFS rate to compare Medicaid payment rates to, as later described in § 447.203(b)(3)(i)(C), of this final rule.

In paragraphs (b)(2)(i) through (iv), we proposed that primary care services, obstetrical and gynecological services, and outpatient behavioral health services would be subject to a comparative payment rate analysis of Medicaid payment rates and personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency would be subject to a payment rate disclosure of Medicaid payment rates. We begin with a discussion about the importance of primary care services, obstetrical and gynecological services, and outpatient behavioral health services as proposed in § 447.203(b)(2)(i) through (iii), and the reason for their inclusion in this proposed requirement. Then, we will discuss the importance and justification for including personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency as proposed in § 447.203(b)(2)(iv).

In § 447.203(b)(2)(i) through (iii), we proposed to require primary care services, obstetrical and gynecological services, and outpatient mental health and substance use disorder services be included in the comparative payment rate analysis, because we believe that these categories of services are critical preventive, routine, and acute medical services in and of themselves, and that they often serve as gateways to access to other needed medical services, including specialist services, laboratory and x-ray services, prescription drugs, and other mandatory and optional Medicaid benefits that States cover. Including these categories of services in the comparative payment rate analysis would require States to closely examine their Medicaid FFS payment rates to comply with section 1902(a)(30)(A) of the Act. As described in the recent key findings from public comments on the February 2022 RFI that we published, payment rates are a key driver of provider participation in the Medicaid program.[209] By proposing that States compare their Medicaid payment rates for primary care services, obstetrical and gynecological services, and outpatient mental health and substance use disorder services to Medicare payment rates, States would be required to analyze if and how their payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.

In the proposed rule, we noted our belief that Medicare payment rates for these services are likely to serve as a reliable benchmark for a level of payment sufficient to enlist providers to furnish the relevant services to a beneficiary because Medicare delivers services through a FFS delivery system across all geographical regions of the US and historically, the vast majority of physicians accept new Medicare patients, with extremely low rates of physicians opting out of the Medicare program, suggesting that Medicare's payment rates are generally consistent with a high level of physician willingness to accept new Medicare patients.[210] Additionally, Medicare payment rates are publicly published in an accessible and consistent format by CMS making Medicare payment rates an available and reliable comparison point for States, rather than private payer data which typically is considered proprietary information and not generally available to the public. Therefore, we explained that the proposed requirement that States develop and publish a comparative payment rate analysis would enable States, CMS, and other interested parties to closely examine the relationship between State Medicaid FFS payment rates and those paid by Medicare. This analysis would continually help States to ensure that their Medicaid payment rates are set at a level that is likely sufficient to meet the statutory access standard under section 1902(a)(30)(A) of the Act that payments be sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.

We noted our belief that the comparative payment rate analysis would provide States, CMS, and other interested parties with clear and concise information for identifying when there is a potential access to care issue, such as Medicaid payment rates not keeping pace with changes in corresponding Medicare rates and decreases in claims volume and beneficiary utilization of services. As discussed later in this section, numerous studies have found a relationship between Medicaid payment rates and provider participation in the Medicaid program and, given the statutory standard of ensuring access for Medicaid beneficiaries, a comparison of Medicaid payment rates to other payer rates, particularly Medicare payment rates as justified later in this rule, is an important barometer of whether State payment rates and policies are sufficient for meeting the statutory access standard under section 1902(a)(30)(A) of the Act.

We proposed to focus on these particular services because they are critical medical services and of great importance to overall beneficiary health. Beginning with primary care, these services provide access to preventative services and facilitate the development of crucial doctor-patient relationships. Primary care providers often deliver preventive health care services, including immunizations, screenings for common chronic and infectious diseases and cancers, clinical and behavioral interventions to manage chronic disease and reduce associated risks, and counseling to support healthy living and self-management of chronic diseases; Medicaid coverage of preventative health care services promotes disease prevention which is critical to helping people live longer, healthier lives.[211] Accessing primary care services can often result in beneficiaries receiving referrals or recommendations to schedule an appointment with physician specialists, such as gastroenterologists or neurologists, that they would not be able to obtain without the referral or recommendation by the primary care physician. Additionally, primary care physicians provide beneficiaries with orders for laboratory and x-ray services as well as prescriptions for necessary medications that a beneficiary would not be able to access without the primary care physician. Research over the last century has shown that the impact of the doctor-patient relationship on

[209] Summary of Public Comments in response to the CMS 2022 Request for Information: Access to Coverage and Care in Medicaid & CHIP. December 2022. For the report, see *https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-report.pdf.*

[210] Physicians and practitioners who do not wish to enroll in the Medicare program may ''opt-out'' of Medicare. This means that neither the physician, nor the beneficiary submits the bill to Medicare for services rendered. Instead, the beneficiary pays the physician out-of-pocket and neither party is reimbursed by Medicare. A private contract is signed between the physician and the beneficiary that states that neither one can receive payment from Medicare for the services that were performed. See *https://data.cms.gov/provider-characteristics/medicare-provider-supplier-enrollment/opt-out-affidavits.*

[211] *https://www.medicaid.gov/medicaid/benefits/prevention/index.html.*

patient's health care experience, health outcomes, and health care costs exists [212] and more recent studies have shown that the quality of the physician-patient relationship is positively associated with functional health among patients.[213] Another study found that higher primary care payment rates reduced mental illness and substance use disorders among non-elderly adult Medicaid enrollees, suggesting that positive spillover from increasing primary care rates also positively impacted behavioral health outcomes.[214] Lastly, research has shown that a reduction in barriers to accessing primary care services has been associated with helping reduce health disparities and the risk of poor health outcomes.[215] [216] These examples illustrate how crucial access to primary care services is for overall beneficiary health and to enable access to other medical services. We solicited comments on primary care services as one of the proposed categories of services subject to the comparative payment rate analysis requirements in proposed § 447.203(b)(2)(i).

Similar to primary care services, both obstetrical and gynecological services and outpatient behavioral health services provide access to preventive and screening services unique to each respective field. A well-woman visit to an obstetrician–gynecologist often provides access to screenings for cervical and breast cancer; screenings for Rh(D) incompatibility, syphilis infection, and hepatitis B virus infection in pregnant persons; monitoring for healthy weight and weight gain in pregnancy; immunization against the human papillomavirus infection; and perinatal depression screenings among other recommended preventive services.[217] [218] Behavioral health care promotes mental health, resilience, and wellbeing; the treatment of mental and substance use disorders; and the support of those who experience and/or are in recovery from these conditions, along with their families and communities. Outpatient behavioral health services can overlap with preventative primary care and obstetrical and gynecological services, for example screening for depression in adults and perinatal depression screenings, but also provide unique preventive and screening services such as screenings for unhealthy alcohol use in adolescents and adults, anxiety in children and adolescents, and eating disorders in adolescents and adults, among other recommended preventive services.[219]

The US is simultaneously experiencing a maternal health crisis and mental health crisis, putting providers of obstetrical and gynecological and outpatient behavioral health services, respectively, at the forefront.[220] [221] According to Medicaid and CHIP Payment and Access Commission (MACPAC), ''Medicaid plays a key role in providing maternity-related services for pregnant women, paying for slightly less than half of all births nationally in 2018.'' [222] Given Medicaid's significant role in maternal health during a time when maternal mortality rates in the US continue to worsen and the racial disparities among mothers continues to widen,[223] [224] accessing obstetrical and gynecological care, including care before, during, and after pregnancy is crucial to positive maternal and infant outcomes.[225] We solicited comments on obstetrical and gynecological services as one of the proposed categories of services subject to the comparative payment rate analysis requirements in proposed § 447.203(b)(2)(ii).

Improving access to behavioral health services is a critical, national issue facing all payors, particularly for Medicaid which plays a crucial role in mental health care access as the single largest payer of services and has a growing role in payment for substance use disorder services, in part due to Medicaid expansion and various efforts by Congress to improve access to behavioral health services.[226] [227] Several studies have found an association between reducing the uninsured rate through increased Medicaid enrollment and improved and expanded access to critically needed behavioral health services.[228] Numerous studies have found positive outcomes associated with Medicaid expansion: increases in the insured rate and access to care and medications for adults with depression, increases in coverage rates and a greater likelihood of being diagnosed with a mental health condition as well as the use of prescription medications for a mental health condition for college students from disadvantaged backgrounds,[229] and a decrease in delayed or forgone necessary care in a nationally representative sample of non-elderly adults with serious psychological distress.[230] While individuals who are covered by Medicaid have better access to behavioral health services compared to people who are uninsured, some coverage gaps remain in access to behavioral health care for many people, including those with Medicaid.

In the proposed rule, we noted that some of the barriers to accessing

[212] Cockerham, W.C. (2021). *The Wiley Blackwell Companion to Medical Sociology* (1st ed.). John Wiley & Sons.

[213] Olaisen, R.H., Schluchter, M.D., Flocke, S.A., Smyth, K.A., Koroukian, S.M., & Stange, K.C. (2020). Assessing the longitudinal impact of physician-patient relationship on Functional Health. *The Annals of Family Medicine, 18*(5), 422–429. *https://doi.org/10.1370/afm.2554*.

[214] Maclean, Johanna Catherine, McCleallan, Chandler, Pesko, Michael F., and Polsky, Daniel. (2023). Medicaid reimbursement rates for primary care services and behavioral health outcomes. Health economics, 1–37. *https://doi.org/10.1002/hec.4646*.

[215] Starfield, B., Shi, L., & Macinko, J. (2005). Contribution of primary care to health systems and health. The Milbank quarterly, 83(3), 457–502. *https://doi.org/10.1111/j.1468-0009.2005.00409.x*.

[216] *https://health.gov/healthypeople/priority-areas/social-determinants-health/literature-summaries/access-primary-care*.

[217] Rh(D) incompatibility is a preventable pregnancy compilation where a woman who is Rh negative is carrying a fetus that is Rh positive (Rh factor is a protein that can be found on the surface of red blood cells). When the blood of an Rh-positive fetus gets into the bloodstream of an Rh-negative woman, her body will recognize that the Rh-positive blood is not hers. Her body will try to destroy it by making anti-Rh antibodies. These antibodies can cross the placenta and attack the fetus's blood cells. This can lead to serious health problems, even death, for a fetus or a newborn. Prevention of Rh(D) incompatibility requires screening for Rh negative early in pregnancy (or before pregnancy) and, if needed, giving a medication to prevent antibodies from forming.

[218] *https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2018/10/well-woman-visit*.

[219] *https://www.uspreventiveservicestaskforce.org/uspstf/topic_search_results?topic_status=P*.

[220] *https://www.whitehouse.gov/wp-content/uploads/2022/06/Maternal-Health-Blueprint.pdf*.

[221] *https://www.whitehouse.gov/briefing-room/statements-releases/2022/05/31/fact-sheet-biden-harris-administration-highlights-strategy-to-address-the-national-mental-health-crisis/*.

[222] *https://www.macpac.gov/wp-content/uploads/2020/01/Medicaid%E2%80%99s-Role-in-Financing-Maternity-Care.pdf*.

[223] *https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2020/maternal-mortality-rates-2020.htm*.

[224] *https://www.nytimes.com/2022/02/23/health/maternal-deaths-pandemic.html?smid=url-share*.

[225] *https://www.cms.gov/About-CMS/Agency-Information/OMH/equity-initiatives/rural-health/09032019-Maternal-Health-Care-in-Rural-Communities.pdf*.

[226] *https://www.medicaid.gov/medicaid/access-care/downloads/coverage-and-behavioral-health-data-spotlight.pdf*.

[227] *https://www.medicaid.gov/medicaid/benefits/behavioral-health-services/index.html*.

[228] *https://www.cbpp.org/research/health/to-improve-behavioral-health-start-by-closing-the-medicaid-coverage-gap*.

[229] Cowan, Benjamin W. & Hao, Zhuang. (2021). Medicaid expansion and the mental health of college students. Health economics, 30(6), 1306–1327. *https://www.nber.org/system/files/working_papers/w27306/w27306.pdf*.

[230] Novak, P., Anderson, A.C., & Chen, J. (2018). Changes in Health Insurance Coverage and Barriers to Health Care Access Among Individuals with Serious Psychological Distress Following the Affordable Care Act. Administration and policy in mental health, 45(6), 924–932. *https://doi.org/10.1007/s10488-018-0875-9*.

behavioral health treatment in Medicaid reflect larger system-wide access problems: overall shortage of behavioral health providers in the United States and relatively small number of psychiatrists who accept any form of insurance or participate in health coverage programs.[231] Particularly for outpatient behavioral health services for Medicaid beneficiaries, one reason physicians are unwilling to accept Medicaid patients is because of low Medicaid payment rates.[232] One study found evidence of low Medicaid payment rates by examining outpatient Medicaid claims data from 2014 in 11 States with a primary behavioral health diagnosis and an evaluation and management (E/M) procedure code of 99213 (Established patient office visit, 20–29 minutes) or 99214 (Established patient office visit, 30–39 minutes) and found that psychiatrists in nine States were paid less, on average, than primary care physicians.[233] These pieces of research and data about the importance of outpatient behavioral health services and the existing challenges beneficiaries face in trying to access outpatient behavioral health services underscore how crucial access to outpatient behavioral health services is, and that adequate Medicaid payment rates for these services is likely to be an important driver of access for beneficiaries. We solicited comments on outpatient behavioral health services as one of the proposed categories of services subject to the comparative payment rate analysis requirements in proposed § 447.203(b)(2)(iii) which we are finalizing as ''Outpatient mental health and substance use disorder services.''

In § 447.203(b)(2)(iv), we proposed to require personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency in the payment rate disclosure requirements proposed in § 447.203(b)(3)(ii). We noted that many HCBS providers nationwide are facing workforce shortages and high staff turnover that have been exacerbated by the COVID–19 pandemic, and these issues and related difficulty accessing HCBS can lead to higher rates of costly, institutional stays for beneficiaries.[234] As with any covered service, the supply of HCBS providers has a direct and immediate impact on beneficiaries' ability to access high quality HCBS, therefore, we included special considerations for LTSS, specifically HCBS, through two proposed provisions in § 447.203. The first provision in proposed paragraph (b)(2)(iv) would require States to include personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency to be included in the payment rate disclosure in proposed paragraph (b)(3)(ii). The second provision in paragraph (b)(6), discussed in the next section, would require States to establish an interested parties' advisory committee to advise and consult on rates paid to certain HCBS providers. We explained that this provision is intended to help contextualize lived experience of direct care workers and beneficiaries who receive the services they deliver by providing direct care workers, beneficiaries and their authorized representatives, and other interested parties with the ability to make recommendations to the State Medicaid agency regarding the sufficiency of Medicaid payment rates for these specified services to help ensure sufficient provider participation so that these HCBS are accessible to beneficiaries consistent with section 1902(a)(30)(A) of the Act.

The proposed payment rate disclosure would require States to publish the average hourly payment rates made to individual providers and to providers employed by an agency, separately, if the rates vary, for each category of services specified in § 447.203(b)(2)(iv). No comparison to Medicare payment rates would be required in recognition that Medicare generally does not cover and pay for these services, and when these services are covered and paid for by Medicare, the services are very limited and provided on a short-term basis, rather than long-term basis as with Medicaid HCBS. While Medicare covers part-time or intermittent home health aide services (only if a Medicare beneficiary is also getting other skilled services like nursing and/or therapy at the same time) under Medicare Part A (Hospital Insurance) or Medicare Part B (Medical Insurance), Medicare does not cover personal care or homemaker services.[235]

We proposed to require these services be subject to a payment rate disclosure because this rule aims to standardize data and monitoring across service delivery systems with the goal of improving access to care. To remain consistent with the proposed HCBS provisions at § 441.311(d)(2) and (e), where we proposed to require annual State reporting on access and payment adequacy metrics for homemaker, home health aide, and personal care services, we proposed to include these services, provided by individual providers and providers employed by an agency in the FFS payment rate disclosure proposed in 447.203(b)(2). We explained that we selected these specific services because we expect them to be most commonly conducted in individuals' homes and general community settings and, therefore, constitute the vast majority of FFS payments for direct care workers delivering services under FFS. We acknowledged that the proposed analyses required of States in the HCBS provisions at § 441.311(d)(2) and (e) and in the FFS provisions at § 447.203(b)(2) are different, although, unique to assessing access in each program and delivery system. We proposed to include personal care, home health aide, and homemaker services for consistency with HCBS access and payment adequacy provisions, and also to include these services in the proposed provisions of § 447.203(b)(2) to require States to conduct and publish a payment rate disclosure. We noted our belief the latter proposal is important because the payment rate disclosure of personal care, home health aide, and homemaker services would provide CMS with sufficient information, including average hourly payment rates, claims volume, and number of Medicaid enrolled beneficiaries who received a service as specified in proposed § 447.203(b)(3)(ii), from States for ensuring compliance with section 1902(a)(30)(A) of the Act, which requires that payments be consistent with efficiency, economy, and quality of care and sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.

Additionally, we explained that this proposal to include personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency is

[231] *https://www.kff.org/medicaid/issue-brief/medicaids-role-in-financing-behavioral-health-services-for-low-income-individuals/.*

[232] *https://www.healthaffairs.org/do/10.1377/forefront.20190401.678690/full/.*

[233] Mark, Tami L., Parish, William, Zarkin, Gary A., and Weber, Ellen (2020). Comparison of Medicaid Reimbursements for Psychiatrists and Primary Care Physicians. Psychiatry services 71(9), 947–950. *https://doi.org/10.1176/appi.ps.202000062.*

[234] *https://www.kff.org/coronavirus-covid-19/event/march-30-web-event-unsung-heroes-the-crucial-role-and-tenuous-circumstances-of-home-health-aides-during-the-pandemic/; https://www.macpac.gov/wp-content/uploads/2022/03/MACPAC-brief-on-HCBS-workforce.pdf.*

[235] *https://www.medicare.gov/coverage/home-health-services.*

supported by the statutory mandate at section 2402(a) of the Affordable Care Act. Among other things, section 2402(a) of the Affordable Care Act directs the Secretary to promulgate regulations ensuring that all States develop service systems that ensure that there is an adequate number of qualified direct care workers to provide self-directed services. We solicited comments on personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency as the proposed categories of services subject to the payment rate disclosure requirements in proposed § 447.203(b)(2)(iv).

After discussing our proposed categories of services for the comparative payment rate analysis and payment rate disclosure requirements, we discussed the similarities and differences between the proposed rule and services previously included in the AMRP requirements. We explained that while the proposed rule would eliminate the previous triennial AMRP process, there are some similarities between the service categories for which we proposed to require a comparative payment rate analysis or payment rate disclosure in § 447.203(b)(2) and those subject to the previous AMRP requirements under § 447.203(b)(5)(ii). Specifically, § 447.203(b)(5)(ii)(A) previous required the State agency to use data collected through the previous AMRP process to provide a separate analysis for each provider type and site of service for primary care services (including those provided by a physician, FQHC, clinic, or dental care). We proposed the comparative payment rate analysis include primary care services, without any parenthetical description. We explained our belief this is appropriate because the proposed rule includes a comparative payment rate analysis that is at the Current Procedural Terminology (CPT) or Healthcare Common Procedure Coding System (HCPCS) code level, as applicable, the specifics for which are discussed later in this section. This approach requires States to perform less sub-categorization of the data analysis, and as discussed later, the analysis would exclude FQHCs and clinics.

We explained that the previous AMRP process also includes in § 447.203(b)(5)(ii)(C) behavioral health services (including mental health and substance use disorder); however, we proposed that the comparative payment rate analysis only would include outpatient behavioral health services to narrow the scope of the analysis by excluding inpatient behavioral health services (including inpatient behavioral health services furnished in psychiatric residential treatment facilities, institutions for mental diseases, and psychiatric hospitals). While we acknowledged that behavioral health services encompass a broad range of services provided in a wide variety of settings, from outpatient screenings in a physician's office to inpatient hospital treatment, we proposed to narrow the scope of behavioral health services to outpatient services only to focus the comparative payment rate analysis on ambulatory care provided by practitioners in an office-based setting without duplicating existing requirements, or analysis that must be completed to satisfy existing requirements, for upper payment limits (UPL) and the supplemental payment reporting requirements under section 1903(bb) of the Act, as established by Division CC, Title II, Section 202 of the CAA, 2021.

The proposed categories of services are delivered as ambulatory care where the patient does not need to be hospitalized to receive the service being delivered. Particularly for behavioral health services, we proposed to narrow the scope to outpatient behavioral health services to maintain consistency within the categories of service included in the proposed comparative payment rate analysis and payment rate disclosure all being classified as ambulatory care. Additionally, as discussed further in this section of the final rule, we proposed that the comparative payment rate analysis would be conducted on a CPT/HCPCS code level, focusing on E/M codes. By narrowing the comparative payment rate analysis to E/M CPT/HCPCS codes, we proposed States' analyses includes a broad range of core services which would cover a variety of commonly provided services that fall into the categories of service proposed in paragraphs (b)(2)(i) through (iii). To balance State administrative burden with our oversight of State compliance with the access requirement in section 1902(a)(30)(A) of the Act, we also proposed to limit the services to those delivered primarily by physicians and NPPs in an office-based setting for primary care, obstetrical and gynecological, and outpatient behavioral health services. By excluding facility-based services, particularly inpatient behavioral health services, we explained our intent to ensure the same E/M CPT/HCPCS code-level methodology could be used for all categories of services included in the proposed comparative payment rate analysis, including the use of E/M CPT/HCPCS codes used for outpatient behavioral health services. Rather than fee schedule rates, States often pay for inpatient behavioral health services using prospective payment rate methodologies, such as DRGs, or interim payment methodologies that are reconciled to actual cost.[236] These methodologies pay for a variety of services delivered by multiple providers that a patient receives during an inpatient hospital stay, rather than a single ambulatory service billed by a single provider using a single CPT/HCPCS code. Variations in these payment methodologies and what is included in the rate could complicate the proposed comparison to FFS Medicare rates for the services identified in paragraphs (b)(2)(i) through (iii) and could frustrate comparisons between States and sometimes even within a single State. Therefore, we explained that we do not believe the E/M CPT/HCPCS code level methodology proposed for the comparative payment rate analysis would be feasible for inpatient behavioral health services or other inpatient and facility-based services in general.

While we considered including inpatient behavioral health services as one of the proposed categories of services in the comparative payment rate analysis, we ultimately did not because we already collect and review Medicaid and Medicare payment rate data for inpatient behavioral health services through annual UPL and supplemental payment reporting requirements under section 1903(bb) of the Act. SMDL 13–003 discusses the annual submission of State UPL demonstrations for inpatient hospital services, among other services, including a complete data set of payments to Medicaid providers and a reasonable estimate of what Medicare would have paid for the same services.[237] [238] UPL requirements go beyond the proposed requirements by requiring States to annually submit the following data for all inpatient hospital services, depending on the State's UPL methodology, on a provider level basis:

[236] *https://www.cms.gov/icd10m/version37-fullcode-cms/fullcode_cms/Design_and_development_of_the_Diagnosis_Related_Group_(DRGs).pdf.*

[237] *https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/SMD-13-003-02.pdf.*

[238] If a State's payment methodology describes payment at no more than 100 percent of the Medicare rate for the period covered by the UPL, then the State does not need to submit a demonstration. See FAQ ID: 92201. *https://www.medicaid.gov/faq/index.html?search_api_fulltext=ID%3A92201&sort_by=field_faq_date&sort_order=DESC.*

Medicaid charges, Medicaid base payments, Medicaid supplemental payments, Medicaid discharges, Medicaid case mix index, Medicaid inflation factors, other adjustments to Medicaid payments, Medicaid days, Medicare costs, Medicare payments, Medicare discharges, Medicare case mix index, Medicare days, UPL inflation factors, Medicaid provider tax cost, and other adjustments to the UPL amount. If we proposed and finalized inpatient behavioral health services as one of the categories of services subject to the comparative payment rate analysis, then this final rule would require States to biennially submit the following data for only inpatient behavioral health services on a CPT/HCPCS code level basis: base Medicaid FFS fee schedule payment rate for select E/M CPT/HCPCS codes (accounting for rate variation based on population (pediatric and adult), provider type, and geographical location, as applicable), the corresponding Medicare payment rates, Medicaid base payment rate as a percentage of Medicare payment rate, and the number of Medicaid-paid claims. While the UPL requires aggregated total payment and cost data at the provider level and the proposed comparative payment rate analysis calls for more granular base payment data at the CPT/HCPCS code level, the UPL overall requires aggregate Medicaid provider payment data for both base and supplemental payments as well as more detailed data for calculating what Medicare would have paid as the upper payment amount. Therefore, we explained that proposing to require States include Medicaid and Medicare payment rate data for inpatient behavioral health services in the comparative payment rate analysis would be duplicative of existing UPL requirements that are inclusive of and more comprehensive than the payment information proposed in the comparative payment rate analysis.

Additionally, section 1903(bb) of the Act requires us to establish a Medicaid supplemental payment reporting system that collects detailed information on State Medicaid supplemental payments, including total quarterly supplemental payment expenditures per provider; information on base payments made to providers that have received a supplemental payment; and narrative information describing the methodology used to calculate a provider's payment, criteria used to determine which providers qualify to receive a payment, and explanation describing how the supplemental payments comply with section 1902(a)(30)(A) of the Act. Section 1903(bb)(1)(C) of the Act requires us to make State-reported supplemental payment information publicly available. For States making or wishing to make supplemental payments, including for inpatient behavioral health services, States must report supplemental payment information to us, and we must make that information public and, therefore, transparent. Although the proposed rule sought to increase transparency, with the proposed provisions under § 447.203(b)(1) through (5) focusing on transparency of FFS base Medicaid FFS fee schedule payment rate, including inpatient behavioral health services as a category of service in § 447.203(b)(2) subject to the comparative payment rate analysis would be duplicative of the existing upper payment limit and supplemental payment reporting requirements, which capture and make transparent base and supplemental payment information for inpatient behavioral health services. However, we solicited comments regarding our decision not to include inpatient behavioral health services as one of the categories of services subject to the comparative payment rate analysis requirements in proposed § 447.203(b)(2) in the final rule, should we finalize the comparative payment rate analysis proposal.

The AMRP process also previously included in § 447.203(b)(5)(ii)(D) pre- and post-natal obstetric services including labor and delivery; we proposed to include these services in the comparative payment rate analysis requirements under proposed § 447.203(b)(2)(ii), but we explained in the proposed rule that we intended to broaden the scope of this category of services to include both obstetrical and gynecological services. This expanded proposed provision would capture a wider array of services, both obstetrical and gynecological services, for States and CMS to assess and ensure access to care in Medicaid FFS is at least as great for beneficiaries as is generally available to the general population in the geographic area, as required by with section 1902(a)(30)(A) of the Act. Lastly, similar to previous § 447.203(b)(5)(ii)(E), which specifies that home health services were included in the previous AMRP process, we proposed to include personal care, home health aide, and homemaker services, provided by individual providers and providers employed by an agency. This refined proposed provision would help ensure a more standardized effort to monitor access across Medicaid delivery systems, including for Medicaid-covered LTSS. We explained our belief that this proposal also would address public comments received in response to the February 2022 RFI.[239] Many commenters highlighted the workforce crisis among direct care workers and the impact on HCBS. Specifically, commenters indicated that direct care workers receive low payment rates, and for agency-employed direct care workers, home health agencies often cite low Medicaid payment as a barrier to raising wages for workers. Commenters suggested that States should be collecting and reporting to CMS the average of direct care worker wages while emphasizing the importance of data transparency and timeliness. We explained that we were responding to these public comments by proposing to require States to transparently publish a payment rate disclosure that collects and reports the average hourly rate paid to individual providers and providers employed by an agency for services provided by certain direct care workers (personal care, home health aide, and homemaker services).

In public comments that we received during the public comment period for the 2015 final rule with comment period, many commenters requested that we require States to publish access to care analyses for pediatric services, including pediatric primary care, behavioral health, and dental care. At the time, we responded that pediatric services did not need to be specified in the required service categories because States were already required through § 447.203(b)(1)(iv) to consider the characteristics of the beneficiary population, ''including . . . payment variations for pediatric and adult populations,'' within the previous AMRPs.[240] Although we proposed to eliminate the previous AMRP requirements, we noted that the proposed rule would continue to include special considerations for pediatric populations that are addressed in the discussion of proposed § 447.203(b)(2).

We proposed to eliminate the following from the previous AMRP process without replacement in the comparative payment rate analysis requirement, § 447.203(b)(5)(ii)(F): Any additional types of services for which a review is required under previous § 447.203(b)(6); § 447.203(b)(5)(ii)(G): Additional types of services for which

[239] Summary of Public Comments in response to the CMS 2022 Request for Information: Access to Coverage and Care in Medicaid & CHIP. December 2022. For the report, see *https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-report.pdf*.

[240] 80 CFR 67576 at 67592.

the State or CMS has received a significantly higher than usual volume of beneficiary, provider or other interested party access complaints for a geographic area, including complaints received through the mechanisms for beneficiary input consistent with previous § 447.203(b)(7); and § 447.203(b)(5)(ii)(H): Additional types of services selected by the State.

We proposed to eliminate § 447.203(b)(5)(ii)(F) and (G) without a direct replacement because the proposed State Analysis Procedures for Rate Reduction or Restructuring described in § 447.203(c) are inclusive of and more refined than the previous AMRP requirements for additional types of services for which a review is required under previous § 447.203(b)(6). Specifically, as discussed later in this section, we proposed in § 447.203(c)(1) that States seeking to reduce provider payment rates or restructure provider payments would be required to provide written assurance and relevant supporting documentation that three conditions are met to qualify for a streamlined SPA review process, including that required public processes yielded no significant access to care concerns for beneficiaries, providers, or other interested parties, or if such processes did yield concerns, that the State can reasonably respond to or mitigate them, as appropriate. If the State is unable to meet all three of the proposed conditions for streamlined SPA review, including the absence of or ability to appropriately address any access concern raised through public processes, then the State would be required to submit additional information to support that its SPA is consistent with the access requirement in section 1902(a)(30)(A) of the Act, as proposed in § 447.203(c)(2). We proposed to modify this aspect of the previous AMRP process, because our implementation experience since the 2017 SMDL has shown that States typically have been able to work directly with the public (including beneficiaries and beneficiary advocacy groups, and providers) to resolve access concerns, which emphasizes that public feedback continues to be a valuable source of knowledge regarding access in Medicaid. We explained our belief that this experience demonstrates that public processes that occur before the submission of a payment SPA to CMS often resolve initial access concerns, and where concerns persist, they will be addressed through the SPA submission and our review process, as provided in proposed § 447.203(c). Rather than services affected by proposed provider rate reductions or restructurings (previous § 447.203(b)(5)(ii)(F)) and services for which the State or CMS received significantly higher than usual volume of complaints (previous § 447.203(b)(5)(ii)(G)) being addressed through the previous AMRP process, these services subject to rate reductions or restructurings and services where a high volume of complaints have been expressed would now be addressed by the State analysis procedures in proposed § 447.203(c). We noted our belief that this approach would ensure public feedback is fully considered in the context of a payment SPA, without the need to specifically require a comparative payment rate analysis for the service(s) subject to payment rate reduction or restructuring under proposed § 447.203(b)(2).

Lastly, we proposed to eliminate previous § 447.203(b)(5)(ii)(H), requiring the previous AMRP process to include analysis regarding ''Additional types of services selected by the State,'' without a direct replacement because our implementation experience has shown that the majority of States did not select additional types of service to include in their previous AMRPs beyond the required services § 447.203(b)(5)(ii)(A) through (G). When assessing which services to include in the proposed rule, we determined that the absence of an open-ended type of service option, similar to § 447.203(b)(5)(ii)(H) is unlikely to affect the quality of the analysis we proposed to require and therefore, we did not include it in the proposed set of services for the comparative payment rate analysis. These proposed shifts in policy were informed by our implementation experience and our consideration of State concerns about the burden and value of the previous AMRP process.

In paragraph (b)(3), we proposed that the State agency would be required to develop and publish, consistent with the publication requirements described in proposed § 447.203(b)(1) for payment rate transparency data, a comparative payment rate analysis and payment rate disclosure. This comparative payment rate analysis is divided into two sections based on the categories of services and the organization of each analysis or disclosure. Paragraph (b)(3)(i) describes the comparative payment rate analysis for the categories of services described in paragraphs (b)(2)(i) through (iii): primary care services, obstetrical and gynecological services, and outpatient behavioral health services. Paragraph (b)(3)(ii) describes the payment rate disclosure for the categories of service described in paragraphs (b)(2)(iv): personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency.

Specifically, in paragraph (b)(3)(i), we proposed that for the categories of service described in paragraphs (b)(2)(i) through (iii), the State's analysis would compare the State's Medicaid FFS payment rates to the most recently published Medicare payment rates effective for the same time period for the E/M CPT/HCPCS codes applicable to the category of service. The proposed comparative payment rate analysis of FFS Medicaid payment rates to FFS Medicare payment rates would be conducted on a code-by-code basis at the CPT/HCPCS code level using the most current set of codes published by us. We explained that this proposal is intended to provide an understanding of how Medicaid payment rates compare to the payment rates established and updated under the FFS Medicare program.

We stated that we would expect to publish the E/M CPT/HCPCS codes to be used for the comparative payment rate analysis in subregulatory guidance along with the final rule, if this proposal is finalized. We proposed that we would identify E/M CPT/HCPCS codes to be included in the comparative payment rate analysis based on the following criteria: the code is effective for the same time period of the comparative payment rate analysis; the code is classified as an E/M CPT/HCPCS code by the American Medical Association (AMA) CPT Editorial Panel; the code is included on the Berenson-Eggers Type of Service (BETOS) code list effective for the same time period as the comparative payment rate analysis and falls into the E/M family grouping and families and subfamilies for primary care services, obstetrics and gynecological services, and outpatient behavioral services (now called outpatient mental health and substance use disorder services in this final rule); and the code has an A (Active), N (Non-Covered), R (Restricted), or T (Injections) code status on the Medicare PFS with a Medicare established relative value unit (RVU) and payment amount for the same time period of the comparative payment rate analysis.[241] [242] [243]

The CMS-published list of E/M CPT/HCPCS codes subject to the comparative

[241] *https://www.ama-assn.org/practice-management/cpt/cpt-evaluation-and-management.*

[242] *https://data.cms.gov/provider-summary-by-type-of-service/provider-service-classifications/restructured-betos-classification-system.*

[243] *https://www.cms.gov/medicare/medicare-fee-for-service-payment/physicianfeesched.*

payment rate analysis would classify each E/M CPT/HCPCS code into a corresponding category of service as described in proposed § 447.203(b)(2)(i) through (iii). As previously discussed, by narrowing the comparative payment rate analysis to CMS-specified E/M CPT/HCPCS codes, we proposed States' analyses include a broad range of core services that would cover a variety of commonly provided services that fall into the categories of service proposed in paragraphs (b)(2)(i) through (iii), while also limiting the services to those delivered primarily by physicians and NPPs in an office-based setting. Based on the categories of services specified in proposed § 447.203(b)(2)(i) through (iii), we stated that we would expect the selected E/M CPT/HCPCS codes to fall under mandatory Medicaid benefit categories, and therefore, that all States would cover and pay for the selected E/M CPT/HCPCS codes. To clarify, we did not narrow the list of E/M CPT/HCPCS codes on the basis of Medicare coverage of a particular code. We are cognizant that codes with N (Non-Covered), R (Restricted), or T code statuses have limited or no Medicare coverage; however, Medicare may establish RVUs, and payment amounts for these codes. Therefore, when Medicare does establish RVUs and payment amounts for codes with N (Non-Covered), R (Restricted), or T (Injections) code statuses on the Medicare PFS, we proposed to include these codes in the comparative payment rate analysis to ensure the analysis includes a comprehensive set of codes, for example pediatric services, including well child visits (for example, 99381 through 99384), that are commonly provided services that fall into the categories of service proposed in paragraphs (b)(2)(i) through (iii) and delivered primarily by physicians and NPPs in an office-based setting, as previously described.

We proposed that the comparative payment rate analysis would be updated no less than every 2 years. Therefore, prior to the start of the calendar year in which States would be required to update their comparative payment rate analysis, we noted our intent to publish an updated list of E/M CPT/HCPCS codes for States to use for their comparative payment rate analysis updates through subregulatory guidance. The updated list of E/M CPT/HCPCS codes would include changes made by the AMA CPT Editorial Panel (such as additions, removals, or amendments to a code definition where there is a change in the set of codes classified as an E/M CPT/HCPCS code billable for primary care services, obstetrics and gynecological services, or outpatient behavioral services) and changes to the Medicare PFS based on the most recent Medicare PFS final rule (such as changes in code status or creation of Medicare-specific codes).[244]

We explained that we would intend to publish the initial and subsequent updates of the list of E/M CPT/HCPCS codes subject to the comparative payment rate analysis in a timely manner that allows States approximately one full calendar year between the publication of the CMS-published list of E/M CPT/HCPCS codes and the due date of the comparative payment rate analysis. We may issue a correction to the Medicare PFS after the final rule is in effect, and this correction may impact our published list of E/M CPT/HCPCS codes. In this instance, for codes included on our published list of E/M CPT/HCPCS codes that are affected by a correction to the most recent Medicaid PFS final rule, we may add or remove an E/M CPT/HCPCS code from the published list, as appropriate, depending on the change to the Medicare PFS. Alternatively, depending on the nature of the change, we stated that we would expect States to accurately identify which code(s) are used in the Medicaid program during the relevant period that best correspond to the CMS-identified E/M CPT/HCPCS code(s) affected by the Medicare PFS correction. We would expect States to rely on the CMS published list of E/M CPT/HCPCS codes subject to the comparative payment rate analysis for complying with the proposed requirements in paragraphs (b)(2) through (4).

We acknowledged that there are limitations to relying on E/M CPT/HCPCS codes to select payment rates for comparative payment rate analysis to aid States, CMS, and other interested parties in assessing if payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area. Providers across the country and within each State deliver a variety of services to patients, including individuals with public and private sources of coverage, and then bill them under a narrow subset of CPT/HCPCS codes that fit into the E/M classification as determined by the AMA CPT Editorial Panel. The actual services delivered can require a wide array of time, skills, and experience of the provider which must be represented by a single five-digit code for billing to receive payment for the services delivered. While there are general principles that guide providers in billing the most representative E/M CPT/HCPCS code for the service they delivered, two providers might perform substantially similar activities when delivering services and yet bill different E/M CPT/HCPCS codes for those activities, or bill the same E/M CPT/HCPCS code for furnishing two very different services. The E/M CPT/HCPCS code itself is not a tool for capturing the exact service that was delivered, but medical documentation helps support the billing of a particular E/M CPT/HCPCS code.

Although they do not encompass all Medicaid services covered and paid for in the Medicaid program which are subject to the requirements in section 1902(a)(30)(A) of the Act, E/M CPT/HCPCS codes are some of the most commonly billed codes and including them in the comparative payment rate analysis would allow us to uniformly compare Medicaid payment rates for these codes to Medicare PFS rates. As such, to balance administrative burden on States and our enforcement responsibilities, we proposed to use E/M CPT/HCPCS codes in the comparative payment rate analysis to limit the analysis to how much Medicaid and the FFS Medicare program would pay for services that can be classified into a particular E/M CPT/HCPCS code. We solicited comments on the proposed comparative payment rate analysis requirement in § 447.203(b)(3)(i), including the proposed requirement to conduct the analysis at the CPT/HCPCS code level, the proposed criteria that we would apply in selecting E/M CPT/HCPCS codes for inclusion in the required analysis, and the proposed requirement for States to compare Medicaid payment rates for the selected E/M CPT/HCPCS codes to the most recently published Medicare non-facility payment rate as established in the annual Medicare PFS final rule effective for the same time period, which is discussed in more detail later in this rule when describing the proposed provisions of § 447.203(b)(3)(i)(C).

In paragraph (b)(3)(i), we further proposed that the State's comparative payment rate analysis would be required to meet the following requirements: (A) the analysis must be organized by category of service as described in § 447.203(b)(2)(i) through (iii); (B) the analysis must clearly identify the base Medicaid FFS fee

[244] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.*

schedule payment rate for each E/M CPT/HCPCS code identified by us under the applicable category of service, including, if the rates vary, separate identification of the payment rates by population (pediatric and adult), provider type, and geographical location, as applicable; (C) the analysis must clearly identify the Medicare PFS non-facility payment rates effective for the same time period for the same set of E/M CPT/HCPCS codes, and for the same geographical location as the base Medicaid FFS fee schedule payment rate, that correspond to the Medicaid payment rates identified under paragraph (b)(3)(i)(B); (D) the analysis must specify the Medicaid payment rate identified under paragraph (b)(3)(i)(B) as a percentage of the Medicare payment rate identified under paragraph (b)(3)(i)(C) for each of the services for which the Medicaid payment rate is published under paragraph (b)(3)(i)(B); and (E) the analysis must specify the number of Medicaid-paid claims within a calendar year for each of the services for which the Medicaid payment rate is published under paragraph (b)(3)(i)(B). We solicited comments on the proposed requirements and content of the items in proposed § 447.203(b)(3)(i)(A) through (E).

In paragraph (b)(3)(i)(A), we proposed to require States to organize their comparative payment rate analysis by the service categories described in paragraphs (b)(2)(i) through (iii). We explained that this proposed requirement is included to ensure the analysis breaks out the payment rates for primary care services, obstetrical and gynecological services, and outpatient behavioral health services separately for individual analyses of the payment rates for each CMS-selected E/M CPT/HCPCS code, grouped by category of service. We solicited comments on the proposed requirement for States to break out their payment rates at the CPT/HCPCS code level for primary care services, obstetrical and gynecological services, and outpatient behavioral health services, separately, in the comparative payment rate analysis as specified in proposed § 447.203(b)(3)(i)(A).

In paragraph (b)(3)(i)(B), after organizing the analysis by § 447.203(b)(2)(i) through (iii) categories of service and CMS-specified E/M CPT/HCPCS code, we proposed to require States to clearly identify the Medicaid base payment rate for each code, including, if the rates vary, separate identification of the payment rates by population (pediatric and adult), provider type, and geographical location, as applicable. We proposed that the Medicaid base payment rate in the comparative payment rate analysis would only include the State's Medicaid fee schedule rate, that is, the State's Medicaid base rate for each E/M CPT/HCPCS code. By specifying the services included in the comparative payment rate analysis by E/M CPT/HCPCS code, we noted that we would expect the Medicaid base payment rate in the comparative payment rate analysis to only include the State's Medicaid fee schedule rate for that particular E/M CPT/HCPCS code as published on the State's Medicaid fee schedule effective for the same time period covered by the comparative payment rate analysis. As an example, the State's Medicaid fee schedule rate as published on the Medicaid fee schedule effective for the time period of the comparative payment rate analysis for 99202 is listed as $50.00. This rate would be the Medicaid base payment rate in the State's comparative payment rate analysis for comparison to the Medicare non-facility rate, which is discussed later in this section.

Medicaid base payment rates are typically determined through one of three methods: the resource-based relative value scale (RBRVS), a percentage of Medicare's fee, or a State-developed fee schedule using local factors.[245] The RBRVS system, initially developed for the Medicare program, assigns a relative value to every physician procedure based on the complexity of the procedure, practice expense, and malpractice expense. States may also adopt the Medicare fee schedule rate, which is also based on RBRVS, but select a fixed percentage of the Medicare amount to pay for Medicaid services. States can develop their own PFSs, typically determined based on market value or an internal process, and often do this in situations where there is no Medicare or private payer equivalent or when an alternate payment methodology is necessary for programmatic reasons. States often adjust their payment rates based on provider type, geography, site of services, patient age, and in-State or out-of-State provider status. Additionally, base Medicaid FFS fee schedule payment rate can be paid to physicians in a variety of settings, including clinics, community health centers, and private offices.

We acknowledged that only including Medicaid base payments in the analysis does not necessarily represent all of a provider's revenues that may be related to furnishing services to Medicaid beneficiaries, and that other revenues not included in the proposed comparative analysis may be relevant to a provider's willingness to participate in Medicaid (such as beneficiary cost sharing payments, and supplemental payments). We discussed that public comments we received on the 2011 proposed rule and responded to in the 2015 final rule with comment period regarding the previous AMRPs expressed differing views regarding which provider ''revenues'' should be included within comparisons of Medicaid to Medicare payment rates. One commenter ''noted that the preamble of the 2011 proposed rule refers to 'payments' and 'rates' interchangeably but that courts have defined payments to include all Medicaid provider revenues rather than only Medicaid FFS rates.'' The commenter stated that if the final rule consider[ed] all Medicaid revenues received by providers, States may be challenged to make any change to the Medicaid program that might reduce provider revenues.'' [246] We proposed to narrow the base Medicaid FFS fee schedule payment rate to the amount listed on the State's fee schedule in order for the comparative payment rate analysis to accurately and analogously compare Medicaid fee schedule rates to Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year.

We explained our belief that this approach would represent the best way to create a consistent metric across States against which to evaluate access. Specifically, we did not propose to include supplemental payments in the comparative payment rate analysis. Requiring supplemental payment data be collected and included under this rule would be duplicative of existing requirements. State supplemental payment and DSH payment data are already subject to our review in various forms, such as through DSH audits for DSH payments, and through annual upper payment limits demonstrations, and through supplemental payment reporting under section 1903(bb) of the Act.[247] [248] As such, we explained that

[245] *https://www.macpac.gov/wp-content/uploads/2017/02/Medicaid-Physician-Fee-for-Service-Payment-Policy.pdf.*

[246] 80 FR 67576 at 67581.

[247] CMS State Medicaid Director Letter: SMDL 13–003. March 2013. Federal and State Oversight of Medicaid Expenditures. Available at *https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/SMD-13-003-02.pdf.*

[248] CMS State Medicaid Director Letter: SMDL 21–006. December 2021. New Supplemental Payment Reporting and Medicaid Disproportionate Share Hospital Requirements under the Consolidated Appropriations Act, 2021. Available at *https://www.medicaid.gov/federal-policy-guidance/downloads/smd21006.pdf.*

we do not see a need to add additional reporting requirements concerning supplemental payments as part of the proposals in this rulemaking to allow us the opportunity to review the data. Also, supplemental payments are often made for specific Medicaid-covered services and targeted to a subset of Medicaid-participating providers; not all Medicaid-participating providers, and not all providers of a given Medicaid-covered service, may receive supplemental payments in a State. Therefore, including supplemental payments in the comparative payment rate analysis would create additional burden for States without then also providing an accurate benchmark of how payments may affect beneficiary access due to the potentially varied and uneven distribution of supplemental payments. Accordingly, we proposed to require that States conduct the comparative payment rate analysis for only Medicaid base payment rates for selected E/M CPT/HCPCS codes. For each proposed category of service listed in paragraphs (b)(2)(i) through (iii), this would result in a transparent and parallel comparison of Medicaid base payment rates that all Medicaid-participating providers of the service would receive to the payment rates that Medicare would pay for the same E/M CPT/HCPCS codes.

Additionally, in paragraph (b)(3)(i)(B), we proposed that, if the States' payment rates vary, the Medicaid base payment rates must include a breakdown by payment rates paid to providers delivering services to pediatric and adult populations, by provider type, and geographical location, as applicable, to capture this potential variation in the State's payment rates. This proposed provision to breakdown the Medicaid payment rate is first stated in proposed paragraph (b)(2) and carried through in proposed paragraph (b)(3)(i)(B) to provide clarity to States about how the Medicaid payment rate should be reported in the comparative payment rate analysis.

In paragraph (b)(3)(i)(C), we proposed to require States' comparative payment rate analysis clearly identify the Medicare non-facility payment rates as established in the annual Medicare PFS final rule effective for the same time period for the same set of E/M CPT/HCPCS codes, and for the same geographical location, that correspond to the Medicaid payment rates identified under paragraph (b)(3)(i)(B), including separate identification of the payment rates by provider type. We did not propose to establish a threshold percentage of Medicare non-facility payment rates that States would be required to meet when setting their Medicaid payment rates. Rather, we proposed to use Medicare non-facility payment rates as established in the Medicare PFS final rule for a calendar year as a benchmark to which States would compare their Medicaid payment rates to inform their and our assessment of whether the State's payment rates are compliant with section 1902(a)(30)(A) of the Act. We explained that benchmarking against FFS Medicare, another of the nation's large public health coverage programs, serves as an important data point in determining whether payment rates are likely to be sufficient to ensure access for Medicaid beneficiaries at least as great as for the general population in the geographic area, and whether any identified access concerns may be related to payment sufficiency. Similar to Medicaid, Medicare provides health coverage for a significant number of Americans across the country. In December 2023, total Medicaid enrollment was at 77.9 million individuals [249] while total Medicare enrollment was at 66.8 million individuals.[250] [251] Both the Medicare and Medicaid programs cover and pay for services provided to beneficiaries residing in every State and territory of the United States. As previously described, Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year for covered, non-covered, and limited coverage services generally are determined on a national level as well as adjusted to reflect the variation in practice costs from one geographical location to another. Medicare also ensures that their payment rate data are publicly available in a format that can be analyzed. The accessibility and consistency of the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year, compared to negotiated private health insurance payment rates that typically are considered proprietary information and, therefore, not generally available to the public, makes Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year an available and reliable comparison point for States to use in the comparative payment rate analysis.

Additionally, Medicare is widely accepted nationwide according to recent findings from the National Electronic Health Records Survey. In 2019, 95 percent of physicians accepting new patients overall, and 89 percent of office-based physicians, were accepting new Medicare patients, and the percentage of office-based physicians accepting new Medicare patients has remained stable since 2011 when the value was 88 percent, with modest fluctuations in the years in between.[252] In regards to physician specialties that align with the categories of services in this rule, 81 percent of general practice/family medicine physicians and 81 percent of physicians specializing in internal medicine were accepting new Medicare patients, 93 percent of physicians specializing obstetrics and gynecology were accepting new Medicare patients, and 60 percent of psychiatrists were accepting new Medicare patients in 2019. Although the percentage of psychiatrists who accept Medicare is lower than other types of physicians providing services included in the comparative payment rate analysis, this circumstance is not unique to Medicare amongst payers. For example, 60 percent of psychiatrists were also accepting new privately insured patients in 2019.[253] Therefore, the decreased rate of acceptance by psychiatrists relative to certain other physician specialists does not make Medicare an inappropriate benchmark when evaluated against other options for comparison.[254]

Historically, Medicare has low rates of physicians formally opting out of the Medicare program with 1 percent of physicians consistently opting out between 2013 and 2019 and of that 1 percent of physicians opting out of Medicare, 42 percent were

[249] *https://www.medicaid.gov/medicaid/national-medicaid-chip-program-information/downloads/December-2022-medicaid-chip-enrollment-trend-snapshot.pdf.*

[250] Total Medicare enrollment equals the Tot_Benes variable in the Medicare Monthly Enrollment Data for December (Month) 2023 (Year) at the national level (Bene_Geo_Lvl). Tot_Benes is a count of all Medicare beneficiaries, including beneficiaries with Original Medicare and beneficiaries with Medicare Advantage and Other Health Plans. We utilized the count of all Medicare beneficiaries because Original Medicare, Medicare Advantage, and other Health Plans offer fee-for-service payments to providers. See the Medicare Monthly Enrollment Data Dictionary for more information about the variables in the Medicare Monthly Enrollment Data: *https://data.cms.gov/sites/default/files/2023-02/1ec24f76-9964-4d00-9e9a-78bd556b7223/Medicare%20Monthly%20Enrollment_Data_Dictionary%2020230131_508.pdf.*

[251] *https://data.cms.gov/summary-statistics-on-beneficiary-enrollment/medicare-and-medicaid-reports/medicare-monthly-enrollment.*

[252] *https://www.kff.org/medicare/issue-brief/most-office-based-physicians-accept-new-patients-including-patients-with-medicare-and-private-insurance/.*

[253] *https://www.kff.org/medicare/issue-brief/most-office-based-physicians-accept-new-patients-including-patients-with-medicare-and-private-insurance/.*

[254] *https://www.kff.org/medicare/issue-brief/faqs-on-mental-health-and-substance-use-disorder-coverage-in-medicare/.*

psychiatrists.[255] This information suggests that Medicare's payment rates generally are consistent with a high level of physician willingness to accept new Medicare patients, with the vast majority of physicians willing to accept Medicare's payment rates. For the reasons previously described, we proposed to use Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year as a national benchmark for States to compare their Medicaid payment rates in the comparative payment rate analysis because we believe that the Medicare payment rates for these services are likely to serve as a reliable benchmark for a level of payment sufficient to enlist providers to furnish the relevant services to an individual. We solicited comments on the proposed use of Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year as a benchmark for States to compare their Medicaid payment rates to in the comparative payment rate analysis requirements in proposed § 447.203(b)(3)(i) to help assess if Medicaid payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.

In paragraph (b)(3)(i)(C), we proposed to require States to compare their Medicaid payment rates to the Medicare non-facility payment rates as established in the annual Medicare PFS final rule effective for the same time period as the same set of E/M CPT/HCPCS codes paid under Medicaid as specified under paragraph (b)(3)(i)(B) of this section, including separate identification of the payment rates by provider type. We proposed to require States to compare their payment rates to the corresponding Medicare PFS non-facility rates because we are seeking a payment analysis that compares Medicaid payment rates to Medicare payment rates at comparable location of service delivery (that is, in a non-clinic, non-hospital, ambulatory setting such as a physician's office). States often pay physicians operating in an office based on their Medicaid fee schedule whereas they may pay physicians operating in hospitals or clinics using an encounter rate. The Medicaid fee schedule rate typically reflects payment for an individual service that was rendered, for example, an office visit that is billed as a single CPT/HCPCS code. An encounter rate often reflects reimbursement for total facility-specific costs divided by the number of encounters to calculate a per visit or per encounter rate that is paid to the facility for all services received during an encounter, regardless of which specific services are provided during a particular encounter. For example, the same encounter rate may be paid for a beneficiary who has an office visit with a physician, a dental examination and cleaning from a dentist, and laboratory tests and for a beneficiary who receives an office visit with a physician and x-rays. Encounter rates are typically paid to facilities, such as hospitals, FQHCs, RHCs, or clinics, many of which function as safety net providers that offer a wide variety of medical services. Within the Medicaid program, encounter rates can vary widely in the rate itself and services paid for through the encounter rate. We explained that States demonstrating the economy and efficiency of their encounter rates would be an entirely different exercise to the fee schedule rate comparison proposed in this rule because encounter rates are often based on costs unique to the provider, and States often require providers to submit cost reports to States for review to support payment of the encounter rate. Comparing cost between the Medicaid and Medicare program would require a different methodology, policies, and oversight than the comparative payment rate analysis requirement that we proposed due to the differences within and between each program. While the Medicare program has a broad, national policy for calculating encounter rates for providers, including prospective payment systems for hospitals, FQHCs, and other types of facilities, Medicare calculates these encounter rates differently than States may calculate analogous rates in Medicaid. Therefore, we explained that disaggregating each of their encounter rates and services covered in each encounter rate to compare to Medicare's encounter rates would be challenging for States.

From that logic, we likewise determined that the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year would afford the best point of comparison because it is the most accurate and most analogous comparison of a service-based access analysis using Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year as a benchmark to compare Medicaid fee schedule rates on a CPT/HCPCS code level basis, as opposed to an encounter rate which could include any number of services or specialties. The Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year is described as ''. . . the fee schedule amount when a physician performs a procedure in a non-facility setting such as the office'' and ''[g]enerally, Medicare gives higher payments to physicians and other health care professionals for procedures performed in their offices [compared to those performed elsewhere] because they must supply clinical staff, supplies, and equipment.'' [256] As such, we stated our belief that the Medicaid fee schedule best represents the payment intended to pay physicians and non-physician practitioners for delivery of individual services in an office (non-facility) setting, and the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year represents the best equivalent to that amount and consideration.

For the purposes of the comparative payment rate analysis, we explained in the proposed rule that we would expect States to source the Medicare non-facility payment rate from the published Medicare fee schedule amounts that are established in the annual Medicare PFS final rule through one or both of the following sources: the Physician Fee Schedule Look-Up Tool [257] on *cms.gov* or Excel file downloads of the Medicare PFS Relative Value with Conversion Factor files [258] for the relevant calendar year from *cms.gov.* We acknowledge that the Physician Fee Schedule Look-Up Tool is a display tool that functions as a helpful aid for physicians and NPPs as a way to quickly look up PFS payment rates, but does not provide official payment rate information. While we encouraged States to begin sourcing Medicare non-facility payment rates from the Physician Fee Schedule Look-Up Tool and utilize the Physician Fee

[255] Physicians and practitioners who do not wish to enroll in the Medicare program may ''opt-out'' of Medicare. This means that neither the physician, nor the beneficiary submits the bill to Medicare for services rendered. Instead, the beneficiary pays the physician out-of-pocket and neither party is reimbursed by Medicare. A private contract is signed between the physician and the beneficiary that states that neither one can receive payment from Medicare for the services that were performed. See 2022 opt-out affidavit data published by the Centers for Medicare & Medicaid services: *https://data.cms.gov/provider-characteristics/medicare-provider-supplier-enrollment/opt-out-affidavits.*

[256] *https://www.cms.gov/files/document/physician-fee-schedule-guide.pdf.*

[257] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PFSlookup.*

[258] *https://www.cms.gov/medicare/medicare-fee-for-service-payment/physicianfeesched/pfs-relative-value-files.*

Schedule Guide for instructions on using the Look-Up Tool in the proposed rule, we would like to clarify in this final rule that States should first download and review the Medicare PFS Relative Value with Conversion Factor File where States can find the necessary information for calculating Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year. With the publication of this final rule, we have also issued subregulatory guidance, which includes an instructional guide for identifying, downloading, and using the relevant Excel files for calculating the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year that States will need to include in their comparative payment rate analysis.

Statutory provisions at section 1848 of the Act and regulatory provisions at 42 CFR 414.20 [259] require that most physician services provided in Medicare are paid under the Medicare PFS. The fee schedule amounts are established for each service, generally described by a particular procedure code (including HCPCS, CPT, and CDT) using resource-based inputs to establish relative value units (RVUs) in three components of a procedure: work, practice expense, and malpractice. The three component RVUs for each service are adjusted using CMS-calculated geographic practice cost indexes (GPCIs) that reflect geographic cost differences in each fee schedule area as compared to the national average.[260] [261]

For many services, the Medicare PFS also includes separate fee schedule amounts based on the site of service (non-facility versus facility setting). The applicable PFS the rate for a service, facility or non-facility, is based on the setting where the beneficiary received the face-to-face encounter with the billing practitioner, which is indicated on the claim form by a place of service (POS) code. We proposed States use the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year in the comparative payment rate analysis. We directed States to the Excel file downloads of the ''PFS Relative Value Files'' which include the RVUs, GPCIs, and the ''National Physician Fee Schedule Relative Value File Calendar Year 2023'' file which contains the associated relative value units (RVUs), a fee schedule status indicator, and various payment policy indicators needed for payment adjustment (for example, payment of assistant at surgery, team surgery, or bilateral surgery). We stated that we would expect States to use the formula for the Non-Facility Pricing Amount in ''National Physician Fee Schedule Relative Value File Calendar Year 2023'' file to calculate the ''Non-Facility Price'' using the RVUs, GPCIs, and conversion factors for codes not available in the Look-Up Tool.

We explained that Medicaid FFS fee-schedule payment rates should be representative of the total computable payment amount a provider would expect to receive as payment-in-full for the provision of Medicaid services to individual beneficiaries. Section 447.15 defines payment-in-full as ''the amounts paid by the agency plus any deductible, coinsurance or copayment required by the plan to be paid by the individual.'' Therefore, the State's Medicaid base payment rates used for comparison should be inclusive of total base payment from the Medicaid agency plus any applicable coinsurance and deductibles to the extent that a beneficiary is expected to be liable for those payments. If a State Medicaid fee schedule does not include these additional beneficiary cost-sharing payment amounts, then the Medicaid fee schedule amounts would need to be modified to align with the inclusion of expected beneficiary cost sharing in Medicare's non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year.[262]

In paragraph (b)(3)(i)(C), we proposed that the Medicare non-facility payment rates as established in the annual Medicare PFS final rule must be effective for the same time period for the same set of E/M CPT/HCPCS codes that correspond to the base Medicaid FFS fee schedule payment rate identified under paragraph (b)(3)(i)(B). We included this language to ensure the comparative payment rate analysis is as accurate and analogous as possible by proposing that the Medicaid and Medicare payment rates that are effective during the same time period for the same set of E/M CPT/HCPCS codes. As later described in this rule, in paragraph (b)(4), we proposed the initial comparative payment rate analysis and payment rate disclosure of Medicaid payment rates would be a retroactive analysis of payment rates that are in effect as of January 1, 2025, with the analysis and disclosure published no later than January 1, 2026. For example, the first comparative payment rate analysis a State develops and publishes would compare base Medicaid FFS fee schedule payment rate in effect as of January 1, 2025, to the Medicare non-facility payment rates as established in the annual Medicare PFS final rule effective January 1, 2025, to ensure the Medicare non-facility payment rates are effective for the same time period for the same set of E/M CPT/HCPCS codes that correspond to the Medicaid FFS fee schedule payment rate identified under paragraph (b)(3)(i)(B).

Additionally, in paragraph (b)(3)(i)(C), we proposed that the Medicare non-facility payment rates as established in the annual Medicare PFS final rule used for the comparison must be for the same geographical location as the Medicaid FFS fee schedule payment rate. For States that pay Medicaid payment rates based on geographical location (for example, payment rates that vary by rural or non-rural location, by zip code, or by metropolitan statistical area), we proposed that States' comparative payment rate analyses would need to use the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year for the same geographical location as the Medicaid FFS fee schedule payment rate to achieve an equivalent comparison. We stated that we would expect States to review Medicare's published listing of the current PFS locality structure organized by State, locality area, and when applicable, counties assigned to each locality area and identify the comparable Medicare locality area for the same geographical area as the Medicaid FFS fee schedule payment rate.[263]

We recognized that States that make Medicaid payment based on geographical location may not use the same locality areas as Medicare. For example, a State may use its own State-determined geographical designations, resulting in 5 geographical areas in the State for purposes of Medicaid payment while Medicare recognizes 3 locality areas for the State based on Metropolitan Statistical Area (MSA) delineations determined by the US Office of Management and Budget (OMB) that are the result of the application of published standards to

[259] The Medicare Claims Processing Manual contains additional information about physician service payments in Medicare that are based on the cited statutory and regulatory requirements. *https://www.cms.gov/regulations-and-guidance/guidance/manuals/internet-only-manuals-ioms-items/cms018912.*

[260] *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c12.pdf.*

[261] *https://www.cms.gov/medicare/physician-fee-schedule/search/overview.*

[262] *According to the Medicare Physician Fee Schedule Guide, for most codes, Medicare pays 80% of the amount listed and the beneficiary is responsible for 20 percent.*

[263] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Locality.*

Census Bureau data.[264] In this instance, we would expect the State to determine an appropriate method to accomplish the comparative payment rate analysis that aligns the geographic area covered by each payer's rate as closely as reasonably feasible. For example, if the State identifies two geographic areas for Medicaid payment purposes that are contained almost entirely within one Medicare geographic area, then the State reasonably could determine to use the same Medicare non-facility payment rate as established in the annual Medicare PFS final rule in the comparative payment rate analysis for each Medicaid geographic area. As another example, if the State defined a single geographic area for Medicaid payment purposes that contained two Medicare geographic areas, then the State might determine a reasonable method to weight the two Medicare payment rates applicable within the Medicaid geographic area, and then compare the Medicaid payment rate for the Medicaid-defined geographic area to this weighted average of Medicare payment rates. Alternatively, as discussed in the next paragraph, the State could determine to use the unweighted arithmetic mean of the two Medicare payment rates applicable within the Medicaid-defined geographic area. We solicited comments on the proposed use of Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year as a benchmark for States to compare their Medicaid payment rates to in the comparative payment rate analysis requirements in proposed § 447.203(b)(3)(i) to help assess if Medicaid payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.

We noted our awareness that States may not determine their payment rates by geographical location. For States that do not pay Medicaid payment rates based on geographical location, we proposed that States compare their Medicaid payment rates (separately identified by population, pediatric and adult, and provider type, as applicable) to the Statewide average of Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year for a particular CPT/HCPCS code. The Statewide average of the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year for a particular CPT/HCPCS code would be calculated as a simple average or arithmetic mean where all Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year for a particular CPT/HCPCS code for a particular State would be summed and divided by the number of all Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year for a particular CPT/HCPCS code for a particular State. This calculated Statewide average of the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year would be calculated for each CPT/HCPCS code subject to the comparative payment rate analysis using the Non-Facility Price for each locality in the State as established in the annual Medicare PFS final rule for a calendar year. As previously mentioned, Medicare has published a listing of the current PFS locality structure organized by State, locality area, and when applicable, counties assigned to each locality area, and we would expect States to use this listing to identify the Medicare locality areas in their State. For example, the Specific Medicare Administrative Contractor (MAC) for Maryland is 12302 and there are two Specific Locality codes, 1230201 for BALTIMORE/SURR. CNTYS and 1230299 for REST OF STATE. After downloading and reviewing the CY 2023 Medicare PFS Relative Value Files to identify the Medicare Non-Facility Price(s) for CY 2023 for 99202 in the Specific MAC locality code for Maryland (12302 MARYLAND), the following information can be obtained: Medicare Non-Facility Price of $77.82 for BALTIMORE/SURR. CNTYS and $74.31 for REST OF STATE.[265] These two Medicare Non-Facility Price(s) would be averaged to obtain a calculated Statewide average for Maryland of $76.07.

For States that do not determine their payment rates by geographical location, we proposed that States would use the Statewide average of the Medicare Non-Facility Price(s) as listed on the PFS, as previously described, because it ensures consistency across all States' comparative payment rate analysis, aligns with the geographic area requirement of section 1902(a)(30)(A) of the Act, and ensures the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year that States use in their comparative payment rate analysis accurately reflect how Medicare pays for services. We explained that this proposal would ensure that all States' comparative payment rate analyses consistently include Medicare geographical payment rate adjustments as proposed in paragraph (b)(3)(i)(C). As previously discussed, we proposed that States that do pay varying rates by geographical location would need to identify the comparable Medicare locality area for the same geographical area as their Medicaid FFS fee schedule payment rate. However, for States that do not pay varying rates by geographical location, at the operational level, the State is effectively paying a Statewide Medicaid payment rate, regardless of geographical location, that cannot be matched to a Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year in a comparable Medicare locality area for the same geographical area as the Medicaid FFS fee schedule payment rate. Therefore, to consistently apply the proposed provision that the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year must be for the same geographical location as the Medicaid FFS fee schedule payment rate, States that do not pay varying rates by geographical location would be required to calculate a Statewide average of the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year to compare the State's Statewide Medicaid payment rate.

Additionally, we proposed that States that do not determine their payment rates by geographical location should use the Statewide average of the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year to align the implementing regulatory text with the statute's geographic area requirement in section 1902(a)(30)(A) of the Act. Section 1902(a)(30)(A) of the Act requires that Medicaid payments are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area. Therefore, the proposed provisions of this rule, which are implementing section 1902(a)(30)(A) of the Act, must include a method of ensuring we have sufficient information for determining sufficiency of access to care as compared to the general population in the geographic area. As we have

[264] *https://www.census.gov/programs-surveys/metro-micro/about/delineation-files.html.*

[265] *https://www.cms.gov/medicare/physician-fee-schedule/search?Y=0&T=4&HT=0&CT=1&H1=99202&C=43&M=5.*

proposed to use Medicare non-facility payment rates as a benchmark for comparing Medicaid FFS fee schedule payment rate, we believe that utilizing a Statewide average of Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year for States that do not pay varying rates by geographical location would align the geographic area requirement of section 1902(a)(30)(A) of the Act, treating the entire State (throughout which the Medicaid base payment rate applies uniformly) as the relevant geographic area.

We considered requiring States weight the Statewide average of the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year by the proportion of the Medicare beneficiary population covered by each rate, but we did not propose this due to the additional administrative burden this would create for States complying with the proposed comparative payment rate analysis as well as limited availability of Medicare beneficiary and claims data necessary to weight the Statewide average of the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year in this manner. As proposed, States that do not determine their payment rates by geographical location would be required to consider Medicare's geographically determined payment rates by Statewide average of the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year. We explained our belief that an additional step to weight the Statewide average by the proportion of the Medicare beneficiary population covered by each rate would not result in a practical version of the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year for purposes of the comparative payment rate analysis. Additionally, requiring only States that do not determine their payment rates by geographical location to weight Medicare payment rates in this manner would result in additional administrative burden for such States that is not imposed on States that do determine their Medicaid payment rates by geographical location. Additionally, in order to accurately weight the Statewide average of the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year by the proportion of the Medicare beneficiary population covered by each rate, States would likely require Medicare-paid claims data for each code subject to the comparative payment rate analysis, broken down by each of the comparable Medicare locality areas for the same geographical area as the Medicaid FFS fee schedule payment rate that are included in the Statewide average of Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year. While total Medicare beneficiary enrollment data broken down by State and county level is publicly available on *data.cms.gov,* Medicare-paid claims data broken down by the Medicare locality areas used in the Medicare PFS and by code level is not published by CMS and would be inaccessible for the State to use in weighting the Statewide average of the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year by the proportion of the Medicare beneficiary population covered by each rate. Accordingly, we explained our belief that, for States that do not determine their Medicaid payment rates by geographical location, calculating a simple Statewide average of the Medicare non-facility rates in the State would ensure consistency across all States' comparative payment rate analyses, align with the geographic area requirement of section 1902(a)(30)(A) of the Act, and ensure the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year that States use in their comparative payment rate analyses accurately reflect how Medicare pays for services. We solicited comments regarding our decision not to propose requiring States that do not pay varying Medicaid rates by geographical location to weight the Statewide average of the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year by the distribution of Medicare beneficiaries in the State.

Furthermore, in paragraph (b)(3)(i)(C), we proposed that the Medicare non-facility payment rate as established in the annual Medicare PFS final rule must separately identify the payment rates by provider type. We previously discussed that some States and Medicare pay a percentage less than 100 percent of their fee schedule payment rates to NPPs, including, for example, nurse practitioners, physician assistants, and clinical nurse specialists. To ensure a State's comparative payment rate analysis is as accurate as possible when comparing their Medicaid payment rates to Medicare, we proposed that States include a breakdown of Medicare's non-facility payment rates by provider type. The proposed breakdown of Medicare's payment rates by provider type would be required for all States, regardless of whether or how the State's Medicaid payment rates vary by provider type, because it ensures the comparative payment rate analysis accurately reflects this existing Medicare payment policy on the Medicare side of the analysis. Therefore, every comparative payment rate analysis would include the following Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year for the same set of E/M CPT/HCPCS codes paid under Medicaid as described in § 447.203(b)(3)(i)(B): the non-facility payment rate as established in the annual Medicare PFS rate as the Medicare payment rate for physicians and the non-facility payment rate as listed on Medicare PFS rate multiplied by 0.85 as the Medicare payment rate for NPPs.

As previously mentioned in this final rule, Medicare pays nurse practitioners, physician assistants, and clinical nurse specialists at 85 percent of the Medicare PFS rate. Medicare implements a payment policy where the fee schedule amounts, including the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year, are reduced to 85 percent when billed by NPPs, including nurse practitioners, physician assistants, and clinical nurse specialists, whereas physicians are paid 100 percent of the fee schedule amounts Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year.[266] As proposed, States' comparative payment rate analysis would need to match their Medicaid payment rates for each provider type to the corresponding Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year for each provider type, regardless of the State paying varying or the same payment rates to their providers for the same service. As an example of a State that pays varying rates based on provider type, if a State's Medicaid fee schedule lists a rate of $100.00 when a physician delivers and bills for 99202, then the $100.00 Medicaid base payment rate would be compared to 100 percent of the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year. If the same State's Medicaid fee schedule lists a rate of $75 when a nurse practitioner delivers and bills for 99202 (or the State's current approved State plan

[266] *https://www.cms.gov/files/document/physician-fee-schedule-guide.pdf.*

language states that a nurse practitioner is paid 75 percent of the State's Medicaid fee schedule rate), then the $75 Medicaid base payment rate would be compared to the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year multiplied by 0.85. Both Medicare non-facility payments rates would need to account for any applicable geographical variation, including the Non-Facility Price Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year for each relevant locality area or the calculated Statewide average of the Non-Facility Price Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year for all relevant areas of a State, as previously discussed in this section, for an accurate comparison to the corresponding Medicaid payment rate. Alternatively, if a State pays the same $80 Medicaid base payment rate for the service when delivered by physicians and by nurse practitioners, then the $80 would be listed separately for physicians and nurse practitioners as the Medicaid base payment rate and compared to the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year for physicians and the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year multiplied by 0.85 for nurse practitioners.

This granular level of comparison provides States with the opportunity to benchmark their Medicaid payment rates against Medicare as part of the State's and our process for ensuring compliance with section 1902(a)(30)(A) of the Act. For example, a State's comparative payment rate analysis may show that the State's Medicaid base payment rate for physicians is 80 percent of the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year and their Medicaid base payment rate for nurse practitioners is 71 percent of the Medicare non-facility payment rate for NPPs, because the State pays a reduced rate to nurse practitioners. Although Medicare also pays a reduced rate to nurse practitioners, the reduced rate the State pays to nurse practitioners compared to Medicare's reduced rate is still a lower percentage than the physician rate. However, another State's comparative payment rate analysis may show that the State's Medicaid base payment rate for physicians is 95 percent of the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year and their Medicaid base payment rate for nurse practitioners is 110 percent of the Medicare non-facility payment rate because the State pays all providers the same Medicaid base payment rate while Medicare pays a reduced rate of 85 percent of the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year when the service is furnished by an NPP. By conducting this level of analysis through the comparative payment rate analysis, States would be able to pinpoint where there may be existing or potential future access to care concerns rooted in payment rates. We solicited comments on the proposed requirement for States to compare their Medicaid payment rates to the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year, effective for the same time period for the same set of E/M CPT/HCPCS codes, and for the same geographical location as the Medicaid FFS fee schedule payment rate, that correspond to the Medicaid FFS fee schedule payment rate identified under paragraph (b)(3)(i)(B) of this section, including separate identification of the payment rates by provider type, as proposed in § 447.203(b)(3)(i)(C).

In paragraph (b)(3)(i)(D), we proposed to require States specify the Medicaid base payment rate identified under proposed § 447.203(b)(3)(i)(B) as a percentage of the Medicare non-facility payment rate as established in the annual Medicare PFS final rule identified under proposed § 447.203(b)(3)(i)(C) for each of the services for which the Medicaid base payment rate is published under proposed § 447.203(b)(3)(i)(B). For each E/M CPT/HCPCS code that we select, we proposed that States would calculate each Medicaid base payment rate as specified in paragraph (b)(3)(i)(B) as a percentage of the corresponding Medicare non-facility payment rate as established in the annual Medicare PFS final rule specified in paragraph (b)(3)(i)(C). Both rates would be required to be effective for the same time period of the comparative payment rate analysis. As previous components of the proposed comparative payment rate analysis have considered variance in payment rates based on population the service is delivered to (adult or pediatric), provider type, and geographical location to extract the most granular and accurate Medicaid and Medicare payment rate data, we proposed that States would calculate the Medicaid base payment rate as a percentage of the Medicare non-facility payment rate as established in the annual Medicare PFS final rule in the comparative payment rate analysis to obtain an informative metric that can be used in the State's and our assessment of whether the State's payment rates are compliant with section 1902(a)(30)(A) of the Act. As previously discussed, benchmarking against Medicare serves as an important data point in determining whether payment rates are likely to be sufficient to ensure access for Medicaid beneficiaries at least as great as for the general population in the geographic area, and whether any identified access concerns may be related to payment sufficiency. We proposed that States would calculate their Medicaid payment rates as a percentage of the Medicare non-facility payment rate as established in the annual Medicare PFS final rule because it is a common, simple, and informative statistic that can provide us with a gauge of how Medicaid payment rates compare to Medicare non-facility payment rates in the same geographic area. Initially and over time, States, CMS, and other interested parties would be able to compare the State's Medicaid payment rates as a percentage of Medicare's non-facility payment rates to identify how the percentage changes over time, in view of changes that may take place to the Medicaid and/or the Medicare payment rate. We explained that being able to track and analyze the change in percentage over time would help States and CMS identify possible access concerns that may be related to payment insufficiency.

We noted that the organization and content of the comparative payment rate analysis, including the expression of the Medicaid base payment rate as a percentage of the Medicare payment rate, can provide us with a great deal of information about access in the State. For example, we would be able to identify when and how the Medicaid base payment rate as a percentage of the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for E/M CPT/HCPCS codes for primary care services may decrease over time if Medicare adjusts its rates and a State does not and use this information to more closely examine for possible access concerns. This type of analysis would provide us with actionable information to help ensure consistency with section 1902(a)(30)(A) of the Act by using Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year paid across the same geographical

areas of the State as a point of comparison for payment rate sufficiency as a critical element of beneficiary access to care. When explaining the rationale for proposing to use Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year for comparison earlier in this rule, we emphasized the ability to demonstrate to States that certain Medicaid payment rates have not kept pace with changes to Medicare non-facility payment rates and how the comparative payment rate analysis would help them identify areas where they also might want to consider rate increases that address market changes. We solicited comments on the proposed requirement for States to calculate their Medicaid payment rates as a percentage of the Medicare non-facility payment rate for each of the services for which the Medicaid base payment rate is published under proposed paragraph (b)(3)(i)(B), as described in proposed § 447.203(b)(3)(i)(D). We also solicited comments on any challenges States might encounter when comparing their Medicaid payment rates to Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year under proposed § 447.203(b)(3)(i)(D), particularly for any of the proposed categories of service in paragraphs (b)(2)(i) through (iii), as well as suggestions for an alternative comparative analysis that might be more helpful, or less burdensome and equally helpful, for States, CMS, and other interested parties to assess whether a State's Medicaid payment rates are consistent with the access standard in section 1902(a)(30)(A) of the Act.

We noted our awareness in the proposed rule that provider payment rates are an important factor influencing beneficiary access; as expressly indicated in section 1902(a)(30)(A) of the Act, insufficient provider payment rates are not likely to enlist enough providers willing to serve Medicaid beneficiaries to ensure broad access to care; however, there may be situations where access issues are principally due to other causes. For example, even if Medicaid payment rates are generally consistent with amounts paid by Medicare (and those amounts have been sufficient to ensure broad access to services for Medicare beneficiaries), Medicaid beneficiaries may have difficulty scheduling behavioral health care appointments because the overall number of behavioral health providers within a State is not sufficient to meet the demands of the general population. Therefore, a State's rates may be consistent with the requirements of section 1902(a)(30)(A) of the Act even when access concerns exist, and States and CMS may need to examine other strategies to improve access to care beyond payment rate increases. By contrast, comparing a State's Medicaid behavioral health payment rates to Medicare may demonstrate that the State's rates fall far below Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year, which would likely impede beneficiaries from accessing needed care when the demand already exceeds the supply of providers within a State. In that case, States may need to evaluate budget priorities and take steps to ensure behavioral health rates are consistent with section 1902(a)(30)(A) of the Act.

Lastly, in paragraph (b)(3)(i)(E), we proposed to require States to specify in their comparative payment rate analyses the number of Medicaid-paid claims and the number of Medicaid enrolled beneficiaries who received a service within a calendar year for each of the services for which the Medicaid base payment rate is published under paragraph (b)(3)(i)(B). The previous components of the comparative payment rate analysis focus on the State's payment rate for the E/M CPT/HCPCS code and comparing the Medicaid base payment rate to the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year for the same code (separately, for each Medicaid base payment rate by population (adult or pediatric), provider type, and geographic area, as applicable). This component examines the Medicaid-paid claims volume of each E/M CPT/HCPCS code included in the comparative payment rate analysis relative to the number of Medicaid enrolled beneficiaries receiving each service within a calendar year. We proposed to limit the claims volume data to Medicaid-paid claims, and the number of beneficiaries would be limited to Medicaid-enrolled beneficiaries who received a service in the calendar year of the comparative payment rate analysis, where the service would fall into the list of CMS-identified E/M CPT/HCPCS code(s). In other words, a beneficiary would be counted in the comparative payment rate analysis for a particular calendar year when the beneficiary received a service that is included in one of the categories of services described in paragraphs (b)(2)(i) through (iii) for which the State has a Medicaid base payment rate (the number of Medicaid-enrolled beneficiaries who received a service). A claim would be counted in the comparative payment rate analysis for a particular calendar year when that beneficiary had a claim submitted on their behalf by a provider who billed one of the codes from the list of CMS-identified E/M CPT/HCPCS code(s) to the State and the State paid the claim (number of Medicaid-paid claims). With the proposal, we explained that we were seeking to ensure the comparative payment rate analysis reflects actual services received by beneficiaries and paid for by the State or realized access.[267]

We considered but did not propose requiring States to identify the number of unique Medicaid-paid claims and the number of unique Medicaid-enrolled beneficiaries who received a service within a calendar year for each of the services for which the Medicaid base payment rate is published pursuant to paragraph (b)(3)(i)(B). We considered this detail in order to identify the unique, or deduplicated, number of beneficiaries who received a service that falls into one of the categories of services described in in paragraph (b)(2)(i) through (iii) in a calendar year. For example, if a beneficiary has 6 visits to their primary care provider in a calendar year and the provider bills 6 claims with 99202 for the same beneficiary, then the beneficiary and claims for 99202 would only be counted as one claim and one beneficiary. Therefore, we chose not to propose this aspect because we intend for the comparative payment rate analysis to capture the total amount of actual services received by beneficiaries and paid for by the State. We solicited comments regarding our decision not to propose that States would identify the number of unique Medicaid-paid claims and the number of unique Medicaid enrolled beneficiaries who received a service within a calendar year for each of the services for which the Medicaid base payment rate is published pursuant to paragraph (b)(3)(i)(B) in the comparative payment rate analysis as proposed in § 447.203(b)(3)(i)(E).

We also considered but did not propose to require States to identify the total Medicaid-enrolled population who could potentially receive a service within a calendar year for each of the services for which the Medicaid base

[267] Andersen, R.M., and P.L. Davidson (2007). Improving access to care in America: Individual and contextual indicators. In Changing the U.S. health care system: Key issues in health services policy and management, 3rd edition, Andersen, R.M., T.H. Rice, and G.F. Kominski, eds. San Francisco, CA: John Wiley & Sons.

payment rate is published under paragraph (b)(3)(i)(B), in addition to the proposed requirement for States to identify the number of Medicaid-enrolled beneficiaries who received a service. This additional data element in the comparative payment rate analysis would reflect the number of Medicaid-enrolled beneficiaries who could have received a service, or potential access, in comparison to the number of Medicaid-enrolled beneficiaries who actually received a service. We did not propose this aspect because this could result in additional administrative burden on the State, as we already collect and publish similar data through Medicaid and CHIP Enrollment Trends Snapshots published on Medicaid.gov. We also solicited comments regarding our decision not to propose that States would identify the total Medicaid-enrolled population who could receive a service within a calendar year for each of the services for which the Medicaid base payment rate is published pursuant to paragraph (b)(3)(i)(B) in the comparative payment rate analysis as proposed in § 447.203(b)(3)(i)(E).

We proposed to include beneficiary and claims information in the comparative payment rate analysis to contextualize the payment rates in the analysis, and to be able to identify longitudinal changes in Medicaid service volume in the context of the Medicaid beneficiary population receiving services, since utilization changes could be an indication of an access to care issue. For example, a decrease in the number of Medicaid-paid claims for primary care services furnished to Medicaid beneficiaries in an area (when the number of Medicaid-enrolled beneficiaries who received primary care services in the area is constant or increasing) could be an indication of an access to care issue. Without additional context provided by the number of Medicaid enrolled beneficiaries who received a service, changes in claims volume could be attributed to a variety of changes in the beneficiary population, such as a temporary loss of coverage when enrollees disenroll and then re-enroll within a short period of time.

Further, if the Medicaid base payment rate for the services with decreasing Medicaid service volume has failed to keep pace with the corresponding Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year over the period of decrease in utilization (as reflected in changes in the Medicaid base payment rate expressed as a percentage of the Medicare non-facility payment rate as required under proposed § 447.203(b)(3)(i)(D)), then we would be concerned and would further scrutinize whether any access to care issue might be caused by insufficient Medicaid payment rates for the relevant services. With each biennial publication of the State's comparative payment rate analysis, as proposed in § 447.203(b)(4), discussed later in this section, States and CMS would be able to compare the number of paid claims in the context of the number of Medicaid enrolled beneficiaries receiving services within a calendar year for the services subject to the comparative payment rate analysis with previous years' comparative payment rate analyses. Collecting and comparing the number of paid claims data in the context of the number of Medicaid enrolled beneficiaries receiving services alongside Medicaid base payment rate data may reveal trends where an increase in the Medicaid base payment rate is correlated with an increase in service volume and utilization, or vice versa with a decrease in the Medicaid base payment rate correlated with a decrease in service volume and utilization. As claims utilization and number of Medicaid enrolled beneficiaries receiving services are only correlating trends, we acknowledge that there may be other contextualizing factors outside of the comparative payment rate analysis that affect changes in service volume and utilization, and we would (and would expect States and other interested parties to) take such additional factors into account in analyzing and ascribing significance to changes in service volume and utilization. We are solicited comments on the proposed requirement for States to include the number of Medicaid-paid claims and the number of Medicaid enrolled beneficiaries who received a service within a calendar year for which the Medicaid base payment rate is published under proposed paragraph (b)(3)(i)(B), as specified in proposed § 447.203(b)(3)(i)(E).

We noted our belief that the comparative payment rate analysis proposed in paragraph (b)(3) is needed to best enable us to ensure State compliance with the requirement in section 1902(a)(30)(A) of the Act that payments are sufficient to enlist enough providers so that care and services are available to Medicaid beneficiaries at least to the extent they are available to the general population in the geographic area. As demonstrated by the findings of Sloan, et al.,[268] which have since been supported and expanded upon by numerous researchers, multiple studies examining the relationship between Medicaid payment and physician participation,[269] [270] at the State level,[271] and among specific provider types,[272] [273] have found a direct, positive association between Medicaid payment rates and provider participation in the Medicaid program. While multiple factors may influence provider enrollment (such as administrative burden), section 1902(a)(30)(A) of the Act specifically concerns the sufficiency of provider payment rates. Given this statutory requirement, a comparison of Medicaid payment rates to other payer rates is an important barometer of whether State payment policies are likely to support the statutory standard of ensuring access for Medicaid beneficiaries such that covered care and services are available to them at least to the extent that the same care and services are available to the general population in the geographic area.

The AMRP requirements previous addressed this standard under section 1902(a)(30)(A) of the Act by requiring States to compare Medicaid payment rates to the payment rates of other public and private payers in current

[268] Sloan, F. et al ''Physician Participation in State Medicaid Programs.'' *The Journal of Human Resources,* Volume 13, Supplement: National Bureau of Economic Research Conference on the Economics of Physician and Patient Behavior, 1978, p. 211–245. *https://www.jstor.org/stable/145253?seq=1#metadata_info_tab_contents.* Accessed August 16, 2022.

[269] Chen, A. ''Do the Poor Benefit from More Generous Medicaid Policies'' SSRN Electronic Journal, January 2014., p. 1–46. *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2444286.* Accessed June 16, 2022.

[270] Holgash, K. and Martha Heberlein, ''Physician Acceptance of New Medicaid Patients: What Matters and What Doesn't'' *Health Affairs,* April 10, 2019. *https://www.healthaffairs.org/do/10.1377/forefront.20190401.678690/#:~:text=Physicians%E2%80%99%20acceptance%20of%20new%20Medicaid%20patients%20is%20only,of%20Medicaid%20patients%20already%20in%20the%20physician%E2%80%99s%20care.* Accessed June 16, 2022.

[271] Fakhraei, H. ''Payments for Physician Services: An analysis of Maryland Medicaid Reimbursement Rates'' *International Journal of Healthcare Technology and Management, Volume 7,* Numbers 1–2, January 2005, p. 129–142. *https://www.researchgate.net/publication/228637758_Payments_for_physician_services_An_analysis_of_Maryland_Medicaid_reimbursement_rates.* Accessed June 16, 2022.

[272] Berman, S., et al. ''Factors that Influence the Willingness of Private Primary Care Pediatricians to Accept More Medicaid Patients,'' *Pediatrics,* Volume 110, Issue 2, August 2002, p. 239–248. *https://publications.aap.org/pediatrics/article-abstract/110/2/239/64380/Factors-That-Influence-the-Willingness-of-Private?redirectedFrom=fulltext?autologincheck=redirected.* Accessed June 16, 2022.

[273] Suk-fong S., Tang, et al ''Increased Medicaid Payment and Participation by Office-Based Primary Care Pediatricians,'' *Pediatrics,* Volume 141, number 1, January 2018, p. 1–9. *https://publications.aap.org/pediatrics/article/141/1/e20172570/37705/Increased-Medicaid-Payment-and-Participation-by.* Accessed June 16, 2022.

§ 447.203(b)(1)(v) and (b)(3). While we proposed to eliminate the previous AMRP requirements, we noted our belief that our proposal to require States to compare their Medicaid payment rates for services under specified E/M CPT/HCPCS codes against Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year for the same codes, as described in § 447.203(b)(3), would well position States and CMS to continue to meet the statutory access requirement. Some studies examining the relationship between provider payments and various access measures have quantified the relationship between the Medicaid-Medicare payment ratio and access measures. Two studies observed that increases in the Medicaid-Medicare payment ratio is associated with higher physician acceptance rates of new Medicaid patients and with an increased probability of a beneficiary having an office-based physician as the patient's usual source of care.[274] [275] We explained that these studies led us to conclude that Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year are likely to be a sufficient benchmark for evaluating access to care, particularly ambulatory physician services, based on provider payment rates.

By comparing FFS Medicaid payment rates to corresponding FFS Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year, where Medicare is a public payer with large populations of beneficiaries and participating providers whose payment rates are readily available, we aim to establish a uniform benchmarking approach that allows for more meaningful oversight and transparency and reduces the burden on States and CMS relative to the previous AMRP requirements that do not impose specific methodological standards for comparing payment rates and that contemplate the availability of private payer rate information that has proven difficult for States to obtain due to its often proprietary nature. We noted that this aspect of the proposal specifically responds to States' expressed concerns that the previous AMRP requirement to include ''actual or estimated levels of provider payment available from other payers, including other public and private payers'' was challenging to accomplish based on the general unavailability of this information, as discussed elsewhere in this final rule.

Following the 2011 proposed rule, and as addressed by us through public comment response in the 2015 final rule with comment period, States expressed concerns that private payer payment rates were proprietary information and not available to them and that large private plans did not exist within some States so there were no private payer rates to compare to, therefore, the State would need to rely on State employee health plans or non-profit insurer rates.[276] States also expressed that other payer data, including public and private payers, in general may be unsound for comparisons because of a lack of transparency about the payment data States would have compared their Medicaid payment rates to. We discussed how, since 2016, we have learned a great deal from our implementation experience of the previous AMRP process. We have learned that very few States were able to include even limited private payer data in their previous AMRPs. States that were able include private payer data were only able to do so because the State had existing Statewide all payer claiming or rate-setting systems, which gave them access to private payer data in their State, or the State previously based their State plan payment rates off of information about other payers (such as the American Dental Association's Survey of Dental Fees) that gave them access to private payer data.[277] Based on our implementation experience and concerns from States about the previous requirement in § 447.203(b)(1)(v) to obtain private payer data, we proposed to require States only compare their Medicaid payment rates to Medicare's, for which payment data are readily and publicly available.

Next, in paragraph (b)(3)(ii), we proposed that for each category of services described in proposed paragraph (b)(2)(iv), the State agency would be required to publish a payment rate disclosure that expresses the State's payment rates as the average hourly payment rates, separately identified for payments made to individual providers and to providers employed by an agency, if the rates differ. The payment rate disclosure would be required to meet specified requirements. We explained that we intended this proposal to remain consistent with the proposed HCBS provisions at § 441.311(d)(2) and (e) and to take specific action regarding direct care workers per Section 2402(a) of the Affordable Care Act. HCBS and direct care workers that deliver these services are unique to Medicaid and often not covered by other payers, which is why we proposed a different analysis of payment rates for providers of these services that does not involve a comparison to Medicare. As previously stated, Medicare covers part-time or intermittent home health aide services (only if a Medicare beneficiary is also getting other skilled services like nursing and/or therapy at the same time) under Medicare Part A (Hospital Insurance) or Medicare Part B (Medical Insurance); however, Medicare does not cover personal care or homemaker services. Therefore, comparing personal care and homemaker services to Medicare, as we proposed in paragraph (b)(3)(i) for other specified categories of services, would not be feasible for States, and a comparison of Medicaid home health aide payment rates to analogous rates for Medicare would be of limited utility given the differences in circumstances when Medicaid and Medicare may pay for such services.

As previously discussed, private payer data are often considered proprietary and not available to States, thereby eliminating private payers as feasible point of comparison. Even if private payer payment rate data were more readily available, like Medicare, many private payers do not cover HCBS as HCBS is unique to the Medicaid program, leaving Medicaid as the largest or the only payer for personal care, home health aide, and homemaker services. Given Medicaid's status as the most important payer for HCBS, we believe that scrutiny of Medicaid HCBS payment rates themselves, rather than a comparison to other payer rates that frequently do not exist, is most important in ascertaining whether such Medicaid payment rates are sufficient to enlist adequate providers so that the specified services are available to Medicaid beneficiaries at least to the same extent as to the general population in the geographic area. We acknowledge that individuals without insurance may self-pay for medical services provided in their home or community; however, similar to private payer data, self-pay data is unlikely to be available to States. Because HCBS coverage is unique to Medicaid, Medicaid beneficiaries are generally the only individuals in a given geographic area with access to HCBS.

[274] Holgash, K. and Martha Heberlein, *Health Affairs,* April 10, 2019.

[275] Cohen, J.W., *Inquiry,* Fall 1993.

[276] Alaska Department of Health and Social Services, Comment Letter on 2011 Proposed Rule (July 7, 2011), *https://www.regulations.gov/comment/CMS-2011-0062-0102.*

[277] *https://www.medicaid.gov/sites/default/files/2019-12/co-amrp-2016.pdf, https://www.medicaid.gov/sites/default/files/2019-12/md-amrp-16.pdf, https://www.medicaid.gov/sites/default/files/2019-12/sd-amrp-16.pdf.*

Through the proposed payment rate disclosure, Medicaid payments rates would be transparent and comparable among States and would assist States to analyze if and how their payment rates are compliant with section 1902(a)(30)(A) of the Act.

As noted previously in this section, we proposed to require States to express their rates separately as the average hourly payments made to individual providers and providers employed by an agency, if the rates differ, as applicable for each category of service specified in proposed § 447.203(b)(2)(iv). We noted our belief that expressing the data in this manner would best account for variations in types and levels of payment that may occur in different settings and employment arrangements. Individual providers are often self-employed or contract directly with the State to deliver services as a Medicaid provider while providers employed by an agency are employed by the agency, which works directly with the Medicaid agency to provide Medicaid services. These differences in employment arrangements often include differences in the hourly rate a provider would receive for services delivered, for example, providers employed by an agency typically receive benefits, such as health insurance, and the cost of those benefits is factored into the hourly rate that the State pays for the services delivered by providers employed by an agency (even though the employed provider does not retain the entire amount as direct monetary compensation). However, these benefits are not always available for individual providers who may need to separately purchase a marketplace health plan or be able to opt into the State-employee health plan, for example. Therefore, the provider employed by an agency potentially could receive a higher hourly rate because benefits are factored into the hourly rate they receive for delivering services, whereas the individual provider might be paid a rate that does not reflect employment benefits.

With States expressing their payment rates separately as the average hourly payment rate made to individual and agency employed providers for personal care, home health aide, and homemaker services, States, CMS, and other interested parties would be able to compare payment rates among State Medicaid programs. Such comparisons may be particularly relevant for States in close geographical proximity to each other or that otherwise may compete to attract providers of the services specified in proposed paragraph (b)(2)(iv) or where such providers may experience similar costs or other incentives to provide such services. For example, from reviewing all States' payment rate analyses for personal care, home health aide, and homemaker services, we would be able to learn that two neighboring States have similar hourly rates for providers of these services, but a third neighboring State has much lower hourly rates than both of its neighbors. This information could highlight a potential access issue, since providers in the third State might have an economic incentive to move to one of the two neighboring States where they could receive higher payments for furnishing the same services. Such movement could result in beneficiaries in the third State having difficulty accessing covered services, compared to the general population in the tri-State geographic area.

In paragraph (b)(3)(ii), we proposed that the State's payment rate disclosure must meet the following requirements: (A) the State must organize the payment rate disclosure by category of service as specified in proposed paragraph (b)(2)(iv); (B) the disclosure must identify the average hourly payment rates, including, if the rates vary, separate identification of the average hourly payment rates for payments made to individual providers and to providers employed by an agency by population (pediatric and adult), provider type, and geographical location, as applicable; and (C) the disclosure must identify the number of Medicaid-paid claims and the number of Medicaid enrolled beneficiaries who received a service within a calendar year for each of the services for which the Medicaid base payment rate is published under proposed paragraph (b)(3)(ii)(B). We solicited comments on the proposed requirements and content of the items in proposed § 447.203(b)(3)(ii)(A) through (C).

In paragraph (b)(3)(ii)(A), we proposed to require States to organize their payment rate disclosures by each of the categories of services specified in proposed paragraph (b)(2)(iv), that is, to break out the payment rates for personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency, separately for individual analyses of the payment rates for each category of service and type of employment structure. We solicited comments on the proposed requirement for States to break out their payment rates for personal care, home health aide, and homemaker services separately for individual analyses of the payment rates for each category of service in the comparative payment rate analysis, as described in proposed § 447.203(b)(3)(ii)(A).

In paragraph (b)(3)(ii)(B), we proposed to require States identify in their disclosure the Medicaid average hourly payment rates by applicable category of service, including, if the rates vary, separate identification of the average hourly payment rates for payments made to individual providers and to providers employed by an agency, as well as by population (pediatric and adult), provider type, and geographical location, as applicable. Given that direct care workers deliver unique services in Medicaid that are often not covered by other payers, we proposed to require a payment rate disclosure, instead of comparative payment rate analysis. To be clear, we did not propose to require a State's payment rate disclosure for personal care, home health aide, and homemaker services be broken down and organized by E/M CPT/HCPCS codes, nor did we propose States compare their Medicaid payment rates to Medicare for these services.

We proposed to require States to calculate their Medicaid average hourly payment rates made to providers of personal care, home health aide, and homemaker services, separately, for each of these categories of services, by provider employment structures (individual providers and agency employed providers). For each of the categories of services in paragraph (b)(3)(ii)(A), one Medicaid average hourly payment rate would be calculated as a simple average (arithmetic mean) where all payment rates would be adjusted to an hourly figure, summed, then divided by the number of all hourly payment rates. As an example, the State's Medicaid average hourly payment rate for personal care providers may be $10.50 while the average hourly payment rate for a home health aide is $15.00. A more granular analysis may show that within personal care providers receiving a payment rate of $10.50, an individual personal care provider is paid an average hourly payment rate of $9.00, while a personal care provider employed by an agency is paid an average hourly payment rate of $12.00 for the same type of service. Similarly for home health aides, a more granular analysis may show that within home health aides receiving a payment rate of $15.00, an individual home health aide is paid an average hourly payment rate of $13.00, while a home health aide employed by an agency is paid an average hourly payment rate of $17.00.

We explained that we understand that States may set payment rates for personal care, home health aide, and

homemaker services based on a particular unit of time for delivering the service, and that time may not be in hourly increments. For example, different States might pay for personal care services using 15-minute increments, on an hourly basis, through a daily rate, or based on a 24-hour period. By proposing to require States to represent their rates as an hourly payment rate, we would be able to standardize the unit (hourly) and payment rate for comparison across States, rather than comparing to Medicare. To the extent a State pays for personal care, home health aide, or homemaker services on an hourly basis, the State would simply use that hourly rate in its Medicaid average hourly payment rate calculation of each respective category of service. However, if for example a State pays for personal care, home health aide, or homemaker services on a daily basis, we would expect the State to divide that rate by the number of hours covered by the rate.

Additionally, and similar to proposed paragraph (b)(3)(i)(E), we proposed in paragraph (b)(3)(ii)(B), that, if the States' Medicaid average hourly payment rates vary, the rates must separately identify the average hourly payment rates for payments made to individual providers and to providers employed by an agency, by population (pediatric and adult), provider type, and geographical location, as applicable. We included this proposed provision with the intent of ensuring the payment rate disclosure contains the highest level of granularity in each element. As previously discussed, States may pay providers different payment rates for billing the same service based on the population being served, provider type, and geographical location of where the service is delivered. We solicited comments on the proposed requirement for States to calculate the Medicaid average hourly payment rate made separately to individual providers and to agency employed providers, which accounts for variation in payment rates by population (pediatric and adult), provider type, and geographical location, as applicable, in the payment rate disclosure.

In paragraph (b)(3)(ii)(C), we proposed to require that the State disclosure must identify the number of Medicaid-paid claims and the number of Medicaid enrolled beneficiaries who received a service within a calendar year for each of the services for which the Medicaid payment rate is published under proposed paragraph (b)(3)(ii)(B), so that States, CMS, and other interested parties would be able to contextualize the previously described payment rate information with information about the volume of paid claims and number of beneficiaries receiving personal care, home health aide, and homemaker services.

We proposed that the number of Medicaid-paid claims and number of Medicaid enrolled beneficiaries who received a service be reported under the same breakdown as paragraph (b)(3)(ii), where the State provides the number of paid claims and number of beneficiaries receiving services from individual providers versus agency-employed providers of personal care, home health aide services, and homemaker services. As with the comparative payment rate analysis, we proposed the claims volume data would be limited to Medicaid-paid claims and the number of beneficiaries would be limited to Medicaid enrolled beneficiaries who received a service in the calendar year of the payment rate disclosure, where the services fall into the categories of service for which the average hourly payment rates are published pursuant to paragraph (b)(3)(ii)(B). In other words, the beneficiary would be counted in the payment rate disclosure for a particular calendar year when the beneficiary received a service that is included in one of the categories of services described in paragraph (b)(2)(iv) for which the State has calculated average hourly payment rates (the number of Medicaid enrolled beneficiaries who received a service). A claim would be counted when that beneficiary had a claim submitted on their behalf by a provider who billed for one of the categories of services described in paragraph (b)(2)(iv) and the State paid the claim (number of Medicaid-paid claims). We noted we were seeking to ensure the payment rate disclosure reflects actual services received by beneficiaries and paid for by the State, or realized access.[278]

Similar to the comparative payment rate analysis, we considered but did not propose requiring States to identify the number of unique Medicaid-paid claims and the number of unique Medicaid enrolled beneficiaries who received a service within a calendar year for each of the services for which the average hourly payment rates are published pursuant to paragraph (b)(3)(ii)(B). We also considered but did not propose to require States to identify the total Medicaid enrolled population who could receive a service within a calendar year for each of the services for which the average hourly payment rates are published pursuant to paragraph (b)(3)(ii)(B) in addition to proposing States identify the number of Medicaid enrolled beneficiaries who received a service. As discussed in the comparative payment rate discussion, we solicited comments on our decision not to require these levels of detail for the payment rate disclosure.

Also similar to the comparative payment rate analysis requirement under proposed paragraph (b)(3)(i)(E), we explained that this disclosure element would help States, CMS, and other interested parties identify longitudinal changes in Medicaid service volume and beneficiary utilization that may be an indication of an access to care issue. Again, with each biennial publication of the State's comparative payment rate analysis and payment rate disclosure, States and CMS would be able to compare the number of Medicaid-paid claims and number of Medicaid enrolled beneficiaries who received a service within a calendar year for services subject to the payment rate disclosure with previous years' disclosures. Collecting and comparing data on the number of paid claims and number of Medicaid enrolled beneficiaries alongside Medicaid average hourly payment rate data may reveal trends, such as where a provider type that previously delivered a low volume of services to beneficiaries has increased their volume of services delivered after receiving an increase in their payment rate.

We acknowledged that one limitation of using the average hourly payment rate is that the statistic is sensitive to highs and lows, so one provider receiving an increase in their average hourly payment rate would bring up the average overall while other providers may not see an improvement. As these are only correlating trends, we also acknowledged that there may be other contextualizing factors outside of the payment rate disclosure that may affect changes in service volume and utilization. We solicited comments on the proposed requirement for States to include the number of Medicaid-paid claims and number of Medicaid enrolled beneficiaries who received a service within a calendar year for which the Medicaid payment rate is published under paragraph (b)(3)(ii)(B), as specified in proposed § 447.203(b)(3)(ii)(C).

Additionally, in recognition of the importance of services provided to individuals with intellectual or

[278] Andersen, R.M., and P.L. Davidson. 2007. Improving access to care in America: Individual and contextual indicators. In Changing the U.S. health care system: Key issues in health services policy and management, 3rd edition, Andersen, R.M., T.H. Rice, and G.F. Kominski, eds. San Francisco, CA: John Wiley & Sons.

developmental disabilities and in an effort to remain consistent with the proposed HCBS payment adequacy provisions at § 441.302(k) (discussed in section II.B.5 of this rule), we solicited comments on whether we should propose a similar provision that would require at least 80 percent of all Medicaid FFS payments with respect to personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency must be spent on compensation for direct care workers. In this final rule, we want to clarify that this request for comment was distinct from the proposal at § 441.302(k) as discussed in section II.B.5 of this rule. The payment adequacy provision finalized in § 441.302(k) is applicable to rates for certain specified services authorized under section 1915(c) of the Act, as well as sections 1915(j), (k), and (i) of the Act as finalized at §§ 441.464(f), 441.570(f), and 441.745(a)(1)(vi), respectively. The request for comment in this section of the rule considered expanding that requirement to Medicaid FFS payments under FFS State plan authority.

In paragraph (b)(4), we proposed to require the State agency to publish the initial comparative payment rate analysis and payment rate disclosure of its Medicaid payments in effect as of January 1, 2025, as required under § 447.203(b)(2) and (b)(3), by no later than January 1, 2026. Thereafter, the State agency would be required to update the comparative payment rate analysis and payment rate disclosure no less than every 2 years, by no later than January 1 of the second year following the most recent update. The comparative payment rate analysis and payment rate disclosure would be required to be published consistent with the publication requirements described in proposed § 447.203(b)(1) for payment rate transparency data.

As previously discussed in this final rule, we proposed that the Medicaid payment rates included in the initial comparative payment rate analysis and payment rate disclosure would be those in effect as of January 1, 2025. Specifically, for the comparative payment rate analysis, we proposed States would conduct a retrospective analysis to ensure CMS can publish the list of E/M CPT/HCPCS codes for the comparative payment rate analysis and States have timely access to all information required to complete comparative payment rate analysis. As described in paragraph (b)(3)(i)(C), we proposed States would compare their Medicaid payment rates to the Medicare non-facility payment rates as established in the annual Medicare PFS final rule effective for the same time period for the same set of E/M CPT/HCPCS codes, therefore, the Medicare non-facility payment rates as published on the Medicare PFS for the same time period as the State's Medicaid payment rates would need to be available to States in a timely manner for their analysis and disclosure to be conducted and published as described in paragraph (b)(4). Medicare publishes its annual PFS final rule in November of each year and the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year are effective the following January 1. For example, the 2025 Medicare PFS final rule would be published in November 2024 and the Medicare non-facility payment rates as established in the annual Medicare PFS final rule would be effective January 1, 2025, so States would compare their Medicaid payment rates effective as of January 1, 2025, to the Medicare PFS payment rates effective January 1, 2025, when submitting the initial comparative payment rate analysis that we proposed would be due on January 1, 2026.

Also, previously discussed in this final rule, we noted our intent to publish the initial and subsequent updates to the list of E/M CPT/HCPCS codes subject to the comparative payment rate analysis in a timely manner that allows States approximately one full calendar year between the publication of the CMS-published list of E/M CPT/HCPCS codes and the due date of the comparative payment rate analysis. Because the list of E/M CPT/HCPCS codes is derived from the relevant calendar year's Medicare PFS, the Medicare non-facility payment rates as established in the annual Medicare PFS final rule that the State would need to include in their comparative payment rate analysis would also be available to States. We explained that we expect approximately one full calendar year of the CMS-published list of E/M CPT/HCPCS codes and Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year being available to States would provide the States with sufficient time to develop and publish their comparative payment rate analyses as described in paragraph (b)(4). We considered proposing the same due date and effective time period for Medicaid and Medicare payment rates where the initial publication of the comparative payment rate analysis would be due January 1, 2026, and would contain payment rates effective January 1, 2026; however, we believe a 2-month time period between Medicare publishing its PFS payment rates in November and the PFS payment rates taking effect on January 1 would be an insufficient amount of time for CMS to publish the list of E/M CPT/HCPCS codes subject to the comparative payment rate analysis and for States to develop and publish their comparative payment rate analyses by January 1. While the proposed payment rate disclosure would not require a comparison to Medicare, we proposed to use the same due date and effective period of Medicaid payment rates for both the proposed comparative payment rate analysis and payment rate disclosure to maintain consistency.

We noted our expectation the proposed initial publication timeframe would provide sufficient time for States to gather necessary data, perform, and publish the first required comparative payment rate analysis and payment rate disclosure. We determined this timeframe was sufficient based on implementation experience from the previous AMRP process, where we initially proposed a 6-month timeframe between the January 4, 2016, effective date of the 2015 final rule with comment period in the **Federal Register**, and the due date of the first AMRP, July 1, 2016. At the time, we believed that this timeframe would be sufficient for States to conduct their first review for service categories newly subject to ongoing AMRP requirements; however, after receiving several public comments from States on the 2015 final rule with comment period that State agency staff may have difficulty developing and submitting the initial AMRPs within the July 1, 2016 timeframe, we modified the policy as finalized in the 2016 final rule.[279] Specifically, we revised the deadline for submission of the initial AMRP until October 1, 2016 and we made a conforming change to the deadline for submission in subsequent review periods at § 447.203(b)(5)(i) to October 1.[280] We also found that, despite this additional time, some State were still late in submitting their first AMRP to us. Therefore, we noted our belief that a proposed initial publication date of January 1, 2026, thereby providing States with approximately 2 years between the effective date of the final rule and the due date of the first comparative payment rate analysis and payment rate disclosure, would be sufficient. In alignment with the proposed payment rate transparency requirements, we proposed an alternate date if this rule is finalized at a time that

[279] 81 FR 21479 at 21479–21480.

[280] 81 FR 21479 at 21480.

does not allow for States to have a period of 2 years from the effective date of the final rule and the proposed January 1, 2026, date to publish the initial comparative payment rate analysis and payment rate disclosure. We proposed an alternative date of July 1, 2026, for the initial comparative payment rate analysis and payment rate disclosure and for the initial comparative payment rate analysis and payment rate disclosure to include Medicaid payment rates approved as of July 1, 2025, to allow more time for States to comply with the initial comparative payment rate analysis and payment rate disclosure requirements. We acknowledged that the date of the initial comparative payment rate analysis and payment rate disclosure publication would be subject to change based on the final rule publication schedule and effective date. If further adjustment is necessary beyond the July 1, 2026, timeframe to allow more time for States to comply with the payment rate transparency requirements, then we proposed that we would adjust date of the initial payment rate transparency publication in 6-month intervals, as appropriate.

Also, in § 447.203(b)(4), we proposed to require the State agency to update the comparative payment rate analysis and payment rate disclosure no less than every 2 years, by no later than January 1 of the second year following the most recent update. We proposed that the comparative payment rate analysis and payment rate disclosure would be required to be published consistent with the publication requirements described in proposed paragraph (b)(1) for payment rate transparency data. After publication of the 2011 proposed rule, and as we worked with States to implement the previous AMRP requirements after publication of the 2015 final rule with comment period, many States expressed concerns that the previous requirements of § 447.203, specifically those in previous § 447.203(b)(6) imposed additional analysis and monitoring requirements in the case of provider rate reductions or restructurings that could result in diminished access, were overly burdensome. As described in the 2018 and 2019 proposed rules, ''a number of States expressed concern regarding the administrative burden associated with the requirements of § 447.203, particularly those States with a very high beneficiary enrollment in comprehensive, risk-based managed care and a limited number of beneficiaries receiving care through a FFS delivery system.'' [281] [282] Additionally, from our implementation experience, we learned that the triennial due date for updated AMRPs required by previous § 447.203(b)(5)(ii) was too infrequent for States or CMS to identify and act on access concerns identified by the previous AMRPs. For example, one State timely submitted its initial ongoing AMRP on October 1, 2016, consistent with the requirements in § 447.203(b)(1) through (5), and timely submitted its first AMRP update (the next ongoing AMRP) 3 years later, on October 1, 2019. The 2016 AMRP included data about beneficiary utilization and Medicaid-participating providers accepting new Medicaid patients from 2014 to 2015 (the most recent data available at the time the State was developing the AMRP), while the 2019 AMRP update included similar data for 2016 to 2017 (the most recent data then available). The 2019 AMRP showed that the number of Medicaid-participating providers accepting new Medicaid patients significantly dropped in 2016, and the State received a considerable number of public comments during the 30-day public comment period for the 2019 AMRP update prior to submission to us per the requirements in § 447.203(b) and (b)(2). This data lag between a drop in Medicaid-participating providers accepting new Medicaid patients in 2016 and CMS receiving the next AMRP update with information about related concerns in 2019 illustrates how the infrequency of the triennial due date for the AMRP updates could allow a potential access concern to develop without notice by the State or CMS in between the due dates of the ongoing AMRP updates. Although § 447.203(b)(7) previously required States to have ongoing mechanisms for beneficiary and provider input on access to care, and States are expected to promptly respond to concerns expressed through these mechanisms that cite specific access problems, beneficiaries and providers themselves may not be aware of even widespread access issues if such issues are not noticed before published data reveal them.

We also learned from our previous AMRP implementation experience that the timing of the ongoing AMRP submissions required by previous § 447.203(b)(5)(ii) and access reviews associated with rate reduction or restructuring SPA submissions required by § 447.203(b)(6) have led to confusion about the due date and scope of routine, ongoing AMRP updates and SPA-connected access review submissions, particularly when States were required to submit access reviews within the 3-year period between AMRP updates when proposing a rate reduction or restructuring SPA, per the requirements in previous § 447.203(b)(6). For example, one State timely submitted its initial ongoing AMRP on October 1, 2016, consistent with the requirements in § 447.203(b)(1) through (5), then the State submitted a SPA that proposed to reduce provider payment rates for physical therapy services with an effective date of July 1, 2018, along with an access review for the affected service completed within the prior 12 months, consistent with the requirements in § 447.203(b)(6). The State's access review submission consisted of its 2016 AMRP submission, updated with data from the 12 months prior to this SPA submission, with the addition of physical therapy services for which the SPA proposed to reduce rates. Because the State submitted an updated version of its 2016 AMRP in 2018 in support of the SPA submission, the State was confused whether its next AMRP update submission was due in 2019 (3 years from 2016), or in 2021 (3 years from 2018). Based on the infrequency of a triennial due date for AMRP updates and the numerous instances of similar State confusion during the implementation process for the previous AMRPs, we identified that the triennial timeframe was insufficient for the proposed comparative payment rate analysis and payment rate disclosure.

As we considered a new timeframe for updates to the comparative payment rate analysis and payment rate disclosure to propose in this rulemaking, we initially considered proposing to require annual updates. However, we explained our belief that annual updates would add unnecessary administrative burden as annual updates would be too frequent because many States do not update their Medicaid fee schedule rates for the codes subject to the comparative payment rate analysis and payment rate disclosure on an annual basis. As proposed, the categories of services subject to the proposed comparative payment rate analysis and payment rate disclosure are for office-based visits and, in our experience, the Medicaid payment rates generally do not change much over time due to the nature of an office visit.[283] Office visits primarily

[281] 83 FR 12696 at 12697.

[282] 84 FR 33722 at 33723.

[283] We acknowledged that Medicaid primary care payment increase, a provision in the Patient Protection and Affordable Care Act (ACA, Pub. L. 111–148, as amended), temporarily raised Medicaid

include vital signs being taken and the time a patient meets with a physician or NPP; therefore, States would likely have a considerable amount of historical payment data for supporting the current payment rates for such services. Given the relatively stable nature of payment rates for office visits, our proposal aimed to help ensure the impact of the comparative payment rate analysis is maximized for ensuring compliance with section 1902(a)(30)(A) of the Act while minimizing unnecessary burden on States by holding all States to a proposed update frequency of 2 years to capture all Medicaid (and corresponding Medicare) payment rate changes.

As the proposed rule sought to reduce the amount of administrative burden from the previous AMRP process on States while also fulfilling our oversight responsibilities, we explained our belief that updating the comparative payment rate analysis and payment rate disclosure no less than every 2 years would achieve an appropriate balance between administrative burden and our oversight responsibilities with regard to section 1902(a)(30)(A) of the Act. We noted our intent for the comparative payment rate analysis and payment rate disclosure States develop and publish to be time-sensitive and useful sources of information and analysis to help ensure compliance with section 1902(a)(30)(A) of the Act. If this proposal is finalized, we stated that both the comparative payment rate analysis and payment rate disclosure would provide the State, CMS, and other interested parties with cross-sectional data of Medicaid payment rates at various points in time. This data could be used to track Medicaid payment rates over time as a raw dollar amount and as a percentage of Medicare non-facility payment as established in the annual Medicare PFS final rule for a calendar year, as well as changes in the number of Medicaid-paid claims volume and number of Medicaid enrolled beneficiaries who receive a service over time. The availability of this data could be used to inform State policy changes, to compare payment rates across States, or for research on Medicaid payment rates and policies. While we noted our belief that the comparative payment rate analysis and payment rate disclosure would provide useful and actionable information to States, we explained that we did not want to overburden States with annual updates to the comparative payment rate analysis and payment rate disclosure. As we proposed to replace the previous triennial AMRP process with less administratively burdensome processes (payment rate transparency publication, comparative payment rate analysis, payment rate disclosure, and State analysis procedures for rate reductions and restructurings) for ensuring compliance with section 1902(a)(30)(A) of the Act, we stated our belief that annual updates to the comparative payment rate analysis and payment rate disclosure would negate at least a portion of the decrease in administrative burden from eliminating the previous AMRP process.

With careful consideration, we stated our belief that our proposal to require updates to the comparative payment rate analysis and payment rate disclosure to occur no less than every 2 years is reasonable. We noted our expectation that the proposed biennial publication requirement for the comparative payment rate analysis and payment rate disclosure after the initial publication date would be feasible for State agencies, provide a straightforward timeline for updates, limit unnecessary State burden, help ensure public payment rate transparency, and enable us to conduct required oversight. We solicited comments on the proposed timeframe for the initial publication and biennial update requirements for the comparative payment rate analysis and payment rate disclosure as proposed in § 447.203(b)(4).

Lastly, we also proposed in paragraph (b)(4) to require States to publish the comparative payment rate analysis and payment rate disclosure consistent with the publication requirements described in proposed paragraph (b)(1) for payment rate transparency data. Paragraph (b)(1) would require the website developed and maintained by the single State Agency to be accessible to the general public. We proposed States utilize the same website developed and maintained by the single State Agency to publish their Medicaid FFS payment rates and their comparative payment rate analysis and payment rate disclosure. We solicited comments on the proposed required location for States to publish their comparative payment rate analysis and payment rate disclosure proposed in § 447.203(b)(4).

In § 447.203(b)(5), we proposed a mechanism to ensure compliance with paragraphs (b)(1) through (b)(4). Specifically, we proposed that, if a State fails to comply with the payment rate transparency and comparative payment rate analysis and payment rate disclosure requirements in paragraphs (b)(1) through (b)(4) of proposed § 447.203, including requirements for the time and manner of publication, that, under section 1904 of the Act and procedures set forth in regulations at 42 CFR part 430 subparts C and D, future grant awards may be reduced by the amount of FFP we estimate is attributable to the State's administrative expenditures relative to the total expenditures for the categories of services specified in paragraph (b)(2) of proposed § 447.203 for which the State has failed to comply with applicable requirements, until such time as the State complies with the requirements. We also proposed that unless otherwise prohibited by law, FFP for deferred expenditures would be released after the State has fully complied with all applicable requirements. We explained that this proposed enforcement mechanism is similar in structure to the mechanism that applies with respect to the Medicaid DSH reporting requirements in § 447.299(e), which specifies that State failure to comply with reporting requirements will lead to future grant award reductions in the amount of FFP CMS estimates is attributable to expenditures made for payments to the DSH hospitals as to which the State has not reported properly. We proposed this long-standing and effective enforcement mechanism because we believed it is proportionate and clear, and to remain consistent with other compliance actions we take for State non-compliance with statutory and regulatory requirements. We solicited comments on the proposed method for ensuring compliance with the payment rate transparency and comparative payment rate analysis and payment rate disclosure requirements, as specified in proposed § 447.203(b)(5).

We received public comments on these proposed provisions. The following is a summary of the comments we received and our responses.

Comparative Payment Rate Analysis Comments and Responses

Comment: Among comments received on the comparative payment rate analysis, the majority of commenters generally supported the proposal to require States to develop and publish a comparative payment rate analysis of Medicaid payment rates for certain categories of services. These commenters specifically supported the proposed categories of services, comparing only base payment rates,

physician fees for evaluation and management services (Current Procedural Terminology codes 99201–99499) and vaccine administration services and counseling related to children's vaccines (Current Procedural Terminology codes 90460, 90461, and 90471–90474). This provision expired on December 31, 2014. *https://www.macpac.gov/wp-content/uploads/2015/03/An-Update-on-the-Medicaid-Primary-Care-Payment-Increase.pdf.*

breakdown of Medicaid payment rates by population (pediatric and adult), use of Medicare non-facility rates as a benchmark for comparing Medicaid rates, and number of Medicaid services as a data element in the comparative payment rate analysis. Commenters in support of the comparative payment rate analysis agreed with CMS that the analysis requirement would help to ensure necessary information, specifically Medicaid payment rates and the comparison to Medicare, is available to CMS for ensuring compliance with section 1902(a)(30)(A) of the Act and to interested parties for raising access to care concerns through public processes.

However, a couple of commenters expressed opposition to the proposed comparative payment rate analysis. Commenters in opposition stated the proposed comparative payment rate analysis requirements would be administratively burdensome on States and create challenges for States in benchmarking services to Medicare because Medicare uses a rate setting methodology that is different from each State's Medicaid program. These commenters expressed concerns about the burden associated with the comparative payment rate analysis, specifically about further burden on States that do not use the same procedure/diagnostics codes or same payment methodologies as Medicare, as well as data challenges to stratify State payment rates by population, provider type, and geographic location, and challenges of comparing community mental health center payment rates to the Medicare equivalent.

Response: We appreciate the commenters' support of the comparative payment rate analysis at § 447.203(b)(3)(i). We are finalizing the comparative payment rate analysis provisions as proposed apart from some minor revisions that ensure clarity and consistent terminology throughout § 447.203(b), as well as update the name of ''outpatient behavioral health services'' to ''outpatient mental health and substance use disorder services'' and the compliance timeframe, as discussed earlier in this section. We list and describe the specific revisions we made to the regulatory language for the comparative payment rate analysis provision at § 447.203(b)(2) through (b)(5) at the end of this section of responses to comments.

We disagree with commenters regarding burden of the comparative payment rate analysis and challenges benchmarking services to Medicare. As documented in section III. of this final rule, the FFS provisions, including the payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements (§ 447.203(b)(1) through (5)), interested parties' advisory group requirements (§ 447.203(b)(6)), and State analysis procedures for payment rate reductions or payment restructuring (§ 447.203(c)), are expected to result in a net burden reduction on States compared to the previous AMRP requirements. Additionally, as addressed in another comment response generally discussing commenters' concerns about State burden, we have described numerous flexibilities States have for compliance with this final rule. Specifically for the comparative payment rate analysis, States have flexibility to (1) utilize contractors or other third party websites to publish the payment rate transparency publication on (however, we remind States that they are still requiring to publish the hyperlink to the website where the publication is located on the State Medicaid agency's website as required in § 447.203(b)(1)(ii) of this final rule); and (2) for the requirement that States break down their payment rates by geographical location, as applicable, States have the flexibility to determine an appropriate method to accomplish the comparative payment rate analysis that aligns the geographic area covered by each payer's rate as closely as reasonably feasible. Additionally, we are providing an example list that defines the categories of services subject to the comparative payment rate analysis through the finite number of E/M CPT/HCPCS codes in the list, if it were in effect for CY 2023 and an illustrative example of a compliant comparative payment rate analysis (including to meet accessibility standards) through subregulatory guidance that we will issue prior to the effective date of this final rule.

We do not expect States to experience excessive burden or challenges in benchmarking services to Medicare because we will issue subregulatory guidance prior to the effective date of this final rule, including a hypothetical example list of the CMS-published list of E/M CPT/HCPCS codes that would be subject to the comparative payment rate analysis, if the comparative rate analysis requirements were applicable with respect to payment rates in effect for CY 2023, where all codes on the CMS-published list of E/M CPT/HCPCS codes have an existing Medicare payment rate. By ensuring there is an existing Medicare payment rate for States to compare their Medicaid payment rate to and providing States with information about where and how to find the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year for these codes to include in their analysis (that is, through Excel file downloads of the Medicare PFS Relative Value Files),[284] we do not expect States to face challenges with identifying the applicable Medicare benchmark rates.

Regarding States that do not use same procedure/diagnostics codes as Medicare, as described in the proposed rule, E/M CPT/HCPCS codes are comprised of primarily preventive services which are generally some of the most commonly billed codes in the U.S.,[285] therefore, we do not believe there will be issues with States not using the same procedure/diagnostics codes as Medicare. However, we recognize that States may amend existing CPT/HCPCS codes with additional numbers or letters for processing in their own claims system. If a State does not use the exact code included in the CMS-published list of E/M CPT/HCPCS codes, then we expect the State to review the CMS-published list of E/M CPT/HCPCS codes and identify which of their codes are most comparable for purposes of the comparative payment rate analysis. We anticipate States may need to review code descriptions as part of the process of identifying which codes on the CMS-published list of E/M CPT/HCPCS codes are comparable to the codes that States utilizes.

Regarding States that expect to experience challenges benchmarking services to Medicare because they do not use the same payment methodologies as Medicare, while Medicare and State Medicaid agencies may use different methodologies to determine the rate published on their fee schedules, the comparative payment rate analysis only requires the base Medicaid FFS fee schedule payment rates as published on the State's fee schedule and Medicare's rate as published on the PFS for a particular code to be published in the analysis. The methodology to determine the payment rate is not relevant to the comparative payment rate analysis, therefore, having different methodologies to determine the rate does not affect a States' ability to comply with the comparative payment rate analysis requirements. Under the comparative payment rate analysis requirements we are finalizing in this final rule, Medicare rates serve as a benchmark to which States will compare certain of their base Medicaid FFS fee schedule payment rates to

[284] 88 FR 27960 at 28012.

[285] 88 FR 27960 at 28009.

inform their and our assessment of whether the State's payment rates are compliant with section 1902(a)(30)(A) of the Act.

Regarding commenters' concerns about data challenges to stratify State payment rates by population, provider type, and geographic location for the comparative payment rate analysis, we acknowledge that not all States pay varied payment rates by population (pediatric and adult), provider type, and geographical location, which is why we proposed and are finalizing language noting ''if the rates vary'' and ''as applicable'' in the regulatory text. Therefore, States that do not pay varied payment rates by population (pediatric and adult), provider type, and geographical location will not need to list varied rates based on factors that the State does not use in its rates. For example, a State that pays different rates by population (pediatric and adult) but does not vary the rates by provider type or geographic location will list separate payment rates for services furnished to a pediatric and to an adult beneficiary, but will not list separate rates based on provider type or geographical location. If the State pays a single Statewide payment rate for a single service, the State will only include the State's single Statewide payment rate in the comparative payment rate analysis. For States that do pay varied payment rates by population (pediatric and adult), provider type, and geographical location, in accordance with § 430.10 and given that States are the stewards of setting and maintaining Medicaid FFS payment rates, States are required to maintain sufficient records about current payment rates, including when payment rates vary, to enable them to meet the comparative payment rate analysis requirements of this final rule.

Regarding the commenter's concerns about comparing community mental health center payments to Medicare rates, we would like to clarify that mental health services provided in a facility-based setting, such as FQHC, RHC, CCBHC, or clinics (as defined in § 440.90) are excluded from the comparative payment rate analysis due to the challenges we expect States to face in disaggregating their rates (including PPS rates paid to FQHCs or RHCs which are often paid encounter, per visit, or provider-specific rates and all-inclusive per-visit rates, encounter rates, per visit rates, or provider-specific rates paid to clinics (as defined in § 440.90)) for comparison to Medicare, as discussed in the proposed rule.[286]

[286] 88 FR 27960 at 28011–28012.

Comment: We received a comment requesting clarification about the entity responsible for publishing the comparative payment rate analysis.

Response: The State agency is required to publish a hyperlink where the comparative, as well as the payment rate disclosure and payment rate transparency publication, on the State Medicaid agency's website. As finalized in this rule, § 447.203(b)(3) requires that States' comparative payment rate analysis, as well as payment rate disclosure, must be published consistent with the publication requirements in paragraphs (b)(1) and (b)(1)(ii). Paragraph (b)(1) requires the State ''. . . publish all Medicaid fee-for-service fee schedule payment rates on a website that is accessible to the general public.'' As discussed in an earlier response to comments in this section, this language has been revised from what we originally proposed to permit States the flexibility to continue to utilize contractors and other third parties for developing and publishing their fee schedules on behalf of the State. We continue to require that ''[t]he website where the State agency publishes its Medicaid fee-for-service payment rates must be easily reached from a hyperlink on the State Medicaid agency's website.'' in § 447.203(b)(1)(ii).

Comment: One commenter requested clarification regarding how the comparative payment rate analysis will be organized, particularly if the FFS rates included in the analysis would be organized by CPT code.

Response: As finalized by this rule, § 447.203(b)(3)(i) requires that ''State[s] must conduct the comparative payment rate analysis at the Current Procedural Terminology (CPT) or Healthcare Common Procedure Coding System (HCPCS) code level, as applicable, using the most current set of codes published by CMS . . .'' As such, the publication is required to be organized at the CPT level. However, to the extent there are differences in a State's rates based on population (pediatric and adult), provider type, and geographical location, the publication may need to have multiple CPT-level rate comparisons to account for each differing rate.

Comment: One commenter raised concerns regarding the accessibility of the comparative payment rate analysis due to the extensive amount of data, which may be overwhelming and difficult for individuals to understand, for example individuals with disabilities and those who use screen readers. The commenter recommended that CMS require the analysis and disclosure be contained in a designated website, rather than linked from the State Medicaid agency's website to avoid creating potential confusion. They further recommended CMS require States include plain language descriptions of the published payment rate data to ensure the analysis is accessible for individuals with disabilities.

Response: We understand the concern that the amount of data in the analysis could prove overwhelming to some individuals. However, we believe it is important for these data to be easily reached for those interested parties that are trying to locate it. Transparency, particularly the requirement that States must publicly publish their payment rates, helps to ensure that interested parties have basic information available to them to understand Medicaid payment levels and the associated effects of payment rates on access to care so that they may raise concerns to State Medicaid agencies via the various forms of public processes available to interested parties. Therefore, as finalized in this rule, § 447.203(b)(1) requires the State ''. . . publish all Medicaid fee-for-service fee schedule payment rates on a website that is accessible to the general public.'' As discussed in an earlier response to comments in this section, this language has been revised from what we originally proposed to permit States the flexibility to continue to utilize contractors and other third parties for developing and publishing their fee schedules on behalf of the State. We continue to require at § 447.203(b)(1)(ii) that the website where the State agency publishes its Medicaid FFS payment rates must be easily reached from a hyperlink on the State Medicaid agency's website.

As described in the proposed rule, longstanding legal requirements to provide effective communication with individuals with disabilities and the obligation to take reasonable steps to provide meaningful access to individuals with limited English proficiency also apply to the State's website containing Medicaid FFS payment rate information. We invite States to reach out to CMS for technical guidance regarding compliance with the comparative payment rate analysis. We also encourage States to review the subregulatory guidance, which includes an example of what a compliant comparative payment rate analysis might look like, that will be issued prior to the effective date of this final rule.

Comment: A couple of commenters suggested that the proposed breakdown of the comparative payment rate analysis would result in an

overwhelming volume of information for the average individual viewing the data. One commenter suggested requiring States to report the aggregate fee schedule rate, instead of breaking down a State's payment rates by categories of services in addition to population, provider type and geographic location to ensure data is accessible and meaningful to someone viewing the data.

Response: We understand the commenters' concerns about the potential for the comparative payment rate analysis to contain a large amount of information. However, the level of detail we are requiring will afford States, CMS, and the public the best opportunity to assess individual rates and how they might impact access to certain services. Our hope is that the requirements and guidance around the elements to include, and the consistency this will create across States, will make the data readily navigable and understandable, even though a high volume of information may need to be presented to account for the array of services subject to the comparative payment rate analysis requirement and the potential complexity of the State's payment rate structure.

We assume the commenter who suggested an aggregated fee schedule rate meant we should only require States publish a single Statewide payment rate or a calculated Statewide average Medicaid payment rate if they do have varying payment rates for a service by population (pediatric and adult), provider type, and/or geographic location. We are not adopting this suggestion because only requiring an aggregated fee schedule rate would lose the opportunity for States, CMS, and the public to contextualize payment rates and how they might be impacting access for different populations in different geographical areas, or for beneficiaries seeking services from particular provider types. However, we note that States have the flexibility to add an aggregated fee schedule rate in addition to breaking down a State's payment rates for a given service by population (pediatric and adult), provider type, and geographic location, as applicable, with their comparative payment rate analysis if they so choose. If a State utilizes this flexibility to include this or optional additional information, then required data elements in § 447.203(b)(2) through (3) must be listed first on the State's website to ensure the analysis presents payment rate information in a clear and accurate way, particularly for States that do pay varied rates based on population (pediatric and adult), provider type, and/or geographic location and opted to include an aggregated fee schedule rate (that is, a calculated Statewide average Medicaid payment rate).

The previous AMRP process established a transparent data-driven process to measure access to care in States; however, during the implementation period, we found that States produced varied AMRPs that were difficult to interpret or to use in assessing compliance with section 1902(a)(30)(A) of the Act. With this final rule, we are focusing on payment rate transparency and streamlining information States are required to publish. Therefore, we expect the comparative payment rate analysis to be easier to understand and more consistent across States than the previous AMRPs.

Comment: A few commenters suggested narrowing the scope of the comparative payment rate analysis to a representative subset of services or commonly used services with a Medicare equivalent. On the other hand, one commenter stated that limiting the scope of the comparative payment rate analysis to E/M codes would not be adequate to meaningfully assess access to care for all services under the proposed categories of services.

Response: We appreciate the commenters' suggestions on the scope of the comparative payment rate analysis. Prior to the effective date of this final rule, we will issue subregulatory guidance, including a hypothetical example list of the E/M CPT/HCPCS codes that would be subject to the comparative payment rate analysis, if the comparative rate analysis requirements were applicable with respect to payment rates in effect for CY 2023. The initial CMS-published list of the E/M CPT/HCPCS codes to be published no later than July 1, 2025, will contain a finite number of E/M CPT/HCPCS codes subject to the initial comparative payment rate analysis. While the commenters did not specify their recommendation for what a representative subset of services would include or how they would identify commonly provided services with a Medicare equivalent, we believe the criteria we used to select the E/M CPT/HCPCS codes for the comparative payment rate analysis [287] fulfills these commenters' suggestion for a representative set of commonly provided services with Medicare payment rates for comparison. We believe the categories of services included in the rule (primary care services, obstetrical and gynecological services, and outpatient mental health and substance use disorder services) are a representative subset of Medicaid services available to beneficiaries that are of great importance to overall beneficiary health, as described in the proposed rule.[288] Additionally, E/M CPT/HCPCS codes are some of the most commonly billed codes and one of the criteria in the CMS-published list of the E/M CPT/HCPCS codes is that the Medicare PFS has a payment amount on the fee schedule, therefore, we believe our list of codes includes commonly used services with a Medicare equivalent payment rate.

Also as previously discussed in detail in an earlier response to comments in this section, for purposes of the payment rate transparency provision in § 447.203(b)(1), Medicaid FFS fee schedule payment rates are FFS payment amounts made to a provider, and known in advance of a provider delivering a service to a beneficiary by reference to a fee schedule. For consistency, we are using the same description of Medicaid FFS fee schedule payment rates to describe the payment rates that need to be included in the comparative payment rate analysis in paragraph (b)(3)(ii)(B) of this section which would also consider bundled payment rates to be Medicaid FFS fee schedule payment rates for the purposes of the comparative payment rate analysis. We would also like to clarify that while prospective payment system rates for services provided in inpatient hospitals, outpatient hospitals, inpatient psychiatric facilities, inpatient rehabilitation facilities, long-term care hospitals, and nursing facilities are subject to the payment rate transparency publication, these rates are effectively excluded from the comparative payment rate analysis because of the criteria we discussed in the proposed rule that we used to identify which CPT/HCPCS codes would be subject to the analysis (that is, the code is classified as an E/M CPT/HCPCS code by the AMA CPT Editorial Panel and the code has an A (Active), N (Non-Covered), R (Restricted), or T (Injections) code status on the Medicare PFS with a Medicare established RVU and payment amount for the same time period of the comparative payment rate analysis).[289] Prospective payment system rates are generally used to pay for institutional services (for example, hospitals and nursing facilities) where E/M services are not provided. Prospective payment system rates are also not listed on the Medicare PFS because they do not pay

[287] 88 FR 27960 at 28008.

[288] 88 FR 27960 at 28003.

[289] 88 FR 27960 at 28008.

for a single code, and therefore, they would not have a code or a payment rate on the PFS. Also, as discussed in an earlier response to comments, PPS rates for FQHCs and RHCs are not subject to the payment rate transparency publication requirement under § 447.203(b)(1). Rather than further broadening the services subject to the comparative payment rate analysis requirement, we want our initial focus of this rulemaking to be on establishing the new payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements, providing States with support during the compliance period, and ensuring these data are available to beneficiaries, providers, CMS, and other interested parties for the purposes of assessing access to care issues.

We disagree with the commenter that our scope of services subject to the comparative payment rate analysis will not provide a meaningful assessment of access. To reemphasize, we believe this list of codes, including primary care services, obstetrical and gynecological services, and outpatient mental health and substance use disorder services, are critical medical services and of great importance to overall beneficiary health, as described in the proposed rule.[290] We acknowledge that the code list is limited to services delivered in an ambulatory setting, such as a physician's office, and services that are paid a Medicaid FFS fee schedule rate within the meaning of this final rule. Therefore, the code list for the comparative payment rate analysis excludes services delivered in a facility setting and/or services States pay for using a prospective payment system, for example hospitals, nursing facilities, FQHCs, and RHCs; however, we believe these limitations are appropriate to balance administrative burden on States and our enforcement responsibilities. As previously discussed, we believe that asking States to disaggregate their prospective payment system rates for facility-based services to compare to Medicare's prospective payment system rates often would be challenging for States. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

Comment: A couple of commenters suggested aligning the proposed categories of services with Medicaid service categories as defined in statute and regulation to minimize confusion and ambiguity about the services subject to the comparative payment rate analysis. Another commenter suggested, rather than requiring a specified set of services, that CMS require the comparative payment rate analysis based on the percentage of services paid for by the State (that is, each State would include the services they pay the most for in their Medicaid program).

Response: We understand commenters' concerns about possible confusion of the categories of services subject to the comparative payment rate analysis that do not align directly with a Medicaid services category. Prior to the effective date of this final rule, we will issue subregulatory guidance including a hypothetical example list of the E/M CPT/HCPCS codes that would be subject to the comparative payment rate analysis, if the comparative rate analysis requirements were applicable with respect to payment rates in effect for CY 2023. This example list defines the categories of services subject to the comparative payment rate analysis through the finite number of E/M CPT/HCPCS codes in the list, if it were in effect for CY 2023. The initial CMS-published list of the E/M CPT/HCPCS codes actually subject to the comparative payment rate analysis will be published no later than July 1, 2025. We believe this list of codes will eliminate any confusion and ambiguity commenters expressed in response to the proposed rule because it will contain the actual E/M CPT/HCPCS codes subject to the initial comparative payment rate analysis. We will only be including codes that satisfy all the defined criteria set forth in this rule. This list will be updated every other year after 2025, that is, July 1, 2027, 2029, so on and so forth. We expect States to review the CMS-published list of the E/M CPT/HCPCS codes to identify the base Medicaid FFS fee schedule payment rate as specified in § 447.203(b)(3)(i)(B) that is required to be included in the comparative payment rate analysis.

We are not adopting the commenter's suggestion to require the comparative payment rate analysis be based on the percentage of services paid for by the State (that is, each State would include the services they pay the most for in their Medicaid program), rather than requiring a specified set of services. In the comparative payment rate analysis, we are striving for consistency and comparability between States and Medicare, therefore, we have decided to require States use the same categories of services and CMS published list of E/M CPT/HCPCS codes for the analysis.

Comment: A couple of commenters suggested alternative terms for the categories of services in the proposed rule. One commenter recommended using the terms ''substance use disorder and mental health services'' in place of ''behavioral health services'' and requiring the comparative payment rate analysis include separate analyses for each condition. Another commenter suggested using gender-inclusive language such as ''reproductive and sexual health services'' in place of ''obstetrical and gynecological services'' as a category of services in the comparative payment rate analysis.

Response: We appreciate the commenters' suggestions. We understand and appreciate the commenter's request for further granularity in the comparative payment rate analysis by specifying ''substance use disorder and mental health services'' in place of ''behavioral health services.'' We have decided to revise the outpatient behavioral health services category of service in § 447.203(b)(2)(iii) and finalize it as ''Outpatient mental health and substance use disorder services.'' While this revision does not change the criteria used to identify the discrete codes included in the BETOS E/M family grouping and families and subfamilies for the CMS published list of E/M CPT/HCPCS subject to the comparative payment rate analysis, this revision does ensure this final rule is consistent with the services in the Managed Care final rule (as published elsewhere in this **Federal Register**) for consistency across Medicaid FFS and managed care delivery systems and reflects a more granular level of service description as suggested by the commenter.

We agree with the importance of gender-inclusive language, where appropriate. However, current medical and procedural terminology generally still uses the terminology ''obstetrical and gynecological services.'' We determined consistent language would provide interested parties the most clarity. Additionally, we selected obstetrical and gynecological services as a category of service due Medicaid's key role in providing and paying for maternity-related services for pregnant women during a maternal health crisis in the US.[291] We acknowledge that using the term ''reproductive and sexual health services'' would be inclusive of more services, that is, male reproductive services in addition to pregnancy and female reproductive services. However, if we were to utilize the term ''reproductive and sexual health

[290] 88 FR 27960 at 28003.

[291] 88 FR 27960 at 28004.

services'' then this would expand the number of services that would be subject to comparative rate analysis and increase burden on States complying with the analysis. We want our initial focus to be on establishing the new payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements, providing States with support during the compliance period, and ensuring these data are available to beneficiaries, providers, CMS, and other interested parties for the purposes of assessing access to care issues. Therefore, we are finalizing ''obstetrical and gynecological services'' as a category of service in § 447.203(b)(2)(ii) subject to the comparative payment rate analysis. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

Comment: A couple of commenters raised concerns about inpatient behavioral health services not being a category of service in the comparative payment rate analysis. One of those commenters disagreed with CMS' justification that including inpatient behavioral health services would be duplicative of the information captured through UPL demonstrations because UPL demonstrations do not include the same level of analysis as proposed in the comparative payment rate analysis. In particular, the commenter stated that UPL demonstrations do not ensure hospital base payments are adequate, do not track if Medicaid payments align with Medicare payment rate increases, and the new supplemental payment reporting requirements established by the CAA, 2021 focus on supplemental payments, rather than base payments. Additionally, one commenter recommended that, if inpatient behavioral health services are not subject to the comparative payment rate analysis, CMS take alternative steps to assess access to inpatient behavioral health services, such as monitoring care transitions between inpatient and outpatient facilities during temporary or permanent transitions to inpatient care.

Response: We understand the commenters' concerns about excluding inpatient behavioral health services from the categories of services subject to the comparative payment rate analysis. We acknowledge the importance of inpatient behavioral health services in the spectrum of behavioral health services for which coverage is available under the Medicaid program. As discussed in the proposed rule, we recognize that Medicaid plays a crucial role in mental health care access as the single largest payer of these services with a growing role in payment for substance use disorder services, in part due to Medicaid expansion and various efforts by Congress to improve access to mental health and substance use disorder services.[292] In this final rule, we are revising the outpatient behavioral health services category of service in § 447.203(b)(2)(iii) and finalizing it as ''Outpatient mental health and substance use disorder services.'' While the scope of the comparative payment rate analysis requirement is limited to outpatient mental health and substance use disorder services, to the extent States pay for inpatient behavioral health services (including inpatient services furnished in psychiatric residential treatment facilities, institutions for mental diseases, and psychiatric hospitals) with a Medicaid FFS fee schedule payment rate that falls within the meaning of this rule, as discussed in an earlier response to comments in this section, then those payment rates would be subject to the payment rate transparency publication. In addition to subjecting certain inpatient behavioral health payment rates to the payment rate transparency publication requirement, we already collect and review Medicaid and Medicare payment rate data for inpatient behavioral health services through annual UPL demonstrations and supplemental payment reporting requirements under section 1903(bb) of the Act. We recognize UPL data are not an exact duplicate of the data required under the policies we are finalizing in this rule. With this final rule, our focus is on improving our oversight of Medicaid payment rates to identify where rates may be negatively impacting access to care while minimizing burden imposed on States, which requires us to prioritize areas of focus. Although the UPL and the supplemental payment reporting requirements under section 1903(bb) of the Act represent a different array of data, they still afford us an opportunity for payment oversight. Therefore, we chose to focus on services and rates not covered by those requirements.

We disagree with the commenter that UPL demonstrations do not ensure hospital base payments are adequate and do not track if Medicaid payments align with Medicare payment rate increases. We began requiring annual UPL demonstrations in 2013 to ensure CMS and States have a better understanding of the variables surrounding rate levels, supplemental payments and total providers participating in the Medicare and Medicaid programs and the funding supporting each of the payments subject to UPL demonstrations.[293] UPL demonstrations are a comparison of total Medicaid payments for a particularly benefit category to a reasonable estimate of what Medicare would have paid. Therefore, UPL demonstrations fundamentally track if Medicaid payments align with Medicare payment rates at an aggregate level and provide CMS with important information for assessing if payment rates comply with economy and efficiency provisions at section 1902(a)(30)(A) of the Act, specifically how total Medicaid payments compare to what Medicare would have paid for similar services where Medicare acts as a payment limit, or ceiling, for economic and efficient. We do acknowledge that the new supplemental payment reporting requirements under section 1903(bb) of the Act focus on supplemental payments, rather than base payments; however, base payment data continues to be collected through UPL demonstrations, providing us, in the aggregate, with detailed information about both base and supplemental payments for hospitals.

Additionally, the comparative payment rate analysis utilizes Medicare rates as a benchmark to which States will compare their Medicaid FFS fee schedule payment rate to inform their and our assessment of whether the State's payment rates are compliant with section 1902(a)(30)(A) of the Act. We are not requiring States to meet a threshold percentage of Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year or align with Medicare payment rate increases.

We acknowledge the commenter's request for CMS to take alternative steps to assess access to inpatient behavioral health services, such as monitoring care transitions between inpatient and outpatient facilities during temporary or permanent transitions to inpatient care. We want our initial focus to be on establishing the new payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements, providing States with support during the compliance period, and ensuring these data are available to beneficiaries, providers, CMS, and other interested parties for the purposes of

[292] 88 FR 27960 at 28004.

[293] *https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/SMD-13-003-02.pdf.*

assessing access to care issues. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate. We are committed to helping States and their providers undertake efforts to improve transitions and improve medical and LTSS coordination by providing technical assistance, resources, and facilitating the exchange of information about promising practices of high quality, high impact, and effective care transition models and processes and we encourage States to review existing resources about improving care transitions on *Medicaid.gov*.[294]

Comment: Some commenters submitted comments about behavioral health services as a category of service in the comparative payment rate analysis. A few commenters suggested particular or additional categories of services for behavioral health services, including inpatient behavioral health services, substance use disorder services, mental health services, intensive outpatient services, partial hospitalization care, opioid treatment programs, services delivered by providers who do not bill E/M codes, and specialist services provided to individuals with chronic diseases and disabilities. These commenters also suggested including codes outside of the E/M category, such as ''H'' HCPCS codes that psychologists, social workers, and marriage and family therapists often bill to ensure a comprehensive analysis of behavioral health services in the comparative payment rate analysis.

Response: We appreciate commenters' suggestion for the comparative payment rate analysis. As stated previously, we are excluding inpatient behavioral health services because existing UPL and supplemental payment reporting requirements under section 1903(bb) of the Act provide for payment oversight for inpatient behavioral health services, and with the provisions of this final rule, we chose to focus on services and payment rates not covered by those requirements. Additionally, we are not considering behavioral health services, now called outpatient mental health and substance use disorder services in this final rule, outside the E/M category as suggested by commenters because E/M CPT/HCPCS codes are some of the most commonly billed codes and including them in the comparative payment rate analysis would allow us to uniformly compare Medicaid payment rates for these codes to Medicare PFS rates. If we were to expand outside of E/M category of codes, then it is possible Medicare may not have rates established on the Medicare PFS for States to compare their base Medicaid FFS fee schedule payment rates too in the comparative payment rate analysis. Based on the criteria used to narrow the scope of the comparative payment rate analysis, we are requiting that the code has an A (Active), N (Non-Covered), R (Restricted), or T (Injections) code status on the Medicare PFS with a Medicare established RVU and payment amount for the same time period of the comparative payment rate analysis as well as the code must be included in the BETOS Classification System which only includes Psychotherapy—Group and Psychotherapy—Nongroup (family) under the E/M (category), Behavioral Health Services (subcategory). Psychotherapy is a type of treatment, or service, that can help individuals experiencing a wide array of mental health conditions and emotional challenges, including substance use disorder and mental health.[295] While the CMS published list of E/M CPT/HCPCS codes will not specifically include intensive outpatient services, partial hospitalization care, opioid treatment programs, services delivered by providers who do not bill E/M codes, specialist services provided to individuals with chronic diseases and disabilities, or H codes for Alcohol and Drug Abuse Treatment [296] as suggested by commenters, we believe the services included on the CMS published list of E/M CPT/HCPCS codes are critical medical services and of great importance to overall beneficiary health, as described in the proposed rule.[297] As previously discussed, the CMS published list of E/M CPT/HCPCS codes narrows the scope of the comparative payment rate analysis to selected services delivered in an ambulatory setting, such as a physician's office, and services that are paid a Medicaid FFS fee schedule rate within the meaning of this final rule to balance administrative burden on States and our enforcement responsibilities. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

Comment: A couple of commenters expressed concerns regarding the exclusion of facility-based services from the comparative payment rate analysis. These commenters requested CMS consider additional provisions for services that are delivered by facility-based providers, which are often paid via an encounter rate, reimbursement of actual cost, or cost-based payment methodologies. One commenter suggested requiring States that pay for behavioral health services using cost-based payment methodologies publish the provider's payment rate compared to provider's actual incurred cost because States are already collecting this information from providers as it is necessary for the State's cost-based payment methodology.

Response: We appreciate the commenter's suggestions. We assume by encounter rate that the commenters were referring more broadly to PPS rates paid to both institutional facilities, such as hospitals and nursing facilities which are often paid encounter or per diem rates, as well as non-institutional facilities, such as FQHCs or RHCs which are often paid encounter, per visit, or provider-specific rates, as discussed in detail in an earlier response to comments in this section. We did not propose and are not finalizing in this rule the requirement that States disaggregate each of their PPS rates (including encounter, per diem, per visit, and provider-specific rates) and services covered in each rate to compare to Medicare's prospective payment system rates when Medicare pays a prospective payment system rate for the same service. Likewise, we also did not propose and are not finalizing in this rule the requirement that States publish cost reports or provider's unique cost information when the State's methodology is reimbursement of actual cost or cost-based methodologies and services covered in the reimbursement methodology to compare to actual incurred cost. Therefore, any policies that require States to disaggregate each of their PPS rates and services covered in each PPS rate or publish cost reports or provider's unique cost information in order to compare to Medicare's prospective payment system rates or the commenter's suggestion to compare to actual incurred cost, would be challenging for States because we would require a different methodology, policies, and oversight relative to the comparative payment rate analysis, as

[294] *https://www.medicaid.gov/medicaid/quality-of-care/quality-improvement-initiatives/improving-care-transitions/index.html.*

[295] *https://www.psychiatry.org/patients-families/psychotherapy.*

[296] *https://www.aapc.com/codes/hcpcs-codes-range/.*

[297] 88 FR 27960 at 28003.

discussed in the proposed rule.[298] As we are seeking an appropriate balance between administrative burden and our oversight responsibilities with regard to section 1902(a)(30)(A) of the Act, requiring States to publish cost-based Medicaid payments as well as actual, incurred cost for each unique provider would impose more burden on States that was not accounted for in the proposed rule. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

Comment: Several commenters recommended changes to the analysis, such as additional categories of services or revisions to the proposed categories of services subject to the comparative payment rate analysis. While some commenters generally recommended expanding the categories of services, including all mandatory Medicaid services, other commenters recommended specific additional categories of services, provider types, or costs such as supplies. Those recommendations included: physician specialist services and specialty/specialist care (for example, cancer care); subspecialty services (for example, pediatric ophthalmology); services provided by NPPs; services delivered in clinics and other settings; prosthetic supplies (for example, ostomy and urological supplies), home health services (for example, homemaker and home health aide), sexual and reproductive health services (for example, midwives, doulas, providers who primarily serve the sexual and reproductive health needs of people assigned male at birth, etc.); dental and oral health services (including pediatric dentistry), ground emergency medical transportation services; cell and gene therapies; hospital and emergency department services; vaccine administration services; and habilitation and rehabilitation services provided by physical therapists. Commenters also suggested processes to add services when certain criteria are met, for example, adding any service to the comparative payment rate analysis when access concerns are raised or identified.

Response: We thank the commenters for the many recommendations for additional or alternate categories of service. In order to balance Federal and State administrative burden with our shared obligation to ensure compliance with section 1902(a)(30)(A) of the Act (and our obligation to oversee State compliance with the same), we are finalizing this rule with a narrow scope of categories of services subject to the comparative payment rate analysis and not including additional categories of services suggested by commenters. As discussed in the proposed rule, we chose primary care services, obstetrical and gynecological services, and outpatient behavioral health services (which we are finalizing as outpatient mental health and substance use disorder services) because they are critical medical services and of great importance to overall beneficiary health.[299] Primary care providers often deliver preventative health care services, write referrals or recommendations to schedule an appointment with physician specialists, and write orders for lab and x-ray services and prescriptions that a beneficiary would not be able to access without the primary care provider, therefore, access to a primary care provider is often a gateway to accessing other care. Obstetrical and gynecological providers and behavioral health providers also deliver preventive services respective to their field, such as well-woman visits and screenings for behavioral health conditions (such as alcohol disorders, anxiety, and eating disorders), respectively. As described in the proposed rule, the U.S. is simultaneously experiencing a maternal health crisis and mental health crisis, putting providers of obstetrical and gynecological and mental health and substance use disorder services at the forefront.[300]

We clarify that we did propose to include in the comparative payment rate analysis a couple of the services commenters suggested: care delivered by NPPs, and sexual and reproductive health services (to the extent these are included within the category of obstetrical and gynecological services). If a State's base Medicaid FFS fee schedule payment rate varies by provider type for a particular code subject to the comparative payment rate analysis, then the payment rates must be separately identified by provider type, including, but not limited to, physician, nurse practitioner, and physician assistant, as specified in § 447.203(b)(3)(i)(B). While we are not including the broader category of sexual and reproductive health services, obstetrical and gynecological services are one of the categories of services subject to the analysis. Lastly, homemaker and home health aide services are subject to the payment rate disclosure, but not the comparative payment rate analysis because of a lack of comparable Medicare payment rate.

Finally, we are not including the following services suggested by commenters in the comparative payment rate analysis: services delivered in clinics and other settings (as the commenter did not specify, we assume the commenter meant settings similar to clinics (as defined in § 440.90)), sexual and reproductive health services (for example, midwives, doulas, providers who primarily serve the sexual and reproductive health needs of people assigned male at birth, etc.) to the extent these are not included within the category of obstetrical and gynecological services, hospital and emergency department services, and medical supplies. Our current access strategy focuses broadly on Medicaid FFS fee schedule payment rates for outpatient practitioner services. As described in the proposed rule, encounter rates (generally based on total facility-specific costs divided by the number of encounters to calculate a per visit or per encounter rate that is paid to the facility for all services received during an encounter, regardless of which specific services are provided during a particular encounter) are typically paid to facilities, such as hospitals, FQHCs, RHCs, and clinics, and proposing States demonstrate the economy and efficiency of their encounter rates would be an entirely different exercise to the comparative payment rate analysis.[301] Therefore, we are not including services delivered in clinics and other settings (as the commenter did not specify, we assume the commenter meant settings similar to clinics (as defined in § 440.90)) or hospital and emergency department services in the comparative payment rate analysis. As previously stated, obstetrical and gynecological services are one of the categories of services subject to the analysis, but we are not including the broader category of sexual and reproductive health services because our focus in this rule is ensuring access to care to services that can most directly respond to the maternal health crisis occurring the U.S. As Medicaid plays a key role in providing and paying for maternity-related services for pregnant women, obstetrical and gynecological services generally represent the services received before, during, and after pregnancy.[302]

[298] 88 FR 27960 at 28012.

[299] 88 FR 27960 at 28003.

[300] 88 FR 27960 at 28004.

[301] 88 FR 27960 at 28012.

[302] 88 FR 27960 at 28004.

We note that one of the criteria used to narrow the CMS published list of E/M CPT/HCPCS codes requires that the code is included on the Berenson-Eggers Type of Service (BETOS) code list effective for the same time period as the comparative payment rate analysis and falls into the E/M family grouping and families and subfamilies for obstetrics and gynecological services; this includes prostate cancer screenings (G0102). Additionally, our current access strategy focuses on Medicaid FFS fee schedule payment rates for the provision of outpatient practitioner services, rather than medical supplies.

We are also not including the suggestion to create processes to add services to the comparative payment rate analysis when certain criteria are met, for example, adding any service to the comparative payment rate analysis when access concerns are raised or identified, because these situations will generally trigger the processes in § 447.203(c) which include similar requirements to the comparative payment rate analysis (that is, requiring State publish or submit information to CMS about Medicaid payment rates, number of Medicaid beneficiaries receiving services, and number of Medicaid services furnished/paid claims). Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

Comment: A few commenters submitted specific CPT/HCPCS codes and services for CMS' consideration when developing the CMS-published list of E/M CPT/HCPCS codes subject to the comparative payment rate analysis. These codes and services included specific obstetric codes including surgical procedures billed by providers of obstetric-gynecological services, reproductive care codes, pediatric ophthalmology codes including surgical procedures and clinical evaluations, vaccine administration, and other E/M codes. We also received requests to require analysis of the most frequently billed surgical codes for obstetrical-gynecological services, as well as behavioral health services that do not have E/M codes or a Medicare analog.

Response: We appreciate the commenters' suggestions. Prior to the effective date of this final rule, we will issue subregulatory guidance including a hypothetical example list of the E/M CPT/HCPCS codes that would be subject to the comparative payment rate analysis, if the comparative rate analysis requirements were applicable with respect to payment rates in effect for CY 2023. This example list defines the categories of services subject to the comparative payment rate analysis through the finite number of E/M CPT/HCPCS codes in the list, if it were in effect for CY 2023. Several of the commenter's suggested codes are included in the example list; however, this list is subject to change when the first CMS-published list of the E/M CPT/HCPCS codes subject to the comparative payment rate analysis for CY 2025 is published no later than July 1, 2025. Of the specific codes suggested by commenters, we can confirm that the following codes would be included in the CMS published list of E/M CPT/HCPCS codes subject to the analysis, if it were in effect for CY 2023: CPT 59400–59612, 58300–58301, 59120–59160, 59812–59857, 99401–99404, 90832–90853, 90791–90792, 96158, and 96165. Because of the criteria outlined in the proposed rule intended to narrow the scope of codes subject to the comparative payment rate analysis, CPT 59852 and 59857, peer support services, psychosocial rehab, and assertive community treatment, as well as vaccine administration codes are excluded from the comparative payment rate analysis due to their classification outside of the BETOS Classification System as E/M codes that are primary care, obstetrical and gynecological services, or outpatient mental health and substance use disorder services. Additionally, pediatric ophthalmology surgical procedures and the top 10 surgical codes billed by obstetrician-gynecologists to the Medicaid program are excluded from the analysis because one of the criteria used to narrow the scope of the comparative payment rate analysis was that for a code to be included on the CMS published list of E/M CPT/HCPCS codes, the code has to be included on the Berenson-Eggers Type of Service (BETOS) code list effective for the same time period as the comparative payment rate analysis and falls into the E/M family grouping and families and subfamilies for primary care services, obstetrics and gynecological services, and outpatient behavioral services (now called outpatient mental health and substance use disorder services in this final rule). E/M CPT/HCPCS codes are some of the most commonly billed codes and including them in the comparative payment rate analysis would allow us to uniformly compare Medicaid payment rates for these codes to Medicare PFS rates. Therefore, we narrowed the scope of codes to just E/M codes and surgical codes fall outside of this scope. As described in the proposed rule, the following criteria were used to identify the E/M CPT/HCPCS codes to be included in the comparative payment rate analysis: the code is effective for the same time period of the comparative payment rate analysis; the code is classified as an E/M CPT/HCPCS code by the AMA CPT Editorial Panel; the code is included on the Berenson-Eggers Type of Service (BETOS) code list effective for the same time period as the comparative payment rate analysis and falls into the E/M family grouping and families and subfamilies for primary care services, obstetrics and gynecological services, and outpatient behavioral services (now called outpatient mental health and substance use disorder services in this final rule); and the code has an A (Active), N (Non-Covered), R (Restricted), or T (Injections) code status on the Medicare PFS with a Medicare established RVU and payment amount for the same time period of the comparative payment rate analysis. As discussed in an earlier response to comments in this section, the revision from outpatient behavioral services to outpatient mental health and substance use disorder services does not change the criteria used to identify the discrete codes included in the BETOS E/M family grouping and families and subfamilies for the CMS published list of E/M CPT/HCPCS subject to the comparative payment rate analysis. While the payment rate transparency publication does not require a comparison to the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year, it does require transparency of Medicaid payment rates by requiring States publicly publish all Medicaid FFS fee schedule payment rates, which will often include a number of the services requested by commenters to be subject to the comparative payment rate analysis. Our primary goal with the payment rate transparency publication is ensuring Medicaid payment rates are publicly available in such a way that a member of the public can readily determine the amount that Medicaid would pay for a given service. Transparency helps to ensure that interested parties have basic information available to them to understand Medicaid payment levels and the associated effects of payment rates on access to care so that they may raise concerns to State Medicaid agencies via the various forms of public process available to interested parties. Given that our work to better ensure access in the Medicaid program is

ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

Comment: A few commenters suggested additional data elements and analyses for the comparative payment rate analysis. A couple of commenters suggested data elements specifically for comparing FQHC and non-FQHC settings: number of primary care claims provided in FQHC and non-FQHC settings, number of patients served in FQHC and non-FQHC settings, total spending in FQHC and non-FQHC settings. Commenters also suggested data elements specifically for nursing facility payments, such as comparing payments to total cost of care, examining the relationship between payments and quality of care and health disparities in nursing facilities, and trend data on medical inflation and practice costs.

Response: We appreciate commenters' suggestions for the comparative payment rate analysis. As described in the proposed rule, we excluded encounter rates often paid for facility-based services, including FQHC and nursing facility services, from the comparative payment rate analysis due to the challenges we expect States to face in disaggregating encounter rates for comparison to Medicare. While we are not adopting these suggestions, we note that States have the flexibility to add the elements described to their comparative payment rate analysis if they so choose. We would encourage any State choosing to disclose additional comparative payment rate analysis for facility-based services also to publish detailed information about the State's methodology for disaggregating its payment rates, as applicable, and identifying analogous Medicare payment rates for comparison.

Comment: We received a few comments in response to our consideration of requiring States to identify the number of unique Medicaid-paid claims and the number of unique Medicaid-enrolled beneficiaries who received a service within a calendar year for each of the services for which the Medicaid base payment rate is published pursuant to paragraph (b)(3)(i)(B). We received one comment that opposed requiring the unique number of claims and beneficiaries while a few commenters encouraged CMS to require this data element to improve the collection and quality of data on Medicaid service utilization.

Response: We appreciate the commenters' feedback. As described in the proposed rule, we considered but did not propose requiring States to identify the number of unique Medicaid-paid claims and the number of unique Medicaid-enrolled beneficiaries who received a service within a calendar year.[303] Upon further review, we determined the request regarding unique beneficiaries was inaccurately framed, as a beneficiary would not duplicate. Nevertheless, we decided not to require States to identify the number of Medicaid-paid claims (bold added to highlight the difference between data element we considered and the data element we are finalizing in this rule). Instead, we are finalizing the comparative payment rate analysis to require States to include the number of Medicaid-paid claims (which may duplicate codes) and the number of Medicaid-enrolled beneficiaries who received a service within a calendar year for each of the services for which the base Medicaid FFS fee schedule payment rate is published pursuant to paragraph (b)(3)(i)(B) of this section, as proposed. Although we do see value in obtaining unique, or deduplicated, claims counts, we did not propose this data element because we intend for the comparative payment rate analysis to capture the total amount of actual services received by beneficiaries and paid for by the State. To illustrate, and to correct the example provided in the proposed rule, for a beneficiary with 6 visits to their primary care provider in a calendar year where the provider bills 6 claims with CPT code 99202 for the same beneficiary, the State is required to report 6 claims for CPT code 99202. The beneficiary count would remain 1. If 6 separate beneficiaries each received a service and the provider bills CPT code 99202 for all of them, the claims count would still be 6, but the beneficiary count would also be 6. Given that our access work is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule for any additional changes we may propose through future rulemaking.

Comment: One commenter recommended CMS allow States to have a 6-month period to account for lags in claims reporting by providers and States paying providers' claims for codes required to be in the comparative payment rate analysis.

Response: We believe the commenter was referring to the claims run out period where a State may not have received all of their providers' claims for the codes subject to the comparative payment rate analysis by the time the analysis is due, which could result in an undercount of both claims for services furnished and beneficiaries who received a service during the year. In response to comments and based on the timing of this final rule, we have revised the timeframes for the comparative payment rate analysis. The regulatory language finalized in this rule at paragraph (b)(4) now states the following, ''[t]he State agency must publish the initial comparative payment rate analysis and payment rate disclosure of its Medicaid payment rates in effect as of July 1, 2025, as required under paragraphs (b)(2) and (3) of this section, by no later than July 1, 2026. Thereafter, the State agency must update the comparative payment rate analysis and payment rate disclosure no less than every 2 years, by no later than July 1 of the second year following the most recent update.'' Therefore, for the initial comparative payment rate analysis, States will need to include their claims and beneficiary data required in paragraph (b)(3)(i)(E) for CY 2025 in the analysis to be published no later than July 1, 2026. This timing provides a 6-month period for claims run out, as requested by the commenter.

Comment: One commenter raised concerns regarding the requirement to separately identify the base Medicaid FFS fee schedule payment rate by provider type without the inclusion of an additional analysis to assess whether the State's rate setting process complies with the Mental Health Parity and Addiction Equity Act (MHPAEA or the Parity Act).

Response: CMS works closely with State Medicaid agencies to ensure compliance with MHPAEA in Medicaid managed care arrangements, Medicaid alternative benefit plans (managed care and FFS), and CHIP benefits (managed care and FFS) whenever changes to coverage of mental health or SUD benefits are proposed by States. Parity requirements do not apply to MH or SUD benefits for enrollees who receive only Medicaid non-ABP FFS State plan coverage; however, CMS encourages States to comply with parity for all Medicaid beneficiaries.[304] [305] Congress has not extended MHPAEA requirements to non-ABP Medicaid benefits provided solely through FFS delivery systems. Nonetheless, we encourage our State Medicaid agency

[303] 88 FR 27960 at 28016.

[304] *https://www.medicaid.gov/medicaid/benefits/behavioral-health-services/parity/index.html.*

[305] *https://www.medicaid.gov/sites/default/files/2023–09/cmcs-mental-health-parity-092023.pdf.*

partners to ensure their non-ABP FFS benefits voluntarily comply with MHPAEA. Moreover, CMS reviews State proposals regarding rate reductions or restructuring to ensure compliance with overarching requirements under section 1902(a)(30)(A) of the Social Security Act ''to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan, at least to the extent that such care and services are available to the general population in the geographic area.'' This review thus helps promote the fundamental objective of MHPAEA to ensure access to mental health and substance use disorder treatment services.

Comment: One commenter requested clarification about the Medicare rate to be used in the comparative payment rate analysis.

Response: As finalized by this rule, § 447.203(b)(3)(i)(C) requires States to compare their base Medicaid FFS fee schedule payment rate to the Medicare non-facility payment rates as established in the annual Medicare PFS final rule effective for the same time period for the same set of E/M CPT/HCPCS codes, and for the same geographical location as the base Medicaid FFS fee schedule payment rate, that correspond to the base Medicaid FFS fee schedule payment rate rates identified under paragraph (b)(3)(i)(B) of this section, including separate identification of the payment rates by provider type. That is, States are required to compare their base Medicaid FFS fee schedule payment rates to the corresponding Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year. As described in the proposed rule, we expected States to source the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year from the published Medicare fee schedule amounts on the Medicare PFS through one or both of the following sources: the Physician Fee Schedule Look-Up Tool [306] on *cms.gov* or Excel file downloads of the Medicare PFS Relative Value Files [307] for the relevant calendar year from *cms.gov*. We acknowledge that the Physician Fee Schedule Look-Up Tool is a display tool that functions as a helpful aid for physicians and NPPs as a way to quickly look up PFS payment rates, but does not provide official payment rate information. While we encouraged States to begin sourcing Medicare non facility payment rates from the Physician Fee Schedule Look-Up Tool and utilize the Physician Fee Schedule Guide for instructions on using the Look-Up Tool in the proposed rule, we would like to clarify in this final rule that States should first by downloading and reviewing the Medicare PFS Relative Value with Conversion Factor File where States can find the necessary information for calculating Medicare non facility payment rates. Prior to the effective date of this final rule, we will issue subregulatory guidance, which includes an instructional guide for identifying, downloading, and using the relevant Excel files for calculating the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year that States will need to include in their comparative payment rate analysis. Therefore, for the initial comparative payment rate analysis, after Medicare's publication of the CY 2025 Physician Fee Schedule rate by November 2024, we encourage States to begin sourcing Medicare non-facility payment rates as established in the annual Medicare PFS final rule for CY 2025 by downloading and reviewing the CY 2025 Medicare PFS Relative Value with Conversion Factor File from cms.gov.[308]

Comment: While we received overwhelming support from commenters for proposing to use Medicare non-facility rates for comparison to Medicaid rates in the comparative payment rate analysis, some commenters expressed concerns or suggested alternative comparison points. Many commenters stated that Medicare payment rates are low and have not kept up with inflation; therefore, these commenters stated that Medicare is not an appropriate comparison point for payment rates for many services, including dental, anesthesiology, and physical therapy. Some commenters stated that there is limited comparability between Medicaid and Medicare due to the differences in coverage of services and populations (for example, Medicare's limited coverage of pediatric services, behavioral health services (including substance use disorder and mental health care), and dental care) which results in fundamentally different payment rate methodologies. A few commenters expressed that Medicare is not a perfect comparator and should not be used as the standard for adequacy of Medicaid payment rates, but agreed it was a useful starting place because Medicare rates are publicly available. One commenter stated that States aligning Medicaid payment rates with Medicare rates for psychiatrist services as well as decreasing administrative burden could help encourage more providers to enroll in Medicaid.

Many commenters who opposed using Medicare non-facility rates for the comparative payment rate analysis offered alternative suggestions for States to compare their payment rates to. Several commenters suggested private payer rates. One commenter suggested Medicaid rates from geographically similar States that CMS identifies for States. A few commenters suggested rates from Federal or State employee dental plans. Two commenters suggested FAIR Health data [309] (particularly for dental services). One commenter suggested Medicare Advantage for dental, vision, and hearing services. We also received a comment suggesting CMS develop an alternative to Medicare as a point of comparison in the comparative payment rate analysis, particularly for inpatient administered therapies that are paid using DRGs.

Response: We thank the commenters for their support of using the Medicare non-facility rates for comparison to Medicaid rates in the comparative payment rate analysis. We understand the commenters' concerns about using Medicare as a benchmark for Medicaid rates to be compared to in the comparative payment rate analysis; however, we do not agree that Medicare payment rates are low and have not kept up with inflation. As described in the proposed rule, Medicare PFS payment rates are established for each service, generally described by a particular procedure code (including HCPCS, CPT, and CDT),) using resource-based inputs to establish RVUs in three components of a procedure: work, practice expense, and malpractice. The three component RVUs for each service are adjusted using CMS-calculated geographic practice cost indexes (GPCIs) that reflect geographic cost differences in each fee schedule area as compared to the national average.[310] The Medicare PFS is revised annually by CMS ensure that our payment systems are updated to reflect changes in medical practice and the

[306] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PFSlookup.*

[307] *https://www.cms.gov/medicare/medicare-fee-for-service-payment/physicianfeesched/pfs-relative-value-files.*

[308] *https://www.cms.gov/medicare/medicare-fee-for-service-payment/physicianfeesched/pfs-relative-value-files.*

[309] We assume the commenter was referring to *https://www.fairhealth.org/.*

[310] 88 FR 27960 at 28012. Note this language has been revised for accuracy in this final rule,

relative value of services, as well as changes in the statute.[311]

With regard to commenters who raised concerns about using Medicare as a point of comparison, we disagree with the commenter that differences in coverage and populations limits comparability between Medicare and Medicaid in any way that would make Medicare an inappropriate comparator. As described in the proposed rule, Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year are utilized in this rule as a benchmark to compare Medicaid fee schedule rates on a CPT/HCPCS code level basis.[312] Medicare PFS payment rates simply serve as a point of comparison for CMS to consider in assessing if Medicaid payments are consistent with section 1902(a)(30)(A) of the Act. Differences in the methodology that Medicare uses and States use to determine their FFS fee schedule payment rates does not compromise the value of Medicare as a reliable benchmark for assessing payment rate sufficiency for enlisting providers to furnish services to an individual, as required by section 1902(a)(30)(A) of the Act. As described in the proposed rule, Medicare and Medicaid programs cover and pay for services provided to beneficiaries residing in every State and territory of the United States, Medicare payment rates are publicly available, and broad provider acceptance of Medicare makes Medicare non-facility payment rates as established on the Medicare PFS for a calendar year an available and reliable comparison point for States to use in the comparative payment rate analysis.[313] Also as described in the proposed rule, base Medicaid FFS fee schedule payment rate are typically determined through one of three methods: the resource-based relative value scale (RBRVS), a percentage of Medicare's fee, or a State-developed fee schedule using local factors.[314] The RBRVS system, initially developed for the Medicare program, assigns a relative value to every physician procedure based on the complexity of the procedure, practice expense, and malpractice expense. States may also adopt the Medicare fee schedule rate, which is based on RBRVS, but select a fixed percentage of the Medicare amount to pay for Medicaid services. States can develop their own fee schedules, typically determined based on market value or an internal process, and often do this in situations where there is no Medicare or private payer equivalent or when an alternate payment methodology is necessary for programmatic reasons. Again, one of the criteria for including codes on the CMS-published list of E/M CPT/HCPCS codes subject to the comparative payment rate analysis is that there must be a payment rate on the Medicare PFS so States have a Medicare payment rate to compare their Medicaid base payment to.

We also disagree with commenters that there is limited comparability between Medicaid and Medicare due to the differences in coverage of services and populations. We acknowledge that Medicare and Medicaid vary in terms of covered services and populations served; however, the Medicare PFS includes payment rates for covered, non-covered, and limited coverage services and applies the same resource-based formula to ensure all PFS rates are determined on a national level as well as adjusted to reflect the variation in practice costs from one geographical location to another. As described in the proposed rule, Medicare PFS non-facility rates serves as a reliable benchmark for assessing the level of payment sufficiency to enlist providers to furnish the relevant services to an individual for the following reasons.[315] As we have narrowed the scope of the comparative payment rate analysis to E/M CPT/HCPCS codes, Medicare PFS non-facility payment rates are comparable to Medicaid FFS fee schedule payment rates because both fee schedule rates are generally for services provided in a physician's office and specify the rate paid to a provider for delivering an individual service (that is, a single FFS payment for a single service, rather than an encounter rate paying for any number for services). The accessibility and consistent format of the published Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year makes these rates an available and reliable comparison point for States to use in the comparative payment rate analysis for the foreseeable future as the Medicare PFS is free to the public, updated on an annual basis, and posted online on an easily located website, relative to private payer rates that States would need to request access to and perhaps pay for the information. Medicare also has a low rate of physicians formally opting out of the program, suggesting that Medicare's payment rates generally are consistent with a high level of physician willingness to furnish services to Medicare patients, with the vast majority of physicians willing to accept Medicare's payment rates. Additionally, Medicare is another of the nation's large public health coverage programs which serves as an important data point in determining whether payment rates are likely to be sufficient to ensure access for Medicaid beneficiaries at least as great as for the general population in the geographic area, and whether any identified access concerns may be related to payment sufficiency.

We appreciate commenters' alternative suggestions to using Medicare as a benchmark in the comparative payment rate analysis; however, we are not incorporating these suggestions due to the following reasons. As discussed in the proposed rule, we learned from our implementation experience with the previous AMRP process that very few States were able to include even limited private payer data in their AMRPs due to the payment data being proprietary or unsound due to a lack of transparency about the construction of the payment data or because States did not have large private plans in their State so there were no private payer rates to compare to. This resulted in States being unable fully to comply with the previous AMRP regulations, to the extent they required an analysis that included private payer rate information.[316] Without this final rule, requiring States to compare their Medicaid rates to geographically similar States would not be possible because not all States currently post their Medicaid FFS fee schedule payment rates in a transparent and consistent format that would permit data analysis among States. While some States were able to compare their payment rates to other States' rates in their previous AMRPs, this was inconsistent across AMRPs and risked a subjective comparison where States selected which rates and States they compared themselves to. Requiring a comparison to Medicare ensures all States are using the same consistent data point to compare their rates to. Regarding the suggestion that CMS could identify the geographically similar States for States to compare their payment rates to, this would require a different approach than what we proposed due to the variation across State Medicaid programs and would require careful consideration and policy development to ensure that any proposal would be consistent with the statutory requirement in section

[311] *https://www.federalregister.gov/documents/2023/11/16/2023-24184/medicare-and-medicaid-programs-cy-2024-payment-policies-under-the-physician-fee-schedule-and-other.*

[312] 88 FR 27960 at 28012.

[313] 88 FR 27960 at 28011.

[314] 88 FR 27960 at 28010.

[315] 88 FR 27960 at 28011.

[316] 88 FR 27960 at 28018.

1902(a)(30)(A) of the Act that looks to the ''geographic area'' in determining whether payment rates are sufficient. Similarly, we would also not require States compare their rates to rates from Federal or State employee dental plans because this information might not be generally available to State Medicaid agencies.

At this time and for the purposes of the comparative payment rate analysis, we are not advocating or requiring States source payment rate information from any particular data source other than the State's own Medicaid agency (who is responsible for setting and paying the payment rates required in the analysis and, therefore has direct access to base Medicaid FFS fee schedule payment rates required in the analysis) and publicly available Medicare fee schedule rates (which we have previously described as an available and reliable comparison point for States to use in the comparative payment rate analysis). Therefore, we are not requiring States compare their rates to FAIR Health data because this data source is outside of the State agency and Medicare's publicly available fee schedule rates. We would also not require States compare their rates to Medicare Advantage for dental, vision, and hearing services because these are not categories of services subject to the comparative payment rate analysis. As previously stated, only codes listed on the CMS-published list of E/M CPT/HCPCS codes are subject to the comparative payment rate analysis. The list does not include dental, anesthesiology, physical therapy, vision, and hearing services and these services, among others not on the CMS-published list of E/M CPT/HCPCS codes, are not subject to the comparative payment rate analysis requirement. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

For the previously stated reasons, we believe the Medicare payment rates for the categories of services subject to the comparative payment rate analysis are likely to serve as a reliable benchmark for a level of payment sufficient to enlist providers to furnish the relevant services to an individual. Therefore, we are finalizing this rule with the requirement that States use the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year as the comparison point for States to compare their Medicaid payment rates to in the comparative payment rate analysis.

We would also like to clarify that the provisions in this final rule do not require States to change their payment rates, including requiring States to align their Medicaid payment rates with Medicare rates for psychiatrist services. Although we intend for States to consider the information produced for the payment rate transparency publication, comparative payment rate analysis, and payment rate disclosure in an ongoing process of evaluating the State's payment rate sufficiency and when considering changing payment rates or methodologies (and we intend to make similar use of the information in performing our oversight activities and in making payment SPA approval decisions, for example), we did not propose and are not finalizing that any payment rate changes necessarily would be triggered by the proposed requirements.

Comment: Some commenters were concerned about how States would be expected to conduct the comparative payment rate analysis for services that Medicaid pays for, but Medicare does not. A few commenters suggested CMS develop a methodology for calculating a proxy rate for Medicaid services with no equivalent Medicare rate or Medicaid services that are provided very infrequently in Medicare, so Medicare rates are not a reliable comparison. Two commenters suggested working with MedPAC or MACPAC to set appropriate comparison points for services that are not covered by Medicare, for example contraceptive and pregnancy-related services.

Response: To clarify, only codes listed on the CMS-published list of E/M CPT/HCPCS codes are subject to the comparative payment rate analysis. All codes on this list have an existing Medicare payment rate, therefore, the development of a proxy rate is unnecessary. Codes outside of this list, including services that Medicaid pays for, but Medicare does not, are not subject to the comparative payment rate analysis requirement. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

We disagree with the commenter that Medicare rates are not a reliable comparison when services are provided infrequently to Medicare beneficiaries. As previously described, Medicare PFS payment rates are computed using a resource-based formula made up of three components of a procedure's RVU: physician work, practice expense, and malpractice as well as geographical differences in each locality area of the country.[317] The Medicare PFS is revised annually by CMS to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute.[318] Despite a service being covered and paid for infrequently by Medicare, the payment rates on the Medicare PFS are consistently updated with relevant data on a frequent, annual basis.

Comment: A few commenters suggested alternative update frequencies for the comparative payment rate analysis. Commenter suggestions included updates annually, every 3 years, and every 4 years. Commenters' justification ranged from more frequent than 2 years due to the need for timely publication of Medicaid data to less frequent to align with the State's existing rate study schedule or because they did not believe rates would change significantly during a 2-year period. Additionally, one commenter suggested CMS require States to document when rates have not changed between comparative payment rate analysis biennial publications.

Response: We are finalizing the payment rate transparency requirements, including the comparative payment rate analysis, with an applicability date of July 1, 2026; however, we are not changing the proposed timeframe of 2 years for States to update their publications. We believe requiring updates to the comparative payment rate analysis every 2 years balances State burden with maintaining up-to-date information. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

Comment: One commenter expressed concerns about cross walking a State's geographical areas to Medicare in the comparative payment rate analysis. The commenter stated that States may define a geographical region differently than Medicare and result in a complex and confusing analysis that would be contrary to CMS' transparency goals.

Response: As discussed in the proposed rule, we recognize that States

[317] 88 FR 27960 at 28012.

[318] *https://www.federalregister.gov/documents/2023/11/16/2023-24184/medicare-and-medicaid-programs-cy-2024-payment-policies-under-the-physician-fee-schedule-and-other.*

that make Medicaid payment based on geographical location may not use the same locality areas as Medicare.[319] We expect the State to determine an appropriate method to accomplish the comparative payment rate analysis that aligns the geographic area covered by each payer's rate as closely as reasonably feasible. For example, if the State identifies two geographic areas for Medicaid payment purposes that are contained almost entirely within one Medicare geographic area, then the State reasonably could determine to use the same Medicare non-facility payment rate as established in the annual Medicare PFS final rule in a calendar year in the comparative payment rate analysis for each Medicaid geographic area. As another example, if the State defined a single geographic area for Medicaid payment purposes that contained two Medicare geographic areas, then the State might determine a reasonable method to weight the two Medicare payment rates applicable within the Medicaid geographic area, and then compare the Medicaid payment rate for the Medicaid-defined geographic area to this weighted average of Medicare payment rates. States could also calculate the unweighted arithmetic mean of the two Medicare payment rates applicable within the Medicaid-defined geographic area. While States have flexibility in mapping their geographical areas to Medicare's for the comparative payment rate analysis, we invite States to reach out to CMS for technical assistance.

Comment: A few commenters stated that other factors besides rates impact access to care. Commenters suggested CMS consider regional cost differences, provider shortages (including number of providers and their location), and the unique needs of specific populations (such as dually eligible beneficiaries, or beneficiaries in rural areas of a State) as factors that impact access to care.

Response: We agree with commenters that other factors besides rates impact access to care.[320] After considering feedback received from States and other interested parties about the previous AMRP process issued through the 2015 final rule with comment period, as well as our obligation to ensure continued compliance with section 1902(a)(30)(A) of the Act, we are finalizing a streamlined and standardized process to assess access to care that focuses on payment rate transparency. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

Comment: A couple of commenters expressed concerns regarding the privacy of beneficiary information when it comes to the requirement that the comparative payment rate analysis and payment rate disclosure must specify the number of Medicaid-paid claims and the number of Medicaid enrolled beneficiaries who received a service. Commenters suggested CMS provide an exception when the volume of claims or beneficiaries is small.

Response: We take privacy and our obligations to protect beneficiary information very seriously. We remind States of their obligations to comply with applicable Federal and State privacy laws with respect to such information, such as the HIPAA Privacy Rule and Federal Medicaid requirements in section 1902(a)(7) of the Social Security Act and 42 CFR part 431, subpart F. We are not requiring States to publish any beneficiary-identifiable information in the comparative payment rate analysis or payment rate disclosure. We expect States will ensure that any claims and Medicaid beneficiary data made publicly available under these requirements have been de-identified in accordance with the HIPAA Privacy Rule at 45 CFR 164.514(b).

We strongly encourage States to have policies to ensure that all information, particularly claims and beneficiary data, published in their comparative payment rate analysis and payment rate disclosure is de-identified prior to publishing on July 1, 2026. Such policies should address circumstances in which the number of Medicaid-paid claims and/or Medicaid enrolled beneficiaries is small. For example, States may consider implementing a small cell size suppression policy for publishing data on the State's website, similar to CMS' cell size suppression policy that no cell (for example, admissions, discharges, patients, services, etc.) containing a value of 1 to 10 can be reported directly.[321] We invite States to reach out to CMS regarding any data privacy concerns that may impact a States' compliance with the comparative payment rate analysis or payment rate disclosure requirements.

Additionally, to address privacy concerns at the individual level, we would like to share the following resources for filing civil rights and HIPAA complaints with the Office for Civil Rights:

- Filing a civil rights complaint;[322] and
- Filing a health information privacy or security complaint.[323]

Comment: A commenter raised concerns that the comparative payment rate analysis would incentivize States to raise payment rates for the categories of services subject to the analysis, but might also lead or contribute to rate cuts for other services, since the proposed rule would not provide that States may not cut some rates to make funds available to raise other rates.

Response: We understand the commenter's concerns about the effects of the comparative payment rate analysis in practice. We emphasize that the comparative payment rate analysis will afford more transparency to CMS and the public about rates for primary care, obstetrical and gynecological, and outpatient mental health and substance use disorder services, and will also provide States with an opportunity to identify where existing rates could create an access issue for the services subject to the comparative payment rate analysis requirement. If a State chooses to raise payment rates for the categories of services subject to the analysis, and in order to do so seeks to reduce rates for other services, then the State would be required to follow the State Analysis Procedures for Rate Reduction or Restructuring in § 447.203(c) to ensure the proposed rate reductions do not reduce access to care to the services for which payment rates would be reduced below the statutory standard. A public input process to raise access concerns with States is described in § 447.203(c)(4) of this final rule. We are confident our policies finalized in this rule will work in conjunction with each other to ensure ongoing and improved access to care.

Comment: A couple of commenters requested clarification regarding the circumstance whereby a comparative payment rate analysis reveals that a State's Medicaid payment rates are significantly below Medicare rates. One commenter suggested requiring States to submit a corrective action plan in those instances.

Response: Transparency, particularly the requirement that States must publicly publish their payment rates and compare their payment rates to Medicare, helps to ensure that interested parties have basic

[319] 88 FR 27960 at 28013

[320] 88 FR 27960 at 28016–28017.

[321] *https://resdac.org/articles/cms-cell-size-suppression-policy.*

[322] *https://www.hhs.gov/civil-rights/filing-a-complaint/index.html.*

[323] *https://www.hhs.gov/hipaa/filing-a-complaint/complaint-process/index.html.*

information available to them to understand Medicaid payment levels and the associated effects of payment rates on access to care so that they may raise concerns to State Medicaid agencies via the various forms of public process available to interested parties. We intend to utilize the information published by States in their payment rate transparency publication and comparative payment rate analysis whenever the provisions of § 447.203(c) are invoked, when a State submits a SPA that proposes to reduce provider payment rates or restructure provider payments in circumstances when the changes could result in diminished access. We did not propose and are not requiring States to submit a corrective action plan when Medicaid payment rates included in the comparative payment rate analysis are lower than Medicare payment rates. While the results of a comparative payment rate analysis would not themselves require a corrective action plan, § 447.203(c)(5) does require a State to submit a corrective action plan to remedy an access deficiency within 90 days from when it is identified to the State.

Comment: One commenter requested that CMS make UPL demonstration data and methodologies publicly available for purposes of data analysis, particularly for inpatient behavioral health services as CMS did not propose to include these services in the comparative payment rate analysis.

Response: While the comparative payment rate analysis is limited in scope to base Medicaid FFS fee schedule payment rates, the payment rate transparency publication does include PPS rates that are considered fee schedules payment rates within the meaning of this final rule, including for inpatient hospital, outpatient hospital, and nursing facility services. The PPS rates, which are generally the base payment for these services, and reported through UPLs, will be publicly available through the payment rate transparency publication. We acknowledge that supplemental payments as well as UPL data and methodologies typically are not publicly available currently. Nevertheless, UPL demonstrations provide us with an opportunity for payment oversight and we consider UPL demonstrations in assessing State compliance with the access requirement in section 1902(a)(30)(A) of the Act.[324] As previously discussed in an earlier response to comments, we stated that UPL demonstrations provide CMS with important information for assessing if payment rates comply with economy and efficiency provisions at section 1902(a)(30)(A) of the Act, specifically how total Medicaid payments compare to what Medicare would have paid for similar services where Medicare acts as a payment limit, or ceiling, for economic and efficient. Requiring supplemental payments as well as UPL data and methodologies be publicly available would contribute to our transparency efforts; however, the current reporting format of UPL data would not align with § 447.203(b)(1)(iii) which requires Medicaid FFS fee schedule payment rates be published and organized in such a way that a member of the public can readily determine the amount that Medicaid would pay for a given service. Therefore, we would need to develop a different methodology, policies, and oversight than what is being finalized in this rule to ensure UPL data is transparent. With this final rule, our focus is on improving our oversight of Medicaid payment rates to identify where rates may be negatively impacting access to care while minimizing burden imposed on States, which requires us to prioritize areas of focus. We want our initial focus to be on establishing the new payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements, providing States with support during the compliance period, and ensuring the data required under this final rule are available to beneficiaries, providers, CMS, and other interested parties for the purpose of assessing access to care issues.

Payment Rate Disclosure Comments and Responses

Comment: We received general support for our proposal to require States to develop and publish a payment rate disclosure for certain HCBS. Commenters specifically expressed support for the proposed categories of services and calculation of the average hourly payment rate.

However, a couple of comments expressed opposition of the payment rate disclosure provision. Commenters in opposition stated the proposed payment rate disclosure requirements would be administratively burdensome for States and that it was unclear how calculating an average hourly payment rate along with publishing data about claims and beneficiaries would be valuable and informative for payment policy purposes.

Response: We appreciate the commenters' support of the payment rate disclosure provision at § 447.203(b)(3)(ii). We are finalizing the payment rate disclosure provisions with an additional category of service, habilitation, a few minor revisions for clarification purposes and consistent terminology usage within § 447.203(b), and an update to the compliance timeframe, the latter of which was discussed earlier in this section. The addition of habilitation services to the payment rate disclosure is further discussed in a later response to comments in this section. In this final rule, we are revising the regulatory language to clarify which services and payment rates are subject to this requirement. We proposed in § 447.203(b)(3)(ii) that the State would be required to publish the ''average hourly payment rate, separately identified for payments made to individual providers and to providers employed by an agency, if the rates vary'' for each category of service specified in paragraph (b)(2)(iv). We are finalizing in § 447.203(b)(3)(ii) that States are required to publish the ''average hourly **Medicaid fee-for-service fee schedule** payment rates, separately identified for payments made to individual providers and **provider agencies,** if the rates vary.'' (new language identified in bold). We proposed in § 447.203(b)(3)(ii)(B) that the State would be required to ''identify the average hourly payment rates by applicable category of service, including, if the rates vary, separate identification of the average hourly payment rates for payments made to individual providers and to providers employed by an agency, by population (pediatric and adult), provider type, and geographical location, as applicable.'' We are finalizing in § 447.203(b)(3)(ii)(B) that the States are required to ''identify the average hourly Medicaid fee-for-service fee schedule payment rates by applicable category of service, including, if the rates vary, separate identification of the average hourly Medicaid fee-for-service fee schedule payment rates for payments made to individual providers and provider agencies, by population (pediatric and adult), provider type, geographical location, **and whether the payment rate includes facility-related costs,** as applicable.'' (new language identified in bold). For clarification and consistent terminology usage of ''Medicaid fee-for-service fee schedule payment rates,'' similar revisions were made in § 447.203(b)(2)(iv) and (b)(3)(ii)(B) and (C) and described in detail at the end of responses to comments in this section. We utilized the term ''average hourly Medicaid fee-for-service fee schedule payment rates'' in the payment rate disclosure for

[324] 88 FR 27960 at 28006.

consistency throughout § 447.203(b) where the term Medicaid FFS fee schedule payment rates is used to describe what payment rates are subject to the payment rate transparency publication in § 447.203(b)(1)(i). Additionally, we are incorporating the term ''provider agencies'' for clarification purposes to more accurately reflect what payment rate we are requiring be published. Lastly, we added the requirement that payments that include facility-related costs must be separately identified to ensure transparency of payment rates that may differ due to the inclusion of facility-related costs. Additional information about these regulatory language changes is discussed in later responses to comments in this section.

We disagree with the commenters regarding administrative burden of the payment rate disclosure. As documented in section III. of this final rule, the FFS provisions, including the payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements (§ 447.203(b)(1) through (5)), interested parties' advisory group requirements (§ 447.203(b)(6)), and State analysis procedures for payment rate reductions or payment restructuring (§ 447.203(c)), are expected to result in a net burden reduction on States compared to the previous AMRP requirements. Additionally, as addressed in another comment response generally discussing commenters' concerns about State burden, we have described numerous flexibilities States will have for compliance with this final rule. Specifically for the payment rate disclosure, and as discussed in a later response to comments, States have flexibility to (1) utilize contractors or other third party websites to publish the payment rate disclosure on (however, we remind States that they are still requiring to publish the hyperlink to the website where the publication is located on the State Medicaid agency's website as required in § 447.203(b)(1)(ii) of this final rule), (2) format and organize the payment rate disclosure how they chose (that is, we are not requiring certain codes be included as required in the comparative payment rate analysis) (however, we remind States that the disclosure is still subject to the publication requirements described in proposed paragraphs (b)(1) and (b)(1)(ii) for payment rate transparency data), and (3) calculate the average hourly Medicaid FFS fee schedule payment rate as a simple average or arithmetic mean where all payment rates would be adjusted to an hourly figure, summed, then divided by the number of all hourly payment rates, rather than a weighted average which would impose more burden on States to calculate. Additionally, we are providing an illustrative example of a compliant payment rate disclosure (including to meet accessibility standards) through subregulatory guidance that we will issue prior to the effective date of this final rule.

We are not identifying codes for the categories of services subject to the payment rate disclosure. We are providing States with flexibility in determining which codes to include in the calculated average hourly Medicaid FFS fee schedule payment rate for the payment rate disclosure because States may use a wide variety of codes to bill and pay for personal care, home health aide, homemaker, and habilitation services, such as HCPCS codes T1019–T1022 and/or CPT codes 99500- 99602. For example, HCPCS codes T1019–T1022 for home health services includes T1019 (personal care services that are part of the individualized plan of treatment, per 15 minutes), T1020 (personal care services that are part of the individualized plan of treatment, per diem), T1021 (home health aide or certified nurse assistant, per visit), and T1022 (contracted home health agency services, all services provided under contract, per day). One State may use T1019 or T1020 depending on the unit (daily or per diem), a second State may only use T1021, and a third State may use none of these codes. We expect States to review their Medicaid FFS fee schedule payment rates for the payment rate and unit the State uses to pay for each of category of service and calculate the Medicaid average hourly Medicaid FFS fee schedule payment rate for personal care, home health aide, homemaker, and habilitation services, separately by service and provider employment structure as well as for payments that include facility-related costs, as provided in this final rule and discussed in later responses to comments in this section.

Additionally, the list of possible codes States may pay for personal care, home health aide, homemaker, and habilitation services is already limited by the available CPT/HCPCS codes, so we did not see a need to narrow the codes with a CMS-published list of E/M CPT/HCPCS like the comparative payment rate analysis. As previously discussed, we recognize that States may amend existing CPT/HCPCS codes with additional numbers or letters for processing in their own claims system. If a State does not use CPT or HCPCS codes as published by AMA and CMS, then we expect the State to review the published lists of CPT or HCPCS codes and identify which of their codes are most comparable for purposes of the payment rate disclosure. We anticipate States may need to review code descriptions of CPT and HCPCS codes for personal care, home health aide, homemaker, and habilitation services as part of the process of identifying which CPT and HCPCS codes are comparable to the codes that States utilizes. We want to ensure the full scope of personal care, home health aide, homemaker, and habilitation services, and providers of these services, are included in the payment rate disclosure for transparency purposes, rather than narrowing the scope to certain codes and/or provider types, which would result in a limited disclosure of provider payment rates.

Regarding commenters that were unclear how calculating an average hourly payment rate along with publishing data about claims and beneficiaries would be valuable and informative for payment policy purposes, we are requiring States to separately identify the average hourly Medicaid FFS fee schedule payment rates for personal care, home health aide, homemaker, and habilitation services by population (pediatric and adult), provider type, geographical location, and whether the payment rate includes facility-related costs, as applicable, and by provider employment structures (individual providers and provider agencies). Calculating an average hourly Medicaid FFS fee schedule payment rate for categories of services subject to the payment rate disclosure will ensure a standardized unit and permit States, CMS, and other interested parties to compare payment rates among State Medicaid programs. As discussed in the proposed rule, HCBS and direct care workers that deliver these services are unique to Medicaid and often not covered by other payers, which is why we are proposing a different disclosure of payment rates for providers of these services that does not involve a comparison to Medicare. Additionally, private payer data and self-pay data are often considered proprietary and not available to States, thereby eliminating private payers as feasible point of comparison. Because HCBS coverage is unique to Medicaid, Medicaid beneficiaries are generally the only individuals in a given geographic area with access to HCBS that is covered by a third-party payer.[325]

[325] 88 FR 27960 at 28019

Comment: Some commenters requested CMS clarify and add to the proposed categories of services included in the payment rate disclosure requirements. A few commenters requested clarification regarding whether services covered under waiver authority or State plan authority are subject to the disclosure requirements. A couple of commenters suggested adding regulatory language to explicitly include services provided through State plan and waiver authority in the payment rate disclosure. Another couple of commenters requested clarification specifically about self-directed services when an individual has budget authority and residential services. A few commenters encouraged CMS to require States to report payment rate variations by populations served (that is, populations receiving services under a waiver versus State plan authority) due to States varying rates for the same service furnished to different targeted populations under different coverage authorities.

A few commenters recommended additional categories of services to the proposed categories of services subject to the payment rate disclosure. While some commenters recommended expanding the categories of services generally, a number of commenters specifically recommended expanding the categories of service to include habilitation services (including residential habilitation services, day habilitation services, and home-based habilitation services).

Response: Personal care, home health aide, homemaker, and habilitation services provided under FFS State plan authority, including sections 1915(i), 1915(j), 1915(k) State plan services; section 1915(c) waiver authority; and under section 1115 demonstration authority are subject to the payment rate disclosure described in § 447.203(b)(3)(ii). We are clarifying that, consistent with the applicability of other HCBS regulatory requirements to such demonstration projects, the requirements for section 1915(c) waiver programs and section 1915(i), (j), and (k) State plan services included in this final rule, apply to such services included in approved section 1115 demonstration projects, unless we explicitly waive or identify as not applicable one or more of the requirements as part of the approval of the demonstration project. Please see section II.B for additional information on the inclusion of section 1115 demonstrations under the provisions of this final rule. While we appreciate the commenters' suggestion to add regulatory language to explicitly include services provided through State plan and waiver authority in the payment rate disclosure, we are not incorporating this suggestion as we previously provided clarification on which authorities are subject to the disclosure.

As previously discussed, self-directed services delivery models under which an individual beneficiary has budget authority do not constitute a fee schedule payment methodology for purposes of the payment rate transparency publication requirement, as well as the payment rate disclosure. Generally, under such self-directed services delivery models, the individual beneficiary determines a reasonable payment rate for the service in the State-authorized budget for that beneficiary. As such, these types of payment rates are excluded from the disclosure requirement. Regarding commenters' request for clarification about residential services being subject to the disclosure, as discussed in a later response to comments, personal care, home health aide, homemaker, and habilitation services, are inherently delivered in a home or community setting, outside of an institutional or residential facility. However, we acknowledge that the addition of habilitation services to the disclosure would now include residential habilitation services and we further address this in the later portion of this comment response.

We appreciate commenters' suggestion to require States report payment rate variations by populations served (that is, populations receiving services under a waiver versus State plan authority). However, that level of detailed reporting is beyond the scope of what we are seeking to implement in this current rulemaking, and would represent additional burden to States. We are requiring States to separately identify the average hourly Medicaid FFS fee schedule payment rates for personal care, home health aide, homemaker, and habilitation services by various factors that we believe will provide beneficial insights into these rates.

As stated in the proposed rule, we intend to standardize data and monitoring across service delivery systems with the goal of improving access to care, to the extent possible, and particularly for the payment rate disclosure requirements in § 447.203(b)(2)(iv) and (3)(ii), we intend to remain consistent with the HCBS provisions we are finalizing at § 441.311(d)(2) and (e).[326] Given the addition of habilitation services to these HCBS provisions in this final rule as well as the Managed Care final rule (as published elsewhere in this **Federal Register**) provisions at § 438.207(b)(3)(ii) and after consideration of comments, we are adding habilitation services, including residential habilitation, day habilitation, and home-based habilitation services, to the payment rate disclosure requirements in § 447.203(b)(2)(iv) and (3)(ii). Specifically, the regulatory language finalized in this rule at § 447.203(b)(2)(iv) requires States to publish the average hourly Medicaid FFS payment rate for personal care, home health aide, homemaker, and habilitation services, as specified in § 440.180(b)(2) through (4) and (6) in the payment rate disclosure. We note that § 447.203(b)(2)(iv) refers to ''habilitation'' services, without distinguishing between residential habilitation services, day habilitation services, and home-based habilitation services. As previously discussed in section II.B., these categories will be further described in subregulatory guidance. As discussed in a later response to comments in this section, we also adding a requirement in the payment rate disclosure that States must separately identify the Medicaid FFS fee schedule payment rates for services that include facility-related costs. We believe this distinction will generally only arise for habilitation service rates, but we are applying it across all four service categories to remain consistent with the amended provisions at § 441.311(e)(2), and for consistency in reporting across all four services within the payment rate disclosure.

As discussed in the proposed rule, we initially proposed to include in the payment rate disclosure requirement only personal care, home health aide, and homemaker services because they are most commonly conducted in beneficiaries' homes and general community settings and, therefore, constituted the majority of FFS payments for direct care workers delivering services under FFS.[327] However, and as previously stated, we agree with commenters' recommendation that the payment rate disclosure should include payment rates for habilitation services. As such, and to remain consistent with the HCBS provisions at § 441.311(d)(2) and (e) finalized in this rule, we are adding habilitation services as a category of service subject to the payment rate disclosure.

We acknowledge that habilitation services are also generally high-volume,

[326] 88 FR 27960 at 28005.

[327] 88 FR 27960 at 28005.

high-cost services particularly in States where individuals with intellectual or developmental disabilities receive personal care services through habilitation. In other words, we acknowledge that some States design the delivery of and payment rates for habilitation services to include personal care services in these instances. If we were to exclude habilitation services from the payment rate disclosure provisions, then we would effectively exclude an important component of personal care services provided to individuals with intellectual or developmental disabilities from the payment rate disclosure, which would not align with our intent to ensure transparency of payment rates of personal care services within this provision. In instances where States combine the delivery and payment of habilitation services with personal care services, requiring reporting on both services supports our goal of enhancing the transparency of payment rates that support the delivery of personal care services while accommodating the potential variation in classification a State utilizes. We want to note a State has the option to indicate when a habilitation service rate includes personal care services or otherwise provide further data nuances while meeting the requirements of this final rule. In addition, this change provides clarity to States that might have reported on habilitation services under the personal care category of services in the payment rate disclosure were it not for this revision to the disclosure. Given the variation in how States deliver and pay for habilitation services, separately identifying habilitation as a category of service supports our payment rate transparency goals to ensure that interested parties have basic information available to them to understand Medicaid payment levels and the associated effects of payment rates on access to care so that they may raise concerns to State Medicaid agencies via the various forms of public process available to interested parties.

As previously discussed in detail in an earlier response to comments in section II. of this final rule, including habilitation services in HCBS reporting requirements at § 441.311(d)(2) and (e), as well as the payment rate disclosure at § 447.203(b)(2) and (3)(ii), will ensure that services of particular importance to certain beneficiary populations, namely individuals with intellectual or developmental disabilities, are not excluded from our efforts to promote payment rate transparency in the interest of ensuring adequate access to care. As previously stated, in accordance with commenters' recommendation, and to remain consistent with the proposed HCBS provisions at § 441.311(d)(2) and (e) as stated in the proposed rule,[328] we are adding habilitation services to the payment rate disclosure to ensure transparency of rates that disproportionately affect access to services required by a unique population, individuals with intellectual or developmental disabilities.

Comment: A few commenters expressed concern over certain terms used in the proposed rule. Two commenters noted the terms ''rates,'' ''payments,'' ''wage,'' and ''compensation'' were used throughout the rule and were concerned about potential confusion about complying with the payment rate disclosure with the terms not clearly defined. One commenter was concerned the payment rate disclosure required States to request detailed financial records and information from provider organizations/agencies, which are often private businesses. Another couple of commenters requested a Federal-level definition or description of ''provider type'' and ''geographical location'' in the context of the payment rate disclosure.

Response: The payment rate disclosure requires States to separately identify the average hourly Medicaid FFS fee schedule payment rates for personal care, home health aide, homemaker, and habilitation services by population (pediatric and adult), provider type, geographical location, and whether the payment rate includes facility-related costs, as applicable, and by provider employment structures (individual providers and provider agencies). We are not requiring in the payment rate disclosure provisions at § 447.203(b)(3)(ii) that States collect wage, compensation (including benefits), or financial records and information from provider agencies or to publish information about the compensation the provider agency pays to its employee, where applicable. In section II.C. of this final rule, wage is only mentioned while summarizing comments received on the February 2022 RFI.[329] Likewise, compensation is only mentioned in section II.C. of this final rule while describing the difference between individual providers and provider agencies and when requesting public comments on whether we should have proposed a provision similar to the HCBS provisions we proposed at § 441.302(k)(3)(i) (where we proposed to require at least 80 percent of all Medicaid FFS payments for certain services be spent on compensation for direct care workers). Therefore, we are not requiring that States collect wage or compensation (including benefits) information from provider agencies to publish information about the compensation that the provider agency pays to its employee in the payment rate disclosure provisions at § 447.203(b)(3)(ii). We consistently used average hourly payment rate to refer to the payment rate that States are required to publish in the payment rate disclosure. As finalized in this rule, we are replacing the term ''average hourly payment rate'' with ''average hourly Medicaid FFS fee schedule payment rate'' for clarity and consistency throughout § 447.203(b).

We are not specifying a Federal definition for provider type because of the variety of provider types a State could license and pay for delivering Medicaid services. States are responsible for licensing providers in their State and have the flexibility to license a wide variety of provider types for personal care, home health aide, homemaker, and habilitation services, including, but not limited to, personal care attendants, home health aides, certified nursing assistants, or registered nurses. We would like to ensure the full scope of providers of personal care, home health aide, homemaker, and habilitation services across States are included in the payment rate disclosure for transparency purposes.

Finally, we also are not providing a Federal definition of geographical location. Because the payment rate disclosure does not involve a comparison to Medicare (or other payer), the data need only reflect the State's specific circumstances. Different States have different methods of assigning payment rates to particular regions and are therefore best situated to determine how rates must reflect their State-determined geographical designations.

Comment: A few commenters requested clarification regarding what CMS meant by ''individual providers'' and ''providers employed by an agency'' in the payment rate disclosure. Commenters were generally unsure if States are required to publish the average hourly payment rate paid to the agency or the compensation the agency pays to its employee. One commenter

[328] 88 FR 27960 at 28005.

[329] Summary of Public Comments in response to the CMS 2022 Request for Information: Access to Coverage and Care in Medicaid & CHIP. December 2022. For the report, see *https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-report.pdf.*

requested clarification on what CMS considers ''payments made to individual providers'' and ''payments made. . .to providers employed by an agency.'' Another commenter noted an example where agencies have multiple direct care workers as employees and was unsure from the language in the proposed rule (''providers employed by agency'') what CMS considered to be the payment rate, either total compensation (including benefits) divided by total hours, or the hourly base wage of the direct care workers. One commenter specifically noted the use of the terms ''direct care worker'' and ''provider'' are both used in 42 CFR 447.203(b)(3)(ii) and stated these terms are often misaligned. The commenter explains that ''direct care worker'' or ''home care worker'' refers to personal care aides and home health aides, who provide hands-on services to those in need while ''providers'' are the agencies that employ direct care workers, train and screen them (health status and background checks), supervise them, schedule their services, reimburse their travel expenses, and support their professional development as well as liaise with service recipients and their families, handle all service billing, prepare for and respond to emergencies, and ensure day-to-day compliance with State and Federal standards.

Response: We appreciate the commenters' examples to illustrate the requested areas of clarification in the rule. As previously stated, in this final rule, we are revising the language ''to providers employed by an agency'' in § 447.203(b)(2)(iv), (b)(3)(ii), and (b)(3)(ii)(B) and finalizing the language as ''provider agencies'' for clarification purposes to more accurately reflect what payment rate we are requiring be published which is discussed shortly in this response to comments. To clarify, in the payment rate disclosure, we are requiring States to calculate and publish the average hourly Medicaid FFS fee schedule payment rate that States pay to individual providers and provider agencies, if the rates vary, and for payments that include facility-related costs. As described in the proposed rule and this final rule, individual providers in the context of the payment rate disclosure at § 447.203(b)(3)(ii) refers to individuals that are direct care workers and often self-employed or contract directly with the State to deliver services as a Medicaid provide; additionally, the individual provider bills the States directly and is paid directly by the State for services provided. To clarify, individual providers does not refer to providers delivering services through self-directed models with service budget authorized under 42 CFR 441.545, as these are not considered Medicaid FFS fee schedule payment rates for the purposes of the payment rate transparency publication, as well as the payment rate disclosure at § 447.203(b)(3)(ii), which was discussed in an earlier response to commenters.

Provider agency in the context of the payment rate disclosure at § 447.203(b)(3)(ii) refers to the agency contracted or enrolled with the State to deliver Medicaid services and the agency in turn employs or contracts with direct care workers as employees of the agency that works directly with the Medicaid agency to provide Medicaid services; additionally, the agency bills the State directly and is paid directly by the State for services their employees or contractors provide. Also, as previously stated, to the extent a State pays a provider agency a Medicaid FFS fee schedule payment rate (as discussed in detail in an earlier response to comments in this section), then those payment rates are subject to the payment rate disclosure requirements at § 447.203(b)(3)(ii).

As previously discussed in an earlier response to comments in this section, we are not requiring in the payment rate disclosure provisions at § 447.203(b)(3)(ii) that States collect wage or compensation (including benefits) information from provider agencies to publish information about the compensation the provider agency pays to its employee. While the comment focuses on the daily work of a ''direct care worker'' and the functions of a ''provider'' to distinguish these terms, for the purposes of this rule, we focused on the type of employment structure (that is, individual provider or provider agency) to best account for variations in types and levels of payment that may occur for different provider types. We clarify that the codified regulation text for § 447.203(b)(3)(ii) does not include the phrase ''direct care worker.''

Comment: Many commenters raised concerns and requested clarification regarding CMS requiring the payment rate being an hourly unit in the payment rate disclosure. A few commenters requested CMS clearly define what to include in the average hourly payment rate (for example, wages or benefits) to ensure the average hourly payment rates are comparable across States. A couple of commenters requested clarification on how States should convert half day, per diem, or per visit payment rates into an average hourly payment rate while one commenter requested CMS permit States to publish an average payment rate in the unit the State pays to ease burden on States. Lastly, one commenter stated that services, such as adult day habilitation or assisted living waiver, that cannot be calculated as an hourly rate should be reported as daily rates.

Response: For personal care, home health aide, homemaker, or habilitation services under FFS State plan authority, including sections 1915(i), 1915(j), 1915(k) State plan services; section 1915(c) waiver authority; and under section 1115 demonstration authority, this final rule requires States to publish a payment rate disclosure that expresses the State's payment rates as the average hourly Medicaid FFS fee schedule payment rates, separately identified for payments made to individual providers and provider agencies, if the rates vary, and for payments that include facility-related costs, as applicable. States have flexibility in operating their Medicaid programs to set payment rates and payment policies for services that cover a particular unit of time for delivering the service and, therefore, States currently pay for these services in a wide range of units, from minutes to hourly to daily to monthly units. As described in the proposed rule, because of Medicaid's status as the most important payer for HCBS and lack of other points of comparison (that is, Medicare, private payers, self-pay), transparency and comparability among States is most important for assessing compliance with section 1902(a)(30)(A) of the Act. To ensure the payment rate disclosure supports our transparency efforts to help ensure that interested parties have basic information available to them to understand Medicaid payment levels and the associated effects of payment rates on access to care so that they may raise concerns to State Medicaid agencies via the various forms of public processes available to interested parties, we are requiring States publish their payment rates in a uniform and comparable format, that is, an average hourly Medicaid FFS fee schedule payment rate. As previously discussed in an earlier response to comments in this section, we are not requiring in the payment rate disclosure provisions at § 447.203(b)(3)(ii) that States to collect wage, compensation (including benefits), or financial records and information from provider agencies or to publish information about the compensation the provider agency pays to its employee, where applicable.

Regarding commenters requesting clarification on how States should convert half day, per diem, or per visit payment rates into an average hourly

payment rate, we would like to clarify that States that pay for the categories of services specified in paragraph (b)(2)(iv) in a unit other than an hourly payment rate are expected to calculate an hourly payment rate using the unit of the rate the State pays for the service and the number of hours covered by that unit. For example, if a State provides home health aide services as a half day or on a per diem (daily) or per visit basis, then the State would be expected to divide their payment rate for a half day, day, or visit by the number of hours covered by the rate, such as 8 hours for a full day, to calculate an average hourly Medicaid FFS fee schedule payment rate for the payment rate disclosure. States have flexibility in operating their Medicaid programs to set payment rates and payment policies for services that cover a particular unit of time for delivering the service. We expect States have a maximum number of hours factored into their payment rate for services set on a per diem or per visit basis and States should use that maximum number in calculating the average hourly Medicaid FFS fee schedule payment rate, which is a simple average (arithmetic mean) where all payment rates are summed, then divided by the number of all hourly payment rates. Regarding commenters who stated that services, such as adult day habilitation or assisted living waiver, that cannot be calculated as an hourly rate should be reported as daily rates, we are not incorporating this suggestion into the final rule as we would expect States to use the previously described process to calculate an hourly payment rate from a per diem (daily) rate.

As previously mentioned in an earlier response to comments, this final rule adds habilitation services to the categories of services subject to the payment rate disclosure. This final rule is also adding a requirement that States must separately identify whether the average hourly Medicaid FFS fee schedule payment rate for services includes facility-related costs in § 447.203(b)(2) and (3)(ii)(B) to remain consistent with HCBS provisions finalized in this rule at § 441.311(e)(2). We recognize that habilitation services can mean residential habilitation, day habilitation, or home-based habilitation services; as such, payment rates for habilitation services generally may include facility-related costs, as in the case of residential or day habilitation services delivered in a residential group home or day center, whereas home-based habilitation would not include facility-related costs.[330] We remind States that we proposed an ''as applicable'' clause in § 447.203(b)(3)(ii)(B) that applies to the ways payment rates can vary (that is, by employment structure, population (pediatric and adult), provider type, geographical location). The requirement to identify whether a payment rate includes facility-related costs would also be covered by the ''as applicable'' clause. As such, we would not expect States to identify facility-related costs for personal care, home health aide, homemaker, and habilitation service payment rates when they are delivered in a home-based setting. While § 447.203(b)(2) and (3)(ii)(B) requires that States must separately identify whether the average hourly Medicaid FFS fee schedule payment rate includes facility-related costs may not apply to all services and delivery sites (that is, in home or community settings), we believe this provision will help to ensure transparency of payment rates that may differ due to the inclusion of facility-related costs.

Comment: One commenter requested clarification regarding individually negotiated rates and bundled rates being included in the average hourly payment rate calculation in the payment rate disclosure.

Response: As previously described in detail in an earlier response to comments in this section, we interpret the commenter's reference to ''negotiated rates'' to mean a provider payment rate where the individual provider's final payment rate is agreed upon through negotiation with the State Medicaid agency. For consistency with the payment rate transparency publication requirement, negotiated rates are not subject to the payment rate disclosure provision because these payment rates are not subject to the payment rate transparency publication as negotiated rates are not Medicaid FFS fee schedule payment rates that are known in advance of a provider delivering a service to a beneficiary.

Also, as previously discussed in detail in an earlier response to comments in this section, for purposes of the payment rate transparency provision in § 447.203(b)(1), Medicaid FFS fee schedule payment rates are FFS payment amounts made to a provider, and known in advance of a provider delivering a service to a beneficiary by reference to a fee schedule. For consistency, we are using the same description of Medicaid FFS fee schedule payment rates to describe the payment rates that need to be included in the payment rate disclosure in paragraph (b)(3)(ii)(B) of this section which would also consider bundled payment rates to be Medicaid FFS fee schedule payment rates for the purposes of the payment rate disclosure.

We also clarify that while PPS rates for services provided in inpatient hospitals, outpatient hospitals, inpatient psychiatric facilities, inpatient rehabilitation facilities, long-term care hospitals, and nursing facilities are subject to the payment rate transparency publication, these PPS rates are effectively excluded from the payment rate disclosure because the categories of services specified in § 447.203(b)(2)(iv), personal care, home health aide, homemaker, and habilitation services, inherently delivered in a home or community setting, outside of an institutional facility.

Comment: Many commenters suggested additional data elements and levels of analysis for the payment rate disclosure. A couple of commenters suggested additional breakdowns of the average hourly payment rates, including when a State pays different rates for higher level of need or complexity (such as paying tiered rates for a single service when provided on nights, weekends, or in a particular geographical area), demographic information (such as gender and race of the direct care worker), and type of service provided. Another commenter suggested CMS require States to identify the average portion of the average payment rate that is used for compensation to pay the direct care worker in the payment rate disclosure to enable easier comparison of compensation between individual providers and to providers employed by an agency. One commenter suggested requiring States to publish the rates that provider agencies pay their employees to ensure payment rates are fully disclosed at the State and provider levels. One commenter suggested additional data elements be reported by States in the payment rate disclosure: Medicaid-authorized payment rates; minimum base wages that would be paid to direct care workers if the proposed 80 percent requirement is met; average Medicaid payment rates and average direct care worker wages; the minimum, maximum, and median rates of wages; and number of direct care workers employed by the agency.

[330] We remind States that room and board is generally only coverable and payable to an individual who has been admitted to a medical institution as an ''inpatient'' as defined in 42 CFR 440.2 and 435.1010. Therefore, room and board in a facility setting that provides residential or day habilitation service must be excluded from the average hourly Medicaid FFS fee schedule payment rate for habilitation services.

Response: We appreciate commenters' suggestions for the payment rate disclosure. As previously discussed in an earlier response to commenters, in this final rule, we are revising the proposed language ''to providers employed by an agency'' in in § 447.203(b)(2)(iv), (b)(3)(ii), and (b)(3)(ii)(B) and finalizing it as ''provider agencies'' for clarification purposes to more accurately reflect what payment rate we are requiring be published, that is, the payment rate the State pays a provider agency for services its employees have delivered. While the commenters did not provide additional explanation or examples of what they meant by requiring an additional break down of the average hourly payment rate by ''type of service provided,'' we clarify that the payment rate disclosure requires States to publish the average hourly Medicaid FFS fee schedule payment rate for personal care, home health aide, homemaker, and habilitation services, which are types of services, separately. Additionally, while we are not explicitly requiring States break down their payment rates by higher level of need or complexity, we did propose and are finalizing the requirement to break down the average hourly Medicaid FFS fee schedule payment rate by geographical location, which was one of the examples of additional criteria the commenter provided for suggested further breakdown.

However, we are not incorporating the other suggestions to require the other, additional breakdowns of the average hourly payments rates as suggested by commenters or to require additional data elements be reported by States in the payment rate disclosure, to remain consistent across provisions of this final rule. If we were to include these suggestions only for the payment rate disclosure, then the payment rate breakdowns would be inconsistent with the payment rate transparency publication and comparative payment rate analysis in terms of requiring, for example, demographic information about the direct care worker. During the initial compliance period of this final rule and in consideration of the numerous, concurrent regulatory changes States are facing, we believe consistency, where possible, across provisions will contribute to our goal to standardize data and monitoring across service delivery systems with the goal of improving access to care.

Likewise, we are not incorporating the suggestion to identify the average portion of the average payment rate that is used for compensation to pay the direct care worker in the payment rate disclosure. While the suggestion aligns with the intent of HCBS provisions we are finalizing in this rule at § 441.302(k) as discussed in section II.B.5 of this rule, we did not propose to require 80 percent of all payments with respect to services at § 440.180(b)(2) through (4) must be spent on compensation for direct care workers within the payment rate disclosure, as discussed in a later response to comments in this section. As we remain focused on consistency, because we are not requiring a certain percentage of all payments be spent on compensation for direct care workers, we are also not requiring at § 447.203(b)(3)(ii) that States to identify the average portion of the average payment rate that is used for compensation to pay the direct care worker.

We are also not incorporating the suggestion to require States publish the rates that provider agencies pay their employees because, similar to private payer data as a point of rate comparison, rates that provider agencies pay their employees is generally considered proprietary and this information may not be available to States. As previously discussed in an earlier response to comments in this section, we are not requiring in the payment rate disclosure provisions at § 447.203(b)(3)(ii) that States to collect wage, compensation (including benefits), or financial records and information from provider agencies or to publish information about the compensation the provider agency pays to its employee, where applicable.

We want our initial focus to be on establishing the new payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements, providing States with support during the compliance period, and ensuring these data are available to beneficiaries, providers, CMS, and other interested parties for the purposes of assessing access to care issues. While we are not adopting these suggestions, we note that States have the flexibility to add the elements described to their payment rate disclosure publication if they so choose. We will also review how our finalized policies work in conjunction with other policies finalized in this rule to identify any potential areas for future enhancements suggested by the commenters.

Comment: One commenter suggested CMS could ease burden on States by collecting State payment rates from Dual Special Needs Plans (D–SNPs) through Medicare Advantage, rather than requiring States to calculate and publish their average hourly payment rate for the payment rate disclosure.

Response: We appreciate the commenters' suggestion; however, D–SNPs do not provide us with the specific data elements (that is, State Medicaid payment rates, number of Medicaid-paid claims, and number of Medicaid enrolled beneficiaries) we are requiring in this rule. Some D–SNPs only cover Medicare services and do not directly pay for Medicaid services. Other D–SNPs do cover Medicaid services (either directly or through an affiliated Medicaid managed care plan), but this rule only applies to Medicaid FFS payment rates. Therefore, as D–SNPs do not collect or provide us with Medicaid payment rate information that is relevant to this rule, we will not be incorporating this suggestion. Additionally, we believe that the States, as stewards of Medicaid payment rates in the Medicaid program, would be the party best situated to publish and analyze their own payment rate information for the payment rate transparency requirements finalized in this rule, including the payment rate disclosure. States' ownership of payment rate information will ensure accurate payment rate transparency publications, comparative payment rate analyses, and payment rate disclosures.

Comment: A few commenters suggested alternative timelines for States updating their payment rate disclosures. One commenter suggested extending the requirement for updates to the payment rate disclosure to every 3 years, instead of the proposed 2 years, to align with the State's existing data publication cycle. However, another commenter suggested the update frequency of the payment rate disclosure be every year.

Response: We are finalizing the payment rate transparency requirements, including the payment rate disclosure, with an applicability date of July 1, 2026; however, we are not changing the proposed timeframe of 2 years for States to update their payment rate disclosure. We believe requiring updates to the payment rate disclosure every 2 years appropriately balances State burden and maintaining up-to-date information in the payment rate disclosure.

Comment: Most commenters were supportive in response to our request for public comment on whether we should propose a provision to what we proposed at § 441.302(k) (where we proposed to require that at least 80 percent of all Medicaid FFS payments with respect to personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency must be spent on compensation for direct care

workers) in § 447.203(b) on the basis that this provision would help address the direct care workforce crisis and access issues. One commenter suggested that if such a provision were proposed and implemented, then CMS should implement an accountability requirement where States would be required to validate that direct care workers are receiving 80 percent of all Medicaid FFS payments.

Some commenters opposed this consideration and suggested that, if this provision is finalized, the requirement would negatively affect access to care. These commenters aligned with those in opposition to the proposed HCBS provisions at § 441.302(k), as discussed in section II.B.5 of this rule. These commenters opposed this because the policy does not consider that given low levels of payment for relevant services, the remaining 20 percent of the payment rate would be insufficient for the administrative costs (that is, staff, technology, training, travel, oversight) of running a business, provider agencies are already challenged by worker shortages, providers would withdraw from the Medicaid program or stop serving Medicaid beneficiaries, and the requirement would be ineffective without supportive policies in place to implement standards for determining sufficient Medicaid payment rates that provide competitive wages, promote quality services, and ensure compliance with all State and Federal regulations. Commenters in opposition recommended alternatives including: a lower percentage than 80 percent of all Medicaid FFS payments going to compensation for direct care workers, establishing quality outcome metrics, and focusing on wage review and transparency.

Response: We thank commenters for their input and suggestions. We also understand the commenters' concerns. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, particularly from the HCBS provisions finalized in this rule at § 441.302(k) as discussed in section II.B.5, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

Comment: Many commenters expressed concerns about requiring States to publish the average hourly payment rate that States pay for personal care, home health aide, and homemaker services. These commenters were generally concerned that requiring States to publish this information could result in unintended consequences or be ineffective for assessing and improving access to care. The unintended consequences commenters were primarily concerned about included contributing to providers leaving areas where there are low Medicaid payment rates which could create or exacerbate access to care issues in that area and misunderstandings of the required average hourly payment rate without additional context about employee benefits (for example, paid time off, health insurance, pension, employee assistance program) that are not easily disaggregated from an hourly Medicaid service payment rate. Regarding commenter concerns that publishing the average hourly rate would be ineffective, one commenter stated that their State already publishes provider rates, and it has not resolved issues with low and unequal payment rates among providers employed by agencies.

Response: We understand commenters' concerns about the effects of the payment rate disclosure in practice. Regarding commenters' concerns that providers could leave an area where there are low Medicaid payment rates, we would like to emphasize that the payment rate disclosure requirements will afford more transparency to CMS and the public about rates for HCBS, but they will also provide States with an opportunity to identify where existing rates could create an access issue. If the difference in rates between two areas enlists more providers to one area over another, States may need to consider revisions to their payment rates to comply with section 1902(a)(30)(A) of the Act to ''assure that payments . . . are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.'' Therefore, if the transparency created by the payment rate disclosure requirements induces providers to switch locations, affecting access to care, we would expect States to address the rate disparities that the commenter has correctly identified are negatively impacting access.

Regarding commenters' concerns that there could be misunderstandings of the published average hourly payment rate without additional context about employee benefits, the payment rate disclosure provisions at § 447.203(b)(3)(ii) requires States to separately identify the average hourly Medicaid FFS fee schedule payment rates for personal care, home health aide, homemaker, and habilitation services by population (pediatric and adult), provider type, geographical location, and whether the payment rate includes facility-related costs, as applicable, and by provider employment structures (individual providers and provider agencies). As previously discussed in an earlier response to comments in this section, we are not requiring in the payment rate disclosure provisions at § 447.203(b)(3)(ii) that States to collect wage, compensation (including benefits), or financial records and information from provider agencies or to publish information about the compensation the provider agency pays to its employee, where applicable. In other words, we are focused on payment rate transparency for personal care, home health aide, homemaker, and habilitation services rather than what the providers of these services does with their payment rate (that is, pay for employee benefits). Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

We disagree with the commenters that publishing the average hourly Medicaid FFS fee schedule payment rate of personal care, home health aide, homemaker, and habilitation providers through the payment rate disclosure requirement will be ineffective, including because one commenter's State already publishes this information, and the commenter has not seen improvement in low and unequal payment rates among providers employed by agencies. We believe a broad requirement for all States that provide personal care, home health aide, homemaker, and habilitation services through the FFS delivery system will help ensure consistency across delivery systems in monitoring and ensuring access to care, particularly with the HCBS provisions at § 441.311(d)(2) and (e), which require annual State reporting on access and payment adequacy metrics for the same set of services as the payment rate disclosure as well as with the Managed Care final rule (as published elsewhere in this **Federal Register**) provisions at § 438.207(b)(3)(ii) for Medicaid to require a payment analysis of the total amount paid for homemaker services, home health aide services, and personal care services and the percentage that results from dividing the total amount paid by the amount the State's Medicaid FFS program would have paid for the same claims. While the commenter did not provide additional details about

their State's publication of payment rates, we believe that with a broad rate transparency requirement across delivery systems, we can reasonably expect that States, CMS, and interested parties will have transparent payment rate information available to them across delivery systems. Transparency would continually help States and CMS to ensure that their Medicaid payment rates are set at a level that is likely sufficient to meet the statutory access standard under section 1902(a)(30)(A) of the Act that payments be sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area. Transparency also helps to ensure that interested parties have basic information available to them to understand Medicaid payment levels and the associated effects of payment rates on access to care so that they may raise concerns to State Medicaid agencies via the various forms of public process available to interested parties.

Comment: Several commenters expressed concern over low payment rates in Medicaid, particularly for HCBS, dental services, and behavioral health care, and the negative impact on access to care. Many commenters suggested that the primary causes of these low payment rates in Medicaid are stagnant and insufficient payment rates left unadjusted for rising costs, inflation, new regulatory requirements, and increased service expectations over time, particularly for the HCBS direct care workforce.

A few of these commenters suggested CMS could address these issues directly by requiring States conduct regular rate reviews (for example, annual, biennial, triennial, or when a programmatic change occurs), publish the results, and update their payment rates, when necessary, based on criteria that CMS sets. One commenter suggested this could be achieved thorough regular SPA and waiver reviews where CMS could prevent stagnant and insufficient rates from being maintained. Particularly for HCBS, one commenter recommended setting a national standard base pay rate for direct care workers as determined by the States' cost of living index or requiring States have parity for all State payment rates, regardless of geographic location, but allow differences in payment rates for services provided to pediatric and adult populations.

Response: We appreciate the commenters' suggestions. However, we are limited in our authority to directly address the commenters' concerns regarding stagnant and insufficient payment rates. With limited statutory exceptions (such as for hospice services under section 1902(a)(13)(B) of the Act and FQHC/RHC services under section 1902(bb) of the Act, which each establish a floor for provider payment rates which prohibits States from implementing rate reductions below the amount calculated through the methodology provided in the statute), we do not have the authority to require States update their payment rates to a particular level. Section 1902(a)(30)(A) of the Act requires that State plans assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area. Under the statutory authority at section 1902(a)(30)(A) of the Act and through this final rule, we are requiring States to develop and publish a payment rate transparency publication, comparative payment rate analysis of certain services, and payment rate disclosure for certain HCBS, which are directed at helping the States and CMS ensure that State payment rates are consistent with the payment standards under section 1902(a)(30)(A) of the Act.

While we are not explicitly requiring that States update their payment rates to a particular level or regularly submit SPAs and/or waivers (except where desired by the State to implement a programmatic change, consistent with existing requirements) waivers in this rulemaking, we believe there are three requirements within our statutory authority and finalized by this rule that effectively address the concerns raised by commenters. First, this final rule requires States to review their payment rates during the development and publication of their payment rate transparency publications, comparative payment rate analyses, and payment rate disclosures. Specifically, the payment rate transparency publication requires States to regularly review their rates in the course of publishing them and maintaining the current accuracy of the publication, including publishing the date the payment rate publication website was last updated, which will reveal any rates that may be stagnant and potentially insufficient. States must also ensure the data in the publication is kept current (that is, updates must be made within 1 month of a rate change). With this final rule, we focused on transparency to help ensure that interested parties have basic information available to them to understand Medicaid payment levels and the associated effects of payment rates on access to care so that they may raise concerns to State Medicaid agencies via the various forms of public process available to interested parties. We acknowledge the provisions finalized in this rule do not specifically require rate reviews to ensure payment rates are adjusted for rising costs, inflation, new regulatory requirements, and increased service expectations that commenters suggested are factors contributing to a crisis in the HCBS direct care workforce. However, this provision creates a process to help validate that payment rates are compliant with section 1902(a)(30)(A) of the Act.

Second, this final rule requires States to establish an advisory group for interested parties to advise and consult on certain current and proposed Medicaid provider payment rates to ensure the relevant Medicaid payment rates are sufficient to ensure access to homemaker services, home health aide services, and personal care services for Medicaid beneficiaries at least as great as available to the general population in the geographic area. We strongly encourage States to use this group as part of a process to conduct rate reviews and encourage eligible participants (including direct care workers, beneficiaries, beneficiaries' authorized representatives, and other interested parties impacted by the services rates in question, as determined by the State) to join their State's interested parties advisory group once established to bring their concerns directly to States that are setting the payment rates for HCBS.

Third, this final rule establishes a two-tiered approach for determining the level of access analysis States would be required to conduct when proposing provider payment rate reductions or payment restructurings. The first tier of this approach, § 447.203(c)(1), sets out three criteria for States to meet when proposing payment rate reductions or payment restructurings in circumstances when the changes could result in diminished access that, if met, would not require a more detailed analysis to establish that the proposal meets the access requirement in section 1902(a)(30)(A) of the Act. However, meeting the three criteria described in the first tier does not guarantee that the SPA would be approved, if other applicable Federal requirements are not met. The second tier of this approach, § 447.203(c)(2) requires the State to conduct a more extensive access analysis in addition to providing the results of the analysis in the first tier. We believe this two-tiered approach, in

combination with updated public process requirements in § 447.203(c)(4) (which this final rule relocates from § 447.203(b)(7)) will help us ensure that a State's proposed Medicaid payment rates and/or payment structure are consistent with the access requirement in section 1902(a)(30)(A) of the Act at the time the State proposes a payment rate reduction or payment restructuring in circumstances when the changes could result in diminished access.

After consideration of public comments, we are finalizing all provisions under § 447.203(b)(2) to (4) as proposed, apart from the following changes.

• Deleted the word ''following'' in two places in the following sentence in § 447.203(b)(2) ''The State agency is required to develop and publish a comparative payment rate analysis of Medicaid payment rates for each of the **following** categories of services in paragraphs (b)(2)(i) through (iii) of this section and a payment rate disclosure of Medicaid payment rates for each of the **following** categories of services in paragraph (b)(2)(iv) of this section, as specified in paragraph (b)(3) of this section.'' The finalized language now states ''The State agency is required to develop and publish a comparative payment rate analysis of Medicaid payment rates for each of the categories of services in paragraphs (b)(2)(i) through (iii) of this section and a payment rate disclosure of Medicaid payment rates for each of the categories of services in paragraph (b)(2)(iv) of this section, as specified in paragraph (b)(3) of this section.'' (bold added to emphasize the deleted word).

• Replaced ''Medicaid payment rates'' with ''Medicaid fee-for-service fee schedule payment rates'' in § 447.203(b)(2) with regard to the comparative payment rate analysis. The finalized language now states ''. . . publish a comparative payment rate analysis of Medicaid fee-for-service fee schedule payment rates. . .'' for clarification and consistent terminology usage within § 447.203(b).

• Replaced ''Medicaid payment rates'' with ''average hourly Medicaid fee-for-service fee schedule payment rates'' in § 447.203(b)(2) with regard to the payment rate disclosure. The finalized language now states ''. . . [publish] . . . payment rate disclosure of the average hourly Medicaid fee-for-service fee schedule payment rates'' for clarification and consistent terminology usage within § 447.203(b).

• Revised sentence structure organization and added clarifying language to the proposed language stating how the Medicaid FFS payment rates published in the comparative payment rate analysis and the payment rate disclosure need to be listed, if the rates vary. The proposed language in § 447.203(b)(2) stated ''The State agency is required to develop and publish a comparative payment rate analysis of Medicaid payment rates for each of the following categories of services in paragraphs (b)(2)(i) through (iii) of this section and a payment rate disclosure of Medicaid payment rates for each of the following categories of services in paragraph (b)(2)(iv) of this section, as specified in paragraph (b)(3) of this section. If the rates vary, the State must separately identify the payment rates by population (pediatric and adult), provider type, and geographical location, as applicable.''

++ Added the following sentence to address payment rate variation for the comparative payment rate analysis: ''If the rates vary, the State must separately identify the payment rates by population (pediatric and adult), provider type, and geographical location, as applicable.'' in § 447.203(b)(2).

++ Revised the following sentence to add payment rate variation related to facility-related costs for the payment rate disclosure: ''If the rates vary, the State must separately identify the payment rates by population (pediatric and adult), provider type, geographical location, **and whether the payment rate includes facility-related costs,** as applicable.'' (new language identified in bold).

The language is finalized as ''The State agency is required to develop and publish a comparative payment rate analysis of Medicaid fee-for-service fee schedule payment rates for each of the categories of services in paragraphs (b)(2)(i) through (iii) of this section. **If the rates vary, the State must separately identify the payment rates by population (pediatric and adult), provider type, and geographical location, as applicable. The State agency is further required to develop and publish** a payment rate disclosure of the average hourly Medicaid fee-for-service fee schedule payment rates for each of the categories of services in paragraph (b)(2)(iv) of this section, as specified in paragraph (b)(3) of this section. If the rates vary, the State must separately identify the payment rates by population (pediatric and adult), provider type, geographical location, **and whether the payment rate includes facility-related costs,** as applicable.'' in paragraph (b)(2). (new language identified in bold).

• Updated ''Outpatient behavioral health services'' as a category of service in § 447.203(b)(2)(iii) to ''Outpatient mental health and substance use disorder services.''

• Added ''habilitation'' as a category of service in the payment rate disclosure described in § 447.203(b)(2)(iv) and added a reference to § 440.180(b)(6). The finalized language now states ''Personal care, home health aide, homemaker, **and habilitation** services, as specified in § 440.180(b)(2) through (4) and (6), provided by individual providers and provider agencies (new language identified in bold).

• Clarified which publication requirements apply to the comparative payment rate analysis and payment rate disclosure in § 447.203(b)(3) and (b)(4) to align with a previously described update to the organizational structure of paragraph (b)(1) to add romanettes to specify the ''publication requirements described in paragraph (b)(1) **through (b)(1)(ii)** of this section.'' (new language identified in bold).

• Replaced ''Medicaid base payment rates'' with ''base Medicaid fee-for-service fee schedule payment rates'' in § 447.203(b)(3)(i)(B) through (E) for clarification and consistent terminology usage within § 447.203(b).

• Replaced ''Medicare non-facility payment rate'' with ''Medicare non-facility payment rate as established in the annual Medicare Physician Fee Schedule final rule'' in § 447.203(b)(3)(i)(C) and (D) for clarification.

• Added ''and whether the payment rate includes facility-related costs'' in § 447.203(b)(3)(ii)(B) to account for facility-related costs in habilitation settings, particularly residential habilitation or day habilitation. The finalized language now states, ''[t]he disclosure must identify the average hourly Medicaid fee-for-service fee schedule payment rates by applicable category of service, including, if the rates vary, separate identification of the average hourly Medicaid fee-for-service fee schedule payment rates for payments made to individual providers and provider agencies, by population (pediatric and adult), provider type, geographical location, **and whether the payment rate includes facility-related costs,** as applicable in § 447.203(b)(3)(ii)(B) (new language identified in bold).

• Replaced ''average hourly payment rate'' with ''average hourly Medicaid fee-for-service fee schedule payment rates'' in § 447.203(b)(3)(ii) and (ii)(B) and (C) for clarification and consistent terminology usage within § 447.203(b).

• Replaced ''to providers employed by an agency'' with ''provider agencies''

in § 447.203(b)(2)(iv), (b)(3)(ii), and (b)(3)(ii)(B) for clarification.

- Replaced ''Medicaid payment rates'' with ''Medicaid fee-for-service fee schedule payment rates'' in § 447.203(b)(4) for clarification and consistent terminology usage within § 447.203(b).
- Updated the applicability date in § 447.203(b)(4) from January 1, 2026 and effective date of the Medicaid payment rates subject to the comparative payment rate analysis and payment rate disclosure from January 1, 2025 to read: ''The State agency must publish the initial comparative payment rate analysis and payment rate disclosure of its Medicaid fee-for-service fee schedule payment rates in effect as of July 1, 2025, as required under paragraphs (b)(2) and (b)(3) of this section, by no later than July 1, 2026. Thereafter, the State agency must update the comparative payment rate analysis and payment rate disclosure no less than every 2 years, by no later than July 1 of the second year following the most recent update.''

c. Interested Parties Advisory Group § 447.203(b)(6)

In the proposed rule, we noted that a fundamental element of ensuring access to covered services is the sufficiency of a provider network.[331] As discussed elsewhere in this rule, the HCBS direct care workforce is currently experiencing notable worker shortages.[332] A robust workforce providing HCBS allows more beneficiaries to obtain necessary services in home and community-based settings. We proposed to use data-driven benchmarks in requiring comparative payment rate analyses relative to Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year for the categories of service specified in proposed § 447.203(b)(2)(i) through (iii), but Medicare non-facility payment rates are generally not relevant in the context of HCBS, as discussed earlier in this section. Furthermore, data alone cannot replace the lived experience of direct care workers and recipients of the services they provide.

Understanding how Medicaid payment rates compare in different geographic areas of a State and across State programs is also an important access to care data point for covered benefits where Medicaid is a predominant payer of services, as in the case of HCBS. In the absence of HCBS coverage and a lack of available payment rate and claims utilization data from other health payers, such as Medicare or private insurers, and with the significant burden and potential infeasibility associated with gathering payment data for individuals who pay out of pocket (that is, self-pay), we noted our belief that it would be a reasonable standard for States to compare their rates to geographically similar State Medicaid program payment rates as a basis for understanding compliance with section 1902(a)(30)(A) of the Act for those services. In addition, even for services where other payers establish payment rates, comparisons to rates paid by other geographically similar States could be important to understanding compliance with section 1902(a)(30)(A) of the Act since Medicaid beneficiaries may have unique health care needs that are not typical of the general population in particular geographic areas.

Section 2402(a) of the Affordable Care Act directs the Secretary to issue regulations ensuring that all States develop service systems that, among other things, improve coordination and regulation of providers of HCBS to oversee and monitor functions, including a complaint system, and ensure that there are an adequate number of qualified direct care workers to provide self-directed services. This statutory mandate, coupled with the workforce shortages exacerbated by the COVID–19 pandemic, necessitates action specific to direct care workers. As such, we proposed to require States to establish an interested parties advisory group to advise and consult on FFS rates paid to direct care workers providing self-directed and agency-directed HCBS, at a minimum for personal care, home health aide, and homemaker services as described in § 440.180(b)(2) through (4), and States may choose to include other HCBS.

We proposed the definition of direct care workers under § 441.302(k)(1)(ii), which is being finalized under § 441.311(e)(1)(ii) in this final rule. We proposed to use that definition to consider a direct care worker a registered nurse, licensed practical nurse, nurse practitioner, or clinical nurse specialist who provides nursing services to Medicaid-eligible individuals receiving HCBS; a licensed nursing assistant who provides such services under the supervision of a registered nurse, licensed practical nurse, nurse practitioner, or clinical nurse specialist; a direct support professional; a personal care attendant; a home health aide; or other individuals who are paid to provide services to address activities of daily living or instrumental activities of daily living directly to Medicaid-eligible individuals receiving HCBS available under part 441, subpart G. A direct care worker may be employed by a Medicaid provider, State agency, or third party; contracted with a Medicaid provider, State agency, or third party; or delivering services under a self-directed service model.

We proposed that the group would consult on rates for service categories under the Medicaid State plan, section 1915(c) waiver and demonstration programs, as applicable, where payments are made to individual providers or providers employed by an agency for, at a minimum, the previously described types of services, including for personal care, home health aide, and homemaker services provided under sections 1905(a), 1915(i), 1915(j), and 1915(k) State plan authorities, and section 1915(c) waivers. These proposed requirements also would extend to rates for HCBS provided under section 1115 demonstrations, as is typical for rules pertaining to HCBS authorized using demonstration authority. We proposed that the interested parties advisory group may consult on other HCBS, at the State's discretion.

In this final rule, we are adding an additional service to the group's purview, habilitation services as found under § 440.180(b)(6). In the proposed rule, we proposed an alignment of services subject to the requirements between the HCBS payment adequacy and access to care metrics requirements, and the payment rate disclosure and interested parties advisory group provisions. Within the payment adequacy and access to care metrics provisions of the proposed rule, we requested comment on whether to expand services subject to those requirements to include habilitation services from the proposed personal care, home health aide, and homemaker services. In this final rule, we are adding habilitation services to the reporting requirements for direct care worker compensation data under § 441.311(e) and access to care metrics under § 441.311(d)(2), and therefore are adding habilitation services to the interested parties' advisory group's purview (and, as previously discussed, to the payment rate disclosure requirements). This addition will create consistency between HCBS-related provisions of this final rule. It will also simplify the process for States to provide the relevant materials to members of the interested parties advisory group, and avoid any confusion on the scope of review. We also want to note the point made in earlier provisions of this final

[331] 88 FR 27960 at 28023.

[332] *https://www.macpac.gov/wp-content/uploads/2022/03/MACPAC-brief-on-HCBS-workforce.pdf.*

rule, that habilitation services can mean residential habilitation, day habilitation, or home-based habilitation services. All three types are included within the ''habilitation services'' we are adding to this provision.

In § 447.203(b)(6), we proposed that the State agency would be required to establish an advisory group for interested parties to advise and consult on provider rates with respect to service categories under the Medicaid State plan, section 1915(c) waiver and demonstration programs, as applicable, where payments are made to the direct care workers specified in § 441.311(e)(1)(ii) for the self-directed or agency-directed services found at § 440.180(b)(2) through (4). In this final rule, as noted, we are adding habilitation services as found at § 440.180(b)(6). The interested parties advisory group would be required to include, at a minimum, direct care workers, beneficiaries and their authorized representatives, and other interested parties. We explained that ''authorized representatives'' refers to individuals authorized to act on the behalf of the beneficiary, and other interested parties may include beneficiary family members and advocacy organizations. To the extent a State's MAC established under proposed § 431.12, if finalized, meets these requirements of this regulation, we proposed that the State could use that committee for this purpose. However, we noted the roles of the MAC under proposed § 431.12 and the interested parties advisory group under proposed § 447.203(b)(6) would be distinct, and the existence or absence of one committee or group (for example, if one of these proposals is not finalized) would not affect the requirements with respect to the other as established in a final rule.

We further proposed in § 447.203(b)(6)(iii) that the interested parties advisory group would advise and consult with the Medicaid agency on current and proposed payment rates, HCBS payment adequacy data as required at § 441.311(e), and access to care metrics described in § 441.311(d)(2), associated with services found at § 440.180(b)(2) through (4), to ensure the relevant Medicaid payment rates are sufficient to ensure access to homemaker services, home health aide services, and personal care services for Medicaid beneficiaries at least as great as available to the general population in the geographic area and to ensure an adequate number of qualified direct care workers to provide self-directed personal assistance services. We want to clarify that the group would not be required to advise and consult on the HCBS payment adequacy data as required under § 441.311(e), and access to care metrics under § 441.311(d)(2), until such a time as those data are available under the newly established requirements. We also want to note again here that we are expanding the service categories to include habilitation services as found at § 440.180(b)(6).

In § 447.203(b)(6)(iv), we proposed that the interested parties' advisory group would meet at least every 2 years and make recommendations to the Medicaid agency on the sufficiency of State plan, 1915(c) waiver, and demonstration direct care worker payment rates, as applicable. The State agency would be required to ensure the group has access to current and proposed payment rates, HCBS provider payment adequacy minimum performance and reporting standards as described in § 441.311(e), and applicable access to care metrics for HCBS as described in § 441.311(d)(2) to produce these recommendations. These materials would be required to be made be available with sufficient time for the advisory group to consider them, formulate recommendations, and transmit those recommendations to the State. If the State has asked the group to consider a proposed rate change, the State would need to provide the group with sufficient time to review and produce a recommendation within the State's intended rate adjustment schedule. We noted that this would be necessary because the group's recommendation would be considered part of the interested parties input described in proposed §§ 447.203(c)(4) and 447.204(b)(3), which States would be required to consider and analyze. The interested parties advisory group would make recommendations to the Medicaid agency on the sufficiency of the established and proposed State plan, section 1915(c) waiver and demonstration payment rates, as applicable. In other words, the group would provide information to the State regarding whether, based on the group's knowledge and experience, current payment rates are sufficient to enlist a sufficiently large work force to ensure beneficiary access to services, and whether a proposed rate change would be consistent with a sufficiently large work force or would disincentivize participation in the work force in a manner that might compromise beneficiary access. We clarify here, as well that the State would not be required to make available the HCBS provider payment adequacy minimum performance and reporting standards under § 441.311(e), and applicable access to care metrics for HCBS under § 441.311(d)(2), until such a time as those data are available per the applicable applicability dates of those respective provisions in this final rule.

We proposed to require States to convene this interested parties' advisory group every 2 years, at a minimum, to advise and consult on current and suggested payment rates and the sufficiency of these rates to ensure access to HCBS for beneficiaries consistent with section 1902(a)(30)(A) of the Act. This timing aligns with the comparative payment rate analysis and payment rate disclosure publication requirements proposed in § 447.203(b)(4), although we noted that this would be a minimum requirement and a State may find that more frequent meetings would be necessary or helpful for the advisory group to provide meaningful and actionable feedback. We further proposed that the process by which the State selects its advisory group members and convenes meetings would be required to be made publicly available, but other matters, such as the tenure of members, would be left to the State's discretion. We want to note that the 2-year cadence could require the group to convene its first meeting and produce a recommendation before the HCBS payment adequacy data as required under § 441.311(e), and access to care metrics under § 441.311(d)(2), will be available. We do not expect the State to furnish information to the group that is not yet available or for the group to comment on those topics for which the State has not yet provided data. We nevertheless are maintaining the 2-year cadence that would require a recommendation 2 years from the effective date of this final rule, as we believe the benefits to the State and group in convening that initial time, even with a limited availability of data for the first meeting, will be beneficial for getting the group to be operational. States have the flexibility to convene the group within a shorter timeframe to adjust the future cadence to align with other publication schedules, if desired.

Finally, in § 447.203(b)(6)(v), we proposed that the Medicaid agency would be required to publish the recommendations of the interested parties' advisory group consistent with the publication requirements described in paragraph (b)(1) of this section for payment rate transparency data, within 1 month of when the group provides the recommendation to the agency. We intend that States would consider, but not be required to adopt, the recommendations of the advisory group. Under this proposal, the work of the

advisory group would be regarded as an element of the State's overall rate-setting process. Additionally, the feedback of this advisory group would not be required for rate changes. That is to say, should a State need or want to adjust rates and it is not feasible to obtain a recommendation from the advisory group in a particular instance, the State would still be permitted to submit its rate change SPA to CMS. However, to the extent the group comments on proposed rate changes, its feedback would be considered part of the interested parties input described in proposed §§ 447.203(c)(4) and 447.204(b)(3), which States would be required to consider and analyze, and submit such analysis to us, in connection with any SPA submission that proposes to reduce or restructure Medicaid service payment rates. In addition, by way of clarification, we noted our intent that the advisory group would be permitted to suggest alternate rates besides those proposed by the State for consideration.

We solicited comments on the proposed interested parties' advisory group and about whether other categories of services should be included in the requirement for States to consult with the interested parties advisory group. We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received many comments expressing general support for the establishment of the interested parties advisory group. Commenters agreed that individuals with lived experience would provide invaluable insight into appropriate rates for direct care services, including both beneficiaries and direct care workers, which the proposed group would include. Commenters also pointed to a number of anticipated benefits, such as helping to increase pay for these valuable workers, giving beneficiaries a voice on decisions that impact them, providing additional insights into a unique area of the healthcare market, identifying what can attract workers, and addressing an area of critical concern for staffing, which is necessary for the stability of access to HCBS. Multiple commenters stated it was important to have payment rate decisions focus on community needs rather than be determined solely by a State's budget, and thus better meeting the needs of beneficiaries. One commenter stated this group would be valuable for staying abreast of the day-to-day provision of services as it relates to current pay rates, while another noted how it is important to focus on rates in a service area for which there is no Medicare comparison. Another stated this proposal should be used as the template for group feedback and reporting for all provider payment systems in a State.

Some commenters also chose to specifically highlight aspects of the proposals for this group they agreed with. These include having a group to advise on wages, the cadence of group meetings, the publication requirements, the composition of the group members, and allowing States to set the tenure for members. One commenter also pointed out how this group will complement payment adequacy requirements by identifying rates that may meet a set threshold for direct compensation but remains low generally.

Response: We thank commenters for taking the time to express support for the provision and for highlighting many of the areas where we expect this group will add value. We are finalizing the provisions related to the interested parties' advisory group as proposed, with the addition of habilitation services. The shortage of direct care workers demands special attention, and we hope that finalizing these requirements will be one of several steps contained in this final rule toward addressing those concerns.

Comment: A very large proportion of commenters on these provisions had recommendations for changes or enhancements to the interested parties advisory group. A number of those comments related to the composition of the group, with commenters requesting certain proportions for types of members, or specific member positions be added generally or defined as an interested party. Specifically, various commenters recommended a required composition of 25 percent beneficiary representation, 25 percent direct care workers, and 25 percent provider employers, such as representatives from an agency providing HCBS and employing direct care workers. Some commenters expressed similar sentiments without precise numbers, instead recommending representation by various individuals: agency-based model providers; consumer-directed model providers; union representatives; patient advocates; program administrators; politicians; or members of the general public. Some commenters recommended that a majority of members be beneficiaries, unpaid beneficiary caregivers, and advocacy organizations. These commenters had concerns about the possibility that certain key voices could be silenced if not sufficiently represented within the overall composition of the group.

A number of commenters stated that the regulations should require other specific member types without defining in what proportion. There were multiple requests to require members from unions, worker advocacy organizations, consumer advocates, and representatives from provider agencies and provider State associations. These commenters wanted to ensure certain technical expertise would be available amongst the group members. For example, a qualified consumer advocate may have knowledge of technical program aspects that other members may not.

One commenter requested nurses be included in the group, and another requested physician anesthesiologists, noting that they are subject to a uniquely structured payment system. Several commenters stated the group should bar employees of the State agency to ensure independence in developing the recommendations.

Finally, a few commenters requested members who were already among those included in the proposed regulation. Specifically, one commenter stated the group should include paid direct service workers, while another stated HCBS providers should be included.

Response: As stated, we are finalizing the interested party advisory group requirement as proposed apart from the addition of habilitation services, and that includes the provisions defining the membership of the group without specifying particular proportions of required membership. We agree generally that additional types of members such as those suggested by commenters could bring unique perspectives or expertise to the group. Nevertheless, we are finalizing as proposed the membership requirements, because we intentionally proposed a great deal of flexibility for States in recognition of the unique circumstances of State Medicaid programs. We also want to ensure States can meaningfully implement the requirements for this group, and every additional member or type of member presents additional considerations for recruitment needed to set up the group, as well as logistical considerations for coordinating meetings. We believe a limited but inclusive list, with considerable State flexibility in determining the composition of the group, will ensure that interested parties' voices are heard and not silenced, but as with any new policy, we will monitor implementation to identify if adjustments may be needed through future rulemaking.

As the proposed rule contained many changes to existing requirements and processes, we were mindful at every

step of the burden this would place on States, and balanced potential State burden against the proposal's potential to help ensure and improve access. After careful consideration, we determined it was more important to implement a basic framework for the interested party advisory group and leave many details of its precise composition and operation to the States. Our access work is ongoing, and we will consider the recommendations provided on the proposed rule for any additional changes we may propose through future rulemaking.

We would encourage States, when recruiting members, to consider the composition of members that would best satisfy the goals of this group and identify where there is a need for technical expertise, sufficient representation, etc., and work to establish the group in a manner that promotes its efficient functioning and meaningful contribution to Medicaid policies in the State. The inclusion of ''other interested parties'' affords States the flexibility to do so. We believe the lived experiences of the members of this group when coupled with the requirements for States to provide relevant documents and reports for the group's consideration, will be adequate to provide the type of perspective on rates we are seeking through this group.

Finally, we want to clarify which members States are required to include as part of the interested parties advisory group. States are required to include direct care workers, beneficiaries, beneficiaries' authorized representatives, and other interested parties impacted by the rates in question, as determined by the State, which may include beneficiary family members (other than those who may be authorized representatives for beneficiaries) and advocacy organizations. Representation from each type of individual specified on this list is required. As such, the group could not be solely beneficiaries, or solely direct care workers, or solely other individuals meeting neither of those criteria but whom a State would deem an interested party.

Comment: Another area where many commenters made suggestions was with respect to the scope of the group's work and the requirements related to consideration of the group's recommendations. Many commenters recommended that CMS require States to consult with the group for any rate or payment methodology changes, highlighting the value of the group's input, and to require a written, public response to the recommendation of the group, with evidence and rationale, where the final rates differ from what the group recommended. One commenter also requested a public comment process for the group's recommendations. Some emphasized the importance of transparency of this process, and one suggested recommendations and responses be made public for a minimum of 30 days prior to the effective date of a new rate. Several commenters, noting the proposal made the group advisory in nature, recommended that States be required to justify when they choose to go against the recommendation of the group, with some of those commenters offering that at a minimum the State must engage again with the group when intending to finalize rates that differ from the group's recommendation, including meaningful negotiations with the providers represented on the group, perhaps with steps defined by CMS to reach consensus. One commenter wanted the public process regulations at § 447.204(a)(2) updated to explicitly include obtaining and considering the interested parties advisory group's input. The importance of the group's recommendation came up in multiple comments, with one stating it is not enough merely to require the State to receive, and provide a written response to, the advisory groups' input, but that we should ensure the group has authority to shape policy.

Some commenters had detailed recommendations for additional requirements related to the group's output. One suggested a structured and routine process for regular review and approval of new rates or changes, with meaningful input from beneficiaries. The commenter requested the structured process to be coupled with a requirement for States to explain the roles and responsibilities of a rate review advisory body. Another wanted CMS to require States to clearly delineate how a proposed rate change has factored in inflation and any unfunded mandates on providers. One commenter stated that the group's recommendations should go to the State Medicaid director, as well as to the governor, the State legislature, and HHS. Like other commenters, this commenter wanted the State to communicate acceptance or denial of recommendations to the group, with explanations of the State's decisions in writing, but also stressed that CMS must monitor the State advisory committees as part of accountability and transparency and provide feedback to the State.

Some comments also contained other, related recommendations for the group's purview. Two commenters recommended the group be allowed to advise and comment on a broad range of HCBS provider rates, with one suggesting CMS consider leveraging the group for feedback on HCBS access issues more broadly. That commenter stressed the importance to the Medicaid program to evaluate rates and access for HCBS, especially considering the unique market power of Medicaid for HCBS infrastructure. A commenter requested the group's rate review consider the experience of individuals dually eligible for Medicare and Medicaid and factors related to Medicare coverage. One commenter stated the group should advocate for creating a sustainable wage program to attract and retain staff to benefit both recipients and providers of the specified services. Another commenter recommended that the group should review and comment on provider payment rates in managed care delivery systems. One commenter, in response for our request for comment on the services under review, stated the group should focus on direct care work across all waiver categories. Finally, a couple commenters sought clarity on how States must acknowledge or respond to the group's recommendations.

Response: We are finalizing as proposed the advisory nature of the interested parties advisory group. We agree that the group's input will be valuable in setting rates, assessing payment adequacy and applicable access to care metrics, and may provide a perspective on rates and access that could be lacking in existing processes. As one commenter noted, Medicaid has an important and large role in the market for HCBS. However, we believe the policies as we are finalizing them strike the right balance of accountability and flexibility for a wholly new rate advisory group process. The State will be required to publish the recommendations of the interested parties advisory group for transparency, under § 447.203(b)(6)(v). In addition, when the group has a recommendation on a proposed rate change, the State will be required to consider and respond to that recommendation as it would be deemed part of the input of interested parties described in §§ 447.203(c)(4) and 447.204(b)(3). In light of the public notice and public input requirements already in place when a State proposes a rate change, and treatment of the recommendation as public input to which a State is required to consider and address under these requirements, we are not establishing any specific, new public notice or comment process requirements for the recommendations

of the interested parties advisory group. The group could recommend a sustainable wage program, but we are not adding a requirement to develop one. We intend for the group to have broad discretion, within their remit, to make recommendations to the State, which could thereby result in such recommendations. We encourage the group to provide feedback to assist the State in implementing a sustainable HCBS program.

By keeping the group's recommendations recommendation advisory only (that is, non-binding on the State), we intend for the State to give serious consideration to the group's recommendations while avoiding the imposition of policy strictures on the State that could require sudden shifts in budget priorities or create conflicts, for example, with the State legislature. Fundamentally, the single State Medicaid agency must maintain ultimate responsibility to operate the State's Medicaid program. Also, because the group is advisory only, we are not including requirements for the State to negotiate with providers or the group on rate changes, or justify when a rate change is made that is not consistent with the recommendation of the group. However, we remind States that the group's recommendation, to the extent it has commented on rates included in a SPA, would be considered part of the public feedback to which the State must respond, under §§ 447.203(c)(4) and 447.204.

As part of the requirement to establish the interested parties' advisory group in this final rule, States will be responsible for giving appropriate guidance to the group so that it understands its role and responsibilities in producing recommendations. We defer to States on how to best communicate this information to the group. We also want to emphasize for States that the information they provide the group can be expected to shape the nature of the group's recommendations. As such, although we are not requiring the State to explain if and how inflation has factored in to a proposed rate, for example, or provide information to the group on costs imposed on providers beyond what is required under the payment adequacy metrics required under 441.311(e), it would benefit a State to provide as much context as possible to the group so that it can produce the strongest, best-informed, most useful recommendations. Because the group's recommendations must be published publicly, interested parties such as State legislators and HHS will be able to see and review any recommendations.

In addition, with the meeting cadence we are finalizing (at least every 2 years), and with recent examples of when a rate change may be needed to be enacted quickly (for example, to address urgent programmatic needs in connection with the COVID–19 pandemic and public health emergency), it is not feasible to require consultation with the group for every possible rate change. We also note that the mandate of the group and the minimum required meeting cadence should not be viewed as limitations, and States have flexibility to rely on this group in ways that will best help to enhance HCBS or Medicaid more broadly. States may have the group review broader HCBS issues or rates if it so chooses; we merely focused the required scope on the most frequently used HCBS. They can also have the group advise on provider payment rates in managed care delivery systems even though that was not our prioritized focus in this new requirement, under the flexibility States have to direct the work of the group. We also note that although we are not requiring dually eligible beneficiaries specifically in the group to maximize the available pool for recruiting beneficiary members of the group, the majority of HCBS recipients are dually eligible. Finally, we appreciate the many recommendations and suggestions that we will consider if and when we examine the regulations for this group for potential changes through future rulemaking as part of our ongoing access work.

Comment: Several commenters had recommendations for the nature of materials, data, explanations, and information the group should have access to, to ensure the group's input could be fully informed by data, both public and internal to the agency, as to how any rates were calculated. These comments included advice on what materials the group should have access to or suggestions of sources the group should be required to review and consider. Specifically, a couple of commenters wanted the group to be required to consult any analyses performed pursuant to the requirements we are finalizing in § 447.203(c), since those analyses would include valuable data on the number of home care claims, the number of enrollees receiving home care services, and the number of providers furnishing such services. Another commenter recommended the group to be required to consult wage data, such as data from the Bureau of Labor Statistics or from unions, to use as a basis of rate recommendations. Another commenter encouraged CMS to partner with the Department of Labor to provide States with data on competitive wages for other occupations with similar low entry level requirements, to avoid putting burden on States while providing the advisory group with State-level economic data to assess the competitiveness of direct care worker wages.

One commenter provided a detailed recommendation for data to provide the group, including explanations and supporting information on how any proposed rates were calculated, in addition to the metrics required under the payment adequacy and reporting requirements provisions of this final rule. Specifically, the commenter stated this information should include clear, consistent definitions of the cost elements that are considered in establishing a rate, noting that if the definitions of cost components such as employee travel or training are not clear and the bases for these calculations are not shared with sufficient granularity, then the advisory group will not be able to meaningfully comment. Similarly, a commenter urged CMS to ensure that the interested parties advisory group have access to both public-facing reports that States are required to produce and publish described in payment transparency provisions of this rule, and to the underlying data that States use to prepare these reports, which may allow the interested parties advisory group to identify trends or access issues that are not readily apparent in the public reports. One commenter recommended that States be required, through a phase-in, to both collect and provide to the group data on turnover and vacancy rates for direct care workers. The commenter explained that tools currently used by States, such as the National Core Indicators-Intellectual and Developmental Disabilities Staff Stability Survey, or the National Core Indicators-Aging and Physical Disabilities tool currently being piloted, only provide data for agency-directed workers, and as such, more information was needed about independent providers in self-directed programs. The commenter noted these are important data elements to assess the adequacy of wages and compensation.

Finally, a few commenters stated that States should make compensation, including information on median wages and historic trends in compensation, available to all members of the public, for transparency and to assist current or future members of the group itself.

Response: We are finalizing as proposed, apart from the addition of habilitation services, the regulation requiring that the group will advise and consult on current and proposed

payment rates, HCBS provider payment adequacy reporting information under § 441.311(e),), and applicable access to care metrics under § 441.311(d)(2), associated with services found at § 440.180(b)(2) through (4) and (6). The responsibility for the group to advise and consult on these matters necessarily implies that the State must ensure that the group is provided access to current and proposed rate information, HCBS provider payment adequacy data, and applicable access to care metrics. We believe that these requirements, coupled with requirements we are finalizing for payment rate disclosures for HCBS at § 447.203(b)(2) through (3), will provide the group with sufficient data to develop and support their recommendations, and we also believe those additional finalized provisions will provide reassurance to commenters interested in more publicly available data. We further note that certain data, such as certain BLS wage data, are already publicly available and can be used by the group. We remind States that they are not limited to the requirements we are finalizing and are free to consider and provide as much data that the State considers relevant and reasonably available to support the group in its work.

We did not propose and are not finalizing any data collection requirements specifically with respect to the interested parties' advisory group to inform their consideration of Medicaid payment rates for certain HCBS, although we understand that currently available tools and data may have some gaps. In view of the otherwise existing information sources just discussed, we do not believe the value of requiring States to identify or develop and make available additional data sources, such as reporting on independent providers in self-directed programs, would outweigh the added burden of a new data collection. We are similarly not taking on any additional data collection to support these efforts, again noting that we think the policies in this final rule will be sufficient, but as with any new or existing policy we will work with our State partners to assist them in establishing these groups and identifying where we can support State efforts that may extend beyond the requirements in this final rule.

Comment: We received a number of comments around various administrative aspects of § 447.203(b)(6), from member recruitment to the meeting cadence. Several commenters stated that the State should publicly recruit members and requested States to publicly disclose the process of how those members are recruited and the process to convene meetings. A few commenters recommended the members have term-limits, coupled with the protection to only be removed for cause during a term, in order to protect the individuals and the group from reprisal or disbandment.

Comments about the meeting cadence varied. A few recommended the group should meet for every rate change proposed by the State, one agreed with a biannual cadence, while another suggested to increase the cadence to annually in addition to meeting for every rate change. Another commenter supported annual meetings and noted that issues impacting the lives of beneficiaries and workers that should be addressed by rates can happen at a more frequent rate than biannual State budget cycles. One commenter stated the meeting cadence should be every 6 months.

A few commenters suggested a number of additional recommendations such as the regulation should include a requirement of recordkeeping, and the regulation should focus on the distinction between independent and agency-employed workers. Finally, one commenter suggested a name change for the group, ''direct care workforce payment advisory committee,'' to clarify the role and importance of the group.

Response: We appreciate the feedback about the specifics of the administration of the interested parties advisory group. We are finalizing these aspects as proposed. The meeting cadence, as noted by the commenter, is intended to align with usual State budgetary cycles. While other factors may impact the needs of beneficiaries, providers and direct care workers, the State budget creates the framework in which decisions and recommendations can be made, and we believe aligning with that cycle appropriately balances the value gained from the interested parties advisory group's recommendations with burden on States. Similarly, we are finalizing the ability of States to determine the tenure of members, as States are best situated to assess their beneficiaries' and workers' ability to participate in an advisory group and for what length of time. Term limits and removal for cause will be at the State's discretion to ensure the effective operation of the group. We note that the regulation does specify that the process by which the State selects interested parties advisory group members and convenes its meetings must be made publicly available, which aligns with recommendations from some commenters.

States have requirements to maintain records of public input under § 447.203(c)(4)(iii), and as stated we would regard the recommendation of the group a form of public input to the extent the group comments on proposed rates.

With respect to individual and agency-employed providers, the payment rate disclosure requirements under § 447.203(b)(3)(ii2)(iv) require States to publish average hourly Medicaid FFS fee schedule payment rates for individual providers and provider agencies separately to the extent they differ, creating a new method through which the State, CMS, and the public can scrutinize any rate difference between individual providers and provider agencies. We are not adding additional requirements for the group to examine further distinctions between individual and provider agencies, but as the group will be reviewing current and proposed rates, they will have the opportunity to see where such rates differ and make recommendations accordingly.

Finally, we appreciate the suggestion to change the name of the group, but we want to remind that the purview of this group is not solely payments for HCBS, although that is the primary focus. The work includes access metrics, specifically HCBS payment adequacy data as required at § 441.311(e), and access to care metrics under § 441.311(d)(2). We understand the name is rather generic, and we will make every effort to ensure any materials or communications are clear about when an ''interested parties advisory group'' is in reference to § 447.203(b)(6).

Comment: We received some comments in opposition to an interested parties advisory group. A primary, recurring element of these comments was related to the burden of establishing this group relative to the value the commenters thought the group would add. One commenter stated this group would be duplicative of other State efforts, without adding value. Another was concerned that the group would establish a pattern for more, similar groups to be created, resulting in significant State burden. Another stated the group would create undue interference in a State's ability to manage its Medicaid program. One commenter stated that limiting the group's purview to three services would create disjointedness in discussions about HCBS or broader rates in general.

One commenter stated that their MCAC (or, following the effective date of this final rule, their MAC), already performs the same functions as the

proposed interested parties advisory group. Another requested an exception to the requirement for States that already have a group established for similar topics. Two commenters in opposition to the requirement had recommendations for adjustments. One commenter stated that the group should not include members who have a conflict of interest because they stand to receive a financial benefit from the decisions of the group, or that the scope of the group's recommendations should exclude payment rates if group members have financial conflicts of interest. Another commenter, who thought the group was unworkable and likely would not be productive, indicated it would be more productive to require States to establish a separate advisory group for each rate setting activity they undertake and to include both industry and consumer (beneficiary) representatives.

Response: We understand that there will be costs and work for States to set up a new advisory group. We do not take lightly the decision to finalize this policy. However, the circumstance of HCBS and the direct care workforce shortage described earlier in this section demand immediate action. We kept the required scope of the group's remit narrow to allow States that need to minimize the work of the group the ability to focus most acutely on certain services and certain topics around rates, access, and payment adequacy. However, we also wrote into these regulations a great deal of flexibility for States. We understand the burden our requirements put on States, which is why we take steps to create and highlight flexibility for States to minimize the burden of new requirements and help ensure that States are able to comply with new requirements in a manner likely to result in the greatest benefit given the particular circumstances of the State and its provider and beneficiary communities. We make these assessments with every rulemaking proposal. The creation of this group does not mean that we necessarily will propose to require the formation of additional similar, discrete groups in the future; we are mindful that any such proposal would be likely to involve additional burden on States, and analysis of that burden would inform any future proposal.

If a State believes the group, in the form which we are finalizing in this final rule, will not add value, there is room to expand and enhance the group to a point where that State realizes value to its program. The group's purview includes the requirement to examine rates for three services, but States can always have the group advise on more. In addition, the group will not be in a position to unduly influence the State's Medicaid program, as its role is only advisory in nature and the single State agency will maintain full responsibility to administer the State's Medicaid program. We also want to remind States what we included in the proposed rule, that to the extent a State's MAC established under § 431.12 meets the requirements of this regulation, the State could utilize that committee for this purpose, thereby eliminating duplication between these entities. Furthermore, while we are unaware of specific examples, if a State has another, extant group that meets the requirements of § 447.203(b)(6), then we expect the State could use that group for this purpose as well, similar to what we indicated for MACs. Finally, we do not agree that having members in the group with a financial interest, such as the direct care workers whose wages may be impacted, and advising on rates creates a problematic conflict of interest. Rather, in the case of direct care workers, we believe their lived experience will supply a valuable perspective, and their input on rates specifically could be useful to the State agency that (although operating under a fiduciary obligation to administer the Medicaid program in the best interest of beneficiaries under section 1902(a)(19) of the Act) also has a fiscal interest in a proposed rate change. This final rule leaves States free to establish conflict of interest policies applicable to the members of the interested parties' advisory group, which we expect States will do in a manner that protects the integrity of the group while not unduly restricting input from individuals with perspectives the final rule is intended to ensure are heard.

Comment: Several commenters responded to language included in the proposed rule that, to the extent a State's MAC established under proposed § 431.12 also meets the requirements of this advisory group regulation, the State could utilize that committee for this purpose. The majority of those comments recommended keeping the MAC separate. These commenters explained that the work involved merits two groups and any overlap of membership between the groups would be acceptable and potentially beneficial. One of those commenters stated that the work of the interested parties' advisory group was much more specialized than that of the MAC. One suggested the interested parties' advisory group be a subgroup of the MAC, similar to the BAG. Finally, one commenter suggested that the MAC and interested parties' advisory group meetings be kept separate, or the MAC could have a dedicated subgroup responsible for HCBS, to ensure adequate attention to the topic. There were a few commenters who appreciated the flexibility to allow for the MAC to serve this dual purpose of meeting both the MAC requirements and the interested parties' advisory group requirements, and one expected some States may pursue this flexibility.

Response: When we were developing the proposed rule, which included proposals under § 431.12 to reconfigure the MCAC as the MAC and BAG (now BAC), we noted that the membership and scope of the MAC could potentially align with what we were proposing for the interested parties' advisory group. While we agree that the work of each is distinct and important, deserving of dedicated time and focus, we also seek to avoid duplication where possible. If a MAC has membership that includes direct care workers, beneficiaries, beneficiaries' authorized representatives, and other interested parties impacted by the services and rates of focus in the interested parties' advisory group, then we believe it would be unnecessarily duplicative to require a separate group and deny the State the ability to include the remit of the interested parties' advisory group in the work of the MAC under the flexibility given to States and their MACs under § 431.12(g)(8), which we are finalizing to include in the MAC's scope ''[o]ther issues that impact the provision or outcomes of health and medical care services in the Medicaid program as determined by the MAC, BAC, or State.'' States potentially also could establish the interested parties' advisory group as a subgroup of the MAC, similar to the BAC, consistent with the requirements of this final rule. States will have the discretion to determine if the groups and/or their meetings need to be kept distinct in order best to fulfil the obligations of each.

However, we caution States that this flexibility is not creating any type of exception. The cadence of required meetings, focus, and work products of the interested parties advisory group are distinct, and States wishing to utilize their MAC will need to take adequate steps to ensure the MAC is meeting the regulatory requirements for both entities. Some States may find keeping the interested parties group distinct will allow for easier recruitment, retention, and focus on the relevant subject matter. We also want to highlight the concerns expressed by commenters requesting the groups be kept distinct and emphasizing

the specialized work of this interested parties advisory group. Although we did not elect to add requirements to keep the groups or meetings distinct, States should do so if combining the groups or their meetings would hinder the work of either the MAC or interested parties advisory group.

Comment: A few commenters requested additional clarity about what support would be available for States to establish the advisory group. A couple of commenters requested CMS confirm that States can claim FFP for activities related to establishing and running this group, similar to the confirmation provided in the MAC/BAG provisions explicitly saying FFP would be available.[333] Others requested CMS make States aware of any available funding streams or opportunities for enhanced match.

Response: In the proposed rule, we specified that ''FFP would be available for expenditures that might be necessary to implement the activities States would need to undertake to comply with the provisions of the proposed rule, if finalized.''[334] As we are finalizing the requirements related to this advisory group, FFP will be available for States claiming qualifying expenditures for related activities. We note that generally, the applicable matching rate will be the general 50 percent administrative matching rate, but to the extent a State incurs expenditures it believes qualify for a higher match rate, higher statutory matching rates potentially could be available to the extent the expenditures meet applicable Federal requirements. There is not a separate, unique funding source for this provision of the final rule.

After consideration of public comments, we are finalizing all provisions under § 447.203(b)(6) with the following changes:

- Added a regulatory reference for habilitation services as a category of service in § 447.203(b)(6)(i). The finalized language now states ''. . . for the self-directed or agency-directed services found at § 440.180(b)(2) through (4) **and (6)**.'' (new language identified in bold).
- Added a regulatory reference for habilitation services and ''habilitation'' as a category of service in § 447.203(b)(6)(iii). The finalized language now states ''. . . associated with services found at § 440.180(b)(2) through (4) **and (6)**, to ensure the relevant Medicaid payment rates are sufficient to ensure access to personal care, home health aide, homemaker, and **habilitation** services'' (new language identified in bold).
- Added language to clarify the ''. . . publication requirements described in paragraph (b)(1) **through (b)(1)(ii)** of this section . . .'' (new language identified in bold).
- Minor technical changes to wording.

3. State Analysis Procedures for Rate Reduction or Restructuring (§ 447.203(c))

As stated previously, the Supreme Court's Armstrong decision underscored the importance of CMS' administrative review of Medicaid payment rates to ensure compliance with section 1902(a)(30)(A) of the Act. CMS' oversight role is particularly important when States propose to reduce provider payment rates or restructure provider payments, since provider payment rates can affect provider participation in Medicaid, and therefore, beneficiary access to care. In § 447.203(c), we proposed a process for State access analyses that would be required whenever a State submits a SPA proposing to reduce provider payment rates or restructure provider payments.

As noted previously, the 2015 final rule with comment period required that, for any SPA proposing to reduce provider payment rates or restructure provider payments in circumstances when the changes could result in diminished access, States must submit a detailed analysis of access to care under previous §§ 447.203(b)(1) and (b)(6) and 447.204(b)(1). This analysis includes, under previous § 447.203(b)(1), the extent to which beneficiary needs are fully met; the availability of care through enrolled providers to beneficiaries in each geographic area, by provider type and site of service; changes in beneficiary utilization of covered services in each geographic area; the characteristics of the beneficiary population (including considerations for care, service and payment variations for pediatric and adult populations and for individuals with disabilities); and actual or estimated levels of provider payment available from other payers, including other public and private payers, by provider type and site of service. Previously, this information was required for any SPA that proposes to reduce provider payment rates or restructure provider payments in circumstances when the changes could result in diminished access, regardless of the provider payment rates or levels of access to care before the proposed reduction or restructuring.

Following the implementation of the 2015 final rule with comment period, as we worked with States to implement the previous AMRP requirements, many States expressed concerns that the requirements that accompany proposed rate reductions or restructurings are overly burdensome. Specifically, States pointed to instances where proposed reductions or restructurings are nominal, or where rate changes are made via the application of a previously approved rate methodology, such as when the State's approved rate methodology ties Medicaid payment rates to a Medicare fee schedule and the Medicare payment rate is reduced. We acknowledged these concerns through previous proposed rulemaking. In the 2018 proposed rule, we agreed that our experience implementing the previous AMRP process from the 2015 final rule with comment period raised questions about the benefit of the access analysis when proposed rate changes include nominal rate reductions or restructurings that are unlikely to result in diminished access to care.[335]

We did not finalize the 2018 proposed rule; instead, in response to feedback, we proposed a rescission of the previous AMRP process in the 2019 proposed rule.[336] In that proposed rule, we indicated that future guidance would be forthcoming to provide information on the required data and analysis that States might submit with rate reduction or restructuring SPAs in place of the previous AMRP process to support compliance with section 1902(a)(30)(A) of the Act.[337] We did not finalize the rescission proposed in the 2019 proposed rule. Although we were concerned that the previous AMRP process was overly burdensome for States and CMS in relation to the benefit obtained in helping ensure compliance with the access requirement in section 1902(a)(30)(A) of the Act, our 2018 and 2019 proposed rules did not adequately consider our need for information and analysis from States seeking to reduce provider payment rates or restructure provider payments to enable us to determine that the statutory access requirement is met when making SPA approval decisions.

To improve the efficiency of our administrative procedures and better inform our SPA approval decisions, we proposed to establish standard information that States would be required to submit with any proposed rate reductions or proposed payment restructurings in circumstances when

[333] 88 FR 27960 at 27967.

[334] 88 FR 27960 at 27962.

[335] 83 FR 12696 at 12697.

[336] 84 FR 3372.2.

[337] Id at 33723.

the changes could result in diminished access, including a streamlined set of data when the reductions or restructurings are nominal, the State rates are above a certain percentage of Medicare payment rates, and there are no evident access concerns raised through public processes; and an additional set of data elements that would be required when States propose FFS provider payment rate reductions or restructurings in circumstances when the changes could result in diminished access and these criteria are not met. For both sets of required or potentially required elements, we proposed to standardize the data and information States would be required to submit with rate reduction or restructuring SPAs. Although the previous AMRP process has helped to improve our administrative reviews and helped us make informed SPA approval determinations, we explained that the proposed procedures would provide us with similar information in a manner that reduces State burden. Additionally, the proposed procedures would provide States increased flexibility to make program changes with submission of streamlined supporting data to us when current Medicaid rates and proposed changes fall within specified criteria that create a reasonable presumption that proposed reductions or restructuring would not reduce beneficiary access to care in a manner inconsistent with section 1902(a)(30)(A) of the Act.

This final rule seeks to achieve a more appropriate balance between reducing unnecessary burden for States and CMS and ensuring that we have the information necessary to make appropriate determinations for whether a rate reduction or restructuring SPA might result in beneficiary access to covered services failing to meet the standard in section 1902(a)(30)(A) of the Act. In § 447.203(c), we proposed to establish analyses that States would be required to perform, document, and submit concurrently with the submission of rate reduction and rate restructuring SPAs, with additional analyses required in certain circumstances due to potentially increased access to care concerns.

We proposed a two-tiered approach for determining the level of access analysis States would be required to conduct when proposing provider payment rate reductions or payment restructurings. The first tier of this approach, proposed at § 447.203(c)(1), sets out three criteria for States to meet when proposing payment rate reductions or payment restructurings in circumstances when the changes could result in diminished access that, if met, would not require a more detailed analysis to establish that the proposal meets the access requirement in section 1902(a)(30)(A) of the Act. The State agency would be required to provide written assurance and relevant supporting documentation that the three criteria specified in those paragraphs are met, as well as a description of the State's procedures for monitoring continued compliance with section 1902(a)(30)(A) of the Act. As explained in more detail later in this section, these criteria proposed in § 447.203(c)(1) represent thresholds we believe would be strong indicators that Medicaid payment rates would continue to be sufficient following the change to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.

We noted that, in the course of our review of a payment SPA that meets these criteria, as with any SPA review, we may need to request additional information to ensure that all Federal SPA requirements are met. We also note that meeting the three criteria described in proposed § 447.203(c)(1) does not guarantee that the SPA would be approved, if other applicable Federal requirements are not met. Furthermore, if any criterion in the first tier is not met, we proposed a second tier in § 447.203(c)(2), which would require the State to conduct a more extensive access analysis in addition to providing the results of the analysis in the first tier. A detailed discussion of the second tier follows the details of the first tier in this section.

Under proposed § 447.203(c)(1)(i), the State would be required to provide a supported assurance that Medicaid payment rates in the aggregate (including base and supplemental payments) following the proposed reduction or restructuring for each benefit category affected by the proposed reduction or restructuring would be at or above 80 percent of the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services. While we acknowledge that 80 percent of Medicare rates may not provide absolute assurance that providers will participate in the Medicaid program, we proposed to use 80 percent as a threshold to help determine the level of analysis and information a State must provide to CMS to support consistency with section 1902(a)(30)(A) of the Act. Establishing this threshold will allow CMS to focus its resources on reviewing payment proposals that are at highest risk for access to care concerns. Notably, there are other provisions of the proposal that would provide opportunities for the public to raise access to care concerns to State agencies and to CMS should the 80 percent prove insufficient to provide for adequate access to care for certain care and services.

In proposed § 447.203(c)(1)(i), we explained that we mean for ''benefit category'' to refer to all individual services under a category of services described in section 1905(a) of the Act for which the State is proposing a payment rate reduction or restructuring. Comparing the payment rates in the aggregate would involve first performing a comparison of the Medicaid to the Medicare payment rate on a code-by-code basis, meaning CPT, CDT, or HCPCS as applicable, to derive a ratio for individual constituent services, and then the ratios for all codes within the benefit category would be averaged by summing the individual ratios then dividing the sum by the number of ratios. For example, if the State is seeking to reduce payment rates for a subset of physician services, the State would review all current payment rates for all physician services and determine if the proposed reduction to the relevant subset of codes would result in an average Medicaid payment rate for all physician services that is at or above 80 percent of the average corresponding Medicare payment rates. For supplemental payments, we are relying upon the definition of supplemental payments in section 1903(bb)(2) of the Act, which defines supplemental payments as ''a payment to a provider that is in addition to any base payment made to the provider under the State plan under this title or under demonstration authority . . . [b]ut such term does not include a disproportionate share hospital payment made under section 1923 [of the Act].'' With the inclusion of supplemental payments, States would need to aggregate the supplemental payments paid to qualifying providers during the State fiscal year and divide by all providers' total service volume (including service volume of providers that do not qualify for the supplemental payment) to establish an aggregate, per-service supplemental payment amount, then add that amount to the State's fee schedule rate to compare the aggregate Medicaid payment rate to the corresponding Medicare payment rate. As this supported assurance in proposed § 447.203I(1)(i) is expected to be provided with an accompanying

SPA, we noted that CMS may ask the State to explain how the analysis was conducted if additional information is needed as part of the analysis of the SPA. We solicited comments on the proposed § 447.203I(1)(i) supported assurance that Medicaid payment rates in the aggregate (including base and supplemental payments) following the proposed reduction or restructuring for each benefit category affected by the proposed reduction or restructuring would be at or above 80 percent of the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services should include a weighted average of the payment rate analysis by service volume, number of beneficiaries receiving the service, and total amount paid by Medicaid for the code in a year using State's Medicaid utilization data from the MMIS claims system rather than using a straight code-by-code analysis.

We explained that we understand this approach may have a smoothing effect on the demonstrated overall levels of Medicaid payment within a benefit category under the State plan. In many circumstances, only a subset of providers are recipients of Medicaid supplemental payments with the rest of the providers within the benefit category simply receiving the State plan fee schedule amount. This could result in a demonstration showing the Medicaid payments being high relative to Medicare, but the actual payments to a large portion of the providers would be less than the overall demonstration would suggest. As an alternative, we considered whether to adopt separate comparisons for providers who do and who do not receive supplemental payments, where a State makes supplemental payments for a service to some but not all providers of that service. We solicited comments on the proposed approach and this alternative.

We selected FFS Medicare, as opposed to Medicare Advantage, as the proposed payer for comparison for a number of reasons. A threshold issue is payment rate data availability: private payer data may be proprietary or otherwise limited in its availability for use by States. In addition, Medicare sets its prices rather than negotiating them through contracts with providers, and is held to many similar statutory standards as Medicaid with respect to those prices, such as efficiency, access, and quality.[338] For example, section 1848(g)(7) of the Act directs the Secretary of HHS to monitor utilization and access for Medicare beneficiaries provided through the Medicare fee schedule rates, and directs that the Medicare Payment Advisory Commission (MedPAC) shall comment on the Secretary's recommendations. In developing its comments, MedPAC convenes and consults a panel of physician experts to evaluate the implications of medical utilization patterns for the quality of and access to patient care. In a March 2001 report, MedPAC summarized its evaluation of Medicare rates, stating ''Medicare buys health care products and services from providers who compete for resources in private markets. To ensure beneficiaries' access to high-quality care, Medicare's payment systems therefore must set payment rates for health care products and services that are: high enough to stimulate adequate numbers of providers to offer services to beneficiaries, sufficient to enable efficient providers to supply high-quality services, given the trade-offs between cost and quality that exist with current technology and local supply conditions for labor and capital, and low enough to avoid imposing unnecessary burdens on taxpayers and beneficiaries through the taxes and premiums they pay to finance program spending.'' [339] Medicare's programmatic focus on beneficiary access aligns with the requirements of section 1902(a)(30)(A) of the Act.

In addition, Medicare PFS fee schedule rates are stratified by geographic areas within the States, which we seek to consider as well to ensure that payment rates are consistent with section 1902(a)(30)(A) of the Act. The fee schedule amounts are established for each service, generally described by a particular procedure code (including HCPCS, CPT, and CDT),) using resource-based inputs to establish relative value units (RVUs) in three components of a procedure: work, practice expense, and malpractice. The three component RVUs for each service are adjusted using CMS-calculated geographic practice cost indexes (GPCIs) that reflect geographic cost differences in each fee schedule area as compared to the national average. The current Medicare PFS locality structure was implemented in 2017 in accordance with the Protecting Access to Medicare Act of 2014 (PAMA 2014). Under the current locality structure, there are 112 total PFS localities.[340]

When considering geography in their rate analyses, we noted that we expect States to conduct a code-by-code analysis of the ratios of Medicaid-to-Medicare provider payment rates for all applicable codes within the benefit category, either for each of the GPCIs within the State, or by calculating an average Medicare rate across the GPCIs within the State (such as in cases where a State does not vary its rates by region). In cases where a State does vary its Medicaid rates based on geography, but that variation does not align with the Medicare GPCI, we explained that the State should utilize the Medicare payment rates as published by Medicare for the same geographical location as the base Medicaid FFS fee schedule payment rate to achieve an equivalent comparison and align the Medicare GPCI to the locality of the Medicaid payment rates, using the county and locality information provided by Medicare for the GPCIs, for purposes of creating a reasonable comparison of the payment rates.[341] To conduct such an analysis that meets the requirements of proposed § 447.203(c)(1)(i), States may compare the Medicaid payment rates applicable to the same Medicare GPCI to each Medicare rate by GPCI individually, and then aggregate that comparison into an average rate comparison for the benefit category. To the extent that Medicaid payment rates do not vary by geographic locality within the State, the State may also calculate a Statewide average Medicare rate based upon all of the rates applicable to the GPCIs within that State and compare that average Medicare rate

[338] *https://www.healthcarevaluehub.org/advocate-resources/publications/medicare-rates-benchmark-too-much-too-little-or-just-right.*

[339] MedPAC. Report to the Congress: Medicare Payment Policy, March 2001. *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/Mar01Ch1.pdf.* Accessed December 20, 2022.

[340] Section 220(b) of PAMA 204 added section 1848(e)(6) of the Act, which requires that, for services furnished on or after January 1, 2017, the locality definitions for California, which has the most unique locality structure, be based on the Metropolitan Statistical Area (MSA) delineations as defined by the Office of Management and Budget (OMB). The resulting modifications to California's locality structure increased its number of localities from 9 under the previous structure to 27 under the MSA-based locality structure (operational note: for the purposes of payment the actual number of localities under the MSA-based locality structure is 32). Of the 112 total PFS localities, 34 localities are Statewide areas (that is, only one locality for the entire State). There are 75 localities in the other 16 States, with 10 States having 2 localities, 2 States having 3 localities, 1 State having 4 localities, and 3 States having 5 or more localities. The District of Columbia, Maryland, and Virginia suburbs, Puerto Rico, and the Virgin Islands are additional localities that make up the remainder of the total of 112 localities. Medicare PFS Locality Configuration. *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Locality.* Accessed December 21, 2022.

[341] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Locality.*

to the average Medicaid rate for the benefit category.

Once we decided to propose using Medicare payment rates as a point of comparison, we needed to decide what threshold ratio of proposed Medicaid to Medicare payment rates should trigger additional consideration and review for potential access issues. First, we considered how current levels of Medicaid payment compares to the Medicare payment for the same services. In a 2021 *Health Affairs* article, Zuckerman, et al, found that ''Medicaid physician fees were 72 percent of Medicare physician fees for twenty-seven common procedures in 2019.'' [342] This ratio varied by service type. For example, ''the 2019 Medicaid-to-Medicare fee index was lower for primary care (0.67) than for obstetric care (0.80) or for other services (0.78).'' The authors also found that ''between 2008 and 2019 Medicare and Medicaid fees both increased (23.6 percent for Medicare fees and 19.9 percent for Medicaid fees), leaving the fee ratios similar.'' [343]

Next, considering that Medicaid rates are generally lower than Medicare, we wanted to examine the relationship between these rates and a beneficiary's ability to access covered services. This led us to first look into a comparison of physician new patient acceptance rates based on a prospective new patient's payer. In a June 2021 fact sheet, MACPAC found ''in 2017 (the most recent year available), physicians were significantly less likely to accept new patients insured by Medicaid (74.3 percent) than those with Medicare (87.8 percent) or private insurance (96.1 percent).'' [344] MACPAC found this to be true ''regardless of physician demographic characteristics (age, sex, region of the country); and type and size of practice.'' [345]

We then wanted to confirm whether this was related to the rates themselves. In a 2019 *Health Affairs* article, the authors found that, ''higher payment continues to be associated with higher rates of accepting new Medicaid patients. . .physicians most commonly point to low payment as the main reason they choose not to accept patients insured by Medicaid.'' [346] The study found that physicians in States that pay above the median Medicaid-to-Medicare fee ratio accepted new Medicaid patients at higher rates than those in States that pay below the median, with acceptance rates increasing by nearly 1 percentage point (0.78) for every percentage point increase in the fee ratio.[347]

Similarly, in a 2020 study published by the *National Bureau of Economic Research,* researchers found that there was a positive association between increasing Medicaid physician fees and increased likelihood of having a usual source of care, improved access to specialty doctor care, and large improvements in caregivers' satisfaction with the adequacy of health coverage, among children with special health care needs with a public source of health coverage.[348] Further, Berman, et al, focused on pediatricians and looked at Medicaid-Medicare fee ratio quartiles, finding that the percent of pediatricians accepting all Medicaid patients and relative pediatrician participation in Medicaid increased at each quartile, but improvement was most significant up to the third quartile.[349] According to the Kaiser Family Foundation, in 2016, following the expiration of section 1202 of the Affordable Care Act (Pub. L. 111–148), which amended section 1902(a)(13) of the Act to implement a temporary payment floor for certain Medicaid primary care physician services, the third quartile of States had Medicaid-Medicare fee ratios of between 79 and 86 percent for all services provided under all State Medicaid FFS programs.[350] Importantly, considering the proposed requirements at paragraph (c) would pertain to proposed payment rate reductions or payment restructurings in circumstances when the changes could result in diminished access, multiple recent studies have also shown that the association between Medicaid physician fees and measures of beneficiary access are consistent whether physician payments are increased or decreased to reach a particular level at which access is assessed.[351]

The Kaiser Family Foundation found that 23 States have Medicaid-to-Medicare fee ratios of at least 80 percent for all services, 17 States have fee ratios of 80 percent for primary care services, 32 States have fee ratios of 80 percent for obstetric care, and 27 States have fee ratios of 80 percent for other services.[352] Additional studies support the Holgash and Heberlein findings that physicians most commonly point to low payment as the main reason they choose not to accept patients insured by Medicaid, showing that States with a Medicaid to Medicare fee ratio at or above 80 percent show improved access for children to a regular source of care,[353] and decreased use of hospital-based facilities, versus States with a lower Medicaid to Medicare fee ratio.

We noted our concern that higher rates of acceptance by some providers of new patients with payers other than Medicaid (specifically, Medicare and private coverage), and indications by some providers that low Medicaid payments are a primary reason for not accepting new Medicaid patients, may suggest that some beneficiaries could have a more difficult time accessing covered services than other individuals in the same geographic area. We are encouraged by findings that suggest that some increases in Medicaid payment rates may drive increases in provider acceptance of new Medicaid patients, with one study finding that new Medicaid patient acceptance rates increased by 0.78 percent for every percentage point increase in the Medicaid-to-Medicare fee ratio, for certain providers for certain States above the median Medicaid-to-Medicare fee ratio.[354] [355] In line with the Berman

[342] Zuckerman, S. et al. ''Medicaid Physician Fees Remained Substantially Below Fees Paid By Medicare in 2019,'' Health Affairs, Volume 40, Number 2, February 2021. Available at *https://doi.org/10.1377/hlthaff.2020.00611 (accessed December 23, 2022).*

[343] Id.

[344] MACPAC. ''Physician Acceptance of New Medicaid Patients: Finding from the National Electronic Health Records Survey.'' June. 2021. Available at *https://www.macpac.gov/wp-content/uploads/2021/06/Physician-Acceptance-of-New-Medicaid-Patients-Findings-from-the-National-Electronic-Health-Records-Survey.pdf* (accessed December 23, 2023).

[345] Id.

[346] Holgash, K. and Martha Heberlein, ''Physician Acceptance Of New Medicaid Patients: What Matters And What Doesn't.'' *Health Affairs,* April 10, 2019. Available at *https://www.healthaffairs.org/do/10.1377/forefront.20190401.678690/full/* (accessed February 22, 2023).

[347] Id.

[348] Chatterji, P. et al. ''Medicaid Physician Fees and Access to Care Among Children with Special Health Care Needs'' National Bureau of Economic Research, Working Paper 26769, February 2020, p. 2–54. Medicaid Physician Fees and Access to Care among Children with Special Health Care Needs | NBER. Accessed June 16, 2022.

[349] Berman, S., et al. ''Factors that Influence the Willingness of Private Primary Care Pediatricians to Accept More Medicaid Patients'' *Pediatrics.*

[350] *https://www.kff.org/medicaid/state-indicator/medicaid-to-medicare-fee-index.*

[351] Candon, M., et al. ''Declining Medicaid Fees and Primary Care Appointment Availability for New Medicaid Patients'' *JAMA Internal Medicine,* Volume 178, Number 1, January 2018, p. 145–146. Available at *https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2663253.* Accessed June 16, 2022.

[352] *https://www.kff.org/medicaid/state-indicator/medicaid-to-medicare-fee-index.*

[353] Chatterji, P. et al. ''Medicaid Physician Fees and Access to Care Among Children with Special Health Care Needs'' National Bureau of Economic Research, Working Paper 26769, February 2020, p. 2–54. Available at *https://www.nber.org/papers/w26769.* Accessed August 16, 2022.

[354] MACPAC. ''Physician Acceptance of New Medicaid Patients: Finding from the National Electronic Health Records Survey.'' June. 2021. Available at *https://www.macpac.gov/wp-content/*

Continued

study, which found that increases in the percentage of pediatricians participating in Medicaid and of pediatricians accepting new Medicaid patients occurred with Medicaid payment rate increases at each quartile of the Medicaid-to-Medicare fee ratio but were most significant up to the third quartile, we believe that beneficiaries in States that provide this level of Medicaid payment generally may be less likely to encounter access to care issues at rates higher than the general population.[356] In line with the Kaiser Family Foundation reporting of the Medicaid-to-Medicare fee ratio third quartile as ranging from 79 to 86 percent in 2016, depending on the service, we stated our belief that a minimum 80 percent Medicaid-to-Medicare fee ratio is a reasonable threshold to propose in § 447.203(c)(1)(i) as one of three criteria State proposals to reduce or restructure provider payments would be required to meet to qualify for the proposed streamlined documentation process.[357] As documented by the Kaiser Family Foundation, many States currently satisfy this ratio for many Medicaid-covered services, and according to findings by Zuckerman, et al. in *Health Affairs,* in 2019, the average nationwide fee ratio for obstetric care met this proposed threshold.[358] [359] We proposed that this percentage would hold across benefit categories, because we did not find any indication that a lower threshold would be adequate, or that a higher threshold would be strictly necessary, to support a level of access to covered services for Medicaid beneficiaries at least as great as for the general population in the geographic area. We noted that the disparities in provider participation for some provider types may be larger than this overview suggests, as such we proposed a uniform standard in the interest of administrative simplicity but cautioned that States must meet all three of the criteria in proposed paragraph (c)(1) to qualify for the streamlined analysis process; otherwise, the additional analysis specified in proposed paragraph (c)(2) would be required.

Given the results of this literature review, and by proposing this provision as only one part of a three-part assessment of the likely effect of a proposed payment rate reduction or payment restructuring on access to care, as further discussed in this section, we proposed 80 percent of the most recently published Medicare payment rates, as identified on the applicable Medicare fee schedule for the same or a comparable set of Medicare-covered services, as a benchmark for the level of Medicaid payment for benefit categories that are subject to proposed provider payment reductions or restructurings that is likely to enlist enough providers so that care and services are available to Medicaid beneficiaries at least to the extent as to the general population in the geographic area, where the additional tests in proposed § 447.203(c)(1) also are met. While we acknowledge that 80 percent of Medicare rates may not provide absolute assurance that providers will participate in the Medicaid program, we proposed to use 80 percent as a threshold to help determine the level of analysis and information a State must provide to CMS to support consistency with section 1902(a)(30)(A) of the Act. Establishing this threshold will allow CMS to focus its resources on reviewing payment proposals that are at highest risk for access to care concerns. Notably, there are other provisions of the proposal that would provide opportunities for the public to raise access to care concerns to State agencies and to CMS should the 80 percent prove insufficient to provide for adequate access to care for certain care and services.

We explained that the published Medicare payment rates means the amount per applicable procedure code identified on the Medicare fee schedule. The established Medicare fee schedule rate includes the amount that Medicare pays for the claim and any applicable co-insurance and deductible amounts owed by the patient. Medicaid fee-schedule rates should be representative of the total computable payment amount a provider would expect to receive as payment-in-full for the provision of Medicaid services to individual beneficiaries. Section 447.15 defines payment-in-full as ''the amounts paid by the agency plus any deductible, coinsurance or copayment required by the plan to be paid by the individual.'' Therefore, State fee schedules should be inclusive of total base payments from the Medicaid agency plus any applicable coinsurance and deductibles to the extent that a beneficiary is expected to be liable for those payments. If a State Medicaid fee schedule does not include these additional beneficiary cost-sharing payment amounts, then the Medicaid fee schedule amounts would need to be modified to include expected beneficiary cost sharing to align with Medicare's fee schedule.

We noted that Medicaid benefits that do not have a reasonably comparable Medicare-covered analogue, and for which a State proposes a payment rate reduction or payment restructuring in circumstances when the changes could result in diminished access, would be subject to the expanded review criteria proposed in § 447.203(c)(2), because the State would be unable to demonstrate its Medicaid payment rates are at or above 80 percent of Medicare payment rates for the same or a comparable set of Medicare-covered services after the payment rate reduction or payment restructuring. For identifying a comparable set of Medicare-covered services, we stated that we would expect to see services that bear a reasonable relationship to each other. For example, the clinic benefit in Medicaid does not have a directly analogous clinic benefit in Medicare. In Medicaid, clinic services generally are defined in § 440.90, as ''preventive, diagnostic, therapeutic, rehabilitative, or palliative services that are furnished by a facility that is not part of a hospital but is organized and operated to provide medical care to outpatients.'' This can include a number of primary care services otherwise available through physician practices and other primary care providers, such as nurse practitioners. Therefore, in seeking to construct a comparable set of Medicare-covered services to which the State could compare its proposed Medicaid payment rates, the State reasonably could include Medicare payment rates for practitioner services, such as physician and nurse practitioner services, or payments for facility-based services that bear a reasonable similarity to clinic services, potentially including those provided in Ambulatory Surgical Centers. We would expect the State to develop a reasonably comparable set of Medicare-covered services to which its proposed Medicaid payment rates could be compared and to include with its submission an explanation of its reasoning and methodology for

uploads/2021/06/Physician-Acceptance-of-New-Medicaid-Patients-Findings-from-the-National-Electronic-Health-Records-Survey.pdf (accessed December 23, 2023).

[355] Holgash, K. and Martha Heberlein, ''Physician Acceptance Of New Medicaid Patients: What Matters And What Doesn't.'' *Health Affairs,* April 10, 2019. Available at *https://www.healthaffairs.org/do/10.1377/forefront.20190401.678690/full/* (accessed February 22, 2023).

[356] Berman, S., et al. ''Factors that Influence the Willingness of Private Primary Care Pediatricians to Accept More Medicaid Patients'' *Pediatrics.*

[357] *https://www.kff.org/medicaid/state-indicator/medicaid-to-medicare-fee-index.*

[358] Id.

[359] Zuckerman, S. et al. ''Medicaid Physician Fees Remained Substantially Below Fees Paid By Medicare in 2019,'' Health Affairs, Volume 40, Number 2, February 2021. Available at *https://doi.org/10.1377/hlthaff.2020.00611* (accessed December 23, 2022).

constructing the Medicare rate to compare to Medicaid payment rates.

In § 447.203(c)(1)(ii), we proposed that the State would be required to provide a supported assurance that the proposed reduction or restructuring, including the cumulative effect of all reductions or restructurings taken throughout the State fiscal year, would result in no more than a 4 percent reduction in aggregate FFS Medicaid expenditures for each benefit category affected by proposed reduction or restructuring within a single State fiscal year. We explained that the documentation will need to show the change stated as a percentage reduction in aggregate FFS Medicaid expenditures for each affected benefit category. We recognized that the effects of payment rate reductions and payment restructurings on beneficiary access generally cannot be determined through any single measure, and applying a 4 percent threshold without sufficient additional safeguards would not be prudent. Therefore, we proposed to limit the 4 percent threshold as the cumulative percentage of rate reductions or restructurings applied to the overall FFS Medicaid expenditures for a particular benefit category affected by the proposed reduction(s) or restructuring(s) within each State fiscal year. We proposed the cumulative application of the threshold to State plan actions taken within a State fiscal year as opposed to a SPA-specific application to avoid circumstances where a State may propose rate reductions or restructurings that cumulatively exceed the 4 percent threshold across multiple SPAs without providing additional analysis.

For example, if a State proposed to reduce payment rates for a broad set of obstetric services by 3 percent in State fiscal year 2023 and had not proposed any other payment changes affecting the benefit category of obstetric care during the same State fiscal year, that payment change would meet the criterion proposed in § 447.203(c)(1)(ii) because it would be expected to result in no more than a 3 percent reduction in aggregate Medicaid expenditures for obstetric care within a State fiscal year. However, if the State had received approval earlier in the State fiscal year to revise its obstetric care payment methodology to include value-based arrangements expected to reduce overall Medicaid expenditures for obstetric care by 2 percent per State fiscal year, then it is likely that the cumulative effect of the proposal to reduce payment rates for a broad set of obstetric services by 3 percent and the Medicaid obstetric care expenditure reductions under the earlier-approved payment restructuring would result in an aggregate reduction to FFS Medicaid expenditures for obstetric services of more than 4 percent in a State fiscal year. If so, the State's proposal would not meet the criterion proposed in § 447.203(c)(1)(ii), and the proposal would be subject to the additional review criteria proposed in § 447.203(c)(2). The State would need to document for our review whether the three percent payment rate reduction proposal for the particular subset of obstetric services would be likely to result in a greater than 2 percent further reduction in aggregate FFS Medicaid expenditures for obstetric care as compared to the expected expenditures for such services for the State fiscal year before any payment rate reduction or payment restructuring; if this expected aggregate reduction is demonstrated to be 2 percent or less, then the proposal still could meet the criterion proposed in § 447.203(c)(1)(ii).

We proposed to codify a 4 percent reduction threshold for aggregate FFS Medicaid expenditures in each benefit category affected by a proposed payment rate reduction or payment restructuring within a State fiscal year. This threshold is consistent with one we proposed in the 2018 proposed rule, which proposed to require the States to submit an AMRP with any SPA that proposed to reduce provider payments by greater than 4 percent in overall service category spending in a State fiscal year or greater than 6 percent across 2 consecutive State fiscal years, or restructure provider payments in circumstances when the changes could result in diminished access.[360] The proposed rule received positive feedback from States regarding its potential for mitigating administrative burden, and providing States with flexibility to administer their programs and make provider payment rate changes. Some States and national organizations requested that we increase the rate reduction threshold to 5 percent and increase the consecutive year threshold to 8 percent.[361] [362] Non-State commenters cautioned CMS against providing too much administrative flexibility and to not abandon the Medicaid access analysis the previous AMRP regulations required. Commenters also raised that 4 and 6 percent may seem nominal for larger medical practices and health care settings, but for certain physician practices or direct care workers a 6 percent reduction in payment could be considerable.[363] This feedback has been essential in considering how we proceed with this rulemaking, in which we emphasize that the size of the rate reduction threshold proposed in § 447.203(c)(1)(ii) would operate in conjunction with the two other proposed elements in § 447.203(c)(1)(i) and (iii) to qualify the State for a streamlined analysis process and would not exempt the proposal from scrutiny for compliance with section 1902(a)(30)(A) of the Act.

We proposed a 4 percent threshold on cumulative provider payment rate reductions throughout a single State fiscal year as one of the criteria of the streamlined process in proposed paragraph (c)(1), and therefore, emphasizing that while we believe this payment threshold to be nominal and unlikely to diminish access to care, we proposed to include paragraph (c)(1)(i) to require States to review current levels of provider payment in relation to Medicare and proposed to include paragraph (c)(1)(iii) to require that States rely on the public process to inform the determination on the sufficiency of the proposed payment rates after reduction or restructuring, with consideration for providers and practice types that may be disproportionately impacted by the State's proposed rate reductions or restructurings.

As previously noted, we would not consider any payment rate reduction or payment rate restructuring proposal to qualify for the streamlined analysis process in the proposed paragraph (c)(1) unless all three of the proposed paragraph (c)(1) criteria are met. Using information from the Kaiser Family Foundation's Medicaid-to-Medicare fee index [364] as an example, only 15 States could have reduced primary care service provider payment rates by up to 4 percent in 2019 and continued to meet the 80 percent of Medicare threshold in proposed paragraph (c)(1). Even those 15 States with rates above the 80 percent of Medicare threshold would be subject to proposed paragraph (c)(2) requirements if the State received significant public feedback that the proposed payment reduction or restructuring would result in an access

[360] 83 FR 12696 at 12698.

[361] Connecticut Department of Social Services. Comment Letter on 2018 Proposed Rule (May 21, 2018), *https://downloads.regulations.gov/CMS-2018-0031-0021/attachment_1.pdf*.

[362] National Association of Medicaid Directors. Comment Letter on 2018 Proposed rule (June 1, 2018), *https://downloads.regulations.gov/CMS-2018-0031-0115/attachment_1.pdf*.

[363] American Academy of Family Physicians, Comment Letter on 2018 Proposed Rule (May 21, 2018), *https://downloads.regulations.gov/CMS-2018-0031-0017/attachment_1.pdf*.

[364] *https://www.kff.org/medicaid/state-indicator/medicaid-to-medicare-fee-index/*.

to care concern, if the State were unable to reasonably respond to or mitigate such concerns. All States with primary care service payment rates below the 80 percent of Medicare threshold, no matter the size of the payment rate reduction or restructuring and no matter whether interested parties expressed access concerns through available public processes, would have to conduct an additional access analysis required under proposed paragraph (c)(2).

We issued SMDL #17–004 to provide States with guidance on complying with regulatory requirements to help States avoid unnecessary burden when seeking approval of and implementing payment changes, because States often seek to make payment rate and/or payment structure changes for a variety of programmatic and budgetary reasons with limited or potentially no effect on beneficiary access to care, and we recognized that State legislatures needed some flexibility to manage State budgets accordingly. We discussed a 4 percent spending reduction threshold with respect to a particular service category in SMDL #17–004 as an example of a targeted reduction where the overall change in net payments within the service category would be nominal and any effect on access difficult to determine (although we reminded States that they should document that the State followed the public process under § 447.204, which could identify access concerns even with a seemingly nominal payment rate reduction). To our knowledge, since the release of SMDL #17–004, the 4 percent threshold for regarding a payment rate reduction as nominal has not resulted in access to care concerns in State Medicaid programs, and it received significant State support for this reason in comments submitted in response to the 2018 proposed rule.[365]

In instances where States submitted payment rate reduction SPAs after the publication of SMDL #17–004, we routinely have asked the State for an explanation of the purpose of the proposed change, whether the FFS Medicaid expenditure impact for the service category would be within a 4 percent reduction threshold, and for an analysis of public comments received on the proposed change, and approved those SPAs to the extent that the State was able to resolve any potential access to care issues and determined that access would remain consistent for the Medicaid population. For example, in the proposed rule, we stated that, of the 849 SPAs approved in 2019, there were 557 State payment rate changes. Of those, 39 were classified as payment rate reductions or methodology changes that resulted in a reduction in overall provider payment. Within those 39, there were 18 SPAs that sought to reduce payments by less than 4 percent of overall spending within the benefit category, most of which were decreases related to changes in Medicare payment formulas. Sixteen of the remaining 21 SPAs fell into an area discussed in SMDL #17–004 as being unlikely to result in diminished access to covered services, where with the State's analytical support, we were able to determine that the payment rates would continue to comply with section 1902(a)(30)(A) of the Act without the State submitting an AMRP with the SPA. Six of these SPAs represented rate freezes meant to continue forward a prior year's rates or eliminate an inflation adjustment. Six SPAs reduced a payment rate to comply with Federal requirements, such as the Medicaid UPLs in §§ 447.272 and 447.321, the Medicaid DME FFP limit in section 1903(i)(27) of the Act, or the Medicaid hospice rate, per section 1902(a)(13)(B) of the Act. Four SPAs contained reductions that resulted from programmatic changes such as the elimination of a Medicaid benefit or shifting the delivery system for a benefit to coverage by a pre-paid ambulatory health plan. Finally, we identified five SPAs for which States were required to submit AMRPs. In each instance, the SPAs were approved by CMS, with three of the SPAs being submitted to us in 2017 and updated for 2019 with the appropriate AMRP data submission required by the 2015 final rule with comment period. Overall, our review of SPAs revealed that smaller reductions may often be a result of elements or other requirements that may be outside of the State's control, such as Federal payment limits or changes in the Medicare payment rate that might be included in a State's proposed payment methodology (such as where some Medicare payment rates for certain services increased and others decreased as a result of the Medicare payment formulas, which may disproportionately impact one benefit category), or coding changes that might affect the amount of payment related to the unit of service. We determined, using this information, that it is necessary to provide States with some degree of flexibility in making changes, even if that change is a reduction in provider payment. For example, if a State submits a SPA to reduce or restructure inpatient hospital base or supplemental payments, where inaction on the State's part would result in the State exceeding the applicable UPL, the State will need to reduce inpatient hospital payments or risk a compliance action against the State for violating Medicaid UPL requirements authorized under section 1902(a)(30)(A) of the Act and implementing regulations in 42 CFR 447 subparts C and F. We recognized that this flexibility does not eliminate the need to monitor or consider access to care when making payment rate decisions, but also recognized the need to provide some relief in circumstances where the State must take a rate action to address an issue of compliance with another statutory or regulatory requirement.

Accordingly, we proposed that, where a State has provided the information required under proposed paragraphs (c)(1)(i) through (iii), we would consider that the proposed reduction would result in a nominal payment adjustment unlikely to diminish access below the level consistent with section 1902(a)(30)(A) of the Act and would approve the SPA, provided all other criteria for approval also are met, without requiring the additional analysis that otherwise would be required under proposed § 447.203(c)(2).

Finally, in § 447.203(c)(1)(iii), we proposed that the State would be required to provide a supported assurance that the public processes described in § 447.203(c)(4) yielded no significant access to care concerns or yielded concerns that the State can reasonably respond to or mitigate, as appropriate, as documented in the analysis provided by the State under § 447.204(b)(3). The State's response to any access concern identified through the public processes, and any mitigation approach, as appropriate, would be expected to be fully described in the State's submission to us.

We noted that the proposed requirement in § 447.203(c)(4) would not duplicate the requirements in previous § 447.204(a)(2), as the previous § 447.204(a)(2) required States to consider provider and beneficiary input as part of the information that States are required to consider prior to the submission of any SPA that proposes to

[365] See, for example: Indiana Family and Social Services Administration. Comment Letter on 2018 Proposed Rule (May 24, 2018), *https://downloads.regulations.gov/CMS-2018-0031-0055/attachment_1.pdf;* Colorado Department of Health Care Policy and Financing. Comment Letter on 2018 Proposed Rule (May 24, 2018), *https://downloads.regulations.gov/CMS-2018-0031-0087/attachment_1.pdf;* The Commonwealth of Massachusetts Executive Office of Health and Human Services Office of Medicaid. Comment Letter on 2018 Proposed Rule (May 21, 2018), *https://downloads.regulations.gov/CMS-2018-0031-0020/attachment_1.pdf.*

reduce or restructure Medicaid service payment rates. The proposed § 447.203(c)(4) describes material that States would be required to include with any SPA submission that proposes to reduce or restructure provider payment rates. As discussed in the CMCS informational bulletin dated June 24, 2016,[366] before submitting SPAs to us, States were required under previous § 447.204(a)(2) to make information available so that beneficiaries, providers, and other interested parties may provide input on beneficiary access to the affected services and the impact that the proposed payment change would have, if any, on continued service access. We explained that States are expected to obtain input from beneficiaries, providers, and other interested parties, and analyze the input to identify and address access to care concerns. States must obtain this information prior to submitting a SPA to us and maintain a record of the public input and how the agency responded to the input. When a State submits the SPA to us, § 447.204(b)(3) requires the State to also submit a specific analysis of the information and concerns expressed in input from affected interested parties. We would rely on this and other documentation submitted by the State, including under proposed § 447.203(c)(1)(iii), (c)(2)(vi), and (c)(4), to inform our SPA approval decisions.

In addition, we noted that States are required to use the applicable public process required under section 1902(a)(13) of the Act, as applicable, and follow the public notice requirement in § 447.205, as well as any other public processes required by State law (for example, State-specified budgetary process requirements), in setting payment rates and methodologies in view of potential access to care concerns. States have an important role in identifying access to care concerns, including through ongoing and collaborative efforts with beneficiaries, providers, and other interested parties. We acknowledged that not every concern would be easily resolvable, but we anticipate that States would be meaningfully engaged with their beneficiary, provider, and other interested party communities to identify and mitigate issues as they arise. We explained that we would consider information about access concerns raised by beneficiaries, providers, and other interested parties when States propose SPAs to reduce Medicaid payment rates or restructure Medicaid payments and would not approve proposals that do not comport with all applicable requirements, including the access standard in section 1902(a)(30)(A) of the Act.

In feedback received regarding implementation of the previous AMRP requirements in the 2015 final rule with comment period, States expressed concern about burdensome requirements to draft, solicit public input on, and update their AMRPs after receiving beneficiary or provider complaints that were later resolved by the State's engagement with beneficiaries and the provider community. we explained that our proposal to require access review procedures specific to State proposals to reduce payment rates or restructure payments would provide an opportunity for the State meaningfully to address and respond to interested parties' input, and seeks to balance State burden concerns with the clear need to understand the perspectives of the interested parties most likely to be affected by a Medicaid payment rate reduction or payment restructuring. Previously, § 447.203(b)(7) requires States to have ongoing mechanisms for beneficiary and provider input on access to care through various mechanisms, and to maintain a record of data on public input and how the State responded to such input, which must be made available to us upon request. We proposed to retain this important mechanism and to relocate it to § 447.203(c)(4). Through the cross reference to proposed § 447.203(c)(4) in proposed § 447.203(c)(1)(iii), we would require States to use the ongoing beneficiary and provider feedback mechanisms to aid in identifying and assessing any access to care issues in cooperation with their interested parties' communities, as a component of the streamlined access analysis criteria in proposed § 447.203(c)(1).

Together, we stated our belief that the proposed criteria of § 447.203(c)(1)(i) through (iii), where all are met, would establish that a State's proposed Medicaid payment rates and/or payment structure are consistent with the access requirement in section 1902(a)(30)(A) of the Act at the time the State proposes a payment rate reduction or payment restructuring in circumstances when the changes could result in diminished access. Importantly, as noted above, proposed § 447.203(c)(4) (proposed to be relocated from previous § 447.203(b)(7)) would ensure that States have ongoing procedures for compliance monitoring independent of any approved Medicaid payment changes.

We previously outlined in SMDL #17–004 several circumstances where Medicaid payment rate reductions generally would not be expected to diminish access: reductions necessary to implement CMS Federal Medicaid payment requirements; reductions that will be implemented as a decrease to all codes within a service category or targeted to certain codes, but for services where the payment rates continue to be at or above Medicare and/or average commercial rates; and reductions that result from changes implemented through the Medicare program, where a State's service payment methodology adheres to the Medicare methodology. We did not propose to codify this list of policies that may produce payment rate reductions unlikely to diminish access to Medicaid-covered services. However, as a possible addition to the proposed streamlined access analysis criteria in proposed § 447.203(c)(1), we solicited comments on whether this list of circumstances discussed in SMDL #17–004 should be included in a new paragraph under proposed § 447.203(c)(1) and, if one or more of these circumstances were applicable, the State's proposal would be considered to qualify for the streamlined analysis process under proposed § 447.203(c)(1) notwithstanding the other criteria in proposed paragraph(c)(1).

In proposed paragraph (c)(1), we specified the full set of written assurances and relevant supporting documentation that States would be required to submit with a proposed payment rate reduction or payment restructuring SPA in circumstances when the changes could result in diminished access, where the requirements in proposed paragraphs (c)(1)(i) through (c)(1)(iii) are met. The inclusion of documentation that confirms all criteria proposed in paragraph (c)(1) are met would exempt the State from the requirements in proposed § 447.203(c)(2), discussed later in this section; however, it would not guarantee SPA approval. Proposed payment rate reduction SPAs and payment rate restructuring SPAs meeting the requirements in proposed § 447.203(c)(1) would still be subject to CMS' standard review requirements for all proposed SPAs to ensure compliance with section 1902(a) of the Act, including implementing regulations in part 430. Specifically, and without limitation, we noted that this includes compliance with section 1902(a)(2) of the Act, requiring financial participation

[366] CMCS Informational Bulletin, ''Federal public notice and public process requirements for changes to Medicaid payment rates.'' Published June 24, 2016. *https://www.medicaid.gov/federal-policy-guidance/downloads/cib062416.pdf.* Accessed November 3, 2022.

by the State in payments authorized under section 1903 of the Act. We review SPAs involving payments to ensure that the State has identified an adequate source of non-Federal share financing for payments under the SPA so that section 1902(a)(2) of the Act is satisfied; in particular, section 1903(w) of the Act and its implementing regulations establish requirements for certain non-Federal share financing sources that CMS must ensure are met. We further noted that a proposed SPA's failure to meet the criteria in proposed paragraph (c)(1) would not result in automatic SPA disapproval; rather, such proposals would be subject to additional documentation and review requirements, as specified in proposed § 447.203(c)(2).

In paragraph (c)(2), we proposed the additional, more rigorous State access analysis that States would be required to submit where the State proposes to reduce provider payment rates or restructure provider payments in circumstances when the changes could result in diminished access where the requirements in paragraphs (c)(1)(i) through (iii) are not met. We explained our belief that this more rigorous access analysis should be required where the State is unable to demonstrate that the proposed paragraph (c)(1) criteria are met, because more scrutiny then is needed to ensure that the proposed payment rates and structure would be sufficient to enlist enough providers so that covered services would be available to beneficiaries at least to the same extent as to the general population in the geographic area. Accordingly, we proposed in § 447.203(c)(2) to have States document current and recent historical levels of access to care, including a demonstration of counts and trends of actively participating providers, counts and trends of FFS Medicaid beneficiaries who receive the services subject to the proposed payment rate reduction or payment restructuring; and service utilization trends, all for the 3-year period immediately preceding the submission date of the proposed rate reduction or payment restructuring SPA, as a condition for approval. As with the previous AMRP process, the information provided by the State would serve as a baseline of understanding current access to care within the State's program, from which the State's payment rate reduction or payment restructuring proposal would be scrutinized.

The 2015 final rule with comment period included requirements that the previous AMRP process include data on the following topics, in previous § 447.203(b)(1)(i) through (v): the extent to which beneficiary needs are fully met; the availability of care through enrolled providers to beneficiaries in each geographic area, by provider type and site of service; changes in beneficiary utilization of covered services in each geographic area; the characteristics of the beneficiary population (including considerations for care, service and payment variations for pediatric and adult populations and for individuals with disabilities); and actual or estimated levels of provider payment available from other payers, including other public and private payers, by provider type and site of service. The usefulness of the previous ongoing AMRP data was directly related to the quality of particular data measures that States selected to use in their AMRPs, and one of the biggest concerns we heard about the process was that States were not always certain that they were providing us with the relevant data that we needed to make informed decisions about Medicaid access to care because the 2015 final rule provided States with a considerable amount of flexibility in determining the type of data that may be provided in support of the State's access analysis included in their AMRP. In addition, States were required to consult with the State's medical advisory committees and publish the draft AMRP for no less than 30 days for public review and comment, per § 447.203(b). Therefore, the final AMRP, so long as the base data elements were met and supported the State's conclusion that access to care in the Medicaid program met the requirements of section 1902(a)(30)(A) of the Act, then the AMRP was accepted by us. As a result, the previous AMRPs were often very long and complex documents that sometimes included data that was not necessarily useful for understanding the extent of beneficiary access to services in the State or for making administrative decisions about SPAs. In an effort to promote standardization of data measures and limit State submissions to materials likely to assist in ensuring consistency of payment rates with the requirements of section 1902(a)(30)(A) of the Act, we proposed to maintain a number of the previously required data elements from the previous AMRP process but to be more precise about the type of information that would be required.

In § 447.203(c)(2), we proposed that, for any SPA that proposes to reduce provider payment rates or restructure provider payments in circumstances when the changes could result in diminished access, where the requirements in paragraphs (c)(1)(i) through (iii) are not met, the State would be required to also provide specified information to us as part of the SPA submission as a condition of approval, in addition to the information required under paragraph (c)(1), in a format prescribed by us. Specifically, in § 447.203(c)(2)(i), we proposed to require States to provide a summary of the proposed payment change, including the State's reason for the proposal and a description of any policy purpose for the proposed change, including the cumulative effect of all reductions or restructurings taken throughout the current State fiscal year in aggregate FFS Medicaid expenditures for each benefit category affected by proposed reduction or restructuring within a State fiscal year. We proposed to collect this information for SPAs that require a § 447.203(c)(2) analysis, but for those that meet the criteria proposed under § 447.203(c)(1), we did not proposed to require a summary of the proposed payment change, including the State's reason for the proposal and a description of any policy purpose for the proposed change beyond that which is already provided as part of a normal State plan submission or as may be requested by CMS through the normal State plan review process; we solicited comments whether these elements should apply to both proposed § 447.203(c)(1) and (c)(2) equally.

In § 447.203(c)(2)(ii), we proposed to require the State to provide Medicaid payment rates in the aggregate (including base and supplemental payments) before and after the proposed reduction or restructuring for each benefit category affected by proposed reduction or restructuring, and a comparison of each (aggregate Medicaid payment before and after the reduction or restructuring) to the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services and, as reasonably feasible, to the most recently available payment rates of other health care payers in the State or the geographic area for the same or a comparable set of covered services. We noted that this proposed element is similar to the previous § 447.203(b)(1)(v) rate comparison requirement, which required the previous AMRPs to include ''[a]ctual or estimated levels of provider payment available from other payers, including other public and private payers, by provider type and site of service.'' However, the proposed analysis specifically would require an aggregate comparison including Medicaid base and supplemental

payments, as applicable, before and after the proposed reduction or restructuring are implemented, compared to the most recently published Medicare payment rates for the same or comparable set of Medicare-covered services and, as reasonably feasible, to the most recently available payment rates of other health care payers in the State or the geographic area for the same or a comparable set of covered services. We found that, first, States struggled with obtaining and providing private payer data as contemplated by the 2015 final rule with comment period, and second, States were confused about how to compare Medicaid rates to Medicare rates where there were no comparable services between Medicare and Medicaid. We wanted to acknowledge the feedback we received from States during the previous AMRP process and modify the requirements in the final rule by focusing on the more readily available Medicare payment data as the most relevant payment comparison for Medicaid, as discussed in detail above. We explained that the E/M CPT/HCPCS code comparison methodology included in the proposed § 447.203(b)(3)(i) and the payment rate disclosure in proposed § 447.203(b)(3)(ii) could serve, at a minimum, as frameworks for States that struggled to compare Medicaid rates to Medicare where there may be no other comparable services between the two programs. Otherwise, where comparable services exist, States would be required to compare all applicable Medicaid payment rates within the benefit category to the Medicare rates for the same or comparable services under proposed § 447.203(c)(2)(ii). For reasons mentioned previously in this section, Medicare through MedPAC engages in substantial analysis of access to care as it reviews payment rates for services, so we noted our belief that this is a sufficient benchmark for the Medicaid payment rate analysis.

In § 447.203(c)(2)(iii), we proposed to require States to provide information about the number of actively participating providers of services in each benefit category affected by the proposed reduction or restructuring. For this purpose, we stated that an actively participating provider is a provider that is participating in the Medicaid program and actively seeing and providing services to Medicaid beneficiaries or accepting Medicaid beneficiaries as new patients. The State would be required to provide the number of actively participating providers of services in each affected benefit category for each of the 3 years immediately preceding the SPA submission date, by State-specified geographic area (for example, by county or parish), provider type, and site of service. The State would be required to document observed trends in the number of actively participating providers in each geographic area over this period. The State could provide estimates of the anticipated effect on the number of actively participating providers of services in each benefit category affected by the proposed reduction or restructuring, by geographic area. This data element is similar to previous § 447.203(b)(1)(ii), under which States must analyze the availability of care through enrolled providers to beneficiaries in each geographic area, by provider type and site of service, in the previous AMRP process; however, the proposal would require specific quantitative information describing the number of providers, by geographic area, provider type, and site of service available to furnish services to Medicaid beneficiaries and would leave less discretion to the States on specific data measures. With all of the data elements included in proposed paragraph (c)(2), we proposed that the data come from the 3 years immediately preceding the State plan amendment submission date, as this would provide us with the most recent data and would allow for considerations for data anomalies that might otherwise distort a demonstration of access to care if only 1 year of data was used.

In § 447.203(c)(2)(iv), we proposed to require States to provide information about the number of Medicaid beneficiaries receiving services through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring. The State would be required to provide the number of beneficiaries receiving services in each affected benefit category for each of the 3 years immediately preceding the SPA submission date, by State-specified geographic area (for example, by county or parish). The State would be required to document observed trends in the number of Medicaid beneficiaries receiving services in each affected benefit category in each geographic area over this period. The State would be required to provide quantitative and qualitative information about the beneficiary populations receiving services in the affected benefit categories over this period, including the number and proportion of beneficiaries who are adults and children and who are living with disabilities, and a description of the State's consideration of the how the proposed payment changes may affect access to care and service delivery for beneficiaries in various populations. The State would be required to provide estimates of the anticipated effect on the number of Medicaid beneficiaries receiving services through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring, by geographic area. We explained that this proposed provision is a combination of previous § 447.203(b)(1)(i) and (iv), which require States to provide an analysis of the extent to which beneficiary needs are met, and the characteristics of the beneficiary population (including considerations for care, service, and payment variations for pediatric and adult populations and for individuals with disabilities). Even though we did not propose to require this analysis to be updated broadly with respect to many benefit categories on an ongoing basis, we proposed to require current information on the number of beneficiaries currently receiving services through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring to inform our SPA review process to ensure that the statutory access standard is met. The inclusion of this beneficiary data is relevant because it provides information about the recipients of Medicaid services and where, geographically, these populations reside to ensure that the statutory access standard is met.

In § 447.203(c)(2)(v), we proposed to require information about the number of Medicaid services furnished through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring. The State would be required to provide the number of Medicaid services furnished in each affected benefit category for each of the 3 years immediately preceding the SPA submission date, by State-specified geographic area (for example, by county or parish), provider type, and site of service. The State would be required to document observed trends in the number of Medicaid services furnished in each affected benefit category in each geographic area over this period. The State would be required to provide quantitative and qualitative information about the Medicaid services furnished in the affected benefit categories over this period, including the number and proportion of Medicaid services furnished to adults and children and who are living with disabilities, and a description of the State's consideration of the how the proposed payment

changes may affect access to care and service delivery. The State would be required to provide estimates of the anticipated effect on the number of Medicaid services furnished through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring, by geographic area. We noted that this proposed data element was similar to that previously required in § 447.203(b)(1)(iii), which required an analysis of changes in beneficiary utilization of covered services in each geographic area. However, as stated earlier, the difference here is that this proposed analysis would be limited to the beneficiary populations impacted by the rate reduction or restructuring, for a narrower set of data points, rather than requiring the State to conduct a full review of the Medicaid beneficiary population every 3 years on an ongoing basis. Even though we did not propose to require this analysis to be updated broadly with respect to many benefit categories on an ongoing basis, we proposed to require current information on the number and types of Medicaid services being delivered to Medicaid beneficiaries through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring to inform our SPA review process to ensure that the statutory access standard is met. The inclusion of this data is relevant because it provides information about the actual distribution of care received by Medicaid beneficiaries and where, geographically, these services are provided to ensure that the statutory access standard is met.

Finally, in § 447.203(c)(2)(vi), we proposed to require a summary of, and the State's response to, any access to care concerns or complaints received from beneficiaries, providers, and other interested parties regarding the service(s) for which the payment rate reduction or restructuring is proposed as required under § 447.204(a)(2). We noted that this proposed requirement mirrors the requirement in § 447.204(b)(3), which requires that for any SPA submission that proposes to reduce or restructure Medicaid service payment rates, a specific analysis of the information and concerns expressed in input from affected interested parties must be provided at the time of the SPA submission. The new proposed § 447.203(c)(2)(vi) would require the same analysis while providing more detail as to what we expect the State to provide. Proposed § 447.203(c)(2)(vi) would require information about concerns and complaints from beneficiaries and providers specifically, as well as from other interested parties, and would underscore that the required analysis would be required to include the State's responses.

Where any of the previously discussed proposed data elements requires an analysis of data over a 3-year period, we proposed this time span to smooth statistical anomalies, and so that data variations can be understood. For example, any 3-year period look-back that includes portions of time during a public health emergency, such as that for the COVID–19 pandemic, might include much more variation in the access to care measures than periods before or after the public health emergency. By using a 3-year period, it is more likely that the State, CMS, and other interested parties would be able to identify and appropriately account for short term disruptions in access-related measures, for example, when the number of services performed dropped precipitously in 2020 as elective visits and procedures were postponed or canceled due to the public health emergency.[367] If the proposed rule only included a 12-month period, for example, it might not be clear that the data represent an accurate reflection of access to care at the time of the proposed reduction or restructuring. For example, a State may see variation in service utilization if there have been programmatic changes that are introduced over time, such as a move to increase care provided through a managed care delivery system in the State through which the FFS utilization declines steadily until managed care enrollment targets are achieved, but a one-time review of that FFS utilization capturing just a 12-month period might not capture data most reflective of the current FFS utilization demonstrating access to care consistent with section 1902(a)(30)(A) of the Act. We solicited comments on the proposed use of a 3-year period where the proposed rule would require data about trends over time in the data elements proposed to be required under § 447.203(c)(2). We also solicited comments on the data elements required in § 447.203(c)(2) as additional State rate analysis.

Proposed paragraph (c)(2) would require that States conduct and provide to us a rigorous analysis of a proposed payment rate reduction's or payment restructuring's potential to affect beneficiary access to care. However, by limiting these analyses to only those proposed payment rate reductions and payment restructurings in circumstances when the changes could result in diminished access that do not meet the criteria in proposed paragraph (c)(1), we believe that the requirements proposed in paragraph (c)(2) would help to enable us to determine whether the proposed State Medicaid payment rates and payment methodologies are consistent with section 1902(a)(30)(A) of the Act while minimizing State and Federal administrative burden, to the extent possible. We would use this State-provided information and analysis to help us understand the current levels of access to care in the State's program, and determine, considering the provider, beneficiary, and other interested party input collected through proposed § 447.203(c)(4), whether the proposed payment rate reduction or payment restructuring likely would maintain access to care for the particular service(s) consistent with the statutory standard in section 1902(a)(30)(A) of the Act. If we approve the State's proposal, the data provided would serve as a baseline for prospective monitoring of access to care within the State.

We explained that the proposed analysis and documentation requirements in paragraph (c)(2) draw, in part, from the requirements of the previous AMRP process in the previous § 447.203(b)(1) and reflect the diverse methods and measures that are and can be used to monitor access to care. We also drew on some of the comments received on the 2011 proposed rule, as discussed in the 2015 final rule with comment period, where several commenters recommended that CMS consider identifying a set of uniform measures that States must collect data on or that CMS weighs more heavily in its analysis.[368] We proposed to provide more specificity on the types of uniform data elements in § 447.203(c) than is provided under previous § 447.203(b)(1). States have shown that they have access to the data listed in the proposed § 447.203(c)(2) when we have requested it during SPA reviews and through the previous AMRP process, and through this proposed rule, we proposed to specify the type of data that we would expect States to provide with rate reduction or restructuring SPAs that do not meet the proposed criteria for streamlined analysis under § 447.203(c)(1). As noted elsewhere in the preamble, the ongoing AMRP requirements previously presented an administratively burdensome process for States to follow every 3 years,

[367] Stuart, B. ''How The COVID–19 Pandemic Has Affected Provision Of Elective Services: The Challenges Ahead.'' *Health Affairs,* October 8, 2020. Available at *https://www.healthaffairs.org/do/10.1377/forefront.20201006.263687* (accessed February 27, 2023).

[368] 80 FR 67576 at 67590.

particularly where we did not provide States with the specific direction on the types of data elements we preferred for States to include. However, the data elements involved in the previous AMRP process in § 447.203(b)(1) can provide useful information about beneficiary access to care in previous § 447.203(b)(1)(i), (iii), and (iv); Medicaid provider availability in previous § 447.203(b)(1)(ii); and about payment rates available from other payers, which may affect Medicaid beneficiaries' relative ability to access care, in previous § 447.203(b)(1)(v). We found that the previous AMRPs were most relevant when updated to accompany a submission of rate reduction or restructuring SPAs as specified in the previous § 447.203(b)(6); accordingly, to better balance ongoing State and Federal administrative burden with our need to obtain access-related information to inform our approval decisions for payment rate reduction or restructuring SPAs, we proposed to end the ongoing AMRP requirement but maintain a requirement that States include similar data elements when submitting such SPAs to us that do not qualify for the proposed streamlined analysis process under § 447.203(c)(1).

We explained that the proposed analyses in paragraph (c)(2) would enable us to focus our review of Medicaid access to care on proposals that are at highest risk to result in diminished access to care, enabling us to more substantively review a proposed rate reduction's or restructuring's potential impact on access (for example, counts of participating providers), realized access (for example, service utilization trends), and the beneficiary experience of care (for example, characteristics of the beneficiary population, beneficiary utilization data, and information related to feedback from beneficiaries and other interested parties collected during the public process and through ongoing beneficiary feedback mechanisms, along with the State's responses to that feedback), while also being able to more quickly work through a review of nominal rate reduction SPAs for which States have demonstrated certain levels of payment and for which the public process did not generate access to care concerns. By including information on provider type and site of service, we believe States would be able to demonstrate access to the services provided under a specific benefit category within a number of different settings across the Medicaid program, such as the availability of physician services delivered in a physician practice, clinic setting, FQHC or RHC, or even in a hospital-based office setting. We noted our belief that defining specific data elements that must be provided to support a payment rate reduction SPA would create a more predictable process for States and for CMS in conducting the SPA review than under the previous AMRP process in § 447.203(b)(6).

Furthermore, data elements proposed to be required under proposed § 447.203(c)(2) would be based on State-specified geographic stratifications, to help ensure we can perform access review consistent with the requirements of section 1902(a)(30)(A) of the Act. We expect that States would have readily available access to geographically differential beneficiary and provider data. We observed that some of this information is available through CMS-maintained resources, such as the Transformed Medicaid Statistical Information System (T–MSIS), and other data is available through the National Plan and Provider Enumeration System (NPPES), but States should have their own data systems that would allow them to generate the most up-to-date beneficiary utilization and provider enrollment data, stratified by geographic areas within the State. States should use the most recent complete data available for each of the proposed data elements, and each would be required to be demonstrated to CMS by State-specified geographic area. We noted our belief that the geographic stratification would enable CMS to establish a baseline for Medicaid access to care within the geographic areas so that we can determine if current levels of access to care are consistent with section 1902(a)(30)(A) of the Act and can make future determinations if access is diminished subsequently within the geographic area. For all of the data elements in proposed § 447.203(c)(2), we stated that the more geographic differentiation that can be provided (that is, the smaller and more numerous the distinct geographic areas of the State that are selected for separate analysis), the more we believe that the State can meaningfully demonstrate that the proposed rate changes are consistent with the access standard in section 1902(a)(30)(A) of the Act, which requires that States assure that payments are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.

If finalized, we stated that we would anticipate releasing subregulatory guidance, including a template to support completion of the analysis that would be required under paragraph (c)(2), prior to the beginning date of the *Comparative Payment Rate Analysis Timeframe* proposed in § 447.203(b)(4). In the intervening period, we would anticipate working directly with States through the SPA review process to ensure compliance with section 1902(a)(30)(A) of the Act.

In § 447.203(c)(3), we proposed mechanisms for ensuring compliance with requirements for State analysis for rate reduction or restructuring, as specified in proposed paragraphs (c)(1) and (c)(2), as applicable. We proposed that a State that submits a SPA that proposes to reduce provider payments or restructure provider payments that fails to provide the required information and analysis to support approval as specified in proposed paragraphs (c)(1) and (2), as applicable, may be subject to SPA disapproval under § 430.15(c). Additionally, States that submit relevant information, but where there are unresolved access to care concerns related to the proposed SPA, including any raised by CMS in our review of the proposal and any raised through the public process as specified in proposed paragraph (c)(4) of this section, or under § 447.204(a)(2), may be subject to SPA disapproval under § 430.15(c). Disapproving a SPA means that the State would not have authority to implement the proposed rate reduction or restructuring and would be required to continue to pay providers according to the rate methodology described in the approved State plan. Proposed paragraph (c)(3) would further provide that if, after approval of a proposed rate reduction or restructuring, State monitoring of beneficiary access shows a decrease in Medicaid access to care, such as a decrease in the provider-to-beneficiary ratio for any affected service, or the State or CMS experiences an increase in the number of beneficiary or provider complaints or concerns about access to care that suggests possible noncompliance with the access requirements in section 1902(a)(30)(A) of the Act, we may take a compliance action. As described in § 447.204(d), compliance actions would be carried out using the procedures described in § 430.35.

As discussed in the prior section, we proposed to move previous § 447.203(b)(7) to § 447.203(c)(4) as finalized in this rule. We did not propose any changes to the public process described in paragraph (b)(7). We proposed that if the other provisions of the proposed rule are finalized, we would redesignate paragraph (b)(7) as paragraph (c)(4). The ability for

providers and beneficiaries to provide ongoing feedback to the State regarding access to care and a beneficiary's ability to access Medicaid services is essential to the Medicaid program in that it provides the primary interested parties the opportunity to communicate with the State and for the State to track and take account of those interactions in a meaningful way. We stated that the ongoing mechanisms for provider and beneficiary feedback must be retained, as this process serves an important role in determining whether or not the public has raised concerns regarding access to Medicaid-covered services, which would inform the State's approach to ongoing Medicaid provider payment rates and methodologies, and whether related proposals would be approvable.

We proposed to move previous § 447.203(b)(8) to § 447.203(c)(5), as finalized in this rule, to better organize § 447.203 to reflect the policies in the proposed rule. We did not propose any changes to the methods for addressing access questions and remediation of inadequate access to care, as described in paragraph (b)(8). We proposed that if the other provisions of the proposed rule are finalized, we would redesignate paragraph (b)(8) as paragraph (c)(5). We stated that it is important to retain this provision because we acknowledge that there may be access issues that come about apart from a specific State payment rate action, and there must be mechanisms through which those issues can be identified, and corrective action taken.

Finally, we proposed to move previous § 447.204(d) to proposed § 447.203(c)(6). We noted our belief that the subject matter, of compliance actions for an access deficiency, is better aligned to the proposed changes in § 447.203. We did not propose any changes to the remedy for the identification of an unresolved access deficiency, as described in § 447.204(d). We proposed that if the other provisions of this proposed rule are finalized, we would redesignate § 447.204(d) as paragraph (c)(6).

We solicited public comment on our proposed procedures and requirements for State analysis when submitting payment rate reduction or payment restructuring SPAs. We received public comments on these proposals. The following is a summary of the comments we received and our responses, organized by regulatory section.

a. General Comments

Comment: Many commenters supported the approaches to reviewing rate changes. Specifically, a number of commenters noted support for the two-tiered process to provide specific levels of information and data with a request to reduce or restructure payment rates in circumstances where such changes could result in diminished access to care, with some commenters specifically supporting the inclusion of concerns raised during the public comment process. Other commenters noted general support for requiring State justification for rate reductions and restructurings as it would provide greater transparency and accountability into State justifications for potentially harmful rate reductions. A couple commenters noted support for CMS' administrative review of rate changes to ensure continued access. One commenter was encouraged that CMS proposed to include protections to mitigate the risk that payment reductions will translate into reduced access. Another commenter agreed with CMS that additional scrutiny is warranted when a rate reduction is more than nominal, and when public concerns are raised regarding the rate. Finally, one commenter expressed appreciation for CMS' detailed review and summary of the literature on the impact of payment rates for providers on access to care for beneficiaries.

Response: We appreciate the support of the commenters on both our overall approach and for certain specific aspects of our proposed policies, which we are finalizing as proposed. We agree that the public process is an important component of Medicaid program changes.

Comment: One commenter supported requiring States to demonstrate that a reduction in payment rates will not adversely impact access to care. The commenter stated that the effort required for States to make such a showing will guard against rate reductions that would be detrimental to Medicaid recipients' ability to access care.

Response: We appreciate the support of the commenter. We believe there will be States, in certain circumstances, that will be able to meet the requirements of the streamlined access process under § 447.203(c)(1). The intention of the § 447.203(c) provisions is to balance the requirement that State's ensure compliance with section 1902(a)(30)(A) of the Act with reducing unnecessary burden in the State's administration of their Medicaid programs. We believe that the streamlined process under § 447.203(c)(1) is itself consistent with the statutory access standard, because the policies in this final rule ensure that only rate reductions or restructurings that are likely to be consistent with that standard will be approvable under this streamlined process.

Comment: One commenter stated that in some States, there is high potential for interruption in access due to delays created by the SPA process. The commenter was concerned that long delays caused by the SPA process can interrupt access to the latest standard of care. They stated that clarification on CMS regulations for SPAs for changes that increase access to the standard of care could reduce the risk of care interruptions.

Similarly, another commenter recommended that CMS give States the flexibility to increase rates to 100 percent of the equivalent Medicare rate without a SPA, and to make midyear adjustments to rates without a SPA. The commenter also indicated SPAs should only be required beyond specified thresholds.

Response: We appreciate the concern of the commenter related to any delays in the approval of SPAs. We are interested in approving approvable SPAs as expeditiously as possible, which is one of the reasons for issuing this final rule with an included template. SPAs generally may be effective no earlier than the first day of the quarter in which they are submitted per 42 CFR 430.20. The policies in this final rule and the template process provide States with clear documentation requirements for SPAs proposing to reduce or restructure provider payment rates. Without exception, our policy, as set forth in § 447.201(b), is that States must receive approval through the SPA process to modify Medicaid payment methodologies. CMS approval ensures that the changes in service payment methodologies comply with all applicable regulatory and statutory requirements and that resulting State expenditures are eligible for FFP. Changes to these requirements are beyond the scope of this rulemaking. In addition, regardless of this final rule, all SPAs are reviewed using the criteria and timeframes outlined in 42 CFR part 430 subpart B.

Comment: One commenter requested that CMS clarify how the § 447.203(c) provisions would apply to performance-based incentives, withholds, and alternative payment models, indicating that States should not be penalized for moving away from a FFS model that is not tied to performance.

Response: Performance-based incentives, innovative care models, and alternative payment models are often designed to improve quality of care, promote better patient outcomes, and reward providers for improvements to quality of care and patient outcomes,

while lowering the cost of care. In the 2015 final rule with comment period, we signaled our interest in working with States in promoting innovative patient care models and delivery system changes that seek to reward the provision of quality patient care that also lowered cost to the Medicaid program.[369]

The provisions of the final rule in § 447.203(c) provide processes for rate reductions or restructurings, with the goal of determining when those changes could result in diminished access. In most instances, a performance-based incentive, innovative care models, or alternative payment models that restructure provider payments do so in a manner that would not result in diminished access and that we would not regard as a restructuring subject to § 447.203(c). For example, a State may propose an episode of care arrangement that bundles all of the care related to a defined medical event, including the care for the event itself, any precursors to the event and follow-up care. As a component of this methodology, the State would make one payment for the whole episode that is meant to encompass the medical event including the precursors and follow-up care, with up-side and down-side incentives paid or collected based on the providers' performance against the mean. Providers must volunteer to enroll in this program, and any other provider would continue to be paid as they normally would under the State plan. Such a restructuring proposal does not diminish access because the providers are electing to participate and understand the risk, but since care must be provided for the performance incentives to be determined and non-participating providers would not experience a change in payment, Medicaid beneficiaries will not experience diminished access to services. We also note that other simple add-on payments for achievement of specified quality targets where there is no possibility of a reduction to any provider's payment would not be considered a restructuring subject to the requirements of § 447.203(c).

However, to the extent that a State implements a performance-based incentive, withhold, or alternative payment model would reduce payment rates, such as models that involve down-side risk arrangements where provider payments could decrease from current levels in certain circumstances, these changes likely would have the potential to result in diminished access to care and therefore would be a restructuring that would fall under the requirements of § 447.203(c). For example, if a State proposed to implement a quality improvement payment arrangement involving downside risk, meaning that providers could their payment rates reduced the State's quality improvement proposal, for which providers were required to participate then CMS could view this arrangement as being a payment reduction or restructuring that could affect access to care. The State in this instance would be expected to conduct the appropriate level(s) of analysis required under § 447.203(c).

We want to note that the requirement to perform an initial or initial and additional analysis under § 447.203(c) does not mean the State will be unable to enact the proposed payment arrangement; it simply means CMS wants to verify that access will not be negatively impacted with additional documentation to demonstrate this fact. As such, this final rule does not limit a State's ability to reduce or restructure rates based on information that the rates are not economic and efficient; rather, it ensures that States take appropriate measures to document access to care consistent with section 1902(a)(30)(A) of the Act. We do not view this as a penalty, as the commenter suggested, but rather a documentation of consistency with the statute. Under the Act, rates must be both economic and efficient, and they also must ensure that individuals have sufficient access to covered services. We interpret section 1902(a)(30)(A) of the Act as requiring a balanced approach to Medicaid rate-setting and we encourage States to use appropriate information and program experience to develop rates to meet all of its requirements. Further, we expect States to document that Medicaid rates are economic and efficient when the State submits changes to payment methodologies through a SPA. If a State is unsure whether its proposed performance-based incentive, innovative care model, or alternative payment models contains a restructuring subject to § 447.203(c), they can engage with CMS prior to submission of a SPA. CMS can and may request § 447.203(c) analyses upon receipt of a proposal as well.

Comment: A few commenters expressed concern that the provisions of § 447.203(c) appear to be operating under the assumption that current payment rates are adequate, with some commenters focusing on HCBS service payment, and concern that there is no express requirement to regularly review the payment methodology to account for inflationary updates. For example, one commenter indicated that there would be no analysis required by a State that today pays less than the cost of delivering care and does not increase rates for the next 5 years, but also does not propose any rate reductions. Another indicated that the new rate review process requires no accountability from a State that may currently have rates below the cost of care or where rates remain static for several years. These commenters strongly encouraged CMS to include provisions that would require States to review current payment rates for adequacy and update payment rates immediately and on an ongoing basis either annually or up to every 2 years to account for inflation, new regulatory requirements that impose costs on providers, and other changes that may impact the cost of doing business.

Response: We agree with the commenter on the importance of States having adequate rates, even when they are not proposing to reduce or restructure those provider payment rates. We direct the commenter to the other provisions of this final rule, including the payment rate transparency publication in § 447.203(b)(1), comparative rate analysis in § 447.203(b)(2), and payment rate disclosure in § 447.203(b)(3), which are intended to make available readily accessible information relevant to whether the rates States currently are paying (beginning with the initial publications on or before July 1, 2026) are adequate. We also note that beneficiaries and providers have opportunities to raise access to care concerns to the State through the State's mechanisms for ongoing beneficiary and provider input described in § 447.203(c)(4). This final rule addresses how States can demonstrate sufficient access to care as required by section 1902(a)(30)(A) of the Act when submitting SPAs that propose to reduce or restructure provider payment rates. Neither provider cost nor inflation is a required review element in meeting the requirements of the final rule. States may certainly consider these elements when engaging in rate setting or conducting rate reviews, but it is not a required component of this final rule.

Comment: Two commenters supported the proposal to revamp previous requirements in effect for SPAs that propose to reduce rate or restructure payments and strongly urged CMS to consider changes to the final rule to ensure the new proposed structure does not permit States to alter rates in ways that negatively impact beneficiary access.

[369] 80 FR 67578 and 67579.

Response: We appreciate the commenters' support. We are finalizing the provisions as proposed. The final rule provides CMS with an administrative process through which States can demonstrate that they have considered access to care and responded to public concerns in the implementation of payment rate reduction or restructuring SPAs. We are confident these steps will ensure rate changes do not impact access in a manner inconsistent with section 1902(a)(30)(A) of the Act.

Comment: Some commenters supported efforts to bring more transparency to the rate-setting process but did not support CMS' proposed change to replace the current rate reduction review process for one that examines proposed rate reductions on a State fiscal year basis. One commenter expressed concern that the proposal to establish an across-the-board threshold for provider payment rate reductions subject to the access review process fails to recognize the need for variable rate assumptions consistent with the characteristics of different Medicaid eligibility groups. The commenters expressed concern that it is not always appropriate to use the same assumptions for all populations or providers serving these eligibility groups, especially for complex populations, and noted that this proposal fails to recognize the impact individual provider rate reductions may have on a class of providers, noting that it is not appropriate to aggregate the impact of provider rate reductions, particularly for services provided to complex populations served under the Temporary Aid for Needy Families; Aged, Blind, and Disabled; and LTSS eligibility groups.

Response: We understand the commenters' concerns. States, under the finalized § 447.203(c)(1) and (2), as applicable, will be required to analyze the impact on provider payments based on the affected benefit category, but we acknowledge that particular services within a benefit category may be provided across different provider classes or settings. For example, physicians may provide services in an office setting, a hospital setting, or a clinic setting. The provider may receive a different payment rate for physician services depending upon the setting where services are performed as a result of differences between facility and non-facility payment rate types, which account for the difference in provider overhead cost assumptions based on the setting where the services occur.

We also note, as the commenter specifically raised concerns regarding complex populations and eligibility groups, that CMS policy has long established policy, consistent with statutory requirements for comparability in amount, duration, or scope of medical assistance, that States may not establish differential rates based upon an individual's eligibility category. States are able to set rates based on a patient's acuity, service complexity, or other service-related consideration, but to set different rates for different eligibility categories could promote inequity across the Medicaid program if providers were offered greater financial incentives to furnish services to beneficiaries in some eligibility groups than others. Such differentiation of payment rates would also not be considered economic and efficient in a manner consistent with section 1902(a)(30)(A) of the Act because some payment rates would be higher than necessary considering relevant service-related factors, for example, if rates were higher for certain eligibility groups than others in relation to the Federal matching rate available for expenditures for the respective groups.

Comment: One commenter recommended CMS clarify that FQHC services are included in protections for payment rate reductions in § 477.203(c).

Response: The requirements in § 447.203(c) are applicable to all Medicaid FFS services under the Medicaid State plan, including services furnished by FQHCs.

Comment: One of the commenters recommended that CMS consider proposals to address stagnant and insufficient Medicaid payment rates that are not high enough to support paying competitive wages. One commenter recommended that CMS require States to perform a one-time rate review analysis (requiring States to submit the data described in paragraph (c)(1) and, if not all three of the requirements are met, (c)(2)) upon implementation of this rule to ensure payment adequacy necessary to support access to quality care.

Response: We understand the commenters' concerns regarding stagnant provider payment rates and rates that may not support competitive wages. We encourage providers to engage with their State Medicaid programs through forums available to them, such as the interested parties advisory group and the mechanisms for ongoing beneficiary and provider input, described in § 447.203(c)(4). In addition, we direct the commenter to the other provisions of this final rule, including the payment rate transparency publication in § 447.203(b)(1), comparative rate analysis in § 447.203(b)(2), and payment rate disclosure in § 447.203(b)(3), which are intended to make available readily accessible information relevant to whether the rates States currently are paying (beginning with the initial publications on or before 7/1/26) are adequate.

We explained in the proposed rule that our primary objective was to replace the previous AMRP process with something that could better assess access while decreasing burden on States. Requiring the analysis described by the commenters would represent an enormous one-time burden on States. We note that we are finalizing the rate transparency and analysis requirements proposed under § 447.203(b), which we expect will provide greater insight into rates relative to access issues, while maintaining a scope that seeks to minimize unnecessary burden on States.

Comment: A few commenters noted how CMS indicated in the preamble of the proposed rule that the term ''benefit category'' under § 447.203(c) would refer to services under a category of services as described in section 1905(a) of the Act. One commenter stated that CMS has declined to define ''benefit category'' in a meaningful way and requested clarification. The commenter was concerned that extremely large swaths of services can be grouped together for the purposes of conducting the analysis, which could circumvent the analysis of real-world impact of payment cuts on specific provider types. Another commenter requested that CMS clarify that the required analyses apply to both home care services (that is, personal care and home health services) provided under section 1905(a) of the Act and to services provided under 1915 authorities. However, rather than treating (for example) personal care services as a single benefit category across all authorities for the purpose of the required analysis, the commenter suggested that CMS view 1905(a) PCS as one benefit and treat the set of HCBS coverable under 1915 and other authorities as a separate single benefit.

Response: Reiterating the definition in the preamble, we mean for ''benefit category'' to refer to all individual services under a category of services described in the Medicaid State plan for which the State is proposing a payment rate reduction or restructuring. Just as with our review of Medicaid payment rates, we do not review the inclusion of individual services within a benefit category unless the intention of a SPA is to specifically add or remove coverage for a particular service from the State plan. Further, we have concerns about the usefulness of information that

would inform our SPA review as the relevant unit of analysis becomes smaller (from benefit category to individual service level). For example, it is unclear that a reduction in the number of group occupational therapy services furnished by therapy providers during a given time frame would indicate that there is an issue with provider payment rates being insufficient to support adequate beneficiary access, or if the reduction merely represented a data anomaly that is unrelated to the rate of payment. We believe that the higher level of review of payment rate sufficiency at the benefit category level is consistent with the requirement in section 1902(a)(30)(A) of the Act that rates be sufficient to ensure that ''care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.''

That being said, if a State proposes to group together services together that are not reasonably considered to be within the same benefit category (including where the grouping is not consistent with how the State covers and/or pays for the services under the State plan) to attempt to meet the paragraph (c)(1) thresholds and avoid the need to submit additional analysis under paragraph (c)(2), we will request additional information from the State including demonstrations that the paragraph (c)(1) criteria are met using a reasonable benefit category definition, or the additional analysis required under paragraph (c)(2), to support SPA approval.

Finally, in response to the commenter that requested that CMS clarify that the required analyses apply to home care services (including personal care and home health services) under section 1905(a) of the Act and to those covered under section 1915 authorities, we affirm that the analyses apply to both types of home care services under State plan, section 1915(c) waiver and demonstration payment rates, as applicable. To the extent that it is applicable, the 1905(a) PCS is one benefit category and the set of HCBS coverable PCS under 1915 and other authorities are considered as individual benefits as the payment methodologies for these services of often distinct methodologies across the different State plan or waiver authorities.

Comment: One commenter suggested CMS provide a template for the code-by-code analysis level to support the State analysis procedures for rate reductions or restructurings.

Response: We produced and are finalizing a template for States to ease the administration of the requirements of this final rule, including a code-by-code analysis to the support the payment analysis. The template will assist the States with meeting the § 447.203(c)(1)(i) and (c)(2)(ii) requirements for an aggregate analysis of Medicaid base and supplemental payments relative to Medicare, but it is important for us to clarify that these provisions do not necessarily require submission to CMS of a code-by-code analysis as suggested by the commenter. Section 447.203(c)(1)(i) requires States to provide written assurance and relevant supporting documentation that Medicaid payment rates in the aggregate (including base and supplemental payments) following the proposed reduction or restructuring for each benefit category affected by the proposed reduction or restructuring would be at or above 80 percent of the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services. Section 447.203(c)(2)(ii) requires States to provide Medicaid payment rates in the aggregate (including base and supplemental payments) before and after the proposed reduction or restructuring for each benefit category affected by proposed reduction or restructuring, and a comparison of each (aggregate Medicaid payment before and after the reduction or restructuring) to the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services and, as reasonably feasible, to the most recently available payment rates of other health care payers in the State or the geographic area for the same or a comparable set of covered services. In each case, the analysis performed would be an aggregate comparison of the State's proposed Medicaid rates to Medicare; however, CMS may request that the State provide supporting documentation, for example, where CMS has concerns with the accuracy of the analysis performed.

Comment: One commenter stated that, while imperfect as a point of comparison, Medicare is at least a reliable source of data that utilizes cost studies and other factors in its own rate setting processes. The commenter stated that if Medicare is retained as the benchmark, they would endorse use of an aggregate, as opposed to code-by-code, comparison with Medicaid rates. They explained that a code-by-code analysis would be extremely difficult, as CMS would need to define a methodology to determine if there is a one-to-one match between service descriptions and procedural codes in Medicare and Medicaid; Medicaid agencies report significant variation in codes and service descriptions.

Response: We agree with the commenter and note that the final rule in § 447.203(c)(1)(i), and the similar provision in § 447.203(c)(2)(ii), require that Medicaid payment rates in the aggregate (including base and supplemental payments) following the proposed reduction or restructuring for each benefit category affected by the proposed reduction or restructuring be compared to the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services. For this purpose, the Medicare services selected for comparison should align reasonably with the Medicaid services covered by the State within the affected Medicaid benefit category. We would expect the State to develop a reasonably comparable set of Medicare-covered services to which its proposed Medicaid payment rates could be compared and to include with its submission an explanation of its reasoning and methodology for constructing the comparison of Medicaid to Medicare payment rates.

Comment: A few commenters opposed the two-tiered approach, believing that this approach is insufficient to ensure access. Those commenters urged CMS to only use the tier two (§ 447.203(c)(2)) analysis on any SPA that proposes to reduce or restructure provider payment rates. One of the commenters opposed the two-tiered system on the basis that it would result in States implementing significant cuts to Medicaid rates without scrutiny for prolonged periods of time as long as they are exempt from second-tier analysis.

Response: We appreciate the commenters' viewpoints, but we are finalizing the two-tiered analysis as proposed. We do not agree that the two-tiered system would result in States implementing significant cuts to Medicaid without scrutiny for prolonged periods of time. We are finalizing § 447.203(c)(1) to require that all three provisions of § 447.203(c)(1) must be met in order for the SPA to qualify for the streamlined analysis provision of the final rule. In our view, the streamlined review for qualifying SPAs under § 447.203(c)(1) is sufficient because the State's payment rates would remain at or above 80 percent of the Medicare rate; the proposed reduction or restructuring would be likely to result in no more than a 4 percent reduction in aggregate FFS Medicaid expenditures for each benefit category affected by

proposed reduction or restructuring within a State fiscal year; and the public process yielded no significant access to care concerns from beneficiaries, providers, or other interested parties regarding the service(s) for which the payment rate reduction or payment restructuring is proposed, or if such processes did yield concerns, the State can reasonably respond to or mitigate the concerns, as appropriate. Taken together, the streamlined State analysis provides safeguards to mitigate the impact of State rate reductions while also providing protection for compounding reductions that could occur over a prolonged period of time. We anticipate that compounding rate reductions or restructurings would lower the possibility that a State's payment rates remain at or above 80 percent of Medicare and the public input process would generate significant provider and beneficiary feedback in the event that such reductions are taken at 4 percent per State fiscal year which would disqualify a State Plan rate reduction or restructuring proposal from meeting the requirements for the streamlined § 447.203(c)(1) process. We included this aspect of the analysis, in part, to protect against a large reduction spread over time through smaller reductions that pass initial scrutiny having an unacceptable negative impact on beneficiary access. As noted above, we anticipate that any State that is making significant cuts to provider payment rates over time will have a significant challenge in meeting the requirements for the initial State analysis in § 447.203(c)(1).

Comment: One commenter noted that the proposed rule would require States to provide additional information to justify their requests for reduced or restructured payment rates in SPAs, but the commenter noted that CMS does not commit to denying the requests where the State proposes payment rates below 80 percent of Medicare and did not agree with CMS's lack of commitment to disapprove such requested rate actions. The commenter did not believe this would sufficiently dissuade rate reductions, and that the language indicating CMS might not approve such proposed payment rate reduction or restructuring SPAs would just generate confusion, as well as attempts by States to ''game the system'' to try to figure out what language they should submit to win approval of their applications.

Response: Much like the previous AMRP process from the 2015 final rule with comment period, the access provisions contained in § 447.203(c) are intended to create a baseline measurement from which the State rate reduction or restructuring proposals may be evaluated. CMS has not taken the position that State payment rate proposals that set provider payment rates below 80 percent of Medicare are to be automatically disapproved, but instead we are committing States to a process by which they demonstrate that access is sufficient in their State so the agency can properly evaluate these State proposals under the section 1902(a)(30)(A) of the Act requirements. SPAs that fail to include the information required under the applicable provisions of § 447.203(c) will be disapproved by CMS. For proposals that do not meet the streamlined State analysis requirements under § 447.203(c)(1), States are required to provide the following with all payment rate reduction or restructuring SPAs: a summary of the proposed change, including the State's reason for the proposal and a description of any policy purpose for the proposed change, including the cumulative effect of all reductions or restructurings taken throughout the current State fiscal year in aggregate FFS Medicaid expenditures for each benefit category affected by proposed reduction or restructuring within a State fiscal year; Medicaid payment rates in the aggregate (including base and supplemental payments) before and after the proposed reduction or restructuring for each benefit category affected by proposed reduction or restructuring, and a comparison of each (aggregate Medicaid payment before and after the reduction or restructuring) to the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services and, as reasonably feasible, to the most recently available payment rates of other health care payers in the State or the geographic area for the same or a comparable set of covered services; information about the number of actively participating providers of services in each benefit category affected by the proposed reduction or restructuring; information about the number of Medicaid beneficiaries receiving services through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring; information about the number of Medicaid services furnished through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring; and a summary of, and the State's response to, any access to care concerns or complaints received from beneficiaries, providers, and other interested parties regarding the service(s) for which the payment rate reduction or restructuring is proposed, as required under § 447.204(a)(2). In addition to being used to establish a baseline, as mentioned above, CMS will use the information in determining whether access is sufficient based on the State's submission of the required data and analysis, including of Medicaid provider enrollment, service utilization, and number of beneficiaries receiving affected services (including observed trends). We expect State proposals to be accompanied by documentation of meaningful engagement with providers, beneficiaries, and potentially other interested parties, to ensure that the proposed payment rate reductions or restructurings will not reduce access to care for Medicaid beneficiaries below the standard set in section 1902(a)(30)(A) of the Act. However, we acknowledge that the individual circumstances of the SPA proposal will inform the precise information required to be submitted under this final rule. We are confident that the provisions of the final rule are clear and outline a process which States will be required to follow when reducing or restructuring provider payment rates which CMS will review on a case-by-case basis, but we are confident that the documentation requirements will not allow States to game the system, as the commenter contends.

Comment: One commenter urged CMS to take an approach that is more straightforward than the two-tiered proposal to better monitor provider payment adequacy. For example, the commenter stated that payment reductions in excess of 5 percent for any given service or CPT code should be reviewed by CMS to determine if beneficiary access is at risk. Another commenter was concerned that CMS' proposed ''aggregate'' standard, reviewing rates across a benefit category rather than at the service-specific level, could mean that some Medicaid services may be paid well below the percentage threshold even if the overall benefit category achieves the threshold. They recommended setting the threshold on a disaggregated basis to protect access to key services and avoid permitting States to obscure low payment rates.

Response: We approve States' rate methodologies for compliance with regulation and statute, but may not approve individual service rates unless a State presents a final rate, or a fee schedule, as the output of a rate methodology. This final rule does not change that policy or imply that CMS will review individual rates for sufficiency in all cases. Reviewing individual rates within a fee schedule

would not necessarily provide a better determination of whether the rates are adequate to enlist sufficient providers into the Medicaid program or not, provided that the State is using a consistent payment rate methodology for the entirety of the fee schedule, since we do not believe that providers generally make decisions about whether to participate with a payer (and accept the payer's rates) based on the rate for a single service. However, we will review individual payment rate codes to the extent that the rate changes fall outside of the typical methodology used by the State in their payment rate setting methodology under the State plan. For example, if the State uses the Medicare fee schedule for items of DME under the Medicaid State plan but decides to alter the payment rate for the oxygen codes (E0441, for example) to set Medicaid-specific rates, we will review those individual payment rate changes as they fall outside of the State's payment rate setting methodology under the State plan. Further, the payment rate transparency publication in § 447.203(b)(1) will require States to publish their fee schedule rates for services specified in that section of the final rule, which will include individual fee schedule payment rates for services for CMS and public review.

b. Initial State Analysis for Rate Reduction or Restructuring (§ 447.203(c)(1))

Comment: One commenter stated their general support for the streamlined initial review process, noting it provides States with clear safe harbor guidelines.

Response: We appreciate the support of the commenter. However, we note that section 447.203(c)(1) does not necessarily provide a ''safe harbor'' guaranteeing approval of a SPA. All applicable Federal requirements must be met for SPA approval. And even where paragraph (c)(1)(i) and (ii) are met because the aggregate Medicaid payment rates for the benefit category after reduction or restructuring would be at or above 80 percent of the most recently published Medicare rates for the same or a comparable set of Medicare-covered services, and the cumulative effect of all reductions or restructurings throughout the current State fiscal year would be likely to result in no more than a 4 percent reduction in aggregate FFS Medicaid expenditures for the benefit category, paragraph (c)(1)(iii) still must be met. That is to say, even when the quantitative standards of the first two prongs of the (c)(1) test are satisfied, we will carefully review the information the State provides to us under section 447.204(b)(3) specifically analyzing any information and concerns expressed in input from affected interested parties in connection with the proposed SPA. As specified in section 447.203(c)(1)(iii), there must be no significant access to care concerns from beneficiaries, providers, or other interested parties regarding the service(s) for which the payment rate reduction or payment restructuring is proposed, or if public processes did yield such concerns, the State must be able to reasonably respond to or mitigate them, as appropriate.

Comment: One commenter noted their support of CMS' first-tier proposal for handling rate reductions. However, they recommended that CMS establish a process for granting States flexibility from the requirements under unique circumstances. For example, a reduction may occur as the result of a decrease in CMS' RVUs or Medicare payment schedules. Some State fee schedules are indirectly tied to CMS RVUs or other Medicare payment schedules, and decreases occurring there are likely to also occur on the State's fee schedule. The commenter stated that an exemption from rate reduction requirements would be justified in this circumstance.

Response: For States that have set their approved State plan payment methodology at the current Medicare RVU prices, CMS would interpret such a methodology as accounting for changes that Medicare makes to components of their RVU-based methodology without the need for additional SPA action on the State's part. This would only include scenarios where the State has specifically indicated that the payment rates for Medicaid services are set at the current Medicare price for the State plan services and would not apply to circumstances where the State creates a static fee schedule that simply relies on a particular snapshot of Medicare prices to inform a State fee schedule, or for methodologies that rely upon a prior iteration of the Medicare prices for the current Medicaid payment rates.

Comment: One commenter suggested that provider associations and participant representatives be part of reviewing and analyzing the impacts on rate reductions and access that would be required under § 447.203(c)(1) and (2).

Response: Section 447.203(c)(4) as finalized in this final rule provides that States must have ongoing mechanisms for beneficiary and provider input (through hotlines, surveys, ombudsman, review of grievance and appeals data, or another equivalent mechanism), through which interested parties can raise concerns about access, including payment sufficiency. Provider associations and participant representatives, which we understand to be representatives of beneficiaries that may be under the age of 21, are able to participate in public engagement through these mechanisms, related to State actions that could result in a reduction or restructuring of State plan payment rates. To be clear, the public process in § 447.203(c)(4) serves as a means for the State to receive feedback on real-time access to care issues that may be addressed on an ad hoc basis; interested parties do not need to wait for the State to develop a payment SPA to raise access to care issues through mechanisms under § 447.203(c)(4). This input, as well as input collected through the public input process under § 447.204, will be considered under § 447.203(c)(1)(iii) and used to determine whether or not the proposed reduction or restructuring SPA is consistent with section 1902(a)(30)(A) of the Act.

Comment: A few commenters suggested CMS use its authority to encourage States toward a national floor for rates, with some stating the Medicaid-to-Medicare fee ratio threshold proposed in § 447.203(c)(1)(i) should become a Federal floor for all SPA and waiver approvals. For example, they recommended that CMS could phase-in an explicit regulatory floor or implement standards tying improvements in Medicaid rates to approvals of related Medicaid flexibilities, such as section 1115 approvals, SDPs, etc. One commenter pointed out that some States have rates well below Medicare levels and change rates infrequently. This means that, assuming a State does nothing, currently inadequate rates could simply persist for decades more under CMS' approach, and in fact regress relative to inflation. Another commenter specifically recommended that CMS require both an initial in-depth analysis of access metrics as well as an analysis over time for any State that implements payment rates lower than Medicare.

Response: Unless explicitly authorized by statute, CMS does not have the authority to establish a national floor for Medicaid payment rates. Refusing to approve any payment rate reductions or restructurings that do not specifically meet the thresholds in § 447.203(c)(1)(i) could be construed as setting a national floor for rates. We understand that some States may infrequently update their payment rates, but section 1902(a)(30)(A) of the Act provides States with flexibility to establish payment rates in a manner that

balances consideration of State budgetary needs and restrictions with the obligation to provide medical assistance under the State plan in accordance with Federal requirements. With the policies finalized throughout this final rule, we hope that both States and the public will more closely examine existing rates. Our policies around rate transparency and adequacy will enhance opportunities to determine where an existing rate may negatively impact access to care and identify for States where a need should be addressed by providing beneficiaries, providers, other and interested parties with easier access to State plan payment rates through payment rate transparency publications, comparative payment rate analyses, and payment rate disclosures. Our policies around the mechanisms for ongoing beneficiary and provider input in § 447.203(c)(4) and addressing access questions and remediation of inadequate access to care in § 447.203(c)(5) will further provide beneficiaries and providers opportunities to engage with States where existing payment rates may have an impact on beneficiaries' access to care.

The purpose of this final rule is to create a process that is less administratively burdensome than the previous, ongoing AMRP process under the 2015 final rule with comment period, while also maintaining a data submission process for payment rate reduction and restructuring SPAs that do not meet the thresholds set out in § 447.203(c)(1), and note that the FFS provisions, including the payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements (§ 447.203(b)(1) through (5)), interested parties' advisory group requirements (§ 447.203(b)(6)), and State analysis procedures for payment rate reductions or payment restructuring (§ 447.203(c)), finalized in this rule are expected to result in a net burden reduction on States compared to the previous AMRP requirements, as discussed in the proposed rule and in section III. of this final rule. This final rule provides CMS and States with an administrative process through which rate reductions or restructurings can be reviewed and approved, so long as the proposed SPA satisfactorily includes the information required under this final rule and meets all applicable Federal requirements.

We note that the policies finalized in § 447.203(c)(2) do include an analysis of data that looks back at a 3-year period of time to help ascertain whether access to care for the relevant services is consistent with the statutory access standard. Further, the rule includes a requirement for ongoing access monitoring to the extent that access issues are identified that require State intervention, as provided in § 447.203(c)(5), which requires the State to take corrective action resulting in measurable and sustainable access improvements.

Comment: One commenter recommended that CMS amend § 447.203(c)(1) and (2) to require States to demonstrate compliance with the Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA), as applicable, for any proposed rate reduction or restructuring and provide technical assistance to States on compliance with this provision that would include guidance on the required comparative analysis both for the standard as written and in operation.

Response: CMS works closely with State Medicaid agencies to ensure compliance with MHPAEA in Medicaid managed care arrangements, Medicaid alternative benefit plans (managed care and FFS), and CHIP benefits (managed care and FFS) whenever changes to coverage of mental health or SUD benefits are proposed by States. We did not specifically require that States demonstrate compliance with the MHPAEA as part of this final rule, as the final rule focuses on payment rates established by the State Medicaid agencies to pay for allowable Medicaid services under the Medicaid State plan through FFS. Congress has not extended MHPAEA requirements to Medicaid benefits provided solely through FFS delivery systems. Nonetheless, we encourage our State Medicaid and CHIP agency partners to ensure their FFS benefits comply with MHPAEA. Moreover, CMS reviews State proposals regarding rate reductions or restructuring to ensure compliance with the requirements of section 1902(a)(30)(A) of the Social Security Act ''to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan, at least to the extent that such care and services are available to the general population in the geographic area.'' This review thus includes the fundamental objective of MHPAEA—to ensure access to mental health and substance use disorder treatment.

Comment: One commenter requested further information on what circumstances CMS would expect to result in diminished access for a SPA that would restructure, but not reduce, rates.

Response: We acknowledge that there may be any number of payment methodology changes that could harm access to care even when there is a restructuring but not reduction in rates, and unfortunately, we are unable to identify all such circumstances in advance. However, as discussed previously, one common type of restructuring is a change in the targeting of supplemental payments. States may alter payments, including in ways that are budget neutral for a benefit category as a whole (that is, they do not decrease overall Medicaid spending for the benefit category), but the changes would reduce payments for some providers, potentially harming beneficiary access.

Comment: One commenter requested that CMS clarify what is meant by ''restructure'' and confirm that this would not include any type of rate increase.

Response: A rate restructuring is a payment action where a State amends its methodology for an interrelated set of rates whereby individual rates may increase, decrease, or remain the same, which the State typically undertakes to achieve some programmatic purpose, such as achieving more efficient payment for services that frequently are furnished together. While a rate restructuring potentially could include rate increases, if increasing rates is the only effect of the rate restructuring, then we generally would not expect these to be circumstances when the changes could result in diminished access, and the requirements of § 447.203(c)(1) through (3) would not have to be met. Although we cannot set forth an exhaustive list of rate restructurings, one common type of restructuring is a change in the targeting of supplemental payments, under which the set of providers qualifying for a supplemental payment might change and/or the amounts received by each provider might increase or decrease. States may use a methodology to identify amounts that a provider would receive, which would not require a SPA to initiate a change in the amounts providers receive. For example, a State sets up supplemental payment pools of $10 million for trauma care centers in the State and that payment pool is distributed based upon a provider's pro rata share of Medicaid services. The amounts paid to providers eligible for that pool may vary from year to year based upon each providers' relative Medicaid utilization within the State, but the total amount of available funds remains the same. If that State submits a SPA to change the distribution methodology or to add more qualifying providers to the payment methodology,

but not change the $10 million pool, then this change would be considered a payment restructuring. If the State were to reduce the total pool from $10 million to $8 million, then that would be considered a reduction. A change in supplemental payments that reduces the total amounts that providers receive or shifts funds from one provider to another could result in access to care issues and is one example of a potential payment restructuring that could negatively impact access to care. Where there is uncertainty, we will work with States to help identify situations where a rate restructuring could diminish access to care such that the processes under § 447.203(c)(1) through (3) will apply.

Comment: One commenter suggested streamlined approval should apply to any rate reduction that meets any one of the three criteria listed in the proposed rule. The commenter specifically recommended providing streamlined approval for rate reductions that result in the rates being 100 percent or higher of the comparable Medicare rate regardless of the reduction in overall expenditures for the benefit category (otherwise stated, without the application of § 447.203(c)(1)(ii)).). Another commenter recommended that CMS' primary goal should be to encourage increasing rates to Medicare levels and generating feedback through processes with interested parties.

Response: To the extent a State proposes a payment rate reduction or restructuring which results in payment rates at or above 100 percent of Medicare, it would certainly meet one of the three criteria in § 447.203(c)(1) for the initial State analysis for rate reduction or restructuring, but would still require that the other two criteria in § 447.203(c)(1) be met. We are requiring all three criteria in § 447.203(c)(1) be satisfied for the State to qualify for the streamlined process, to protect access across varied circumstances. For example, a proposed rate may be 100 percent of Medicare, but if the currently approved Medicaid payment rate is higher such that the change represents a payment reduction, then the proposed rate reduction still could harm beneficiary access to the relevant services and potentially reduce access to below the statutory standard.

Although we generally believe that setting rate thresholds at a level recommended by the commenter (100 percent of the corresponding Medicare rate, or higher) could help support adequate access to care for Medicaid beneficiaries, we believe there are circumstances where balancing State budgetary considerations, and the willingness of providers to accept a given level of payment for services provided to the Medicaid population, will suggest a Medicaid payment rate that diverges from a corresponding Medicare rate but is still consistent with the access requirement under section 1902(a)(30)(A) of the Act.

Comment: One commenter requested that CMS provide additional guidance about how to conduct the Medicaid to Medicare comparison required under § 447.203(c)(1) and (2).

Response: As part of the proposed rule PRA process, we proposed a template for States to use to complete the analyses under § 447.203(c). The template includes detailed instructions for how States should complete each tier and component of the analysis, as applicable. We are finalizing that template as proposed.

Comment: Several commenters inquired about whether the guidance provided in SMDL #17–004 [370] would remain applicable under the new proposals, wherein CMS determined that there were circumstances unlikely to diminish access, and as such, would not invoke the requirements of § 447.203(b)(6) of the 2015 final rule with comment period: reductions necessary to implement CMS Federal Medicaid payment requirements (for example, Federal upper payment limits and financial participation limits), but only in circumstances under which the State is not exercising discretion as to how the requirement is implemented in rates; reductions that will be implemented as a decrease to all codes within a service category or targeted to certain codes, but for services where the payment rates continue to be at or above Medicare and/or average commercial rates; and reductions that result from changes implemented through the Medicare program, where a State's service payment methodology adheres to the Medicare methodology (For example, modifications to diagnostic related groups and the resource based relative value scale, adoption of new Medicare payment systems, consistency with value-based purchasing initiatives, etc.). One commenter specifically inquired about circumstances where payment rates would be below the threshold of 100 percent of the most recently published Medicare rates for the same or comparable services in the impacted benefit area before and after the proposed restructuring. A few other commenters encouraged CMS to allow a tier 1 review for rate reductions in circumstances where rate reductions: (1) are necessary to implement CMS Medicaid payment requirements (for example, UPL); (2) result in payment rates that remain at or above Medicare or average commercial rate amounts; or (3) are prompted by a change in Medicare payment rates when the State's rate methodology adheres to Medicare methodology. One commenter specifically recommended that the exemptions provided under SMDL #17–004 be included in the exemptions under § 447.203(c)(1), specifically citing circumstances in the SMDL where Medicaid payment rate reductions generally would not be expected to diminish access, such as: reductions necessary to implement CMS Federal Medicaid payment requirements; reductions that will be implemented as a decrease to all codes within a service category or targeted to certain codes, but for services where the payment rates continue to be at or above Medicare and/or average commercial rates; and reductions that result from changes implemented through the Medicare program, where a State's service payment methodology adheres to the Medicare methodology.

Response: We did specifically request comment on whether and how the policies discussed in SMDL #17–004 should be included in the final rule, and we thank the commenters for their helpful suggestions. As stated, we are finalizing § 447.203(c)(1) as proposed, and we are not finalizing any exceptions to the tier 1 (or tier 2) analysis. We believe the analysis is warranted under any rate reduction or restructuring. The three circumstances described by commenters from SMDL #17–004 are either inapplicable to this final rule or already accounted for. Specifically, in the first circumstance, where Federal Medicaid payment requirements are otherwise established in statute or regulation, we recognize that States often have multiple ways of complying with multiple Federal requirements that may bear upon payment rates, and the review required in this final rule in § 447.203(c) is necessary to ensure that the State's programmatic decisions are consistent with all applicable Federal requirements including that they ensure sufficient beneficiary access to care. In the third circumstance, reductions that result from changes implemented through the Medicare program, where such a change does not require a SPA to implement would also fall outside of § 447.203(c)(1) through (3), which are only applicable when a State must submit a SPA. The final rule provisions only apply to the extent that a SPA is

[370] SMDL #17–004. November 16, 2017. *https://www.medicaid.gov/sites/default/files/federal-policy-guidance/downloads/smd17004.pdf.*

needed to implement the proposed reduction or restructuring.

The second circumstance is the only one subject to the provisions of this final rule, for reductions that will be implemented as a decrease to all codes within a service category or targeted to certain codes, but for services where the payment rates continue to be at or above Medicare and/or average commercial rates. These reductions or restructurings would need to meet all of the requirements of § 447.203(c)(1) in order to be eligible for the streamlined access review criteria. We decided not to include this criterion from SMDL #17–004 in this final rule because we received a number of comments on this final rule that suggested that providers and beneficiaries should have input where non-nominal rate reductions or restructurings may occur, regardless of the current or proposed payment level. Including this particular provision could provide a State with a means to significantly reduce provider payment rates without needing to engage with the provider and beneficiary community on the impact such a reduction might have on access to care.

Comment: One commenter expressed concern that CMS' proposals would slow or in some cases prevent altogether the adoption of VBP arrangements or other alternative payment models. Under these models, the commenter stated that it is common for some providers to experience increases in payment reflective of outcomes attributable to those providers, and it is also common for some providers to experience decreases in payment, including when aggregate levels of payment are increasing for a relevant service or services. Given that any SPA proposing to implement or substantially modify a VBP payment arrangement could reasonably be considered a proposal to ''restructure'' payments, the commenter was concerned that the proposed rule essentially would treat all VBP payment arrangements as inherently suspect and as requiring additional scrutiny and administrative burden. The commenter encouraged CMS to continue to identify ways to support and encourage the adoption of VBP models in Medicaid, noting that CMS should not adopt rules that create additional obstacles for States seeking to implement VBP models. A few other commenters suggested that streamlined review should be available in situations where rate reductions are used to implement VBPs through a withhold payment rate restructuring that does not reduce the total payments within the overall service category, because the withheld amounts subsequently are paid out based on performance.

Response: We agree with the commenter that VBP arrangements can be useful tools to promote high-quality services for Medicaid beneficiaries while promoting efficient and economic care delivery, fully consistent with beneficiary access to covered services that meets the statutory standard. Although a proposed SPA seeking to implement or significantly modify a VBP arrangement likely may be considered a payment rate restructuring, nothing in the final rule would prohibit or is intended to discourage States from adopting such structures. Performance-based incentives, innovative care models, and alternative payment models are often designed to improve quality of care, promote better patient outcomes, and reward providers for improvements to quality of care and patient outcomes, while lowering the cost of care. In the 2015 final rule with comment period, we signaled our interest in working with States in promoting innovative patient care models and delivery system changes that seek to reward the provision of quality patient care that also lowered cost to the Medicaid program.[371]

The provisions of the final rule in § 447.203(c) provide processes for rate reductions or restructurings, with the goal of determining when those changes could result in diminished access. In most instances, a performance-based incentive, innovative care models, or alternative payment models that restructure provider payments do so in a manner that would not result in diminished access and that we would not regard as a restructuring subject to § 447.203(c). For example, a State may propose an episode of care arrangement that bundles all of the care related to a defined medical event, including the care for the event itself, any precursors to the event and follow-up care. As a component of this methodology, the State would make one payment for the whole episode that is meant to encompass the medical event including the precursors and follow-up care, with up-side and down-side incentives paid or collected based on the providers' performance against the mean. Providers must volunteer to enroll in this program, and any other provider would continue to be paid as they normally would under the State plan. Such a restructuring proposal does not diminish access because the providers are electing to participate and understand the risk, but since care must be provided for the performance incentives to be determined and non-participating providers would not experience a change in payment, Medicaid beneficiaries will not experience diminished access to services. We also note that other simple add-on payments for achievement of specified quality targets where there is no possibility of a reduction to any provider's payment would not be considered a restructuring subject to the requirements of § 447.203(c).

However, to the extent that a State implements a performance-based incentive, withhold, or alternative payment model would reduce payment rates, such as models that involve down-side risk arrangements where provider payments could decrease from current levels in certain circumstances, these changes likely would have the potential to result in diminished access to care and therefore would be a restructuring that would fall under the requirements of § 447.203(c). For example, if a State proposed to implement a quality improvement payment arrangement involving downside risk, meaning that providers could their payment rates reduced the State's quality improvement proposal, for which providers were required to participate then CMS could view this arrangement as being a payment reduction or restructuring that could affect access to care. The State in this instance would be expected to conduct the appropriate level(s) of analysis required under § 447.203(c).

We want to note that the requirement to perform an initial or initial and additional analysis under § 447.203(c) does not mean the State will be unable to enact the proposed payment arrangement; it simply means CMS wants to verify that access will not be negatively impacted with additional documentation to demonstrate this fact. As such, this final rule does not limit a State's ability to reduce or restructure rates based on information that the rates are not economic and efficient; rather, it ensures that States take appropriate measures to document access to care consistent with section 1902(a)(30)(A) of the Act. We do not view this as a penalty, as the commenter suggested, but rather a documentation of consistency with the statute. Under the Act, rates must be both economic and efficient, and they also must ensure that individuals have sufficient access to covered services. We interpret section 1902(a)(30)(A) of the Act as requiring a balanced approach to Medicaid rate-setting and we encourage States to use appropriate information and program experience to develop rates to meet all of its requirements. Further, we expect

[371] 80 FR 67578–67579.

States to document that Medicaid rates are economic and efficient when the State submits changes to payment methodologies through a SPA. If a State is unsure whether its proposed performance-based incentive, innovative care model, or alternative payment models contains a restructuring subject to § 447.203(c), they can engage with CMS prior to submission of a SPA. CMS can and may request § 447.203(c) analyses upon receipt of a proposal as well.

Comment: One commenter strongly suggested that the State rate analysis be required on an annual basis, not only upon rate reductions or restructuring, and further suggested that any rate examinations by CMS should also include rates paid in managed care, noting the volume of HCBS provided under managed care, and as such, focusing only on FFS rates is a disservice to much of the industry.

Response: We intend for the payment rate transparency provisions in § 447.203(b) to provide interested parties with insight into State plan payment rates relative to the Medicare payment rates for the same services. While these payment analyses will be updated every other year, as opposed to annually as mentioned by the commenter, the § 447.203(b) analysis will be available for CMS and for interested parties to review, while the § 447.203(c) analysis will apply only to SPA submissions that propose to reduce or restructure provider payment rates. The § 447.203(c) provisions of this final rule concern SPAs proposing to reduce or restructure payment rates in Medicaid FFS. Other components of this final rule address payment rate adequacy and transparency for HCBS specifically, and access to care in managed care is being addressed through the Managed Care final rule (as published elsewhere in this **Federal Register**).

Comment: One commenter stated that SPAs that would result in Medicaid payments that are at or above 80 percent of Medicare rates for the same or comparable services should be approvable without resorting to the larger access analysis described in proposed § 447.203(c)(2). The commenter noted that it is common for Medicaid to pay a percentage of Medicare rates (for example, 85 percent of Medicare) and stated that a proposed payment methodology should not have to result in Medicaid payments that are exactly the same as Medicare rates to avoid access concerns.

Response: This final rule does not require that the proposed payment methodology result in payments that are exactly the same as Medicare rates, or any specific percentage of the Medicare rates for the same or a comparable set of services. States that have rates at or above 80 percent of Medicare in the aggregate, including base and supplemental payments, can qualify for the streamlined initial State analysis for rate reduction or restructuring in § 447.203(c)(1) of the final rule, provided that the other criteria of § 447.203(c)(1) are met. As discussed in an earlier response to comment in this final rule; however, we do not agree that State payment proposals that meet the 80 percent of Medicare threshold should be exempt from the other qualification criteria specified in § 447.203(c)(1)(ii) and (iii), nor the additional analysis elements in § 447.203(c)(2) if all the criteria for the streamlined process are not met.

Comment: One commenter commended CMS for moving towards more clear and transparent processes for rate analyses associated with State-proposed payment changes. However, the commenter indicated that the first tier's streamlined requirements are unlikely to ever be met, as the commenter noted that there are rarely any changes in rates that are proposed that do not elicit complaints and/or concerns about impacts to access from the public and/or interested parties, even in such circumstances as rate increases. The commenter suggested that CMS reconsider the tier guidelines to make it more feasible for a State to meet the requirements of the initial, streamlined tier.

Response: We disagree that the streamlined requirements are unlikely to ever be met. We discussed a State's ability to meet the streamlined criteria in the preamble, and direct the commenter to sections II.C.3 and III.C.11.d.i. of the final rule, which discusses the overall impact of this policy on State proposals to reduce or restructure provider payment rates. Similar to our experience after the issuance of SMDL #17–004, as discussed in the above referenced sections of the final rule, we anticipate that there will be States that propose rate reductions or restructurings that will be able to demonstrate compliance with § 447.203(c)(1). The final rule provides that significant access concerns can be raised, and the proposal can still meet the (c)(1) threshold, provided that the State can reasonably respond to or mitigate the concerns, as appropriate. States should be working with their provider and beneficiary communities and engaging with constructive criticism and complaints, and provide justification to those interested parties as to why the reductions are necessary, and discuss alternatives considered. An important purpose of § 447.203(c)(1)(iii) is to encourage meaningful engagement between States and s interested parties.

Comment: Multiple commenters recommended that CMS increase the proposed threshold to qualify for the streamlined payment SPA analysis proposed at § 447.203(c)(1)(i) from 80 percent of Medicare, with some commenters suggesting that the threshold be changed to 100 percent of Medicare to make the streamlined process more meaningful. These commenters noted that, although Medicare FFS pays physicians considerably more, on average, than Medicaid, it is not competitive in markets with a large percent of commercial payers and Medicare Advantage plans, which typically pay more than traditional Medicare. Therefore, these commenters stated that setting a benchmark at 80 percent of a rate that is not competitive in many parts of the country would undermine efforts to ensure Medicaid payments comply with section 1902(a)(30)(A) of the Act. Another commenter stated that many people cannot access Medicaid acute-care services of the types that Medicare pays for because States do not pay providers adequate rates to induce them to accept Medicaid as payment, and the commenter noted that this problem has existed for a very long time, and it is not related to whether a State wants to reduce or restructure rates from their current levels. One commenter noted that many providers are already paid at 80 percent of Medicare and thus recommended that it seems appropriate to select a higher standard by which to assess whether a reduction would diminish access. Further, a couple of commenters suggested that if access problems persist after a State has achieved the 80 percent threshold for a suitable period of time, and those problems can be traced to inadequate rates, then the State should be required to raise those rates to 85 percent, then 90 percent and so on until the rates reach 100 percent of the Medicare rate. One commenter suggested that such a graduated approach to the § 447.203(c)(1)(i) threshold should be included regardless of whether there are persistent documented access to care issues. Some commenters had similar recommendations to increase the threshold without recommending a specific number, noting that Medicare payments are often low relative to provider costs, and one of these

commenters also recommended a phase-in approach.

Some commenters suggested that CMS take a different approach for different services where the commenters suggested that Medicare may undervalue a service, such as mental health, or where certain service providers do not take insurance, which leads to higher charges in the private market. One specifically suggested a 100 percent threshold for behavioral health, for these reasons.

Response: We appreciate the viewpoints and suggestions of the commenters. First, where the commenters suggested raising the 80 percent threshold to a higher level, such as a 100 percent threshold, to make the streamlined process more protective of beneficiary access, we believe the 80 percent threshold continues to present a meaningful threshold, particularly as it is coupled with the other standards in § 447.203(c)(1). As we discussed in the preamble, after careful review of the literature, we determined that 80 percent of Medicare would be a reasonable payment rate threshold to aid States' and our assessment of compliance with section 1902(a)(30)(A) of the Act. Based on a review of evidence discuss elsewhere in the proposed rule and preamble of this final rule, we do not currently have evidence that a ratio higher than 80 percent is necessary to ensure compliance with the statutory access standard.[372] However, we are committed to monitoring implementation and would consider proposing a sliding percentage threshold for the Streamlined analysis required under § 447.203(c)(1) through future rulemaking, if it is determined that such a change would be appropriate. The threshold is not a level set for approval (or disapproval) of a SPA, but merely to inform the level of analysis would be required. Additionally, the other commenter's assertion that many providers are already paid at 80 percent of Medicare does not, in our view, indicate a need for stricter thresholds, but rather provides that some States may simply be able to meet the § 447.203(c)(1)(i) threshold. If these providers, the beneficiaries they serve, and/or other interested parties have access-related concerns about current or proposed payment rates in their State, they may raise those concerns to the State through the various available forms of public process, which the State would need to address consistent with § 447.203(c)(1)(iii) to qualify for the streamlined analysis process in the event of a payment SPA that would reduce or restructure rates in circumstances that could result in diminished access. We note that, in general, there is no requirement that payment rates for Medicaid services include explicit consideration of a provider's cost of care. The level of payment rates in relation to provider costs is not necessarily the only or the decisive factor in ensuring access to care consistent with the statutory standard, and we do not require that States establish that rates are sufficient to ensure access by reviewing the relationship of payment rates to provider costs.

Second, we agree that Medicare payment rates are typically higher than Medicaid, but do not agree the fact that some private payer rates and Medicare Advantage rates are higher than Medicare FFS rates requires that we select a threshold rate of higher than 80 percent of the Medicare FFS rate to achieve a meaningful comparison that helps ensure that Medicaid rates are adequate to meet the statutory access standard. In addition, regarding the comment that certain providers that do not take insurance, which leads to higher charges, we do not consider a charged amount to be comparable to a payment rate unless the provider actually receives the charged amount as payment amount from a payer (including self-pay individuals). Some providers bill patients on a sliding fee scale, dependent on factors like the individual's income level, even if the provider does not take insurance. This does not mean that using a provider's customary charge is a reasonable proxy for an economic and efficient payment rate or for a payment level that is necessary to support adequate access to care, because not all providers receive payment at their charge rate, even if they bill the patient directly.

We are finalizing the § 447.203(c)(1)(i) threshold at 80 percent of Medicare FFS because we wanted to balance an achievable threshold for States while also establishing a threshold that we believe would be strongly indicative that Medicaid payment rates would be likely to comply with section 1902(a)(30)(A) of the Act. While we acknowledge that 80 percent of Medicare rates may not provide absolute assurance that a given provider, or a sufficient number of providers, will participate in the Medicaid program, we are using 80 percent as a threshold to determine the level of analysis and information a State must provide to CMS to support consistency of payment rates with section 1902(a)(30)(A) of the Act. Notably, there are other provisions of the final rule that provide opportunities for the public to raise access to care concerns to State agencies and to CMS should Medicaid payment rates be insufficient to ensure adequate provider participation so that the statutory access standard is met, as provided in §§ 447.203(c)(4) and 447.204.

Finally, we acknowledge the commenter that suggested that 80 percent of Medicare does not take into account circumstances in which Medicare may undervalue a service, such as mental health. In the 2024 Medicare PFS final rule, Medicare did finalize an adjustment to the payment for certain timed behavioral health services paid under the PFS.[373] In the same rule, we acknowledged the systemic valuation problem and finalized an adjustment to help mitigate the impact which is scheduled to be phased-in over 4 years. While there are certainly going to be issues within any selected rate comparison approach, do not believe that Medicare payment rates for certain services or in general are insufficient in a manner that would suggest a need to use a threshold higher than 80 percent of the Medicare PFS rate. We acknowledge that the reluctance of some provider types to accept payment from various payers, including public and private payers, is concerning, as this can have a negative effect on access to needed care for Medicaid and Medicare beneficiaries, as well as the public at large, including those who are privately insured. However, to the extent the broader public has difficulty accessing a particular service due to high levels of refusal among providers of that service to accept payment offered by public and private payers, then it is possible that the access standard under section 1902(a)(30)(A) of the Act could be met even if Medicaid beneficiaries are experiencing significant difficultly obtaining services from these providers. Although CMS would encourage States in such circumstances to explore all available options to encourage greater provider participation in Medicaid, we have not seen evidence that leads us to believe this circumstance warrants a different approach to evaluating the sufficiency of payment rates for behavioral health services that is different than the approach for physical health services.

Comment: One commenter recommended that CMS establish a minimum payment threshold that States must adhere to if there are significant, demonstrated access problems, noting

[372] 88 FR 28027 through 28029.

[373] 88 FR 79006.

that States where the 80 percent threshold has been met or exceeded have significantly fewer problems with access to Medicaid services than States where that has not happened. Therefore, the commenter recommended that CMS require States to set all rates under the Medicaid State plan to at least 80 percent of the comparable Medicare rate, unless the State can demonstrate that it does not have a significant access problem with the services for which Medicaid payment rates are below that threshold.

Response: We appreciate the recommendations of the commenters, but the statute does not provide CMS with the authority to establish a floor for Medicaid payment rates as recommended by the commenter, with limited statutory exceptions (such as for hospice services under section 1902(a)(13)(B) of the Act and FQHC/RHC services under section 1902(bb) of the Act, which each establish a floor for provider payment rates which prohibits States from implementing rate reductions below the amount calculated through the methodology provided in the statute). We are finalizing the § 447.203(c)(1) and (2) provisions as proposed. Payment rates are not the sole indicators of access to care, and States should pursue any means to improve access to care to the extent that they are able. To the extent that there are significant access issues where the provider payment rates are at least 80 percent of Medicare, the other components of § 447.203(c)(1) would also be reviewed to determine if the payment rate reductions or restructurings meet the § 447.203(c)(1) thresholds. If there are access to care issues, then in following the process described in this final rule, we anticipate that the public processes in paragraph (c)(4) and § 447.204 may yield significant access to care concerns from beneficiaries, providers, or other interested parties regarding the service(s) for which the payment rate reduction or payment restructuring is proposed. We would only consider approving a payment SPA in such circumstances under the streamlined process under § 447.203(c)(1) if the State were able to reasonably respond to or mitigate the concerns, as appropriate, as documented in the analysis provided by the State pursuant to § 447.204(b)(3).

Comment: One commenter encouraged CMS to conduct enhanced reviews, consistent with § 447.203(c)(2), of payment rates for States that are already below the 80 percent threshold, even if the State has not submitted a triggering rate reduction SPA.

Response: We appreciate the suggestion of the commenter. The payment rate transparency publication, comparative payment rate analysis, and payment rate disclosure requirements we are finalizing in § 447.203(b) will allow States, CMS, and the public a better insight into rates regardless of whether a SPA is submitted. However, we are not requesting a § 447.203(c)(2) analysis where the State has not submitted a SPA because we are moving away from the previous AMRP process from the 2015 final rule with comment period and replacing that process with the new § 447.203 provisions of this final rule. We will continue in our oversight role of the Medicaid program and note that we can initiate a State plan compliance action if we have evidence that the State's Medicaid payment rates do not meet the access standards in section 1902(a)(30)(A) of the Act, regardless of whether the State is seeking to change them with a SPA.

Comment: For the 80 percent of Medicare analysis, two commenters recommended weighting codes in the analysis by service volume to reflect payment levels more meaningfully across the benefit category. These commenters were concerned that CMS' proposed ''aggregate'' standard, reviewing rates across a benefit category rather than at the service-specific level, will mean that some Medicaid services are paid below 80 percent (including frequently provided services) even if the overall benefit category (including equally weighted but infrequently provided services) achieves the 80 percent threshold. They recommended that CMS set the threshold on a disaggregated basis to avoid permitting States to obscure low payment rates for key services.

Response: We approve States' rate methodologies for compliance with regulation and statute, but may not approve individual service rates unless a State presents a final rate, or a fee schedule, as the output of a rate methodology. This final rule does not change that policy or imply that CMS will review individual rates for sufficiency in all cases. Reviewing individual rates within a fee schedule would not necessarily provide a better determination of whether the rates are adequate to enlist sufficient providers into the Medicaid program or not, since we do not believe that providers generally make decisions about whether to participate with a payer (and accept the payer's rates) based on the rate for a single service. However, we will review individual payment rate codes to the extent that the rate changes fall outside of the typical methodology used by the State in their payment rate setting methodology under the State plan, or to the extent that we have reason to believe that common billing codes most frequently used by providers within the State are disproportionately impacted, as determined by the State's public input process, by the payment rate reduction or restructuring proposal. Further, the payment rate transparency publication in § 447.203(b)(1) will require States to publish their fee schedule rates for services specified in that section of the final rule, which will include individual fee schedule payment rates for services for CMS and public review.

Comment: One commenter recommended that, for services for which the State does not use a cost-based payment methodology, CMS should require States to transition to a cost-based methodology. Alternatively, they recommended that CMS require Medicaid rates be no less than 80 percent of Medicare, private insurance, private payment (which we interpret to mean self-pay), or rates for State-furnished or paid services or other comparable service rates.

Response: We appreciate the recommendations of the commenter, but with limited statutory exceptions (such as for hospice services under section 1902(a)(13)(B) of the Act and FQHC/RHC services under section 1902(bb) of the Act, which each establish a floor for provider payment rates which prohibits States from implementing rate reductions below the amount calculated through the methodology provided in the statute), the statute does not provide CMS with the authority to establish a floor or a particular payment methodology for Medicaid payment rates as recommended by the commenter. There is also no statutory requirement to pay providers at the cost of providing services or rates that are equivalent to cost. Prior to 1997, the Omnibus Reconciliation Act of 1980 included the ''Boren Amendment'' which required under then section 1902(a)(13) of the Act that some institutional providers, in particular nursing facilities and intermediate care facilities, receive payments were reasonable and adequate to meet the costs which much be incurred by efficiently and economically operated facilities in order to provide care and services in conformity with applicable State and Federal laws, regulations, and quality and safety standards. In 1997, through the Balance Budget Act of 1997, the Boren Amendment was repealed and replaced with the current section 1902(a)(13) of Act to instead require States to use a public process to set

institutional provider payment rates. Since these statutory changes have occurred, States are not required to consider the cost of care in the development of provider payment rates, but instead rely on input from those providers in their rate setting, which input also is important under the requirements set forth in this final rule. We are finalizing the § 447.203(c)(1) and (2) provisions as proposed.

Comment: A couple of commenters questioned the use of Medicare rates as the basis for comparison in § 447.203(c), as it is not a significant payor of certain Medicaid-covered services and serves a significantly different population. These commenters suggested that services such as substance-use disorder services, facility-based treatment, dental services, and certain LTSS lack a comparable set of Medicare-covered services that would ''bear a reasonable similarity'' to the Medicaid-covered services. One commenter expressed concern about whether States may compare against Medicare rates that are perhaps similar in concept but not in practice. Specifically, the commenter noted that Medicare Home Health Aides and Medicare in-home skilled nursing services seem like they might be comparable to certain Medicaid HCBS and LTSS, but in practice serve different populations in vastly different volumes and as such are not appropriate comparisons. Commenters urged CMS to issue guidance to States on service categories that would require the submission of additional data under this circumstance. One commenter acknowledged that the aggregate comparison, rather than a rate-by-rate comparison, alleviated some of the challenges of finding a Medicare equivalent for certain services.

Further, one commenter suggested a more nuanced approach to examining payment rates as they relate to access, such as benchmarking against rates for a subset of the highest performing States in terms of access to care for these service categories. That commenter cited recent research from the American Dental Association's Health Policy Institute, which does not suggest a strong relationship between the ratio of Medicaid-to-private payer rates and dental provider participation in Medicaid, meaning that a comparison to private payer rates is not necessarily instructive for all services in the absence of Medicare comparator rates.

Response: We are finalizing § 447.203(c)(1) and (2) as proposed. The regulations account for circumstances where Medicare does not cover comparable services, by requiring States to compare, ''as reasonably feasible, to the most recently available payment rates of other health care payers in the State or the geographic area for the same or a comparable set of covered services, ''which comparison is required even if it is impossible to compare'' to the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services because no such set of Medicare-covered services exists. We also agree with the commenter who pointed out that the aggregate comparison at the level of the benefit category makes it more feasible to find a reasonable Medicare comparison. While the regulations allow States some flexibility in determining how to perform the required comparison in developing and submitting their SPA analysis, all State-submitted information will be reviewed by CMS through the SPA process, and we reserve the right to request any additional information necessary to further understand the SPA or the accompanying analysis, which may include a request for additional rate comparison information.

Although we appreciate the concern of the commenter about circumstances where neither Medicare nor private payer rates provide a reasonable analog to assess access to care, we have to balance our requirements against the feasibility of obtaining data for comparison. Although the rate transparency requirements we are finalizing in this rule will increase the availability of State rate data, determining the highest performing States for use as the commenter suggested would require additional burden on both States and the Federal Government to determine which States would be benchmark States for which services. In addition, it is not necessarily clear that this approach would be appropriate to ensure compliance with the statutory access standard, which looks to whether beneficiaries have access to covered services at least as great as that enjoyed by the general population in the same geographic area. We believe the policies we are finalizing strike an appropriate balance that reasonably considers availability of data and State burden, as well as the need to ensure sufficient beneficiary access.

We acknowledge the commenters' concern that services such as substance-use disorder services, facility-based treatment, dental services, and certain LTSS lack a comparable set of Medicare-covered services that would ''bear a reasonable similarity'' to the Medicaid-covered services, and the concern about whether States may compare against Medicare rates that are perhaps similar in concept but not in practice. Particularly for facility-based services, we recognize that Medicare and Medicaid provider types may not be identical in certain cases. However, often, facility-based services furnished by a provider type enrolled in one program are covered when furnished in a different setting or by a provider with a different enrollment type in the other program. In such cases, States should look to the nature of the service rather than, for example, the enrollment type of the provider, to identify a reasonably similar set of Medicare-covered services for comparison. We acknowledge that Medicare also establishes payment rates for certain services for which Medicare seldom pays; however, States still should consider these rates when constructing their comparisons to Medicare in accordance with the provisions of this final rule.

Comment: Some commenters requested that CMS remove the 4 percent threshold under 447.203(c)(1), noting that a 4 percent, or even lower, standard would in most cases be reducing a rate which is already far below Medicare levels. One commenter suggested that if a 1 or 2 percent threshold is not feasible for every State, then CMS should use this standard (that is, 1 or 2 percent, instead of 4 percent) for States whose aggregate Medicaid FFS payments average less than the national average of 72 percent for the most common E/M services.

One of these commenters supported CMS' proposal to assess such rate reductions on a cumulative basis over the course of a State fiscal year. Another commenter urged CMS to consider designing a limit to ensure that States could not implement a large cut (for example, 20 percent) to payments for a particular service, which the commenter perceived as a risk due to our proposal to analyze changes at the benefit category level, where we proposed to examine whether aggregate payment rate changes for the benefit category as a whole would exceed the 4 percent threshold. The commenter also suggested that CMS could also consider disaggregating service analysis in future rulemaking.

Response: We are finalizing § 447.203(c)(1) and (2) as proposed. As discussed previously, the 4 percent threshold is one of three criteria identified in § 447.203(c)(1), which, if not met, will require the State to submit additional information required under § 447.203(c)(2). Where a State's payment rates are already below 80 percent of the Medicare FFS payment rate for the same or a comparable set of services, then any rate reductions from that State would be subject to the requirements of

§ 447.203(c)(2). This feature will ensure States with rates already below 80 percent of comparable Medicare FFS rate levels will have to take additional steps to establish that the rate change will not result in access below the level required under section 1902(a)(30)(A) of the Act. We declined to include a lower threshold because we believe that the 4 percent is sufficient based upon our experience with State proposals received after the publication of SMDL #17–004. State proposals that included a reduction less than or equal to 4 percent of the aggregate FFS Medicaid expenditures for each benefit category impacted by the reduction or restructuring generally did not result in access to care issues for affected services.

Comment: Multiple commenters were concerned that the 4 percent reduction criterion is not nominal, as CMS had described it. These commenters urged CMS to re-assess the appropriateness of the 4 percent threshold.

Response: As discussed in the proposed rule, States often seek to make payment rate and/or payment structure changes for a variety of programmatic and budgetary reasons with limited or potentially no effect on beneficiary access to care, and we recognized that State legislatures needed some flexibility to manage State budgets accordingly.[374] We discussed a 4 percent spending reduction threshold with respect to a particular service category in SMDL #17–004 as an example of a targeted reduction where the overall change in net payments within the service category would be nominal and any effect on access difficult to determine (although we reminded States that they should document that the State followed the public process under § 447.204, which could identify access concerns even with a seemingly nominal payment rate reduction). To our knowledge, since the release of SMDL #17–004 six years ago, the 4 percent threshold for regarding a payment rate reduction as nominal has not resulted in access to care concerns in State Medicaid programs, and it received significant State support for this reason in comments submitted in response to the 2018 proposed rule, as well as in response to the proposed rule in this rulemaking. The provisions of the final rule in § 447.203(c)(1) are not intended to be individually applicable, as they were under the SMDL #17–004, and are instead intended for each element of § 447.203(c)(1) to be met in order for the rate reduction or restructuring SPA to be considered consistent with section 1902(a)(30)(A) of the Act under the streamlined analysis process. In each instance, the State's proposal would need to demonstrate that Medicaid payment rates in the aggregate (including base and supplemental payments) following the proposed reduction or restructuring for each benefit category affected by the proposed reduction or restructuring would be at or above 80 percent of the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services; the proposed reduction or restructuring, including the cumulative effect of all reductions or restructurings taken throughout the current State fiscal year, would be likely to result in no more than a 4 percent reduction in aggregate FFS Medicaid expenditures for each benefit category affected by proposed reduction or restructuring within a State fiscal year; and the public processes described in paragraph (c)(4) and § 447.204 yielded no significant access to care concerns from beneficiaries, providers, or other interested parties regarding the service(s) for which the payment rate reduction or payment restructuring is proposed, or if such processes did yield concerns, the State can reasonably respond to or mitigate the concerns, as appropriate, as documented in the analysis provided by the State pursuant to § 447.204(b)(3).

Comment: One commenter noted that the 4 percent reduction threshold is consistent with the 2018 proposed rule, but suggested that CMS assess any rate reduction compared to broader trends in the economy, particularly when considering rising medical cost and adjusting for inflation, a 4 percent payment cut should not be considered nominal, especially in States where Medicaid payments are already low. Furthermore, the accumulating effect of yearly cuts to provider payments, which could still meet the thresholds of the rule, would be extremely detrimental to access for beneficiaries in the Medicaid program. For example, the Medicare Economic Index (MEI) measures the impact of inflation faced by physicians with respect to practice costs and general wage levels, and as such show the year-over-year change in cost of providing the same basket of services. The commenter stated that rate reductions should be compared against this type of measure rather than against an arbitrary percentage. The commenter also noted that the 4 percent rate reduction threshold would operate in conjunction with the other criteria in § 447.203(c)(1), and therefore not exempt a State proposal from compliance with the broader access framework in the rule, but expressed concern about the disproportionate impact a 4 percent reduction can have on certain practice types, such as pediatric.

Response: We appreciate the suggestion of the commenter. We are finalizing § 447.203(c)(1)(ii) as proposed. We did not want to rely upon the MEI to supply an inflation factor that must be considered in examining the approvability of payment rate changes or restructurings because we wanted to provide flexibility for States within their budgetary constraints. We also note that the comparison of State payment rates to Medicare would accomplish a similar goal to that stated by the commenter. By requiring State rate actions be compared to the most recently published Medicare rate, which are trended forward annually, the (c)(1)(i) threshold does take into account inflation that may occur in the health care industry.

We reiterate the statement of the commenter that the provisions of the final rule in § 447.203(c)(1) are not intended to be individually applicable, as they were under the SMDL #17–004, and are instead intended for each element of § 447.203(c)(1) to be met in order for the rate reduction or restructuring SPA to be considered consistent with section 1902(a)(30)(A) of the Act under the streamlined analysis process. In each instance, the State's proposal would need to demonstrate that Medicaid payment rates in the aggregate (including base and supplemental payments) following the proposed reduction or restructuring for each benefit category affected by the proposed reduction or restructuring would be at or above 80 percent of the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services; the proposed reduction or restructuring, including the cumulative effect of all reductions or restructurings taken throughout the current State fiscal year, would be likely to result in no more than a 4 percent reduction in aggregate FFS Medicaid expenditures for each benefit category affected by proposed reduction or restructuring within a State fiscal year; and the public processes described in paragraph (c)(4) and § 447.204 yielded no significant access to care concerns from beneficiaries, providers, or other interested parties regarding the service(s) for which the payment rate reduction or payment restructuring is proposed, or if such processes did yield concerns, the State can reasonably

[374] 88 FR 28030.

respond to or mitigate the concerns, as appropriate, as documented in the analysis provided by the State pursuant to § 447.204(b)(3).

We disagree that 4 percent is an arbitrary threshold. As noted in a prior response, States often seek to make payment rate and/or payment structure changes for a variety of programmatic and budgetary reasons with limited or potentially no effect on beneficiary access to care, and we recognized that State legislatures needed some flexibility to manage State budgets accordingly. We discussed a 4 percent spending reduction threshold with respect to a particular service category in SMDL #17–004 as an example of a targeted reduction where the overall change in net payments within the service category would be nominal and any effect on access difficult to determine (although we reminded States that they should document that the State followed the public process under § 447.204, which could identify access concerns even with a seemingly nominal payment rate reduction). To our knowledge, since the release of SMDL #17–004, the 4 percent threshold for regarding a payment rate reduction as nominal has not resulted in access to care concerns in State Medicaid programs, and it received significant State support for this reason in comments submitted in response to the 2018 proposed rule and the proposed rule in this rulemaking. In addition, we did not receive comments indicating that specific State rate reductions that were less than 4 percent had an impact on beneficiary access to care in their State Medicaid programs. In addition, the 4 percent threshold is then a measure to ensure that payment rates are not reduced by too significant of an amount over a single State fiscal year. The two quantitative thresholds in paragraphs (c)(1)(i) and (ii), taken together with the public input requirements in paragraph (c)(1)(iii), work in conjunction to ensure that State payment rates are consistent with section 1902(a)(30)(A) of the Act.

Comment: One commenter suggested where States make changes to a cost-related payment methodology that may result in diminished access (for example, by placing a new cap on administrative costs, requiring a ''rebase,'' or otherwise altering cost-reporting procedures), it may be challenging to determine whether the change would result in a 4 percent or more decrease in payment.

Response: We understand the commenter's concern and note that the 4 percent threshold is a cumulative percentage of rate reductions or restructurings applied to the overall FFS Medicaid expenditures for a particular benefit category affected by the proposed reduction(s) or restructuring(s) within each State fiscal year. During the SPA process, States are required to estimate the amount of the financial impact on their CMS form 179 and in their public notice as required by § 447.205(c)(2), which states that the public notice must ''give an estimate of any expected increase or decrease in annual aggregate expenditures.'' Where States are unsure how they should demonstrate whether the proposed change meets the 4 percent threshold in § 447.203(c)(1)(ii), they should look to existing criteria and methodologies used to estimate financial impacts for the CMS form 179 and public notice under § 447.205.

Comment: One commenter noted that § 447.203(c)(1)(iii) requires an assessment of ''significant concerns'' from providers and others, and requested additional detail regarding the definition of ''significant concern,'' and what the State's response to significant concerns must entail. A couple of commenters stated that requiring States to demonstrate that no concerns were raised or to ''address'' concerns raised in public comment would be a difficult requirement to meet, noting that any proposed rate reduction is likely to result in significant public comment. One of these commenters stated it is unclear what level of concern or complaint would shift a State from one tier (that is, the streamlined process under § 447.203(c)(1)) to the next (that is, to requiring the additional analysis under § 447.203(c)(2)). The other of these commenters added that, as CMS does not define the term ''address'' in the rule, it is concerning that a State must meet all of the criteria in § 447.203(c)(1) to qualify for the streamlined analysis.

Response: The term ''significant'' can be dependent upon the circumstances, but we generally consider ''significant concerns'' to mean those that are not easily resolvable through engagement with beneficiaries, providers, and other interested parties. We also note that the regulation does not actually use the word ''address'' but rather requires that, to the extent that States received public input on their proposed SPA to reduce or restructure payment rates that ''yielded . . . significant access to care concerns from beneficiaries, providers, or other interested parties,'' the State must demonstrate that it is able to ''respond to or mitigate the concerns, as appropriate.'' For example, a State may receive a large number of public comments on a proposed rate change, but if all the comments merely seek to clarify an aspect of the change, this situation, despite the high volume of comments, would not be a significant concern, because no concern has been raised other than a request for clarification of the proposal As an alternative example, where providers are raising concerns about the level of payment they would receive under a State's new payment rate proposal, the State could discuss with interested parties other legislative initiatives underway or programmatic goals that might be considered as offsetting any decrease in provider payments that might be expected from the proposed rate action. This is common with value-based purchasing initiatives in States. Section 447.203(c)(4), where we are recodifying § 447.203(b)(7) as finalized in the 2015 final rule with comment period, continues to require that ''States have ongoing mechanisms for beneficiary and provider input on access to care (through hotlines, surveys, ombudsman, review of grievance and appeals data, or another equivalent mechanism), consistent with the access requirements and public process described in § 447.204.'' Furthermore, § 447.203(c)(4)(ii) provides that ''States should promptly respond to public input through these mechanisms . . . with an appropriate investigation, analysis, and response,'' and ''States must maintain a record of data on public input and how the State responded to this input,'' which record the State must make available to us upon request. If the State is not able to demonstrate that its proposal will not decrease access below the statutory standard, including by credibly refuting any reasonable, supported concern raised in public comments that it will harm access excessively, then the proposed rate reduction or restructuring will not meet the requirements for the streamlined (c)(1) process and will be subject to the tier 2 process in paragraph (c)(2), where additional data and analysis will be required to be submitted. In all cases, we will review to ensure that statutory access standard and all other applicable Federal requirements are met.

Comment: A few commenters commended CMS for including the third criterion, which centers the importance of public concerns about rate reductions or restructuring, but these commenters opposed CMS implementing any threshold for rate reduction or restructuring SPAs under § 447.203(c)(1).

Response: We appreciate the support of the commenters. With respect to the inclusion of this criterion as one of three

requirements needed to qualify for a streamlined access analysis and in response to the commenters' opposition to implementing any threshold for rate reductions or restructuring SPAs under § 447.203(c)(1), we note that the intention of this final rule is to balance the administrative burden on the States associated with rate reduction or restructuring SPAs with the need to have sufficient information to make an administrative decision on State payment rate proposals, and whether they satisfy the access standard in section 1902(a)(30)(A) of the Act, while also providing providers, beneficiaries, and interested parties to raise concerns directly to the State through the mechanisms for ongoing beneficiary and provider feedback in § 447.203(c)(4) of the final rule.

Comment: A few commenters strongly supported the public input process provision in § 447.203(c), particularly in § 447.203(c)(1)(iii), since developing robust mechanisms for States to hear feedback from providers and interested parties about access concerns will be critical to assuring that access analysis in connection with payment SPAs has its intended effect. One commenter suggested that CMS should further consider formalizing a specific role for the MAC/BAG in this process.

Response: We appreciate the support of the commenters and note that the public input processes defined in § 447.203(c)(4), where we are recodifying requirements previously located in § 447.203(b)(7), requires that States have ongoing mechanisms for beneficiary and provider input on access to care (through hotlines, surveys, ombudsman, review of grievance and appeals data, or another equivalent mechanism), consistent with the access requirements and public process described in § 447.204. We did not specifically provide a defined role for the MAC or BAC in the regulatory rate reduction or restructuring process, but States are not prohibited from including such entities in their public input process to the extent that they believe it would be valuable. However, if the MAC/BAC under § 431.12 of this final rule, or the interested parties' advisory group under § 447.203(b)(6) produces a comment on a State proposal to reduce or restructure payment rates, then the State would be required to consider and respond to it as public input under § 447.204.

Comment: A few commenters stated that providers that receive Medicaid payments always raise concerns about any proposed rate reduction or restructuring. These concerns are typically framed as concerns about access. While one commenter reiterated the value of the input of providers and other interested parties in the rate-setting process, a requirement to conduct an access analysis any time a provider voices concerns during the public input process is a de facto requirement to conduct an access analysis for all SPAs. The commenter stated that this will increase the administrative burden for States and CMS and undermine the two-tiered level of analysis envisioned by CMS.

Response: We understand the viewpoint of the commenter and can affirm that the mere existence of one or more comments is not in and of itself a measure of whether the comments have raised a significant access to care concern or whether the State is able to respond to and mitigate any significant concern, as appropriate. If comments received do not raise any significant access to care concern, or if they do but the State documents a reasonable response to all significant concerns that demonstrates that the proposal will not reduce access below the statutory standard notwithstanding the concerns, or that mitigations identified by the State will prevent such a degradation of access, then the proposed reduction or restructuring will qualify for the streamlined initial State analysis under § 447.203(c)(1). We also point out that the requirement that States provide adequate notice and consider public comment for payment rate changes is a long-standing requirement of the Medicaid program in 42 CFR part 447, subpart B.

Comment: One commenter expressed concern that § 447.203(c)(1)(iii), which states as a criterion that ''public feedback yielded no significant access to care concerns or yielded concerns that the State can reasonably respond to or mitigate, as appropriate,'' presents a dangerous loophole through which States can drastically cut payment for services, including, for example, specialist office visits, without triggering additional regulatory scrutiny. The commenter expressed doubt that the subjective inquiry on whether State efforts might be reasonable coupled with the non-specific activity the State would undertake (''respond'' or ''mitigate'') would provide an actual hurdle to payment cuts, including cuts that could constrict access for beneficiaries with rare and ultra-rare conditions.

Response: We disagree that this provision provides States with a loophole enact drastic cuts for services. First and foremost, the provision in question is just one of three criteria a State must meet in order to perform only a streamlined access analysis under § 447.203(c)(1). Second, qualification for the streamlined analysis does not result in automatic approval of the SPA. We will still review both the SPA itself and the streamlined analysis as submitted by the State to determine accuracy and whether the State has met all applicable Federal requirements. We fully expect that some States may submit documentation for the streamlined analysis, and CMS will determine that a more extensive analysis under § 447.203(c)(2) is necessary. For example, if we disagreed that a State's streamlined access analysis submission adequately documented that the State had reasonably responded to or mitigated all significant access concerns raised through public processes in connection with a SPA to reduce or restructure payment rates, we would require the State to submit the additional access analysis provided for in this final rule to enable us to verify that the SPA satisfies the access standard in section 1902(a)(30)(A) of the Act.

To be clear, the State's response to any significant access concern identified through the public processes, and any mitigation approach, as appropriate, would be expected to be fully described in the State's submission to us. In addition, § 447.203(c)(4), where we are recodifying § 447.203(b)(7), continues to require that ''States have ongoing mechanisms for beneficiary and provider input on access to care (through hotlines, surveys, ombudsman, review of grievance and appeals data, or another equivalent mechanism), consistent with the access requirements and public process described in § 447.204.'' Furthermore, § 447.203(c)(4)(ii) provides that ''States should promptly respond to public input through these mechanisms . . . with an appropriate investigation, analysis, and response,'' and ''States must maintain a record of data on public input and how the State responded to this input,'' which record the State must make available to us upon request. A major benefit and intent of this repeated emphasis on public process is to protect against the situation the commenter describes. Our regulations ensure other parties besides the State have visibility into a proposed rate reduction or restructuring, and are able to voice related concerns, so we do not need to rely solely on a State's assertion that there are no access-related concerns or that all such concerns have been addressed.

c. Additional State Rate Analysis (§ 447.203(c)(2))

Comment: One commenter expressed support for the proposed changes to strengthen and clarify requirements for the analysis required for reductions in rates or restructuring of provider payments under § 447.203(c)(2); however, the commenter raised concerns about comparing Medicaid rates solely to Medicare rates, as Medicare does not have comparable services for every benefit category in Medicaid. As such, the commenter suggested using private pay where no Medicare payment rates are available.

Response: We appreciate the support of the commenter and point out that a comparison to Medicare payment rates is not the sole means of assessing access to care in this final rule. This final rule requires that, for States submitting a proposed rate reduction or restructuring, the proposed reduction or restructuring must meet all three criteria set out in § 447.203(c)(1), which include the 80 percent of Medicare comparison, or else the additional analysis under § 447.203(c)(2) would be required. We also finalized in in § 447.203(c)(2)(ii) to require a comparison of Medicaid payment rates to Medicare ''and, as reasonably feasible, to the most recently available payment rates of other health care payers in the State or the geographic area for the same or a comparable set of covered services'' but note that the availability of private payer rate information that has proven difficult for States to obtain due to its often proprietary nature. Similarly, under § 447.203(c)(2), a comparison to Medicare rates is just one part of the full, required analysis for States that must complete the tier 2 analysis. The full tier 2 analysis, which we are finalizing as proposed, requires the following in addition to the full tier 1 analysis: a summary of the proposed payment change including the cumulative effect of all reductions or restructurings taken throughout the current State fiscal year in aggregate FFS Medicaid expenditures for each benefit category affected by proposed reduction or restructuring; an analysis of the Medicaid payment rates in the aggregate (including base and supplemental payments) before and after the proposed reduction or restructuring for each benefit category affected by the proposed reduction or restructuring and a comparison of each to the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services and, as reasonably feasible, to the most recently available payment rates of other health care payers in the State or geographic area; information about the number of actively participating providers of services in each benefit category affected by the proposed reduction or restructuring for each of the immediately preceding 3 years including trend information; information about the number of Medicaid beneficiaries receiving services through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring for each of the immediately preceding 3 years including trend and beneficiary population information and anticipated effects; information about the number of Medicaid services furnished through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring for each of the immediately preceding 3 years including trend and service-recipient beneficiary population information and anticipated effects; and a summary of, and the State's response to, any access to care concerns or complaints received from beneficiaries, providers, and other interested parties regarding the service(s) for which the payment rate reduction or restructuring is proposed as required under § 447.204(a)(2). For services for which a Medicare comparator is not available, the § 447.203(c)(2) analysis is required to be submitted by the State along with the SPA proposing to reduce or restructure provider payment rates as the State is unable to demonstrate compliance with § 447.203(c)(1). The regulations being finalized in § 447.203(c)(2)(ii) account for circumstances where Medicare does not cover comparable services, by requiring States to compare, ''as reasonably feasible, to the most recently available payment rates of other health care payers in the State or the geographic area for the same or a comparable set of covered services to the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services because no such set of Medicare-covered services exists.

Comment: One commenter expressed concern that, while CMS understandably seeks to clarify which SPAs are subject to heightened scrutiny under the tier 2 analysis requirements in § 447.203(c)(2), the criteria are skewed toward services that are paid for off a fee schedule, and which correspond to Medicare-covered services.

Response: We acknowledge that there is an administrative ease associated with meeting the requirements of § 447.203(c) where States pay according to a fee schedule. However, it is also possible to compare payment amounts where no such fee schedule exists. State UPL demonstrations are a valuable resource in determining level of payment of both base and supplemental payments compared to a reasonable estimate of the amount that Medicare would pay for the same services, and our experience has shown that States are able to make these comparisons on both a provider-specific level and in the aggregate. The methodology States use for required UPL demonstrations would support the analysis required under § 447.203(c) of this final rule, even where the payment methodology is not based on a fee schedule.

Comment: One commenter noted that the proposed first-tier analysis requires States to compare proposed Medicaid rates to Medicare rates, but as CMS acknowledges in the preamble, the absence of a comparable Medicare service for some services would mean the State would need to perform the full two-step access analysis, since they would not be able to meet all three criteria in § 447.203(c)(1). The commenter stated that this expectation is not clearly reflected in proposed § 447.203(c) and suggested that CMS add language clarifying that when there is no comparable set of Medicare services, the State must perform the second tier of analysis under § 447.203(c)(2). Another commenter expressed support for CMS's preamble provision that, for services in which a reasonably comparable Medicare-covered analogue is not available, the State would be obligated to support its rate reduction or restructuring proposal through the submission of additional information under § 447.203(c)(2).

Response: We reiterate that we are finalizing § 447.203(c)(1) and (2) as proposed. In addition, we are finalizing our statement in preamble that for any service for which the State has proposed to reduce or restructure the Medicaid payments in circumstances when the changes could result in diminished access, for which there are no comparable Medicare services that would enable the State to make the showing required under § 447.203(c)(1)(i), the State is required to conduct the secondary analysis required under § 447.203(c)(2). For example, where Medicare does not cover routine dental care, payment rate reductions or restructurings of such services would be subject to § 447.203(c)(2) since comparable Medicare payment information required under § 447.203(c)(1)(i) of the final rule would be unavailable.

Comment: One commenter stated that the information States are required to

collect and examine, especially the number of providers, beneficiaries, and services, will be particularly valuable in assessing the impact of rate changes on access to home care services. One commenter specifically expressed support for the § 447.203(c)(2)(iii) proposal to require States to provide the number of actively participating providers of services in each affected benefit category for each of the 3 years immediately preceding the SPA submission date, by State-specified geographic area, provider type, and site of service. That commenter acknowledged that this would be valuable information to be made publicly available. Another agreed, saying CMS should require States to publicly post the enhanced analysis, including data submissions, to ensure full transparency.

Response: We appreciate the support of the commenters. At this time, there is no plan for CMS to make the information States provide in these analyses publicly available. Approved SPAs are public facing documents and are posted on Medicaid.gov after they are approved by CMS. Payment rates used to provide the § 447.203(b) and (c) of the final rule should come from these approved SPAs, and these SPAs should help to clarify questions about the State's particular rate model. We further note that the requirements we are finalizing at §§ 447.203(c)(1)(iii), (c)(4), and 447.204 regarding public process and mechanisms for ongoing beneficiary and provider input should provide interested parties opportunity for meaningful input on State rate actions. Otherwise, information may be available upon request from either States or CMS, and we note that some of this information may be subject to Freedom of Information Act (FOIA) disclosure requirements.

Comment: Several commenters expressed that States should be required to provide detailed information described in § 447.203(c)(2)(i) through (vi) about proposed rate reductions or restructuring any time it proposes to reduce rates or restructure rates in a way that could result in diminished access, and not only when the proposed rate fails to meet certain criteria such as those specified in § 447.203(c)(1). These commenters stated concern that the proposed two-tier structure would still permit States to alter rates in ways that harm beneficiary access.

Response: The purpose of this final rule is to create a process that is less administratively burdensome than the previous, ongoing AMRP process outlined in the 2015 final rule with comment period, while also maintaining a data submission process for payment rate reduction and restructuring SPAs that do not meet the thresholds set out in § 447.203(c)(1). The commenters' recommendation seems to suggest something closer to a continuation of the previous AMRP process, whereas we believe this final rule strikes a more appropriate balance of easing State burden where SPAs meet the § 447.203(c)(1) criteria (making them unlikely to result in reducing beneficiary access to care to a level inconsistent with section 1902(a)(30)(A) of the Act), and requiring more rigorous data and analysis requirements for SPAs that do not meet the § 447.203(c)(1) criteria and may present more cause for concern related to beneficiary access to care.

Comment: A commenter recommended that, in addition to requiring States to provide summary information about proposed changes, and information about the rates in aggregate in § 447.203(c), CMS should require States to provide the specific range of rates, including any variation in rates (for example, regional differences, or differences based on provider specialty).

Response: We approve States' rate methodologies for compliance with regulation and statute, but may not approve individual service rates unless a State presents a final rate, or a fee schedule, as the output of a rate methodology. This final rule does not change that policy or imply that CMS will review individual rates for sufficiency in all cases. Reviewing individual rates within a fee schedule would not necessarily provide a better determination of whether the rates are adequate to enlist sufficient providers into the Medicaid program or not, provided that the State is using a consistent payment rate methodology for the entirety of the fee schedule, since we do not believe that providers generally make decisions about whether to participate with a payer (and accept the payer's rates) based on the rate for a single service. However, we will review individual payment rate codes to the extent that the rate changes fall outside of the typical methodology used by the State in their payment rate setting methodology under the State plan, or to the extent that we have reason to believe that common billing codes most frequently used by providers within the State are disproportionately impacted by the payment rate reduction or restructuring proposal. Further, the payment rate transparency publication in § 447.203(b) will require States to publish their fee schedule rates for services specified in that section of the final rule, which will include individual fee schedule payment rates for services for CMS and public review.

Comment: Several commenters noted appreciation that the additional information that would be required from States that seek to reduce payment rates or restructure payments in a manner that could result in decreased access noting their belief that the § 447.203(c)(2) provision will create important safeguards to prevent decisions that are solely based on State budgetary concerns rather than an actual analysis of the cost of providing services in the Medicaid program. A few commenters noted that they were glad to see that, because of the nature of HCBS, the majority of rate reductions for home care services and supports would always be subject to the provisions mandating greater scrutiny under § 447.203(c)(2), because Medicare rates for the same or a reasonably similar set of services generally will not be available to make such SPAs eligible for the streamlined access review process under § 447.203(c)(1).

Response: We appreciate the support of the commenters, but note for clarity, as discussed earlier in this preamble, there is no requirement in the Medicaid program that payment rates be based on provider cost.

Comment: A few commenters recommended that, at a minimum, CMS should require all States to complete the more extensive access analysis under § 447.203(c)(2) shortly after publication of the final rule to establish a baseline assessment of access to care for Medicaid beneficiaries. Such analysis should include FFS as well as managed care, enabling comparison of payment and access within and across delivery systems. These commenters urged that this baseline analysis should serve as a comparison point for future access monitoring. Other commenters suggested that the requirement for the analysis in § 447.203(c) should be decoupled from a State's intention to reduce or restructure rates, suggesting instead that all States should be required to conduct this analysis annually, every 2 years, or at least every 3 years across all rates for all Medicaid FFS and managed care programs for which a Medicare comparison is possible.

Response: We appreciate the suggestion of the commenters. The purpose of this final rule is to create a process that is less administratively burdensome than the previous, ongoing AMRP process outlined in the 2015 final rule with comment period, while also maintaining a data submission process for payment rate reduction and

restructuring SPAs that do not meet the thresholds set out in § 447.203(c)(1), and note that the FFS provisions, including the payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements (§ 447.203(b)(1) through (5)), interested parties' advisory group requirements (§ 447.203(b)(6)), and State analysis procedures for payment rate reductions or payment restructuring (§ 447.203(c)), finalized in this rule are expected to result in a net burden reduction on States compared to the previous AMRP requirements, as discussed in the proposed rule and in section III. of this final rule. This final rule provides CMS and States with an administrative process through which rate reductions or restructurings can be reviewed and approved, so long as the proposed SPA satisfactorily includes the information required under this final rule and meets all applicable Federal requirements. CMS is discontinuing the previous AMRP process in this final rule, and did not propose and is not finalizing a substantially similar process, as we believe doing so would impose a great deal of burden on States and CMS without commensurate programmatic value, as discussed in the proposed rule and in this final rule (88 FR 27965). We note that the § 447.203(c)(4) mechanisms for ongoing beneficiary and provider input provide impacted parties opportunities to raise access concerns or issues to the State at any point through State-provided input processes.

Comment: One commenter requested that CMS clarify the criteria in both tiers which CMS will use to determine the appropriate level of access on which to provide analyses and documentation of adequate access, claiming there are no details available on the criteria. The commenter requested that CMS define a measurable methodology with which to determine and demonstrate adequacy of access to care in relation to the criteria of the analysis required in the applicable provisions of § 447.203(c).

Response: We are finalizing § 447.203(c)(1) and (2) as proposed, and are providing a template which will assist States with the data demonstrations which will be used to comply with the provisions of the final rule. We produced a template that was submitted to OMB for public review under control number 0938–1134 (CMS–10391) and will be submitted for approval with this final rule and a final template will be available shortly thereafter. Between the regulation text, the preamble of this final rule, and the components of the analysis template, we believe that the criteria we will use to evaluate SPA proposals are clear. We are electing not to otherwise define adequate levels of access to care under § 447.203(c) because section 1902(a)(30)(A) of the Act establishes that a measure for access is that payment rates are ''sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area,'' which level of access (based on whatever metric might be selected) will vary based on geographic area and the level of access available to the general population for a given service. Although CMS reserves the right to request additional information, we have developed the template to ensure that a State has a mechanism through which all of the data elements in § 447.203(c) can be gathered and presented in a straightforward format. Completing the applicable fields of the template will ensure that the State provides all required data elements of under § 447.203(c), and we will review the materials provided by the State to determine that the State has demonstrated current and anticipated levels of access under the SPA in a manner demonstrates compliance with section 1902(a)(30)(A) of the Act. CMS will review each proposal and the State-provided supporting information to ensure compliance with section 1902(a)(30)(A) of the Act and all other applicable Federal requirements before approving any SPA.

Comment: One commenter urged CMS to require States to identify the unique number of Medicaid-paid claims for beneficiaries (in addition to the full number of services required in the regulations as proposed) and the unique number of beneficiaries who received services. The commenter also stated that measuring providers' capacity to provide Medicaid services, by including an estimated number of beneficiaries who could have received the respective services, would allow States to fully assess the gaps in service and number of providers required to meet the need, noting that this assessment would be needed to assess proposed rate reductions or restructuring under proposed § 447.203(c).

Response: We are finalizing § 447.203(c)(2)(v) as proposed. The measures mentioned by the commenter are often associated with health care system capacity by looking at enrolled providers with open panels, which is very useful in addressing individual beneficiary requests for services, or finding care for individuals within a geographic area, which are the type of request we would expect to be made through the § 447.203(c)(4) mechanisms for ongoing beneficiary and provider input, and States should be using any information they can to address beneficiary needs in this way. We encourage any interested parties to engage with their State partners to ensure that real-time access to care concerns are able to be addressed by the State as applicable. Further, the provisions of § 447.203(c)(2) are designed to present an overall picture of access to care for each affected benefit category in the State's program. States are welcome to use any additional measures the State believes would be helpful to assess access to care within each affected benefit category, above and beyond the requirements of this final rule.

Comment: One commenter, citing the 3-year period where the proposed rule would require data about trends over time in the data elements proposed to be required under § 447.203(c)(2), supported the use of statistical methods that provide an accurate picture of utilization trends, but recommended that CMS use its discretion in analyzing the information States provide to meet the required data elements. The commenter stated use of a 3-year analysis as a blanket approach may not be required in periods of stable utilization.

Response: The requirements in § 447.203(c)(2)(iii), (iv), and (v) to use 3-year periods are being finalized as proposed. The purpose of the 3-year analysis is to help identify and appropriately account for statistical anomalies that might appear in the data demonstration. Further, we wanted to provide a clear expectation for what States would be required to provide and thereby remove ambiguity, which we believe existed in the previous AMRP process from the 2015 final rule with comment period. In the 2015 final rule with comment period, the previous AMRP data elements were limited to those specified in § 447.203(b)(1)(i) through 447.203(b)(1)(v), which stated that the AMRP and monitoring analysis will consider: the extent to which beneficiary needs are fully met; the availability of care through enrolled providers to beneficiaries in each geographic area, by provider type and site of service; changes in beneficiary utilization of covered services in each geographic area; the characteristics of the beneficiary population (including considerations for care, service and payment variations for pediatric and adult populations and for individuals with disabilities); and actual or estimated levels of provider payment available from other payers, including

other public and private payers, by provider type and site of service. Within the final rule with comment period, there was discussion regarding the types of data States might use to provide the required information, but much of the final rule with comment period left the specifics of the particular data elements up to the States. In this rulemaking, we proposed and are finalizing considerably more detail in § 447.203(c)(2) than was present in the previous AMRP requirements in the former 447.203(b)(1).

We are also finalizing the 3-year time frame for data analysis in this final rule in § 447.203(c)(2) because we determined that a 3-year look back on provider enrollment, beneficiary enrollment, and beneficiary utilization provides sufficient data to show trends in the data while also helping to identify data anomalies. Where the commenter stated that the use of a 3-year analysis as a blanket approach may not be required in periods of stable utilization, we disagree. The commenter's statement implies that a determination would still need to be made that utilization was stable, therefore by requiring 3 years' worth of data, CMS and the State will be able to document that utilization was stable during the prior 3 years.

Comment: One commenter opposed the requirement to provide an additional summary of the proposed payment change, as described in § 447.203(c)(2)(i), to both § 447.203(c)(1) and (2) equally. The commenter was concerned about the administrative burden these requirements place on States, which could delay SPA submission and in turn affect access to services. The commenter also specifically pointed out that SPAs for services without comparable Medicare rates would, by default, need to complete the additional analysis under § 447.203(c)(2), adding administrative burden. The commenter further recommended CMS implement a form similar to the Standard Funding Questions submitted for Medicaid payment SPAs, in which the State would be able to answer a specific set of questions that would capture the analysis that is being sought. Another commenter noted that the § 447.203(c)(2) data submission requirements may impact significant portions of Medicaid services, such as LTSS, and creates administrative burdens, disincentivizing States from modernizing rate methodologies for these services. This commenter recommended that for services without comparable Medicare rates, the initial analysis be sufficient if all other criteria of the initial review (that is, § 447.203(c)(1)(ii) and (iii)) are satisfied.

Response: States are responsible to ensure that their proposed reduction or restructuring SPA submission includes all of the information required under § 447.203(c)(1) prior to submission. If the proposed reduction or restructuring SPA does not meet all of the paragraph (c)(1) requirements, then the State would need to provide the additional analysis required under § 447.203(c)(2).

We understand that there is burden associated with these new requirements. However, as discussed in the proposed rule in section III.C.11.d, this new process will be less burdensome on States than the previous AMRP process. We also do not believe a State could adequately demonstrate access by answering a standard set of questions as suggested by the commenter, as we would be concerned that static questions may not be well suited to solicit the full scope of data elements that could be necessary to evaluate a particular proposal and therefore prefer to keep data submission requirements open-ended so that States are able to provide the most complete and appropriate information possible to stablish that their proposal satisfies section 1902(a)(30)(A) of the Act as implemented in this final rule. We anticipate providing a considerable amount of technical assistance and templates to assist States with the preparation and submission of data and analysis required under § 447.203(c)(1) and (2).

The rule does not limit a State's ability to reduce or restructure rates where the State believes it appropriate to do so, for example, based on information that the rates are not economic and efficient; rather, it ensures that States take appropriate measures to document access to care consistent with section 1902(a)(30)(A) of the Act. This includes efforts to modernize rates, as noted by the commenter, including by implementing or adjusting. VBP arrangements. While we appreciate that the analysis creates a burden for States, we note that we are replacing a process that was more burdensome. For services for which a Medicare comparator is not available, the § 447.203(c)(2) analysis is required to be submitted by the State along with the SPA proposing to reduce or restructure provider payment rates. As the § 447.203(c)(2) elements are based upon and similar to the elements included in the former § 447.203(b)(1) of the 2015 final rule with comment period, we do not believe the new requirements are more burdensome than the 2015 final rule with comment period which created the previous AMRP process. Therefore, we do not believe this final rule disincentivizes States from modernizing payment rates or methodologies as compared to the previous requirements under the 2015 final rule with comment period. For some services, particularly for those for which the State can demonstrate that the § 447.203(c)(1) requirements are met, the final rule considerably reduces burden on States.

Comment: A few commenters urged caution not to impose overly rigid restrictions on States' and CMS' ability to adjust provider payment rates, noting that State Medicaid programs are constrained by the same factors that constrain all State spending, including general economic conditions, State balanced budget requirements, and State general fund revenue. One commenter noted that requiring a significant analysis for proposed reductions in Medicaid FFS payment rates will create administrative burden for States that have been mandated by their legislatures to reduce certain rates or Medicaid spending in general. The commenter noted that in such circumstances, States have a limited number of ''levers'' at their disposal—(1) they can reduce the number of individuals enrolled in Medicaid, (2) they can impose reductions on the covered services that Medicaid beneficiaries receive, or (3) they can adjust provider payment rates. If CMS makes it impossible (or inordinately difficult) to restructure provider payment rates, then States may be forced to make other undesirable reductions to coverage and/or eligibility in order to cope with difficult economic conditions.

Response: We understand the concerns of the commenters. States are required to operate their Medicaid programs within their budgetary constraints, and we agree with the commenter that, of the options available for States facing budgetary issues, none of the available approaches typically is ideal. However, we also note that States are also obligated to comply with section 1902(a)(30)(A) of the Act, which requires States to ''assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.'' The requirement specifically references payment rates for ''care and services available under the plan'' such that the services that are covered under the State plan as both mandatory and optional

benefits, must be supported by adequate payment rates for those services. We anticipate providing a considerable amount of technical assistance to ease the administrative burden on States that both need to reduce rates and need to satisfy the requirements of § 447.203(c) to ensure that the statutory access standard is met. We are also finalizing the template we proposed to accompany these requirements and assist States with supplying the necessary data to fulfil these requirements.

Comment: One commenter recommended that CMS build into the review and approval of all SPAs, waiver amendments, and waiver renewals a process for the review of payment rates. The commenter further suggested that CMS require adequate payment rates prior to approving these amendments and renewals. The commenter indicated that this would allow CMS to review rates more often and prevent years or decades passing without rates being reviewed or adjusted.

Response: CMS reviews all SPAs affecting Medicaid payment for compliance with section 1902(a)(30)(A) of the Act. Outside of the SPA process, the corrective action plan process under § 447.203(c)(5) (which we are recodifying from § 447.203(b)(8)) is available to address access issues that may arise even when the State has not submitted a payment SPA. Further, to the extent that a State submits a SPA that updates coverage of a Medicaid service but does not amend Medicaid payment rates or the rate methodology in the Attachment 4.19A (for Medicaid inpatient services such as inpatient hospital services), 4.19B (for Medicaid non-institutional services such as physician services), or 4.19D (for Medicaid nursing facility services) State plan pages, CMS will not necessarily disapprove that SPA on the basis of insufficient Medicaid payment rates as the payment rates were not submitted along with the corresponding coverage and benefit changes for our consideration. States certainly can submit payment rate information to CMS of the State's own volition or upon request during review of a coverage SPA; however, CMS provides States in this situation (where the SPA would amend State plan coverage, but not payment, pages) with an option to instead defer review of the payment rate compliance issue through a mechanism called a ''companion letter,'' as noted in the 2010 SMDL #10–0020.[375] As noted above, even in the absence of a SPA, the corrective action plan process under § 447.203(c)(5) (which we are recodifying from § 447.203(b)(8)) is available to for CMS to take compliance action where it is aware of an access problem due to insufficient rates.

With the policies finalized throughout this final rule, we hope and anticipate that both States and the public will more closely examine existing rates. Our policies around payment rate transparency publications, comparative payment rate analyses, and payment rate disclosures will enhance opportunities to determine where an existing rate may not be supporting adequate access to care and identify for States where a need for increased payments and/or updated payment methodologies should be addressed. Our policies around the mechanisms for ongoing beneficiary and provider input in § 447.203(c)(4) and addressing access questions and remediation of inadequate access to care in § 447.203(c)(5) will further provide beneficiaries, providers, and other interested parties opportunities to engage with States on existing payment rates and their impact on beneficiaries' access to care.

d. Compliance With Requirements for State Analysis for Rate Reduction or Restructuring (§ 447.203(c)(3))

Comment: A few commenters applauded CMS for including a clear enforcement mechanism for these provisions at § 447.203(c)(3). One of the commenters specifically offered that this provision helpfully codifies CMS's longstanding authority to enforce access standards under section 1902(a)(30)(A) of the Act by denying SPAs or taking compliance action to protect access for Medicaid enrollees.

Response: We appreciate the support of the commenters.

Comment: One commenter opposed the provision at § 447.203(c)(3) that SPAs may be subject to disapproval. The commenter did not believe that approval of a SPA should be contingent on the submission of a satisfactory access analysis required under paragraphs (c)(1) and (c)(2) of this section of the final rule.

Response: The final rule requires States to submit information with their payment rate reduction or restructuring SPAs in circumstances where those types of rate changes may result in diminished access to care. We are requiring this information in order to determine compliance with section 1902(a)(30)(A) of the Act, which requires that a State plan for medical assistance ''assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.'' In the event that a State does not provide the information required under this final rule, we would be unable to determine that the State's proposal is consistent with the statute, and therefore, we would be unable to approve the SPA.

e. Public Input Process (§ 447.203(c)(4))

Comment: Several commenters supported the proposal at § 447.203(c)(4) regarding ongoing mechanisms for beneficiary and provider input on access. One commenter specifically appreciated CMS' recognition of the importance of ongoing feedback from providers and beneficiaries to the State regarding access to care and for the State to track and take account of those interactions in a meaningful way. Another commenter supported this requirement, noting that HCBS recipients enrolled in managed care are currently provided with a grievance system and indicating that FFS recipients must be afforded this same right.

Response: We appreciate the support of the commenters. We believe that the provision in § 447.203(c)(4) of this final rule provides beneficiaries with opportunities to raise their concerns through hotlines, surveys, ombudsman, grievance, and appeals processes that the State makes available, or other equivalent mechanisms offered by the State.

Comment: One commenter recommended that CMS update the public notice requirements in § 447.205 to require notice 30 days before the effective date in order to increase the transparency of the proposed SPA process and ensure that States provide interested parties with meaningful notice and opportunity to provide feedback.

Response: Changes to the public notice requirements in § 447.205 are outside the scope of this rulemaking.

Comment: One commenter recommended that CMS change ''should'' to ''must'' at § 447.203(c)(4)(ii). They pointed out that § 447.203(c)(4)(i) and (iii) under ''Mechanisms for ongoing beneficiary and provider input,'' both use ''must,'' while item (ii) notes States ''should promptly respond to public input through these mechanisms citing specific access problems, with an appropriate investigation, analysis, and

[375] SMDL #10–020, ''Revised State Plan Amendment Review Process.'' Published October 1, 2010. *https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/downloads/SMD10020.pdf.*

response.'' The commenter stated this provision is important and that if it is not mandated on States, some States may ignore it.

Response: This provision is being finalized as proposed because this section is carried over from prior regulatory language at § 447.203(b)(7) and was proposed to be recodified without change. We acknowledge that responses to public input can take time and resources to manage, and point out that this final rule provision is carrying forward the same regulatory language from the 2015 final rule with comment period. In our experience, States do respond timely and appropriately, and therefore did not think it necessary to propose a change to this provision. We note that § 447.203(c)(4)(iii) requires States to maintain a record of data on public input and how the State responded to this input, and the record of input and responses ''will be made available to CMS upon request.''

Comment: One commenter supported requiring States to maintain a record of data on public input and how the State responded to this input, which will be made available to CMS upon request.

Response: We thank the commenter for their support and are finalizing the recodification of § 447.203(b)(7) at § 447.203(c)(4) as proposed.

Comment: One commenter stated that States should establish mechanisms for ongoing monitoring, evaluation, and feedback from beneficiaries, direct care workers, and underserved communities, and that States should create opportunities for meaningful engagement through advisory boards, focus groups, public comment periods, and partnerships with advocacy organizations. The commenter suggested that such an approach ensures that the perspectives and needs of these interested parties are considered in policy development and implementation.

Response: We are finalizing the provisions of § 447.203(c)(4) as proposed, as we believe that the mechanisms for ongoing beneficiary and provider input in paragraph (c)(4) provide opportunities for meaningful engagement by requiring States to develop some of the mechanisms suggested by the commenter. However, in addition to the mechanisms required under § 447.203(c)(4) for ongoing beneficiary and provider input, States are welcome to develop additional processes to facilitate beneficiary and provider feedback, as well as feedback from other interested parties.

Comment: One commenter stated that the mechanisms for ongoing beneficiary and provider input provision in § 447.203(c)(4) lack enforcement to get States to respond in a meaningful way to concerns about access, noting that the question of whether there is a ''deficiency'' will be left to the States themselves to determine. The commenter suggested that there needs to be some way for interested parties to elevate concerns to CMS in a formal fashion when this process does not work at the State level.

Response: The steps States must take to respond to concerns about access raised through input pursuant to § 447.203(c)(4) are detailed in § 447.203(c)(5), which we are finalizing as proposed as a recodification from § 447.203(b)(8). Section 447.203(c)(5) requires States to develop and submit a corrective action plan to CMS within 90 days of discovery of an access deficiency. The submitted action plan must aim to remediate the access deficiency within 12 months. This requirement ensures that the access deficiency is addressed in a timely manner while allowing the State time to address underlying causes of the access issue, be it payment rates, provider participation, etc. These remediation efforts can include but are not limited to: increasing payment rates; improving outreach to providers; reducing barriers to provider enrollment; providing additional transportation to services; or improving care coordination.

Because each State designs and administers its own Medicaid program within the Federal framework, we believe it is most appropriate for beneficiaries and interested parties to raise access concerns with the State directly, rather than to CMS. To the extent that a beneficiary or interested parties' access concerns are not addressed by the State adequately, we continue to urge interested parties to elevate concerns to the State through the § 447.203(c)(4) mechanisms for ongoing beneficiary and provider feedback. We further note that we are finalizing as proposed compliance actions for access deficiencies that have not been remedied under § 447.203(c)(6), as recodified from § 447.204(d).

Comment: One commenter noted that some of the proposed policies, such as strengthening the role of Medicaid beneficiaries in the policymaking process, have been pioneered at the State level.

Response: We appreciate the perspective of the commenter and agree that many of these activities have been pioneered at the State level. We often look to actions undertaken by our State partners to identify areas of policy that may be appropriate to enact at the Federal level.

f. Addressing Access Questions and Remediation of Inadequate Access to Care (§ 447.203(c)(5))

Comment: A couple commenters strongly supported the retention of § 447.203(b)(8) language concerning a State's response to problems with access to Medicaid services, which now appears in § 447.203(c)(5). However, one commenter also expressed concerns about whether that requirement has historically served to require States to make meaningful efforts to correct access issues, considering that the commenter stated there are serious problems with access to Medicaid services in many States today, which the commenter asserted CMS has also acknowledged. The commenter suggested this may be a problem of the resources that CMS devotes to enforcement and insisted that CMS needs to commit to stricter and more effective enforcement of this language.

Response: We appreciate the support of the commenters and the sentiment expressed in the comment. CMS is committed to an agency-wide strategy for oversight and enforcement of Federal requirements concerning access to care. Although the language pointed out by the commenter is unchanged from how it previously appeared in § 447.203(b)(8), we are confident the changes to § 447.203(c)(1)(iii), § 447.203(c)(2)(vi), and § 447.203(c)(4) in this final rule will enhance oversight of access and work to enhance the importance of input from beneficiaries, providers, and other interested parties.

Comment: One commenter noted that concerns around timely access may be identified by enrollees, patient advocacy organizations, or providers long before they become apparent to Medicaid managed care plans or State officials, particularly if those access challenges are specific to a disease group such as complex and rare cancers. The commenter urged CMS to clarify that, if such groups present plausible access concerns to State officials, that can be sufficient to make the State aware of the access issue, such that the State must submit a proposed remedy plan to CMS within 90 days of receiving a report of such concern.

Response: We encourage beneficiaries, patient advocacy organizations, and providers to work closely with States in order to raise issues such as inability to connect patients to care, or inability to find an appointment within the patient's geographic area, through the mechanisms for ongoing beneficiary and provider input the State established under § 447.203(c)(4). Section

447.203(c)(5), which was formerly § 447.203(b)(8), then requires States to submit a corrective action plan to remedy the access deficiency within 90 days from when it is identified to the State. We agree with the commenters that beneficiaries, patient advocacy organizations, and providers raising plausible access concerns to State officials would be considered as identifying an access deficiency when raised to the State through appropriate State channels.

g. Compliance Actions for Access Deficiencies (§ 447.203(c)(6))

Comment: One commenter supported the proposal to clarify that CMS may use the procedures set forth in § 430.35 when necessary to ensure compliance with access requirements.

Response: We appreciate the support of the commenter. We are finalizing as proposed to recodify § 447.204(d) at § 447.203(c)(6).

After consideration of public comments, we are finalizing the provisions of § 447.203(c) as proposed aside from minor typographical corrections.

4. Medicaid Provider Participation and Public Process To Inform Access to Care (§ 447.204)

In § 447.204, we proposed conforming changes to reflect proposed changes in § 447.203, if finalized. These conforming edits are limited to § 447.204(a)(1) and (b) and are necessary for consistency with the newly proposed changes in § 447.203(b). The remaining paragraphs of § 447.204 would be unchanged.

Specifically, we proposed to update the language of § 447.204(a)(1), which previously referenced § 447.203, to reference § 447.203(c). Because we proposed wholesale revisions to § 447.203(b) and the addition of § 447.203(c), the proposed data and analysis referenced in the previous citation to § 447.203 would be located more precisely in § 447.203(c). Previous § 447.204(b)(1) referred to the State's most recent AMRP performed under previous § 447.203(b)(6) for the services at issue in the State's payment rate reduction or payment restructuring SPA; we proposed to remove this requirement to align with our proposal to rescind the previous AMRP requirements in § 447.203(b). Previous § 447.204(b)(2) and (3) required the State to submit with such a payment SPA an analysis of the effect of the change in the payment rates on access and a specific analysis of the information and concerns expressed in input from affected interested parties; we noted our belief that the previous requirements are addressed in proposed § 447.203(c)(1) and (2), as applicable. We explained our belief that the continued inclusion of these paragraphs (b)(2) and (3) would be unnecessary or redundant in light of the proposals in § 447.203(c)(1) and (2), if finalized. The objective processes proposed under § 447.203(c)(1) and (2), which would require States to submit quantitative and qualitative information with a proposed payment rate reduction or payment restructuring SPA, would be sufficient for us to obtain the information necessary to assess the State's proposal with the same or similar information as previously required under § 447.204(b)(2) and (3).

With the removal of § 447.204(b)(1) through (b)(3), we proposed to revise § 447.204(b) to read, ''[t]he State must submit to us with any such proposed State plan amendment affecting payment rates documentation of the information and analysis required under § 447.203(c) of this chapter.''

Finally, as noted in the previous section, we proposed to remove and relocate § 447.204(d), as we believed the nature of that provision is better suited to codification in § 447.203(c)(6).

We solicited comments on the proposed amendments to § 447.204. We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the conforming edits to § 447.204. Another commenter specifically supported the proposal to make technical changes to § 447.204(a) to cross-reference the analysis that CMS proposes to require under § 447.203(c).

Response: We appreciate the support of the commenters.

Comment: One commenter recommended that CMS amend § 447.204(a)(2) to specifically include reference to the interested parties advisory group described in § 447.203(b)(6).

Response: We appreciate the recommendation of the commenter. We are confident that the mechanisms for ongoing beneficiary and provider input in § 447.203(c)(4) of the final rule will provide interested parties opportunity for meaningful input on State rate actions.

After consideration of public comments, we are finalizing the provisions of § 447.204 as proposed.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a ''collection of information'' requirement is submitted to the Office of Management and Budget (OMB) for review and approval. For the purpose of the PRA and this section of the rule, collection of information is defined under 5 CFR 1320.3(c) of the PRA's implementing regulations.

To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In the proposed rule (88 FR 28037 through 28066) we solicited public comment on each of these issues for the following sections of the proposed rule (CMS–2442–P, RIN 0938–AU68) that contained collection of information requirements. Comments were received with respect to ICR #4 (Incident Management System). A summary of the comment and our response is set out below.

A. Wage Estimates

States and the Private Sector: To derive average costs, we used data from the U.S. Bureau of Labor Statistics' (BLS') May 2022 [376] National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes/2022/may/oes_nat.htm*). In this regard, Table 2 presents BLS' mean hourly wage, our estimated cost of fringe benefits and other indirect costs [377] (calculated at 100 percent of salary), and our adjusted hourly wage.

[376] In this final rule, we used the most recently available data, May 2022, from the BLS. This is an update from the proposed rule, (88 FR 27960), which used data from the BLS' May 2021 National Occupational Employment and Wage Estimates for salary estimates.

[377] *https://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework.*

TABLE 2: National Occupational Employment and Wage Estimates

Occupation Title	Occupational Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Other Indirect Costs($/hr)	Adjusted Hourly Wage ($/hr)
Administrative Services Manager	11-3012	55.59	55.59	111.18
Business Operations Specialist	13-1000	40.04	40.04	80.08
Business Operations Specialist, All Other	13-1199	39.75	39.75	79.50
Chief Executive	11-1011	118.48	118.48	236.96
Compensation, Benefits, and Job Analyst	13-1141	36.50	36.50	73.00
Computer and Information Analyst	15-1210	53.15	53.15	106.30
Computer Programmer	15-1251	49.42	49.42	98.84
Data Entry Keyers	43-9021	18.26	18.26	36.52
General and Operations Manager	11-1021	59.07	59.07	118.14
Human Resources Manager	11-3121	70.07	70.07	140.14
Management Analyst	13-1111	50.32	50.32	100.64
Social and Community Service Managers	11-9151	38.13	38.13	76.26
Social Science Research Assistants	19-4061	27.77	27.77	55.54
Statistician	15-2041	50.73	50.73	101.46
Survey Researcher	19-3022	31.94	31.94	63.88
Training and Development Specialist	13-1151	33.59	33.59	67.18

For States and the private sector, the employee hourly wage estimates have been adjusted by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and other indirect costs vary significantly across employers, and because methods of estimating these costs vary widely across studies. Nonetheless, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Beneficiaries: We believe that the costs for beneficiaries undertaking administrative and other tasks on their own time is a post-tax hourly wage rate of $20.71/hr.

We adopt an hourly value of time based on after-tax wages to quantify the opportunity cost of changes in time use for unpaid activities. This approach matches the default assumptions for valuing changes in time use for individuals undertaking administrative and other tasks on their own time, which are outlined in an ASPE report on ''Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices.'' [*] We start with a measurement of the usual weekly earnings of wage and salary workers of $998. [**] We divide this weekly rate by 40 hours to calculate an hourly pre-tax wage rate of $24.95. We adjust this hourly rate downwards by an estimate of the effective tax rate for median income households of about 17 percent, resulting in a post-tax hourly wage rate of $20.71. We adopt this as our estimate of the hourly value of time for changes in time use for unpaid activities.[378] [379] Unlike our State and private sector wage adjustments, we are not adjusting beneficiary wages for fringe benefits and other indirect costs since the individuals' activities, if any, would occur outside the scope of their employment.

B. Adjustment to State Cost Estimates

To estimate the financial burden on States, it was important to consider the Federal government's contribution to the cost of administering the Medicaid program. For medical assistance services, the Federal government provides funding based on an FMAP that is established for each State, based on the per capita income in the State as compared to the national average. FMAPs range from a minimum of 50 percent in States with higher per capita incomes to a maximum of 83 percent in States with lower per capital incomes. For Medicaid, all States receive a 50 percent Federal matching rate for most administration expenditures. States also receive higher Federal matching rates for certain systems improvements, redesign, or operations. As such, and taking into account the Federal contribution to the costs of administering the Medicaid programs for purposes of estimate State burden with respect to collection of information, we elected to use the higher end estimate that the States would contribute 50 percent of the costs, even though the burden would likely be smaller.

C. Information Collection Requirements (ICRs)

1. ICRs Regarding Medicaid Advisory Committee and Beneficiary Advisory Council (§ 431.12)

The following changes will be submitted to OMB for approval under

[378] Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation. 2017. ''Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices.'' *https://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework.*

[379] U.S. Bureau of Labor Statistics. Employed full time: Median usual weekly nominal earnings (second quartile): Wage and salary workers: 16 years and over [LEU0252881500A], retrieved from FRED, Federal Reserve Bank of St. Louis; *https://fred.stlouisfed.org/series/LEU0252881500A.* Annual Estimate, 2021.

control number 0938–TBD (CMS–10845).

Currently, most States have an established Medical Care Advisory Committee (MCAC), which we are renaming the Medicaid Advisory Committee (MAC), whereby each State has the discretion on how to operate its MCAC. A small number of States also use consumer advisory subcommittees as part of their current MCACs, similar to the Beneficiary Advisory Council (BAC) in § 431.12. We reviewed data from 10 States to determine the current status of MCACs and to determine the burden needed to comply with the § 431.12 requirements across 50 States and the District of Columbia.

Under the provision, States will be required to:

- Select members to the MAC and BAC on a rotating and continuous basis.
- Develop and publish a process for MAC and BAC member recruitment and selection of MAC and BAC leadership.
- Develop and publish:

++ Bylaws for governance of the MAC.

++ A current list of MAC and BAC membership.[380]

++ Past meeting minutes, including a summary from the most recent BAC Meeting.

- Develop, publish, and implement a regular meeting schedule for the MAC and BAC.

Additionally, the State must provide and post to its website an annual report written by the MAC to the State describing its activities, topics discussed, recommendations. The report must also include actions taken by the State based on the MAC recommendations.

The requirements will require varying levels of effort by States. For example, a handful of States already have a BAC. However, we believe that most States will be required to create new structures and processes. The majority of States reviewed are already meeting some of the new requirements for MACs, such as publication of meeting schedules, publication of membership lists, and publication of bylaws. However, all MAC bylaws will need to be updated to meet the new requirements. Our review showed that most States are not currently publishing their recruitment and appointment processes for MAC members, and those that did will need to update these processes to meet the new requirements. About half of the States reviewed published meeting minutes with responses and State actions, as required under the new requirements. However, only one State reviewed published an annual report, so this will likely be a new requirement for almost all State MACs. States will not need to modify or build reporting systems to create and post these annual reports. Due to the wide range in the use and maturity of current MCACs across the States, we are providing a range of estimates to address these variations.

We recognize that some States, which do not currently operate a MCAC, will have a higher burden to implement the requirements of § 431.12 to shift to the MAC and BAC structure. However, our research showed that the majority of States do have processes and procedures for their current MCACs, which will require updating, but at a much lower burden. Therefore, we believe it is appropriate to offer average low and high burden estimates.

For a low estimate, we estimate it will take a team of business operations specialists 120 hours at $79.50/hr to develop and publish the processes and report. In aggregate, we estimate an annual burden of 6,120 hours (120 hr/response × 51 responses) at a cost of $486,540 (6,120 hr × $79.50/hr). Taking into account the Federal administrative match of 50 percent, the requirement will cost States $243,270 ($486,540 × 0.50). We also estimate that it will take 40 hours at $140.14/hr for a human resources manager to review and approve bylaws and help with recruitment and appointment and selection of MAC and BAC leadership which will occur every 2 years. In aggregate, we estimate a biennial burden of 2,040 hours (40 hr/response × 51 responses) at a cost of $285,885 (2,040 hr × $140.14/hr). Taking into account the Federal administrative match of 50 percent, the requirement will cost States $142,942 ($285,885 × 0.50). Additionally, we estimate it will take 10 hours at $118.14/hr for an operations manager to review the updates and prepare the required reports for annual publication. In aggregate, we estimate an annual burden of 510 hours (10 hr/response × 51 responses) at a cost of $60,251 (510 hr × $118.14/hr). Taking into account the Federal administrative match of 50 percent, the requirement will cost States $30,125 ($60,251 × 0.50).

We derived the high estimate by doubling the hours from the low estimate. We used this approach because all States already have a MCAC requirement which means the type of work being discussed is already underway in most States and that there is reference point for the type of work described. For example, we estimate it will take a team of business operations specialists 240 hours at $79.50/hr to develop and publish the processes and annual report. In aggregate, we estimate an annual burden of 12,240 hours (240 hr/response × 51 responses) at a cost of $973,080 (12,240 hr × $79.50/hr). Taking into account the Federal administrative match of 50 percent, the requirement will cost States $486,540 ($973,080 × 0.50). We also estimate that it will take 80 hours at $140.14/hr for a human resources manager to review and approve bylaws and help with recruitment and appointment and selection of MAC and BAC leadership which will occur every 2 years. In aggregate, we estimate a biennial burden of 4,080 hours (80 hr/response × 51 responses) at a cost of $571,771 (4,080 hr × $140.14). Taking into account the Federal administrative match of 50 percent, the requirement will cost States $285,885 ($571,771 × 0.50). Additionally, we estimate it will take 20 hours at $118.14/hr for an operations manager to review the updates and prepare the required annual report for publication. In aggregate, we estimate an annual burden of 1,020 hours (20 hr/response × 51 responses) at a cost of $120,503 (1,020 hr × $118.14/hr). Taking into account the Federal administrative match of 50 percent, the requirement will cost States $60,251 ($120,503 × 0.50).

We have summarized the total burden in Table 3. To be conservative and not underestimate our burden analysis, we are using the high end of our estimates to score the PRA-related impact of the finalized requirements.

[380] BAC members may choose to not have their names listed on the publicly posted membership list.

TABLE 3: Summary of High Burden Estimates for Medical Care Advisory Committee Requirements

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
§ 431.12 (develop/ publish report)	51	51	Annual	240	12,240	79.50	973,080	486,540
§ 431.12 (review/approve bylaws)	51	51	Biennial	80	4,080	140.14	571,771	285,885
§ 431.12 (review updates/prepare reports)	51	51	Annual	20	1,020	118.14	120,503	60,251
Total	51	153	varies	Varies	17,340	varies	1,665,354	832,676

While a few commenters made general or high-level comments regarding concerns about burden (which are addressed in section II.A of this final rule) we did not receive specific comments on this ICR. The general comments we received were about the overall burden related to the MAC and BAC provisions and not about the burden estimated in the ICR Table 3 nor the information outlined in this section. In this rule we are finalizing the MAC and BAC reporting requirements and burden estimates as proposed.

2. ICRs Regarding Person-Centered Service Plans (§ 441.301(c)(3); Applied to Other HCBS Authorities at §§ 441.450(c), 441.540(c), and 441.725(c), and 438.72(b) and to Managed Care at § 438.72(b))

The following changes will be submitted to OMB for approval after this final rule is finalized and our survey instrument has been developed. The survey instrument and burden will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. In the meantime, we are setting out our burden figures (see below) as a means of scoring the impact of this rule's changes. The availability of the survey instrument and more definitive burden estimates will be announced in both **Federal Register** notices. The CMS ID number for that collection of information request is CMS–10854 (OMB control number 0938–TBD). Since this will be a new collection of information request, the OMB control number has yet to be determined (TBD) but will be issued by OMB upon their approval of the new collection of information request.

Section 1915(c)(1) of the Act requires that services provided through section 1915(c) waiver programs be provided under a written plan of care (hereinafter referred to as ''person-centered service plans'' or ''service plans''). Existing Federal regulations at § 441.301(c)(1) through (3) address the person-centered planning process and include a requirement at § 441.301(c)(3) that the person-centered service plan be reviewed and revised upon reassessment of functional need, at least every 12 months, when the individual's circumstances or needs change significantly or at the request of the individual.

In 2014, we released guidance for section 1915(c) waiver programs [381] (hereinafter the ''2014 guidance'') that included expectations for State reporting of State-developed performance measures to demonstrate compliance with section 1915(c) of the Act and the implementing regulations in part 441, subpart G through six assurances, including assurances related to person-centered service plans. The 2014 guidance also indicated that States should conduct systemic remediation and implement a Quality Improvement Project when they score below an 86 percent threshold on any of their performance measures.

In this rule, we are finalizing a new requirement at § 441.301(c)(3)(i) to specify that States demonstrate that the person-centered service plan **for every individual** is reviewed, and revised, as appropriate, based upon the reassessment of functional need as required by § 441.365(e), at least every 12 months, when the individual's circumstances or needs change significantly, or at the request of the individual. At § 441.301(c)(3)(ii)(A) we are finalizing a requirement that States demonstrate that a reassessment of functional need was conducted at least annually for at least 90 percent of individuals continuously enrolled in the waiver for at least 365 days. We are also finalizing, at new § 441.301(c)(3)(ii)(B), that States demonstrate that they reviewed for every individual the person-centered service plan and revised the plan as appropriate based on the results of the required reassessment of functional need at least every 12 months for at least 90 percent of individuals continuously enrolled in the waiver for at least 365 days.

We are finalizing the application of these requirements to services delivered under FFS or managed care delivery systems. Further, we are finalizing the application of the finalized requirements sections 1915(j), (k), and (i) State plan services by cross-referencing at §§ 441.450(c), 441.540(c), and 441.725(c), respectively.

In addition, we also proposed (and are finalizing) several changes to current regulations for person-centered planning at § 441.301(c)(1) to reposition, clarify, and remove extraneous language from § 441.301(c)(1).

We are finalizing the person-centered planning requirements at § 441.301(c)(1) and (3) without substantive changes. Below are our burden estimates for these requirements.

[381] Modifications to Quality Measures and Reporting in § 1915(c) Home and Community-Based Waivers. March 2014. Accessed at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/3-cmcs-quality-memo-narrative_0_2.pdf.*

a. One Time Person-Centered Service Plan Requirements: State (§ 441.301(c)(3))

As discussed above, at new § 441.301(c)(3)(ii)(A), we are finalizing a requirement that States demonstrate that a reassessment of functional need was conducted at least annually for at least 90 percent of individuals continuously enrolled in the waiver for at least 365 days. We are also finalizing, at § 441.301(c)(3)(ii)(B), a requirement that States demonstrate for every individual that they reviewed the person-centered service plan and revised the plan as appropriate based on the results of the required reassessment of functional need at least every 12 months for at least 90 percent of individuals continuously enrolled in the waiver for at least 365 days. The burden associated with the person-centered service plan reporting requirements at § 441.301(c)(3)(ii)(A) and (B) affects the 48 States (including the District of Columbia) that deliver HCBS under sections 1915(c), (i), (j), or (k) authorities.[382] We anticipate that States will need to update State policy, as well as oversight and monitoring processes related to the codification of the new 90 percent minimum performance level associated with these requirements.

However, because we are codifying a minimum performance level associated with existing regulations but not otherwise changing the regulatory requirements under § 441.301(c)(3)(ii)(A) and (B), we do not estimate any additional burden related to those requirements. We also hold that there is no additional burden associated with repositioning, clarifying, and removing extraneous language from the regulatory text at § 441.301(c)(1). In this regard we are only estimating burden for updating State policy and oversight and monitoring processes related to the codification of the finalized 90 percent minimum performance level requirement.

We estimate it will take 8 hours at $111.18/hr for an administrative services manager to update State policy and oversight and monitoring processes, 2 hours at $118.14/hr for a general and operations manager to review and approve the updates to State policy and oversight and monitoring processes, and 1 hour at $236.96/hr for a chief executive to review and approve the updates to State policy and oversight and monitoring processes. In aggregate, we estimate a one-time burden of 528 hours (48 States × [8 hr + 2 hr + 1 hr]) at a cost of $65,409 (48 States × [(8 hr × $111.18/hr) + (2 hr × $118.14/hr) + (1 hr × $236.96/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost is $32,704 ($65,409 × 0.50).

TABLE 4: Summary of One-Time Burden Estimates for States for the Person-Centered Service Plan Requirements at § 441.301(c)(3)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Update State policy and oversight and monitoring processes	48	48	Once	8	384	111.18	42,693	21,347
Review and approval of State policy update at the management level	48	48	Once	2	96	118.14	11,341	5,671
Review and approval of State policy update at the chief executive level	48	48	Once	1	48	236.96	11,374	5,687
Total	48	48	Once	Varies	528	Varies	65,409	32,704

b. One Time Person-Centered Service Plan Requirements: Managed Care Plans (§ 441.301(c)(3))

As discussed above, we are requiring managed care delivery systems to also comply with the requirements finalized at § 441.301(c)(3) to demonstrate that a reassessment of functional need was conducted at least annually for at least 90 percent of individuals continuously enrolled in the waiver for at least 365 days and to demonstrate that they reviewed the person centered service plan and revised the plan as appropriate based on the results of the required reassessment of functional need at least every 12 months for at least 90 percent of individuals continuously enrolled in the waiver for at least 365 days. As with the burden estimate for States, we do not estimate an ongoing burden related to the codification of a minimum performance level associated with the requirements at § 441.301(c)(3).

For managed care plans, we estimate it would take 5 hours at $111.18/hr for an administrative services manager to update organizational policy and oversight and monitoring processes related to the codification of a new minimum performance level and 1 hour at $236.96/hr for a chief executive to review and approve the updates to organizational policy and oversight and monitoring processes. In aggregate, we estimate a one-time burden of 966 hours (161 managed care plans × [5 hr + 1 hr]) at a cost of $127,650 (161 managed care plans × [(5 hr × $111.18/hr) + (1 hr × $236.96/hr)]).

[382] Arizona, Rhode Island, and Vermont do not have HCBS programs under any of these authorities.

TABLE 5: Summary of One-Time Burden Estimates for Managed Care Plans for the Person-Centered Service Plan Requirements at § 441.301(c)(3)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Update organizational policy and oversight and monitoring processes	161	161	Once	5	805	111.18	89,500	n/a
Review and approval of policy and oversight and monitoring processes	161	161	Once	1	161	236.96	38,151	n/a
Total	161	161	Once	Varies	966	Varies	127,650	n/a

3. ICRs Regarding Grievance System (§ 441.301(c)(7); Applied to Other HCBS Authorities at §§ 441.464(d)(2)(v), 441.555(b)(2)(iv), and 441.745(a)(1)(iii))

The following changes will be submitted to OMB for approval after this final rule is finalized and when our reporting tools and survey instrument has been developed. The survey instrument and burden will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. In the meantime, we are setting out our burden figures (see below) as a means of scoring the impact of this rule's changes. The availability of the survey instrument and more definitive burden estimates will be announced in both **Federal Register** notices. The CMS ID number for that collection of information request is CMS–10854 (OMB control number 0938–TBD). Since this will be a new collection of information request, the OMB control number has yet to be determined (TBD) but will be issued by OMB upon their approval of the new collection of information request.

At § 441.301(c)(7), we are finalizing requirements that States establish grievance procedures for Medicaid beneficiaries receiving section 1915(c) waiver program services through a FFS delivery system to file a complaint or expression or dissatisfaction related to the State's or a provider's compliance with the person-centered planning and service plan requirements at § 441.301(c)(1) through (3) and the HCBS settings requirements at § 441.301(c)(4) through (6).

We are finalizing at § 441.301(c)(7)(vii) a list of recordkeeping requirements related to grievances. Specifically, at § 441.301(c)(7)(vii)(A), we are finalizing that States maintain records of grievances and review the information as part of their ongoing monitoring procedures. At § 441.301(c)(7)(vii)(B)(*1*) through (*7*), we are finalizing that the record of each grievance must contain the following information at a minimum: a general description of the reason for the grievance, the date received, the date of each review or review meeting (if applicable), resolution and date of the resolution of the grievance (if applicable), and the name of the beneficiary for whom the grievance was filed. Further, at § 441.301(c)(7)(vii)(C), we are finalizing that grievance records be accurately maintained and in a manner that would be available upon our request.

We are finalizing the application of these requirements in § 441.301(c)(7) to sections 1915(j), (k), and (i) State plan services by cross-referencing at §§ 441.464(d)(2)(v), 441.555(b)(2)(iv), and 441.745(a)(1)(iii), respectively. However, to avoid duplication with the grievance requirements for managed care plans at part 438, subpart F, we did not propose to apply these requirements to managed care delivery systems.

We are finalizing the grievance process requirements we proposed at § 441.301(c)(7) with one substantive change. As discussed in section II.B.2. of this final rule, we are not finalizing the requirements we proposed at § 441.301(c)(7)(iv)(B) that States must have a 14-day expedited resolution process in addition to a standard 90-day resolution process for grievances. We do not anticipate that this change affects the burden estimates, as it does not change the recordkeeping requirements finalized at § 441.301(c)(7)(vii). In general, even with this change, the States will still have to perform all activities described below in order to establish and maintain the standard grievance process outlined in § 441.301(c)(7). Additionally, as we encourage States to develop their own expedited grievance process, we are calculating the burden estimate with the assumption that all States will choose to create their own version of an expedited resolution process within the grievance process required at § 441.301(c)(7).

We are finalizing the other grievance process proposals without substantive changes. Burden estimates for our finalized grievance process requirements are below.

a. States

The burden associated with the grievance system requirements finalized at § 441.301(c)(7) affect the 48 States (including the District of Columbia) that deliver at least some HCBS under sections 1915(c), (i), (j), or (k) authorities through FFS delivery systems.[383] [384]

[383] Arizona, Rhode Island, and Vermont do not have HCBS programs under any of these authorities.

[384] While some States deliver the vast majority of HCBS through managed care delivery systems, States would be subject to these requirements if they deliver any HCBS under section 1915(c), (i), (j), or (k) authorities through a fee-for service delivery system. Based on data showing that the percent of LTSS expenditures delivered through managed LTSS delivery systems varied between 3 percent and 93 percent in 2019 across all States with managed LTSS, we assume that all States deliver at least some HCBS through fee-for-service delivery systems (*https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltssexpenditures2019.pdf*). We anticipate that the burden associated with implementing these requirements will be lower for States that deliver the vast majority of HCBS through managed care delivery systems.

While some States may have existing grievance systems in place for their FFS delivery systems, we were unable to determine the number of States with existing grievance systems or whether those grievance systems would meet the finalized requirements at § 441.301(c)(7). As a result, we do not take this information into account in our burden estimate calculated below. We estimate a one-time and ongoing burden to implement these requirements at the State level.

Specifically, States will have to: (1) develop and implement policies and procedures; (2) establish processes and data collection tools for accepting, tracking, and resolving, within required timeframes, beneficiary grievances, including processes and tools for: providing beneficiaries with reasonable assistance with filing a grievance, for accepting grievances orally and in writing, for reviewing grievance resolutions with which beneficiaries are dissatisfied, and for providing beneficiaries with a reasonable opportunity to present evidence and testimony and make legal and factual arguments related to their grievance; (3) inform beneficiaries, providers, and subcontractors about the grievance system; and (4) develop beneficiary notices; and (5) collect and maintain information on each grievance, including the reason for the grievance, the date received, the date of each review or review meeting (if applicable), resolution and date of the resolution of the grievance (if applicable), and the name of the beneficiary for whom the grievance was filed.

i. One-Time Grievance System Requirements: States (§ 441.301(c)(7))

With regard to the one-time requirements, we estimate it will take: 240 hours at $111.18/hr for an administrative services manager to draft policy and procedure content, prepare notices and informational materials, draft rules for publication, and conduct public hearings; 100 hours at $98.84/hr for a computer programmer to build, design, and operationalize internal systems for data collection and tracking; 120 hours at $67.18/hr for a training and development specialist to develop and conduct training for staff; 40 hours at $118.14/hr for a general and operations manager to review and approve policies, procedures, rules for publication, notices, and training materials; and 20 hours at $236.96/hr for a chief executive to review and approve all operations associated with this collection of information requirement. In aggregate, we estimate a one-time burden of 24,960 hours (520 hr × 48 States) at a cost of $2,596,493 (48 States × [(240 hr × $111.18/hr) + (100 hr × $98.84/hr) + (120 hr × $67.18/hr) + (40 hr × $118.14/hr) + (20 hr × $236.96/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be $1,298,246 ($2,596,493 × 0.50).

TABLE 6: Summary of One-Time Burden Estimates for States for the Grievance System Requirements at § 441.301(c)(7)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Draft policy and procedures, rules for publication; prepare beneficiary notices, informational materials; conduct public hearings	48	48	Once	240	11,520	111.18	1,280,794	640,397
Build, design, operationalize internal systems for data collection and tracking	48	48	Once	100	4,800	98.84	474,432	237,216
Develop and conduct training for staff	48	48	Once	120	5,760	67.18	386,957	193,478
Review and approve policies, procedures, rules for publication, notices, and training materials at the management level	48	48	Once	40	1,920	118.14	226,829	113,415
Review and approve all operations in collection of information requirement at the chief executive level	48	48	Once	20	960	236.96	227,482	113,741
TOTAL	48	48	Once	Varies	24,960	Varies	2,596,493	1,298,246

ii. Ongoing Grievance System Requirements: States (§ 441.301(c)(7))

With regard to the on-going requirements, we estimate that approximately 2 percent of 1,460,363 Medicaid beneficiaries who receive HCBS under section 1915(c), (i), (j), or (k) authorities through FFS delivery systems annually [385] will file a grievance or appeal (29,207 grievances = 1,460,363 × 0.02).[386] We estimate it will take: 0.333 hours or 20 minutes at $79.50/hr for a business operations specialist to collect the required information for each grievance from the beneficiary (29,207 total grievances), 0.166 hours or 10 minutes at $36.52/hr for a data entry worker to record the required information on each grievance (29,207 total grievances), 20 hours at $98.84/hr for a computer programmer to maintain the system for storing information on grievances (48 States), 12 hours at $118.14/hr for a general and operations manager to monitor and oversee the collection and maintenance of the required information (48 States), and 2 hours at $236.96/hr for a chief executive to review and approve all operations associated with this collection of information requirement (48 States). In aggregate, we estimate an on-going burden of 16,206 hours at a cost of $1,135,949 ([(29,207 grievances × 0.333 hr × $79.50/hr) + (29,207 grievances × 0.166 hr × $36.52/hr) + (48 States × 20 hr × $98.84/hr) + (48 States × 12 hr × $118.14/hr) + (48 States × 2 hr × $236.96/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost is $567,975 ($1,135,949 × 0.50) per year.

TABLE 7: Summary of Ongoing Burden for States for the Grievance System Requirements at § 441.301(c)(7)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Collect required grievance data and information	48	29,207	On occasion	0.333	9,726	79.50	773,217	386,609
Enter required grievance data and information into data collection and tracking system	48	29,207	On occasion	0.166	4,848	36.52	177,049	88,525
Perform maintenance on system for storing data and information on grievances	48	48	Annually	20	960	98.84	94,886	47,443
Monitor and oversee the collection and maintenance of the required information at the management level	48	48	Annually	12	576	118.14	68,049	34,025
Review and approve all operations associated with collection of information requirement at the executive level	48	48	Annually	2	96	236.96	22,748	11,374
TOTAL	48	29,255 (29,207 + 48)	Varies	Varies	16,206	Varies	1,135,949	567,975

[385] *https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltss-user-brief-2019.pdf.*

[386] We based this percent on an estimate of the percent of Medicaid beneficiaries that file appeals and grievances in Medicaid managed care in Supporting Statement A for the information collection requirements for the Medicaid Managed Care file rule (CMS–2408–F, RIN 0938–AT40). See *https://omb.report/icr/202205-0938-015/doc/121334100* for more information.

4. ICRs Regarding Incident Management System (§ 441.302(a)(6); Applied to Other HCBS Authorities at §§ 441.464(e), 441.570(e), 441.745(a)(1)(v), and to Managed Care at § 438.72(b))

The following changes will be submitted to OMB for approval after this final rule is finalized and our survey instrument has been developed. The survey instrument and burden will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. In the meantime, we are setting out our burden figures (see below) as a means of scoring the impact of this rule's changes. The availability of the survey instrument and more definitive burden estimates will be announced in both **Federal Register** notices. The CMS ID number for that collection of information request is CMS–10854 (OMB control number 0938–TBD). Since this would be a new collection of information request, the OMB control number has yet to be determined (TBD) but will be issued by OMB upon their approval of the new collection of information request.

At § 441.302(a)(6), we are finalizing a requirement that States provide an assurance that they operate and maintain an incident management system that identifies, reports, triages, investigates, resolves, tracks, and trends critical incidents. At § 441.302(a)(6)(i)(A), we are finalizing that States must establish a minimum standard definition of a critical incident. At § 441.302(a)(6)(i)(B) we are finalizing a requirement that States must have electronic incident management systems that, at a minimum, enable electronic collection, tracking (including tracking of the status and resolution of investigations), and trending of data on critical incidents.

We are finalizing the requirements we proposed at § 441.302(a)(6)(i) without substantive changes, but we are finalizing a change to the applicability date for the electronic management system requirement. We had proposed that States would need to comply with the requirements at § 441.302(a)(6) in 3 years. We are finalizing the 3-year applicability date for the requirements at § 441.302(a)(6) with the exception of the electronic incident management system finalized at § 441.302(a)(6)(i)(B), which has a finalized applicability date of 5 years. We do not anticipate that this change will affect the activities described in these burden estimates; the primary effect of this change is to grant States two additional years in which to develop electronic incident management systems, for which they will perform the same activities.

At § 441.302(a)(6)(i)(C), we finalized that States require providers to report to States any critical incidents that occur during the delivery of section 1915(c) waiver program services as specified in a waiver participant's person-centered service plan or are a result of the failure to deliver authorized services. At § 441.302(a)(6)(i)(D), we finalized that States must use claims data, Medicaid Fraud Control Unit data, and data from other State agencies such as Adult Protective Services or Child Protective Services to the extent permissible under applicable State law to identify critical incidents that are unreported by providers and occur during the delivery of section 1915(c) waiver program services, or as a result of the failure to deliver authorized services. At § 441.302(a)(6)(i)(E) we finalized a new requirement that the State must ensure medical records being used as part of the incident management system are handled in compliance with 45 CFR 164.510(b) to ensure that records with protected health information used during critical incident review are obtained and used with beneficiaries' consent. We are finalizing at § 441.302(a)(6)(i)(F) a requirement that States share information on the status and resolution of investigations if the State refers critical incidents to other entities for investigation. We are finalizing at § 441.302(a)(6)(i)(G) a requirement that States separately investigate critical incidents if the investigative agency fails to report the resolution of an investigation within State-specified timeframes. We are finalizing at § 441.302(a)(6)(i)(H) a requirement that States meet the reporting requirements at § 441.311(b)(1) related to the performance of their incident management systems.

At § 441.302(a)(6)(iii), we are the application of these requirements to services delivered under FFS or managed care delivery systems. We also finalized the application of the requirements finalized at § 441.302(a)(6) to sections 1915(j), (k), and (i) State plan services by cross-referencing at §§ 441.570(e), 441.464(e), and 441.745(a)(1)(v), respectively.

With the exception of the change to the effective date for electronic incident management systems noted above, we are finalizing the requirements described herein without substantive modification. Burden estimates for these requirements are discussed below.

We received one comment on the proposed burden estimate for the incident management provision. This comment, and our response, is summarized below.

Comment: One commenter noted that when their State investigated developing a single electronic incident management system in 2014, the State estimated the cost of consolidating multiple State systems into a single system would be $100 million and believed that it would be even more expensive to create such a system now.

Response: We thank the commenter for their feedback. Without more detailed information, provided, we decline to update our burden estimate for the incident management ICR based on this comment. We believe most States that require upgrades to their system could do so within the costs that we estimated; we will provide technical assistance on an as-need basis for States to identify efficient ways to upgrade their systems.

We also note that according to the finalized requirements in § 441.302(a)(6), States must have electronic critical incident systems that, at a minimum, enable electronic collection, tracking (including of the status and resolution of investigations), and trending of data on critical incidents. We are recommending, but not requiring, that States develop a single electronic critical incident system for all of their HCBS programs under sections 1915(c), (i), (j), and (k) authorities, as we believe that a single system will best enable States to prevent the occurrence of critical incidents and protect the health and safety of beneficiaries across their lifespan. We recognize that States may have to make certain decisions about the development of their electronic incident management system according to current system constraints.

a. States

The burden associated with the incident management system requirements proposed at § 441.302(a)(6) will affect the 48 States (including Washington DC) that deliver HCBS under section 1915(c), (i), (j), or (k) authorities.[387] We estimate a one-time and on-going burden to implement these requirements at the State level. The burden for the reporting requirements at § 441.311(b)(1) is included in the ICR #8, which is the ICRs Regarding Compliance Reporting (§ 441.311(b)).

All of the States impacted by § 441.302(a)(6)(i)(B), requiring that States use an information system, as

[387] Arizona, Rhode Island, and Vermont do not have HCBS programs under any of these authorities.

defined in 45 CFR 164.304 and compliant with 45 CFR part 164, have existing incident management systems in place. However, we assume that all States will need to make at least some changes to their existing systems to fully comply with the proposed requirements. Specifically, States will have to update State policies and procedures; implement new or update existing electronic incident management systems; publish revised provider requirements through State notice and publication processes; update provider manuals and other policy guidance; amend managed care contracts; collect required information from providers; use other required data sources to identify unreported incidents; and share information with other entities in the State responsible for investigating critical incidents.

i. One Time Incident Management System Requirements: States (§ 441.302(a)(6))

With regard to the one-time requirements related to § 441.302(a)(6), we estimate it will take: 120 hours at $111.18/hr for an administrative services manager to draft policy content, prepare notices and draft rules for publication, conduct public hearings, and draft contract modifications for managed care plans; 20 hours at $100.64/hr for a management analyst to update provider manuals; 80 hours at $67.18/hr for a training and development specialist to develop and conduct training for providers; 80 hours at $79.50/hr for a business operations specialist to establish processes for information sharing with other entities; 80 hours at $106.30/hr for a computer and information analyst to build, design, and implement reports for using claims and other data to identify unreported incidents; 24 hours at $118.14/hr for a general and operations manager to review and approve managed care contract modifications, policy and rules for publication, and training materials; and 10 hours at $236.96/hr for a chief executive to review and approve all operations associated with this requirement.

In aggregate, we estimate a one-time burden of 19,872 hours (414 hr × 48 States) at a cost of $1,958,292 (48 States × [(120 hr × $111.18/hr) + (20 hr × $100.64/hr) + (80 hr × $67.18/hr) + (80 hr × $79.50/hr) + (80 hr × $106.30/hr) + (24 hr × $118.14/hr) + (10 hr × $236.96/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be $979,146 ($1,958,292 × 0.50).

In addition, we estimate that States, based on the results of the incident management system assessment discussed earlier in section II.B.3. of this preamble, that 82 percent of States, or 39 States (48 States × 0.82), will need to update existing electronic incident management systems, while the remaining 9 States would need to implement new electronic incident management systems, to meet the proposed requirement at § 441.302(a)(6)(i)(B). We estimate based on information reported by some States in spending plans for section 9817 of the American Rescue Plan Act of 2021 that the cost per State to update existing electronic systems is $2 million while the cost per State to implement new electronic systems is $5 million.[388] In aggregate, we estimate a one-time technology burden of $123,000,000 [($2,000,000 × 39 States) + ($5,000,000 × 9 States)]. Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be $61,500,000 ($123,000,000 × 0.50).

BILLING CODE 4120–01–P

[388] Enhanced Federal Financial Participation (FFP) is available at a 90 percent Federal Medical Assistance Percentage (FMAP) rate for the design, development, or installation of improvements of mechanized claims processing and information retrieval systems, in accordance with applicable Federal requirements. Enhanced FFP at a 75 percent FMAP rate is also available for operations of such systems, in accordance with applicable Federal requirements. However, the receipt of these enhanced funds is conditioned upon States meeting a series of standards and conditions to ensure investments are efficient and effective. As a result, we do not assume for the purpose of this burden estimate that States will qualify for the enhanced Federal match. This estimate overestimates State burden to the extent that States qualify for the enhanced Federal match.

TABLE 8: Summary of One-Time Burden for States for the Incident Management System Requirements (§ 441.302(a)(6))

Requirement	No. Respond-ents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Draft policy content, prepare notices and draft rules for publication, conduct public hearings, and draft contract modifications for managed care plans	48	48	Once	120	5,760	111.18	640,397	320,198
Update provider manuals	48	48	Once	20	960	100.64	96,614	48,307
Develop and conduct training for providers	48	48	Once	80	3,840	67.18	257,971	128,986
Establish processes for information sharing with other entities	48	48	Once	80	3,840	79.50	305,280	152,640
Build, design, and implement reports for using claims and other data to identify unreported incidents	48	48	Once	80	3,840	106.30	408,192	204,096
Review and approve managed care contract modifications, policy and rules for publication, and training materials at the management level	48	48	Once	24	1,152	118.14	136,097	68,049
Review and approve all operations associated with this requirement at the executive level	48	48	Once	10	480	236.96	113,741	56,871
Subtotal Labor-Related Burden	*48*	*48*	*Once*	*Varies*	*19,872*	*Varies*	*1,958,292*	*979,146*
Update existing electronic incident management systems	48	39	Once	n/a	n/a	$2,000,000/ system (contractor)	78,000,000	39,000,000
Implement new electronic systems	48	9	Once	n/a	n/a	$5,000,000/ system (contractor)	45,000,000	22,500,000
Subtotal Non-Labor Burden	*48*	*48*	*Once*	*n/a*	*n/a*	*Varies*	*123,000,000*	*61,500,000*
TOTAL	48	96	Once	varies	19,872	Varies	124,958,292	62,479,146

BILLING CODE 4120–01–C

ii. Ongoing Incident Management System Requirements: States (§ 441.302(a)(6))

With regard to the ongoing requirements § 441.302(a)(6), we estimate that there are 0.5 critical incidents annually [389] for each of the 1,889,640 Medicaid beneficiaries who receive HCBS under sections 1915(c), (i), (j), or (k) authorities annually, or 944,820 (1,889,640 × 0.5) critical incidents annually.[390] We further estimate that, based on data on unreported incidents, these requirements will result in the identification of 30 percent more critical incidents annually, or 283,446 (944,820 × 0.3) critical incidents; [391] that 76 percent, or 215,419 (283,446 × 0.76) will be reported for individuals enrolled in FFS delivery systems; [392] and that 10 percent of those for individuals enrolled in FFS delivery systems (21,542 = 215,419 × 0.1) will be made through provider reports and 90 percent (193,877 = 215,419 × 0.9) through claims identification and other sources.[393] We estimate 0.166 hr or 10 minutes at $36.52/hr for a data entry worker to record the information on each reported critical incident reported by providers for individuals enrolled in FFS delivery systems. In aggregate, we estimate an ongoing burden each year of 3,576 hours (21,542 incidents × 0.166 hr) at a cost of $130,594 (3,576 hr × $36.52/hr) to record the information on each reported critical incident reported by providers for individuals enrolled in FFS delivery systems. While States can establish different processes for the reporting of critical incidents for individuals enrolled in managed care, we assume for the purpose of this analysis that the States would delegate provider reporting critical incidents and identification of critical incidents through claims and other data sources to managed care plans and that the managed care plans would be responsible for reporting the identified critical incidents to the State.[394] We further assume that the information reported by managed care plans to the State and identified by the State through claims and other data sources would be in an electronic form. For the 68,027 more critical incidents for individuals enrolled in managed care (283,446 more critical incidents identified × 24 percent for individuals enrolled in managed care), and the 193,877 more critical incidents identified through claims and other data sources for individuals enrolled in FFS (283,446 more critical incidents identified × 76 percent for individuals enrolled in FFS × 90 percent identified through claims and other sources), we estimate 2 minutes (0.0333 hr) at $36.52/hr for a data entry worker to record the information on each of these 261,904 critical incidents (68,027 + 193,877). In aggregate, for § 441.302(a)(6), we estimate an ongoing annual burden of 8,721 hours (261,904 incidents × 0.0333 hr) at a cost of $318,491 (8,721 hr × $36.52/hr) on these critical incidents.

In total, for § 441.302(a)(6), we estimate an ongoing burden each year of 12,297 hours (3,576 hr + 8,721 hr) at a cost of $449,085 ($130,594 + $318,491) to record the information on all critical further estimate it would take 12 hours at $79.50/hr for a business operations specialist to maintain processes for information sharing with other entities; 20 hours at $106.30/hr for a computer and information analyst to update and maintain reports for using claims and other data to identify unreported incidents; 24 hours at $118.14/hr for a general and operations manager to monitor the operations associated with this requirement; and 4 hours at $236.96/hr for a chief executive to review and approve all operations associated with this collection of information requirement in each State. In aggregate, we estimate an ongoing burden of 15,177 hours ([60 hr × 48 States] + 12,297 hr) at a cost of $778,520 ($449,085 + [48 States × ((12 hr × $79.50/hr) + (20 hr × $106.30/hr) + (24 hr × $118.14/hr) + 4 hr × $236.96/hr)]). In addition, we estimate an on-going annual technology-related cost of $500,000 per State for States to maintain their electronic incident management systems. In aggregate, we estimate an ongoing burden of $24,000,000 ($500,000 × 48 States) for States to maintain their electronic incident management systems. In total, we estimate an ongoing annual burden of 15,177 hours at a cost $24,778,520 ($778,520 + $24,000,000). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be $12,389,260 ($24,778,520 × 0.50).

BILLING CODE 4120–01–P

[389] Data on the number of critical incidents is limited. We base our estimate on available public information, such as *https://oig.hhs.gov/oas/reports/region7/71806081.pdf* and *https://dhs.sd.gov/servicetotheblind/docs/2015%20CIR%20Annual%20Trend%20Analysis.pdf.*

[390] *https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltss-user-brief-2019.pdf.*

[391] Data on the number of unreported critical incidents is limited. We base our estimate on available public information, such as *https://pennlive.com/news/2020/01/possible-abuse-of-group-home-residents-wasnt-adequately-tracked-in-pa-federal-audit.html* and *https://www.kare11.com/article/news/local/federal-audit-finds-maine-dhhs-failed-to-investigate-multiple-deaths-critical-incidents/97-463258015.*

[392] *https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltss-user-brief-2019.pdf.*

[393] Data is limited on the identification of critical incidents through various data sources. We conservatively assume that 25 percent of more critical incidents identified as a result of these requirements will be reported by providers even though claims data will likely identify a substantially higher of percentage of claims than will be reported by providers.

[394] Addressing Critical Incidents in the MLTSS Environment: Research Brief, ASPE, *https://aspe.hhs.gov/reports/addressing-critical-incidents-mltss-environment-research-brief-0.*

TABLE 9: Summary of Ongoing Burden for States for the Incident Management System Requirements at § 441.302(a)(6)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Record the information on each reported critical incident reported by providers for individuals enrolled in FFS delivery systems	48	21,542	Annually	0.166	3,576	36.52	130,596	65,298
Record the information on critical incidents for individuals enrolled in managed care and critical incidents identified through claims and other data sources for individuals enrolled in FFS	48	261,904	Annually	0.033	8,721	36.52	318,491	159,245
Maintain processes for information sharing with other entities	48	48	Annually	12	576	79.50	45,792	22,896
Update and maintain reports for using claims and other data to identify unreported incidents	48	48	Annually	20	960	106.30	102,048	51,024
Monitor operations associated with this requirement at the management level	48	48	Annually	24	1,152	118.14	136,097	68,048
Review and approve all operations associated with this collection of information requirement at the executive level	48	48	Annually	4	192	236.96	45,496	22,748
Subtotal: Labor Related Burden	*48*	*283,494 (21,542 + 261,904 + 48)*	*Annually*	*Varies*	*15,177*	*Varies*	*778,520*	*389,260*
Maintain electronic incident management systems (specifically, § 441.302(a)(6)(i)(B))	48	48	Annually	n/a	n/a	500,000/ system (contractor)	24,000,000	12,000,000
Total Technology Cost	*48*	*48*	*Annually*	*n/a*	*n/a*	*500,000 system (contractor)*	*24,000,000*	*12,000,000*
TOTAL	48	283,542 (283,494 + 48)	Annually	Varies	15,177	Varies	24,778,520	12,389,260

BILLING CODE 4120–01–C

b. Service Providers and Managed Care Plans

The burden associated with this final rule will affect service providers that provide HCBS under sections 1915(c), (i), (j), and (k) authorities, as well as managed care plans that States contract with to provide managed long-term services and supports.

The following discussion estimates an ongoing burden for service providers to implement these requirements and both a one-time and ongoing burden for managed care plans.

i. On-Going Incident Management System Requirements: Service Provider

To estimate the number of service providers that will be impacted by this final rule, we used unpublished data from the Provider Relief Fund to estimate that there are 19,677 providers nationally across all payers delivering the types of HCBS that are delivered under sections 1915(c), (i), (j), and (k) authorities. We then prorate the number to estimate the number of providers in the 48 States that are subject to this requirement (19,677 providers nationally × 48 States subject to the proposed requirement/51 States = 18,520 providers). We used data from the Centers for Disease Control and Prevention [395] to estimate the percentage of these HCBS providers that participate in Medicaid and, due to uncertainty in the data and differences in provider definitions, estimate both a lower and upper range of providers affected. At a low end of 78 percent Medicaid participation, we estimate that there are 14,446 providers impacted (18,520 providers × 0.78), while at a high end of 85 percent participation, we estimate that there are 15,742 providers impacted (18,520 providers × 0.85). To be conservative and not underestimate our projected burden analysis, we are using the high end of our estimates to score the PRA-related impact of the changes.

As discussed earlier, we estimate that providers will report 10 percent, or 28,345, of the more critical incidents (283,446 more critical incidents × 0.10) identified annually as a result of these requirements. Based on these figures, we estimate that, on average, each provider will report 1.8 (28,345 incidents/15,742 providers) more critical incidents annually. We further estimate that, on average, it would take a provider 1 hour at $118.14/hr for a general and operations manager to collect the required information and report the information to the State or to the managed care plan as appropriate for each incident.[396] In aggregate, for § 441.302(a)(6), we estimate an ongoing burden of 28,345 hours (28,345 incidents × 1 hr) at a cost of $3,348,678 (28,345 hr × $118.14/hr).

TABLE 10: Summary of Ongoing Burden for Service Providers for the Incident Management System Requirements

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Collect the required information and report the information to the State or to the managed care plan (§ 441.302(a)(6)(i)(C))	15,742 providers	28,345 incidents	Annually	1	28,345	118.14	3,348,678	n/a
Total	15,742 providers	28,345 incidents	Annually	1	28,345	118.14	3,348,678	n/a

ii. One Time Incident Management System Requirements: Managed Care Plans (§ 441.302(a)(6))

As required under § 441.302(a)(6), while States can establish different processes for the reporting of critical incidents for individuals enrolled in managed care, we assume for the purpose of this analysis that the States will delegate provider reporting of critical incidents and identification of critical incidents through claims and other data sources to managed care plans and that the plans will be responsible for reporting the identified critical incidents to the State.[397] We further assume that the information reported by managed care plans to the State would be in an electronic form.

We estimated that there are 161 managed long-term services and supports plans providing services across 25 States.[398] With regard to the one-time requirements at § 441.302(a)(6), we estimate it would take: 20 hours at $111.18/hr for an administrative

[395] *https://www.cdc.gov/nchs/data/series/sr_03/sr03_43-508.pdf.*

[396] The actual amount of time for each incident will vary depending on the nature of the critical incident and the specific reporting requirements of each State and managed care plan. This estimate assumes that some critical incidents will take substantially less time to report, while others could take substantially less time.

[397] Addressing Critical Incidents in the MLTSS Environment: Research Brief, available at *https://aspe.hhs.gov/reports/addressing-critical-incidents-mltss-environment-research-brief-0.*

[398] ''A View from the States: Key Medicaid Policy Changes: Results from a 50-State Medicaid Budget Survey for State Fiscal Years 2019 and 2020,'' *https://www.kff.org/report-section/a-view-from-the-states-key-medicaid-policy-changes-long-term-services-and-supports/.*

services manager to draft policy for contracted providers; 20 hours at $100.64/hr for a management analyst to update provider manuals; 40 hours at $67.18/hr for a training and development specialist to develop and conduct training for providers; 80 hours at $106.30/hr for a computer and information analyst to build, design, and implement reports for using claims and other data to identify unreported incidents; and 6 hours at $236.96/hr for a chief executive to review and approve all operations associated with this requirement. In aggregate, we estimate a one-time burden of 26,726 hours (161 managed care plans × 166 hr) at a cost of $2,712,747 (161 managed care plans × [(20 hr × $111.18/hr) + (20 hr × $100.64/hr) + (40 hr × $67.18/hr) + (80 hr × $106.30/hr) + (6 hr × $236.96/hr)]).

TABLE 11: Summary of One-Time Burden for Managed Care Plans for the Incident Management System Requirements at § 441.302(a)(6)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Draft policy for contracted providers	161	161	Once	20	3,220	111.18	358,000	n/a
Update provider manuals	161	161	Once	20	3,220	100.64	324,061	n/a
Develop and conduct training for providers	161	161	Once	40	6,440	67.18	432,639	n/a
Build, design, and implement reports for using claims and other data to identify unreported incidents	161	161	Once	80	12,880	106.30	1,369,144	n/a
Review and approve all operations associated with this requirement	161	161	Once	6	966	236.96	228,903	n/a
Total	161	161	Once	Varies	26,726	Varies	2,712,747	n/a

iii. Ongoing Incident Management System Requirements: Managed Care Plans (§ 441.302(a)(6))

The ongoing burden to managed care plans consists of the collection and maintenance of information on critical incidents. As noted earlier, we estimate that these requirements will result in the identification of 283,446 more critical incidents annually than are currently identified by States. We further estimate that 24 percent, or 68,027 (283,446 × 0.24), will be reported for individuals enrolled in managed care delivery systems [399] and that 10 percent, or 6,803 (68,027 × 0.10), will be made through provider reports and 90 percent, or 61,224 (68,027 × 0.90), through claims identification and other sources.[400] We estimate that it will take 0.166 hr at $36.52/hr for a data entry worker to record the information on each reported critical incident reported by providers (§ 441.302(a)(6)(i)(B)(*2*)). In aggregate, we estimate an ongoing burden of 1,129 hours (6,803 critical incidents made through provider reports × 0.166 hr) at a cost of $41,231 (1,129 hr × $36.52/hr). We also estimate that it will take: 20 hours at $106.30/hr for a computer and information analyst to update and maintain reports for using claims and other data to identify unreported incidents (§ 441.302(a)(6)(i)(B)(*3*)); 6 hours at $118.14/hr for a general and operations manager to monitor the operations associated with this requirement and report the information to the State (§ 441.302(a)(6)(i)(E)); and 1 hour at $236.96/hr for a chief executive to review and approve all operations associated with this collection of information requirement (§ 441.302(a)(6)(i)(G)). In aggregate, we estimate an ongoing burden of 5,476 hours (1,129 hr + [161 managed care plans × 27 hr]) at a cost of $535,791 ($41,231 + (161 managed care plans × [(20 hr × $106.30/hr) + (6 hr × $118.14/hr) + (1 hr × $236.96/hr)]).

BILLING CODE 4120–01–P

[399] *https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltss-user-brief-2019.pdf.*

[400] Data is limited on the identification of critical incidents through various data sources. We conservatively assume that 25 percent of additional critical incidents identified as a result of these requirements will be reported by providers even though claims data will likely identify a substantially higher of percentage of claims than will be reported by providers.

TABLE 12: Summary of Ongoing Burden for Managed Care Plans for the Incident Management System Requirements

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Record the information on each reported critical incident reported by providers (§441.302(a)(6)(i)(B)(2))	161	6,803	Annually	0.166	1,129	36.52	41,231	n/a
Update and maintain reports for using claims and other data to identify unreported incidents (§441.302(a)(6)(i)(B)(3))	161	161	Annually	20	3,220	106.30	342,286	n/a
Monitor the operations associated with this requirement and report the information to the State (§441.302(a)(6)(i)(E))	161	161	Annually	6	966	118.14	114,123	n/a
Review and approve all operations associated with this requirement (§441.302(a)(6)(i)(G))	161	161	Annually	1	161	236.96	38,151	n/a
Total	161	6,964 (6,803 + 161)	Annually	Varies	5,476	Varies	535,791	n/a

BILLING CODE 4120–01–C

5. ICRs Regarding Payment Adequacy Reporting (§ 441.311(e); Applied to Other HCBS Authorities at §§ 441.474(c), 441.580(i), and 441.745(a)(1)(vii) and to Managed Care at § 438.72(b))

The following changes will be submitted to OMB for approval after this final rule is finalized and when our survey instrument has been developed. The survey instrument will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. In the meantime, we are setting out our burden figures (see below) as a means of scoring the impact of this rule's changes. The availability of the survey instrument and more definitive burden estimates will be announced in both **Federal Register** notices. The CMS ID number for that collection of information request is CMS–10854 (OMB control number 0938–TBD). Since this would be a new collection of information request, the OMB control number has yet to be determined (TBD) but will be issued by OMB upon their approval of the new collection of information request.

We finalized at § 441.311(e)(2) a new requirement that States report to us annually on the percentage of total payments (not including excluded costs) for furnishing homemaker services, home health aide services, personal care, and habilitation services, as set forth in § 440.180(b)(2) through (4) and (6), that are spent on compensation for direct care workers.

Section 441.311(e)(1)(i), as finalized, defines compensation to include salary, wages, and other remuneration as defined by the Fair Labor Standards Act and implementing regulations (29 U.S.C. 201 *et seq.*, 29 CFR parts 531 and 778); benefits (such as health and dental benefits, paid leave, and tuition reimbursement); and the employer share of payroll taxes for direct care workers delivering services authorized under section 1915(c) of the Act. Section 441.311(e)(1)(ii), as finalized, defines direct care workers to include workers who provide nursing services, assist with activities of daily living (such as mobility, personal hygiene, eating), or provide support with instrumental activities of daily living (such as cooking, grocery shopping, managing finances). Specifically, direct care workers include nurses (registered

nurses, licensed practical nurses, nurse practitioners, or clinical nurse specialists) who provide nursing services to Medicaid-eligible individuals receiving HCBS, licensed or certified nursing assistants, direct support professionals, personal care attendants, home health aides, and other individuals who are paid to directly provide services to Medicaid beneficiaries receiving HCBS to address activities of daily living or instrumental activities of daily living. Direct care workers include individuals employed by a Medicaid provider, State agency, or third party; contracted with a Medicaid provider, State agency, or third party; or delivering services under a self-directed service model. (Refer to section II.B.5. of this final rule for complete discussion of these definitions.)

We are also finalizing § 441.311(e) to include a definition of excluded costs at § 441.311ek)(1)(iii). Excluded costs are costs that are not included in the calculation of the percentage of Medicaid payments to providers that is spent on compensation for direct care workers. Such costs are limited to: costs of required trainings for direct care workers (such as costs for qualified trainers and training materials); travel reimbursements (such as mileage reimbursement or public transportation subsidies) provided to direct care workers; and personal protective equipment for direct care workers. This policy was not included in the NPRM calculations. While we do not believe the policy of allowing providers to deduct excluded costs will affect the activities described in this cost estimate, we acknowledge that they may require additional time for some of the activities (such as drafting policy manuals or training providers on the policy.) These costs have been added to the revised burden estimate.

As discussed in section II.B.7. of this rule, we had initially proposed at § 441.311(e) that States would be required to report on the percent of Medicaid compensation spent on compensation for direct care workers providing homemaker, home health aide, and personal care services as defined at § 440.180(b)(2) through (4), and that the State must report this data for each service, with self-directed services reported separately. We are finalizing this requirement to include reporting on an additional service (habilitation services, as defined at § 440.180(b)(6)). We are also finalizing a new requirement that in addition to reporting by service, with separate reporting for self-directed services, States must also report facility-based services separately. Below, we include in our revised calculations the increased anticipated burden associated with the addition of reporting on habilitation services and separate reporting for facility-based services in § 441.311(e). We anticipate an increased burden on States and managed care plans to address data collection on the additional services. While we are increasing our estimate of the number of impacted providers, we do not believe this will change providers' activities associated with this requirement.

To ensure that States are prepared to comply with the reporting requirement at § 441.311(e)(2), we are finalizing a requirement at § 441.311(e)(3) to require that one year prior to the first payment adequacy report, States must provide a status update on their readiness to report the data required in § 441.311(e)(2). This will allow us to identify States in need of additional support to come into compliance with § 441.311(e)(2) and provide targeted technical assistance to States as needed. Our burden estimate below has been revised to include the activities associated with the State's one-time submission of this report. We do not anticipate an additional burden on managed care plans or providers associated with this requirement.

We also finalized at § 441.311(e)(4) an exemption for the Indian Health Service and Tribal health programs subject to 25 U.S.C. 1641, which exempts these providers from the requirements in § 441.311(e). Based on internal figures, we believe that about 100 HCBS provide As discussed in section II.B.7. of this final rule, we are applying the finalized requirements at § 441.311(e) to services delivered in both FFS and managed care delivery systems. We are applying the requirements to services that are delivered in 1915(c), (i) and (k) programs. We note also that the reporting requirement will go into effect 4 years after this rule is finalized.

We are finalizing the requirements at §§ 441.311(e) with the substantive modifications as described above. Burden estimates for the finalized requirements are below. We note an additional change to the burden estimates. As presented in the proposed rule at 88 FR 28047, we had presented the burden estimate of both the payment adequacy reporting requirement at § 441.311(e) and the HCBS payment adequacy minimum performance requirements at § 441.302(k) in a single ICR. Since the publication of the NPRM, upon further consideration we have determined that as §§ 441.302(k) and 441.311(e) represent distinct sets of requirements, it is more appropriate to present the costs associated with § 441.302(k) under a separate ICR (ICR 11) in this section IV. of the final rule.

However, while § 441.311(e) represents a distinct set of requirements from those in § 441.302(k), we also expect that States will employ certain efficiencies in complying with both §§ 441.302(k) and 441.311(e). In particular, we expect that States will build a single IT infrastructure and use the same processes both for collecting data for the reporting requirement at § 441.311(e) and for determining providers' compliance with HCBS payment adequacy performance requirements at § 441.302(k). The burden associated with States' development of infrastructure and processes to determine what percentage of HCBS providers' Medicaid payments for certain HCBS is spent on direct care worker compensation, as well as providers' reporting of this information to the State, is included in this ICR for § 441.311(e). We believe representing these costs under only one ICR avoids duplicative or inflated burden estimates. Burden estimates associated specifically with the minimum performance requirements in § 441.302(k) are presented in ICR 11 of this Collection of Information (section IV. of this final rule.)

a. State Burden

The burden associated with the requirements at § 441.311(e) will affect the 48 States (including Washington DC) that deliver HCBS under sections 1915(c), (i), (j), or (k) authorities.[401] [402] We estimate both a one-time and ongoing burden to implement these requirements at the State level.

Under § 441.311(e), we expect that States will have to: (1) draft new policy (one-time); (2) update provider manuals and other policy guidance to include reporting requirements (including information regarding excluded costs) for each of the services subject to the requirement (one-time); (3) inform providers of services through State notification processes, both initially and annually of reporting requirements (one-time and ongoing); (4) assess State systems and submit a one-time report to us on the State's readiness to comply with the ongoing reporting requirement at 441.311(e)(2) (one-time); (5) collect the information from providers for each service required (ongoing); (6) aggregate the data broken down by each service, as well as self-directed services

[401] Arizona, Rhode Island, and Vermont do not have HCBS programs under any of these authorities.

[402] For purposes of this burden analysis, we are not taking into consideration temporary wage increases or bonus payments that have been or are being made.

(ongoing); (7) derive an overall percentage for each service including self-directed services (ongoing); and (8) report to us on an annual basis (ongoing).

i. One Time Payment Adequacy Reporting Requirements (§ 441.311(e)): State Burden

With regard to the one-time requirements, we estimate it will take: 40 hours at $111.18/hr for an administrative services manager to: draft policy content, and draft provider agreements and contract modifications for managed care plans; 20 hours at $100.64/hr for a management analyst to update provider manuals for each of the affected services; 32 hours at $98.84/hr for a computer programmer to build, design, and operationalize internal systems for collection, aggregation, stratification by service, reporting, and creating remittance advice; 50 hours at $67.18/hr for a training and development specialist to develop and conduct training for providers on the reporting elements and reporting process; 20 hours at $118.14/hr for a general and operations manager to: review, approve managed care contract modifications, policy and rules for publication, and training materials, and to complete the annual reporting and complete the reporting readiness report (required at § 441.311(e)(3)) for submission to CMS; and 10 hours at $236.96/hr for a chief executive to review and approve all operations associated with these requirements.

In aggregate, we estimate a one-time burden of 7,776 hours (172 hr × 48 States) at a cost of $850,285 (48 States × [(40 hr × $111.18/hr) + (20 hr × $100.64/hr) + (32 hr × $98.84/hr) + (50 hr × $67.18/hr) + (20 hr × $118.14/hr) + (10 hr × $236.96/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be $425,143 ($850,285 × 0.50).

BILLING CODE 4120–01–P

TABLE 13: Summary of One-Time Burden for States for the Payment Adequacy Reporting Requirements at § 441.311(e)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Draft policy content, and draft provider agreements and contract modifications for managed care plans	48	48	Once	40	1,920	111.18	213,466	106,733
Update provider manuals for each of the affected service	48	48	Once	20	960	100.64	96,614	48,307
Build, design, and operationalize internal systems for collection, aggregation, stratification by service, reporting, and creating remittance advice	48	48	Once	32	1,536	98.84	151,818	75,909
Develop and conduct training for providers on the reporting elements and reporting process	48	48	Once	50	2,400	67.18	161,232	80,616
Review, approve managed care contract modifications, policy and rules for publication, and training materials, and to complete the annual reporting and complete the reporting readiness report (required at § 441.311(e)(3)) for submission to CMS	48	48	Once	20	960	118.14	113,414	56,707
Review and approve all operations associated with this requirement	48	48	Once	10	480	236.96	113,74	56,780
Total	48	48	Once	Varies	7,776	varies	850,285	425,173

ii. Ongoing Payment Adequacy Reporting Requirements (§ 441.311(e)): State Burden

With regard to the ongoing requirements, we estimate it will take 8 hours at $98.84/hr for a computer programmer to: (1) collect the information from all providers for each service required; (2) aggregate and stratify by each service as well as self-directed services; (3) derive an overall percentage for each service including self-directed and facility-based services; and (4) develop the reports for CMS on an annual basis. We also estimate it will take: 10 hours at $67.18 for a training and development specialist to develop and conduct training for providers on the reporting elements and reporting process; 5 hours at $118.14/hr by a general and operations manager to

review, verify, and approve reporting required at § 441.311(e)(2) to CMS; and 2 hours at $236.96/hr for a chief executive to review and approve all operations associated with these requirements.

In aggregate, we estimate an ongoing burden of 1,200 hours (25 hr × 48 States) at a cost of $121,302 (48 States × [(8 hr × $98.84/hr) + (10 hr × $67.18) + (5 hr × $118.14/hr) + (2 hr × $236.96/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be $60,651 ($121,302 × 0.50) per year.

TABLE 14: Summary of Ongoing Burden for States for Payment Reporting Requirements at § 441.311(e)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Collect information from providers; aggregate and stratify data as required; derive an overall percentage for each service; identify percentages for providers subject to flexibilities; and develop report annually	48	48	Annually	8	384	98.84	37,954	18,977
Develop and conduct annual training for providers on the reporting elements and reporting process	48	48	Annually	10	480	67.18	32,246	16,123
Review, verify and approve reporting as required in § 441.302(k) and § 441.311(e) -to CMS	48	48	Annually	5	240	118.14	28,354	14,177
Review and approve all operations associated with reporting requirements at § 441.302(k) and § 441.311(e)	48	48	Annually	2	96	236.96	22,748	11,374
Total	Varies	48	Annually	Varies	1,200	Varies	121,302	60,651

BILLING CODE 4120–01–C

b. Service Providers and Managed Care Plans

The burden associated with this final rule will affect both service providers that provide the services listed at § 440.180(b)(2) through (4) and (6) across HCBS programs as well as managed care plans that contract with the States to provide managed long-term services and supports. We estimate both a one-time and ongoing burden to implement the reporting requirements § 441.311(e) for both service providers and managed care plans.

As noted in the proposed rule at 88 FR 28049, we had estimated an impact on 11,155 HCBS providers that provided homemaker, home health aide, or personal care services. We are adjusting this burden estimate to account for the inclusion of providers that also provide habilitation services in the finalized requirements in § 441.311(e). To estimate the number of service providers that will be impacted by this final rule, we used unpublished data from the Provider Relief Fund to estimate that there are 19,677 providers nationally across all payers delivering the types of HCBS that are delivered under sections 1915(c), (i) and (k) authorities. We then prorate the number to estimate the number of providers in the 48 States that are subject to this requirement (19,677 providers nationally × 48 States subject to the requirement/51 States = 18,520 providers). We used data from the Centers for Disease Control and Prevention[403] to estimate the percentage of these HCBS providers that participate in Medicaid and, due to uncertainty in the data and differences in provider

[403] *https://www.cdc.gov/nchs/data/series/sr_03/sr03_43-508.pdf.*

definitions, estimate both a lower and upper range of providers affected. At a low end of 78 percent Medicaid participation, we estimate that there are 14,446 providers impacted (18,520 providers × 0.78), while at a high end of 85 percent participation, we estimate that there are 15,742 providers impacted (18,520 providers × 0.85). To be conservative and not underestimate our projected burden analysis, we are using the high end of our estimates to score the PRA-related impact of the changes. We also note that it is possible that some of the providers included in this count do not provide the services impacted by § 441.311(e) (homemaker, home health aide, personal care, or habilitation services.) However, as we believe a significant number of the providers included in this count do provide at least one of these services. We note that from this number (15,742) we are subtracting 100 providers to represent the providers we believe will be eligible for the exemption at § 441.311(e)(4) for HIS and Tribal providers subject to 25 U.S.C. 1641. This brings the estimated number of providers impacted by the reporting requirement at § 441.311(e) to 15,642.

i. One Time HCBS Payment Adequacy Requirements: Service Providers (§ 441.311(e))

With regard to the one-time requirements, we estimate it would take: 35 hours at $73.00/hr for a compensation, benefits and job analysis specialist to calculate compensation, as defined by § 441.(311)(e)(1)(i) for each direct care worker defined at § 441.311(e)(1)(ii); 40 hours at $98.84/hr for a computer programmer to build, design and operationalize an internal system to calculate each direct care worker's compensation as a percentage of total revenues received, aggregate the sum of direct care worker compensation as an overall percentage, and separate self-directed services to report to the State; and 8 hours at $118.14/hr for a general and operations manager to review and approve reporting to the State.

In aggregate, we estimate a one-time burden of 1,298,286 hours (15,642 providers × 83 hr) at a cost of $116,591,088 (15,642 providers × [(35 hr × $73.00/hr) + (40 hr × $98.84/hr) + (8 hr × $118.14/hr)]).

TABLE 15: Summary of One-Time Burden for Service Providers for the Payment Adequacy Reporting Requirements at § 441.311(e)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Calculate compensation for each direct care worker	15,642	15,642	Once	35	547,470	73.00	39,965,310	n/a
Build, design and operationalize an internal system for reporting to the State	15,642	15,642	Once	40	625,680	98.84	61,842,211	n/a
Review and approve reporting to the State	15,642	15,642	Once	8	125,136	118.14	14,783,567	n/a
Total	15,642	15,642	Once	Varies	1,298,286	varies	116,591,088	n/a

ii. Ongoing Payment Adequacy Reporting Requirements (§ 441.311(e)): Service Providers

With regard to the on-going requirements, we estimate it will take 8 hours at $73.00/hr for a compensation, benefits, and job analysis specialist to account for new hires and/or contracted employees; 8 hours at $98.84/hr for a computer programmer to calculate compensation, aggregate data, and report to the State as required; and 5 hours at $118.14/hr for a general and operations manager to review and approve reporting to the State. In aggregate, we estimate an on-going burden of 328,482 hours (15,742 providers × 21 hr) at a cost of $30,743,100 (15,642 providers × [(8 hr × $73.00/hr) + (8 hr × $98.84/hr) + (5 hr × $118.14/hr)]).

TABLE 16: Summary of Ongoing Burden for Service Providers for the HCBS Payment Adequacy Requirements at § 441.311(e)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Account for new hires and/or contracted employees	15,642	15,642	Once	8	125,136	73.00	9,134,928	n/a
Calculate compensation, aggregate data, and report to the State	15,642	15,642	Once	8	125,136	98.84	12,368,442	n/a
Review and approve reporting to the State	15,642	15,642	Once	5	78,210	118.14	9,239,729	n/a
Total	15,642	15,642	Once	Varies	328,482	varies	30,743,100	n/a

iii. On-Time Payment Adequacy Reporting Requirements (§ 441.311(e)): Managed Care Plans

As noted earlier, the burden associated with this final rule will affect managed care plans that contract with the States to provide managed long-term services and supports. We estimate that there are 161 managed long-term services and supports plans providing services across 25 States.[404] We estimate both a one-time and ongoing burden for managed care plans to implement these requirements. Specifically, managed care plans would have to: (1) draft new policy (one-time); (2) update provider manuals for each of the services subject to the requirement (one-time); (3) inform providers of requirements (one-time and ongoing); (4) collect the information from providers for each service required (ongoing); (5) aggregate the data as required by the States (ongoing); and (6) report to the State on an annual basis (ongoing).

With regard to the one-time requirements, we estimate it would take 50 hours at $111.18/hr for an administrative services manager to draft policy for contracted providers; 32 hours at $98.84/hr for a computer programmer to build, design, and operationalize internal systems for data collection, aggregation, stratification by service, and reporting; 40 hours at $67.18/hr for a training and development specialist to develop and conduct training for providers; and 4 hours at $236.96/hr for a chief executive to review and approve reporting to the State. In aggregate, we estimate a one-time burden of 20,286 hours (161 MCPs × 126 hr) at a cost of $1,989,464 (161 MCPs × [(50 hr × $111.18/hr) + (32 hr × $98.84/hr) + (40 hr × $67.18/hr) + (4 hr × $236.96/hr)]).

[404] *https://www.kff.org/report-section/a-view-from-the-states-key-medicaid-policy-changes-long-term-services-and-supports/*; Profiles & Program Features | Medicaid.

TABLE 17: Summary of One-time Burden for Managed Care Plans for the Payment Adequacy Reporting Requirements at § 441.311(e)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Draft policy for contracted providers	161	161	Once	50	8,050	111.18	894,999	n/a
Build, design, and operationalize internal systems for data collection, aggregation, stratification by service, and reporting	161	161	Once	32	5.152	98.84	509,224	n/a
Develop and conduct training for providers	161	161	Once	40	6,440	67.18	432,639	n/a
Review and approve reporting to the State	161	161	Once	4	644	236.96	152,602	n/a
Total	161	161	Once	Varies	20,286	varies	1,989,464	n/a

iv. Ongoing Payment Adequacy Reporting Requirements (§ 441.311(e)): Managed Care Plans

With regard to the ongoing requirements, we estimate it will take: 8 hours at $98.84/hr for a computer programmer to: (1) collect the information from all providers for each service required, (2) aggregate and stratify data as required, and (3) develop report to the State on an annual basis; and 2 hours at $236.96/hr for a chief executive to review and approve the reporting to the State. In aggregate, we estimate an ongoing burden of 1,610 hours (161 MCPs × 10 hr) at a cost of $203,607 (161 MCPs × [(8 hr × $98.84/hr) + (2 hr × $236.96/hr)]).

TABLE 18: Summary of Ongoing Burden for Managed Care Plans for the Payment Adequacy Reporting Requirements at § 441.311(e)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Collect information from providers; aggregate and stratify data as required; and develop report annually	161	161	Annually	8	1,288	98.84	127,306	n/a
Review and approve the report	161	161	Annually	2	322	236.96	76,301	n/a
Total	161	161	Annually	Varies	1,610	varies	203,607	n/a

6. ICRs Regarding Supporting Documentation for HCBS Access (§§ 441.303(f)(6) and 441.311(d)(1); Applied to Managed Care at § 438.72(b)))

The following changes will be submitted to OMB for approval after this final rule is finalized and when our survey instrument has been developed. The survey instrument and burden will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. In the meantime, we are setting out our burden figures (see below) as a means of scoring the impact of this rule's changes. The availability of the survey instrument and more definitive burden estimates will be announced in both **Federal Register** notices. The CMS ID number for that collection of information request is CMS–10854 (OMB control number 0938–TBD). Since this will be a new collection of information request, the OMB control number has yet to be determined (TBD) but will be issued by OMB upon their approval of the new collection of information request.

Section 1915(c) of the Act authorizes States to set enrollment limits or caps

on the number of individuals served in a waiver, and many States maintain waiting lists of individuals interested in receiving waiver services once a spot becomes available. States vary in the way they maintain waiting lists for section 1915(c) waivers, and if a waiting list is maintained, how individuals may join the waiting list. Some States permit individuals to join a waiting list as an expression of interest in receiving waiver services, while other States require individuals to first be determined eligible for waiver services to join the waiting list. States have not been required to submit any information on the existence or composition of waiting lists, which has led to gaps in information on the accessibility of HCBS within and across States. Further, feedback obtained during various interested parties' engagement activities conducted with States and other interested parties over the past several years about reporting requirements for HCBS, as well as feedback received through the RFI[405] discussed earlier, indicate that there is a need to improve public transparency and processes related to States' HCBS waiting lists.

In this final rule, we are finalizing an amendment to § 441.303(f)(6) by adding language to the end of the regulatory text to specify that if the State has a limit on the size of the waiver program and maintains a list of individuals who are waiting to enroll in the waiver program, the State must meet the reporting requirements at § 441.311(d)(1). Per the finalized requirements at § 441.311(d)(1), for States that limit or cap enrollment in a section 1915(c) waiver and maintain a waiting list, States will be required to provide a description annually on how they maintain the list of individuals who are waiting to enroll in a section 1915(c) waiver program. The description must include, but not be limited to, information on whether the State screens individuals on the waiting list for eligibility for the waiver program, whether the State periodically rescreens individuals on the waiver list for eligibility, and the frequency of rescreening, if applicable. In addition, States will be required to report on the number of people on the waiting list if applicable, as well as the average amount of time that individuals newly enrolled in the waiver program in the past 12 months were on the waiting list, if applicable.

We are finalizing these proposals without substantive modifications. Burden estimates for this requirement are presented below.

a. One Time Waiting List Reporting Requirements: States (§ 441.311(d)(1))

The one-time State burden associated with the waiting list reporting requirements in § 441.311(d)(1) will affect the 39 State Medicaid programs with waiting lists for section 1915(c) waivers.[406] We estimate both a one-time and ongoing burden to implement these requirements at the State level. Specifically, States will have to query their databases or instruct their contractors to do so to collect information on the number of people on existing waiting lists and how long they wait; and write or update their existing waiting list policies and the information collected. In some States, HCBS waivers are administered by more than one operating agency, in these cases each will have to report this data up to the Medicaid agency for submission to us.

With regard to the one-time requirements, we estimate it will take: 16 hours at $111.18/hr for an administrative services manager to write or update State policy, direct information collection, compile information, and produce a report; 20 hours at $98.84/hr for a computer programmer or contractor to query internal systems for reporting requirements; 3 hours at $118.14/hr for a general and operations manager to review and approve report; and 2 hours at $236.96/hr for a chief executive to review and approve all reports associated with this requirement. In aggregate, we estimate a burden of 1,599 hours (39 States × 41 hr) at a cost of $178,777 (39 States × [(16 hr × $111.18/hr) + (20 hr × $98.84/hr) + (3 hr × $118.14/hr) + (2 hr × $236.96/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be $89,388 ($178,777 × 0.50).

Assuming no changes to the State waiting list policies, each year States will only need to update the report to reflect the number of people on the list of individuals who are waiting to enroll in the waiver program and average amount of time that individuals newly enrolled in the waiver program in the past 12 months were on the list.

BILLING CODE 4120–01–P

[405] CMS Request for Information: Access to Coverage and Care in Medicaid & CHIP. February 2022. For a full list of question from the RFI, see *https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-questions.pdf.*

[406] *https://www.kff.org/report-section/state-policy-choices-about-medicaid-home-and-community-based-services-amid-the-pandemic-issue-brief/.*

TABLE 19: Summary of One-Time Burden for States for the Waiting List Reporting Requirements at § 441.311(d)(1)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Write or update State policy, direct information collection, compile information, and produce a report	39	39	Once	16	624	111.18	69,376	34,688
Query internal systems for reporting requirements	39	39	Once	20	780	98.84	77,095	38,548
Review and approve report at management level	39	39	Once	3	117	118.14	13,822	6,911
Review and approve all reports associated with this requirement at the executive level	39	39	Once	2	78	236.96	18,483	9,242
Total	39	39	Once	Varies	1,599	Varies	178,777	89,388

b. Ongoing Waiting List Reporting Requirements: States (§ 441.311(d)(1))

With regard to the on-going burden for the section 1915(c) waiver waiting list reporting requirements at § 441.311(d)(1), we estimate it will take: 4 hours at $111.18/hr for an administrative services managers across relevant operating agencies to direct information collection, compile information, and produce a report; 6 hours at $98.84/hr for a computer programmer or contractor to query internal systems for reporting requirements; 3 hours at $118.14/hr for a general and operations manager to review and approve report; and 2 hours at $236.96/hr for a chief executive to review and approve all reports associated with this requirement. In aggregate, we estimate a burden of 585 hours (39 States × 15 hr) at a cost of $72,778 (39 States × [(4 hr × $111.18/hr) + (6 hr × $98.84/hr) + (3 hr × $118.14/hr) + (2 hr × $236.96/hr)]. Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost will be $36,389 ($72,778 × 0.50) per year.

TABLE 20: Summary of Ongoing Burden for States for the Waiting List Reporting Requirements at § 441.311(d)(1)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Direct information collection, compile information, and produce a report	39	39	Annually	4	156	111.18	17,344	8,672
Query internal systems for reporting requirements	39	39	Annually	6	234	98.84	23,129	11,564
Review and approve report at the management level	39	39	Annually	3	117	118.14	13,822	6,911
Review and approve all reports associated with this requirement at the executive level	39	39	Annually	2	78	236.96	18,483	9,241
Total	39	39	Annually	Varies	585	Varies	72,778	36,389

BILLING CODE 4120–01–C

7. ICRs Regarding Additional HCBS Access Reporting (§ 441.311(d)(2)(i); Applied to Other HCBS Authorities at §§ 441.474(c), 441.580(i), and 441.745(a)(1)(vii) and to Managed Care at § 438.72(b))

The following changes will be submitted to OMB for approval after this final rule is finalized and when our survey instrument has been developed. The survey instrument and burden will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. In the meantime, we are setting out our burden figures (see below) as a means of scoring the impact of this rule's changes. The availability of the survey instrument and more definitive burden estimates will be announced in both **Federal Register** notices. The CMS ID number for that collection of information request is CMS–10854 (OMB control number 0938–TBD). Since this will be a new collection of information request, the OMB control number has yet to be determined (TBD) but will be issued by OMB upon their approval of the new collection of information request.

We proposed additional HCBS access reporting at § 441.311(d)(2)(i). We proposed at § 441.311(d)(2)(i) to require States to report annually on the average amount of time from when homemaker services, home health aide services, or personal care services, listed in § 440.180(b)(2) through (4), are initially approved to when services began for individuals newly approved to begin receiving services within the past 12 months. We also proposed at § 441.311(d)(2)(ii) to require States to report annually on the percent of authorized hours for homemaker services, home health aide services, or personal care, as listed in § 440.180(b)(2) through (4), that are provided within the past 12 months. States are allowed to report on a statistically valid random sample of individuals newly approved to begin receiving these services within the past 12 months.

We are finalizing the requirements at § 441.311(d)(2) with a modification to add reporting on habilitation services as defined at § 440.180(b)(6), in addition to the other services. We have adjusted our burden estimates below to reflect additional reporting on habilitation services.

The burden associated with the additional HCBS access reporting requirements at § 441.311(d)(2) will affect the 48 States (including Washington DC) that deliver HCBS under sections 1915I, (i), (j), or (k) authorities.[407] Specifically, States will have to query their databases or instruct their contractors to do so to collect information on the average amount of time from which homemaker services, home health aide services, personal care, and habilitation services, as listed

[407] Arizona, Rhode Island, and Vermont do not have HCBS programs under any of these authorities.

in § 440.180(b)(2) through (4) and (6), are initially approved to when services began, for individuals newly approved to begin receiving services within the past 12 months, and the percent of authorized hours for these services that are provided within the past 12 months. We expect many States will need to analyze report this metric for a statistically valid random sample of beneficiaries. They will then need to produce a report for us within such information. For States with managed long-term services and supports, they will need to direct managed care plans to report this information up to them.

We estimate one-time and ongoing burden to implement the requirements at § 441.311(d)(2) at the State level.

One-Time HCBS Access Reporting Requirements: States (§ 441.311(d)(2))

With regard to the one-time burden related to the HCBS access reporting requirements, we estimate it will take: 30 hours at $111.18/hr for an administrative services manager across relevant operating agencies to direct information collection, compile information, and produce a report; 80 hours at $98.84/hr for a computer programmer or contractor to analyze service authorization and claims data; 50 hours at $101.46/hr for a statistician to conduct data sampling; 4 hours at $118.14/hr for a general and operations manager to review and approve report; and 3 hours at $236.96/hr for a chief executive to review and approve all reports associated with this requirement. In aggregate, we estimate a one-time burden of 8,016 hours (48 States × 167 hr) at a cost of $839,954 (48 States × [(20 hr × $111.18/hr) + (60 hr × $98.84/hr) + (40 hr × $101.46/hr) + (3 hr × $118.14/hr) + (2 hr × $236.96/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost will be $419,977 ($839,954 × 0.50) per year.

BILLING CODE 4120–01–P

TABLE 21: Summary of One-Time Burden for States for the HCBS Access Reporting Requirements at § 441.311(d)(2)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Direct information collection, compile information, and produce a report	48	48	Once	30	1,440	111.18	160,099	80,050
Analyze service authorization and claims data	48	48	Once	80	3,840	98.84	379,546	189,773
Conduct data sampling	48	48	Once	50	2,400	101.46	243,504	121,752
Review and approve report at the management level	48	48	Once	4	192	118.14	22,683	11,341
Review and approve all reports associated with this requirement at the executive level	48	48	Once	3	144	236.96	34,122	17,061
Total	48	48	Once	Varies	8,016	Varies	839,954	419,977

b. Ongoing HCBS Access Reporting Requirements: States (§ 441.311(d)(2))

With regard to the on-going burden related to the HCBS access reporting requirements for States, we estimate it will take: 15 hours at $111.18/hr for an administrative services manager to direct information collection, compile information, and produce a report; 30 hours at $98.84/hr for a computer programmer or contractor to analyze service authorization and claims data; 15 hours at $101.46/hr for a statistician to conduct data sampling; 4 hours at $118.14/hr for a general and operations manager to review and approve report; and 2 hours at $236.96/hr for a chief executive to review and approve all reports associated with this requirement. In aggregate, we estimate a burden of 3,168 hours (48 States × 67 hr) at a cost of $340,861 (48 States × [(15 hr × $111.18/hr) + (30 hr × $98.84/hr) + (15 hr × $101.46/hr) + (4 hr × $118.14/hr) + (2 hr × $236.96/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost will be $170,431 ($340,861 × 0.50) per year.

TABLE 22: Summary of Ongoing Burden for States for the HCBS Access Reporting Requirements at § 441.311(d)(2)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Direct information collection, compile information, and produce a report	48	48	Annually	15	720	111.18	80,050	40,025
Analyze service authorization and claims data	48	48	Annually	30	1,440	98.84	142,330	71,165
Conduct data sampling	48	48	Annually	15	720	101.46	73,051	36,526
Review and approve report at the management level	48	48	Annually	4	192	118.14	22,683	11,341
Review and approve all reports associated with this requirement at the executive level	48	48	Annually	2	96	236.96	22,748	11,374
Total	48	48	Annual	Varies	3,168	Varies	340,861	170,431

c. One-Time HCBS Access Reporting Requirements: Managed Care Plans (§ 441.311(d)(2))

With regard to the one-time HCBS access reporting requirements at § 441.311(d)(2) for managed care plans, we estimate it will take: 15 hours at $111.18/hr for an administrative services manager to direct information collection, compile information, and produce a report to the State; 45 hours at $98.84/hr for a computer programmer to analyze service authorization and claims data; 15 hours at $101.46/hr for a statistician to conduct data sampling; and 2 hours at $236.96/hr for a chief executive review and approval. In aggregate, we estimate a one-time burden of 12,397 hours (161 MCPs × 77 hr) at a cost of $1,305,923 (161 MCPs × [(15 hr × $111.18/hr) + (45 hr × $98.84/hr) + (15 hr × $101.46/hr) + (2 hr × $236.96/hr)]).

TABLE 23: Summary of One-Time Burden for Managed Care Plans for the HCBS Access Reporting Requirements at § 441.311(d)(2)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Direct information collection, compile information, and produce a report to the State	161	161	Once	15	1,610	111.18	179,000	n/a
Analyze service authorization and claims data	161	161	Once	45	5,635	98.84	556,963	n/a
Conduct data sampling	161	161	Once	15	1,610	101.46	163,351	n/a
Review and approve report	161	161	Once	2	322	236.96	76,301	n/a
Total	161	161	Once	Varies	12,397	Varies	1,305,923	n/a

d. Ongoing HCBS Access Reporting Requirements: Managed Care Plans (§ 441.311(d)(2))

With regard to the ongoing requirements associated with the annual collection, aggregation, and reporting of the HCBS access measures at § 441.311(d)(2), we estimate it will require: 5 hours at $111.18/hr for an administrative services manager to direct information collection, compile information, and produce a report to the State; 25 hours at $98.84/hr for a computer programmer to analyze service authorization and claims data; 10 hours at $101.46/hr for a statistician to conduct data sampling; and 2 hours at $236.96/hr for a chief executive to review and approve. In aggregate, we estimate a burden of 6,762 hours (161 MCPs × 42 hr) at a cost of $726,983 (161 MCPs × [(5 hr × $111.18/hr) + (25 hr × $98.84/hr) + (10 hr × $101.46/hr) + (2 hr × $236.96/hr)]).

TABLE 24: Summary of Ongoing Burden for Managed Care Plans for Additional HCBS Access Reporting Requirements at § 441.311(d)(2)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Direct information collection, compile information, and produce a report to the State	161	161	Annually	5	805	111.18	89,500	n/a
Analyze service authorization and claims data	161	161	Annually	25	4,025	98.84	397,831	n/a
Conduct data sampling	161	161	Annually	10	1,610	101.46	163,351	n/a
Review and approve report	161	161	Annually	2	322	236.96	76,301	n/a
Total	161	161	Annually	Varies	6,762	Varies	726,983	n/a

BILLING CODE 4120–01–C

8. ICRs Regarding Compliance Reporting (§ 441.311(b); Applied to Other HCBS Authorities at §§ 441.474(c), 441.580(i), and 441.745(a)(1)(vii) and to Managed Care at § 438.72(b))

a. Ongoing Incident Management System Assessment Requirements: States (§ 441.311(b)(1)

The following changes will be submitted to OMB for approval after this final rule is finalized and when our survey instrument has been developed. The survey instrument and burden will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. In the meantime, we are setting out our burden figures (see below) as a means of scoring the impact of this rule's changes. The availability of the survey instrument and more definitive burden estimates will be announced in both **Federal Register** notices. The CMS ID number for that collection of information request is CMS–10692 (OMB control number 0938–1362).

As discussed in II.B.3 of this final rule, we are finalizing at § 441.302(a)(6), a requirement that States provide an assurance that they operate and maintain an incident management system that identifies, reports, triages, investigates, resolves, tracks, and trends critical incidents. We are finalizing at § 441.311(b)(1)(i) a requirement that States must report, every 24 months, on the results of an incident management system assessment to demonstrate that they meet the requirements in § 441.302(a)(6). We are also finalizing at § 441.311(b)(1)(ii) a flexibility in which we may reduce the frequency of reporting to up to once every 60 months for States with incident management systems that are determined by CMS to meet the requirements in § 441.302(a)(6).

The reporting requirements finalized at § 411.311(b)(1) are intended to standardize our expectations and States' reporting requirements to ensure that States operate and maintain an incident management system that identifies, reports, triages, investigates, resolves, tracks, and trends critical incidents. The requirements were informed by the responses to the HCBS Incident Management Survey (CMS–10692; OMB 0938–1362) recently released to States.

We estimate that the reporting requirement at § 441.311(b)(1) would apply to the 48 States (including Washington DC) that deliver HCBS under sections 1915(c), (i), (j), or (k) authorities. Some States employ the same incident management system across their waivers, while others employ an incident management system specific to each waiver and will require multiple assessments to meet the requirements at § 441.311(b)(1). Based on the responses to the previously referenced survey, we estimate that on average States will conduct assessments on two incident management systems, totaling approximately 96 unique required assessments (48 State Medicaid programs × 2 incident management system assessments per State). Because the requirements under § 441.311(b)(1) are required every 24 months, we estimate 48 assessments on an annual basis (96 unique assessments every 2 years). With regard to the ongoing requirements, we estimate that it will take 1.5 hours at $76.26/hr for a social/community service manager to gather information and complete the required assessment; and 0.5 hours at $118.14/hr for a general and operations manager to review and approve the assessment. In aggregate, we estimate an ongoing annual burden of 96 hours (48 States × 2 hr) at a cost of $8,326 (48 States × [(1.5 hr × $76.26/hr) + (0.5 hr × $118.14/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State

share of this cost would be $4,163 ($8,326 × 0.50) per year.

TABLE 25: Summary of the Ongoing Burden for States for the Incident Management System Assessment Requirements at § 441.311(b)(1)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Gather information and complete the required assessment	48	48	Annually	1.5	72	76.26	5,491	2,745
Review and approve the assessment	48	48	Annually	0.5	24	118.14	2,835	1,418
Total	48	48	Annually	Varies	96	varies	8,326	4,163

b. Reporting on Critical Incidents (§ 441.311(b)(2)), Person-Centered Planning (§ 441.311(b)(3)), and Type, Amount, and Cost of Services (§ 441.311(b)(4))

The following changes will be submitted to OMB for approval after our survey instrument has been developed. The survey instrument and burden will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. In the meantime, we are setting out our burden figures (see below) as a means of scoring the impact of this rule's changes. The availability of the survey instrument and more definitive burden estimates will be announced in both **Federal Register** notices. The CMS ID number for that collection of information request is CMS 0938–0272 (CMS–372(S)).

This final rule codifies existing compliance reporting requirements on critical incidents, person-centered planning, and type, amount, and cost of services. At § 441.311(b)(2), we are finalizing a reporting requirement which requires States to report annually on the minimum performance standards for critical incidents that are finalized at § 441.302(a)(6). At § 441.311(b)(3), we are finalizing a reporting requirement to require States to report annually on the minimum performance standards for person-centered planning that are finalized at § 441.301(c)(3). Similar reporting requirements were previously described in 2014 guidance.[408] We are also finalizing a redesignation of the existing requirement at § 441.302(h)(1) to report on type, amount, and cost of services as § 441.311(b)(4), to make the requirement part of the new consolidated compliance reporting section finalized at § 441.311.

This final rule removes our currently approved burden and replaces it with the burden associated with the amendments to § 441.311(b)(2) through (4). In aggregate, the change will remove 11,132 hours (253 waivers × 44 hr) and $891,451 (11,132 hr × $80.08/hr for a business operations specialist). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost reduction would be minus $445,725 (−$891,451 × 0.50).

[408] *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/3-cmcs-quality-memo-narrative_0_71.pdf.*

TABLE 26: Summary of the Removal of Approved Ongoing Burden for Form 372(S) as a Result of the Requirements at § 441.311(b)(2) through (b)(4)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Remove currently approved burden under control number 0938–0272 (CMS–372(S))	48	(253)	Annually	(44)	(11,132)	80.08	(891,451)	(445,725)
Total	48	(253)	Annually	(44)	(11,132)	80.08	(891,451)	(445,725)

We expect, as a result of the changes discussed in this section, to revise the Form CMS–372(S) and the form's instructions based on the reporting requirements. The consolidated reporting requirements at § 441.311(b)(2) through (4) also assume that 48 States (including Washington DC) are required to submit the Form CMS–372(S) Report on an annual basis. However, a separate form will no longer be required for each of the 253 approved waivers currently in operation. We estimate a burden of 50 hours at $80.08/hr for a business operations specialist to draft each Form CMS–372(S) Report submission. The per response increase reflects the increase to the minimum State quality performance level for person-centered planning (finalized at § 441.301(c)(3)(ii)) and critical incident reporting (finalized at § 441.302(a)(6)(ii)) from the 86 percent threshold established by the 2014 guidance to 90 percent in this final rule. This slight increase to the minimum performance level will help ensure that States are sufficiently meeting all section 1915(c) waiver requirements but may also increase the evidence that some States may need to submit to document that appropriate remediation is being undertaken to resolve any compliance deficiencies. As a result, we estimate a total of 50 hours for each Form CMS–372(S) Report submission, comprised of 30 hours of recordkeeping, collection and maintenance of data, and 20 hours of record assembly, programming, and completing the Form CMS–372(S) Report in the required format. We also estimate 3 hours at $118.14/hr for a general and operations manager to review and approve the report to CMS; and 2 hours at $236.96/hr for a chief executive to review and approve all reports associated with this requirement.

TABLE 27: Summary of the New Burden for Form 372(S) Annual Report on HCBS Waivers, Inclusive of Updates to § 441.311(b)(2) through (4)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Draft Form CMS 372(S) Report submission	48	48	Annually	50	2,400	80.08	192,192	96,096
Review and approve the report at the management level	48	48	Annually	3	144	118.14	17,012	8,506
Review and approve all reports associated with this requirement at the executive level	48	48	Annually	2	96	236.96	22,748	11,374
Total	48	48	Annually	Varies	2,640	varies	231,952	115,976

The net change resulting from reporting requirements on critical incidents, person-centered service planning, and type, amount, and cost of services, finalized in § 441.311(b)(2) through (4) is a burden decrease of 8,492 hours (2,640 hr—11,132 hr) and $329,749 (State share) ($115,976—$445,725).

9. ICRs Regarding Reporting on the Home and Community-Based Services (HCBS) Quality Measure Set (§ 441.311(c); Applied to Other HCBS Authorities at §§ 441.474(c), 441.580(i), and 441.745(a)(1)(vii) and to Managed Care at § 438.72(b)))

The following changes will be submitted to OMB for approval after this final rule is finalized and when our survey instrument has been developed. The survey instrument and burden will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. In the meantime, we are setting out our burden figures (see below) as a means of scoring the impact of this rule's changes. The availability of the survey instrument and more definitive burden estimates will be announced in both **Federal Register** notices. The CMS ID number for that collection of information request is CMS–10854 (OMB control number 0938–TBD). Since this would be a new collection of information request, the OMB control number has yet to be determined (TBD) but will be issued by OMB upon their approval of the new collection of information request.

a. States

At § 441.311(c), we finalized a requirement that States report every other year on the HCBS Quality Measure Set, which is described in section II.B.8. of this final rule. The reporting requirement will affect the 48 States (including Washington DC) that deliver HCBS under section 1915(c), 1915(i), 1915(j), and 1915(k) authorities. We estimate both a one-time and ongoing burden to implement these requirements at the State level. Unlike other reporting requirements finalized at § 441.311, the effective date of § 441.311(c) will be 4 years, rather than 3 years, after the effective date of the final rule.

As finalized at § 441.311(c), the data collection includes reporting every other year on all measures in the HCBS Quality Measure Set that are identified by the Secretary.[409] For certain measures which are based on data already collected by us, the State can elect to have the Secretary report on their behalf.

As finalized at§ 441.312(c)(1)(iii), States are required to establish performance targets, subject to our review and approval, for each of the measures in the HCBS Quality Measure Set that are identified as mandatory for States to report or are identified as measures for which we will report on behalf of States, as well as to describe the quality improvement strategies that they will pursue to achieve the performance targets for those measures.

We are finalizing the requirements at § 441.312 without substantive modification. Our burden estimates are described below.

i. One Time HCBS Quality Measure Set Requirements: States (§ 441.311(c))

This one-time burden analysis assumes that States must newly adopt one of the ''experience of care'' surveys cited in the HCBS Quality Measure Set: The Consumer Assessment of Healthcare Providers and Systems Home and Community-Based (HCBS CAHPS®) Survey, National Core Indicators®-Intellectual and Developmental Disabilities (NCI®-IDD), National Core Indicators-Aging and Disability (NCI–AD)™, or Personal Outcome Measures (POM)® to fully meet the HCBS Quality Measures Set mandatory requirements.

[409] Available at *https://www.medicaid.gov/federal-policy-guidance/downloads/smd22003.pdf.*

Currently most States use at least one of these surveys; however, States may need to use multiple ''experience of care'' surveys, depending on the populations served by the States' HCBS program and the particular survey instruments that States select to use, to ensure that all major population groups are assessed using the measures in the HCBS Quality Measure Set.

The estimate of one-time burden related to the effort associated with the requirements is for the first year of reporting. It assumes that the Secretary will initially require 25 of the 97 measures currently included in the HCBS Quality Measure Set. The estimate disregards costs associated with the voluntary reporting of measures in the HCBS Quality Measure Set that are not yet mandatory, and voluntary stratification of measures ahead of the phase-in schedule, discussed later in this section.

Additionally, we are finalizing a requirement at § 441.312(f) that the Secretary will require stratification by demographic characteristics of 25 percent of the measures in the HCBS Quality Measure Set for which the Secretary has specified that reporting should be stratified 4 years after the effective date of these regulations, 50 percent of such measures by 6 years after the effective date of these regulations, and 100 percent of measures by 8 years after the effective date of these regulations. The burden associated with stratifying data is considered in the ongoing cost estimate only. We anticipate that certain costs will decline after the first year of reporting, but that some of the reduction will be supplanted with costs associated with stratifying data.

With regard to the one-time requirements at § 441.311(c) for reporting on the initial mandatory elements of the HCBS Quality Measure Set, we estimate that will take: 540 hours at $111.18/hr for administrative services managers to conduct project planning, administer and oversee survey administration, compile measures, establish and describe performance targets, describe quality improvement strategies, and produce a report; 40 hours at $101.46/hr for a statistician to determine survey sampling methodology; 500 hours at $63.88/hr for survey researcher(s) to be trained in survey administration and to administer an in-person survey; 200 hours at $36.52/hr for a data entry worker to input the data; 60 hours at $98.84/hr for a computer programmer to synthesize the data; and 5 hours at $236.96/hr for a chief executive to verify, certify, and approve the report. In aggregate, we estimate a one-time burden of 64,560 hours (48 States × 1,345 hr) at a cost of $5,301,830 (48 States × [(540 hr × $111.18/hr) + (40 hr × $101.46/hr) + (500 hr × $63.88/hr) + (200 hr × $36.52/hr) + (60 hr × $98.84/hr) + (5 hr × $236.96/hr)]) Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost will be $2,650,915 ($5,301,830 × 0.50).

BILLING CODE 4120–01–P

TABLE 28: Summary of the One-Time Burden for States for the HCBS Quality Measure Set Requirements at § 441.311(c)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Conduct project planning, administer and oversee survey administration, compile measures, establish and describe performance targets, describe quality improvement strategies, and produce a report	48	48	Once	540	25,920	111.18	2,881,786	1,440,893
Determine survey sampling methodology	48	48	Once	40	1,920	101.46	194,803	97,402
Receive training in survey administration and administer an in-person survey	48	48	Once	500	24,000	63.88	1,533,120	766,560
Input data	48	48	Once	200	9,600	36.52	350,592	175,296
Synthesize data	48	48	Once	60	2,880	98.84	284,659	142,330
Verify, certify, and approve the report	48	48	Once	5	240	236.96	56,870	28,435
Total	48	48	Once	Varies	64,560	varies	5,301,830	2,650,915

ii. Ongoing HCBS Quality Measure Set Requirements: States (§ 441.311(c))

With regard to the ongoing burden of fulfilling requirements at § 441.311(c), every other year, for reporting on mandatory elements of the HCBS Quality Measure Set, including data stratification by demographic characteristics, we estimate it will take: 520 hours at $111.18/hr for administrative services managers to conduct project planning, administer and oversee survey administration, compile measures, update performance targets and quality improvement strategy description, and produce a report; 80 hours at $101.46/hr for a statistician to determine survey sampling methodology; 1,250 hours at $63.88/hr for survey researcher(s) to be trained in survey administration and to administer an in-person survey; 500 hours at $36.52/hr for a data entry worker to input the data; 100 hours at $98.84/hr for a computer programmer to synthesize the data; and 5 hours at $236.96/hr for a chief executive to verify, certify, and approve a State data submission to us. In aggregate, we estimate an ongoing burden of 117,840 hours (48 States × 2,455 hr) at a cost of $8,405,242 (48 States × [(520 hr × $111.18/hr) + (80 hr × $101.46/hr) + (1,250 hr × $63.88/hr) + (500 hr × $36.52/hr) + (100 hr × $98.84/hr) + (5 hr × $236.96/hr)]). Given that reporting is every other year, the annual burden will be 58,920 hours (117,840 hr/2 years) and $4,202,621 ($8,405,242/2 years). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be $2,101,310 ($4,202,621 × 0.50).

TABLE 29: Summary of the Ongoing Burden for States for the HCBS Quality Measure Set Requirements at § 441.311(c)

Requirement	No. Respondents	Total Responses *	Frequency	Time per Response (hr)	Total Time (hr)*	Wage ($/hr)	Total Cost ($)*	State Share ($)*
Conduct project planning, administer and oversee survey administration, compile measures, update performance targets and quality improvement strategy description, and produce a report	48	12 per year) (24 biennially)	Biennial	520	12,480	111.18	1,387,526	1,387,526
Determine survey sampling methodology	48	12 per year) (24 biennially)	Biennial	80	1,920	101.46	194,803	194,803
Receive training in survey administration and administer an in-person survey	48	12 per year) (24 biennially)	Biennial	1,250	30,000	63.88	1,916,400	958,200
Input data	48	12 per year) (24 biennially)	Biennial	500	12,000	36.52	438,240	219,120
Synthesize data	48	12 per year) (24 biennially)	Biennial	100	2,400	98.84	237,216	118,608
Verify, certify, and approve the report	48	12 per year) (24 biennially)	Biennial	5	120	236.96	28,435	14,218
Total	48	12 per year) (24 biennially)	Biennial	Varies	58,920	Varies	4,202,620	2,101,310

*Annualized over 2 years.

BILLING CODE 4120–01–C

b. HCBS Quality Measure Set Requirements: Beneficiary Experience Survey (§ 441.311(c))

State adoption of existing beneficiary experience surveys, contained in the HCBS Quality Measure Set, to fulfill the mandatory reporting requirements includes a burden on beneficiaries. As finalized in § 441.312, a State must newly adopt one of the ''experience of care'' surveys cited in the HCBS Quality Measure Set: The Consumer Assessment of Healthcare Providers and Systems Home and Community Based (HCBS CAHPS®) Survey, National Core Indicators® Intellectual and Developmental Disabilities (NCI® IDD), National Core Indicators Aging and Disability (NCI AD)™, or Personal Outcome Measures (POM)®.

With regard to beneficiary burden, we estimate it will take 45 minutes (0.75 hr) at $20.71/hr for a Medicaid beneficiary to complete a survey every other year that will be used to derive one or more of the measures in the HCBS Quality Measure Set. At 1,000 beneficiaries/State and 48 States, we estimate an aggregate burden of 36,000 hours (1,000 beneficiary responses/State × 48 States × 0.75 hr/survey) at a cost of $745,560 (36,000 hr × $20.71/hr). Given that survey is every other year, the annual burden will be 18,000 hours (36,000 hr/2 years) and $372,780 ($745,560/2 years).

TABLE 30: Summary of Ongoing Beneficiary Experience Survey Burden for the HCBS Quality Measure Set Requirements at § 441.311(c)

Requirement	No. Respondents	Total Responses *	Frequency	Time per Response (hr)	Total Time (hr)*	Wage ($/hr)	Total Cost ($)*	State Share ($)
Complete beneficiary experience survey	48,000	24,000	Biennial	0.75	18,000	20.71	372,780	n/a
Total	48,000	24,000	Biennial	0.75	18,000	20.71	372,780	n/a

*Annualized over 2 years.

10. ICRs Regarding Website Transparency (§ 441.313; Applied to Other HCBS Authorities at §§ 441.486, 441.595, and 441.750, and to Managed Care at § 438.72(b))

The following changes will be submitted to OMB for approval after our survey instrument has been developed. The survey instrument and burden will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. In the meantime, we are setting out our burden figures (see below) as a means of scoring the impact of this rule's changes. The availability of the survey instrument and more definitive burden estimates will be announced in both **Federal Register** notices. The CMS ID number for that collection of information request is CMS–10854 (OMB control number 0938–TBD). Since this would be a new collection of information request, the OMB control number has yet to be determined (TBD) but will be issued by OMB upon their approval of the new collection of information request.

We are finalizing a new section, at § 441.313, titled, ''website Transparency, to promote public transparency related to the administration of Medicaid-covered HCBS under section 1915(c) of the Act.'' Specifically, at § 441.313(a), we proposed to require States to operate a website that meets the availability and accessibility requirements at § 435.905(b) and that provides the data and information that States are required to report under the newly finalized reporting section at § 441.311. At § 441.313(a)(1), we proposed to require that the data and information that States are required to report under § 441.311 be provided on one website, either directly or by linking to the web pages of the managed care organization, prepaid ambulatory health plan, prepaid inpatient health plan, or primary care case management entity that is authorized to provide services. At § 441.313(a)(2), we proposed to require that the web page include clear and easy to understand labels on documents and links.

At § 441.313(a)(3), we proposed to require that States verify the accurate function of the website and the timeliness of the information and links at least quarterly. At § 441.313(c), we proposed to apply these requirements to services delivered under FFS or managed care delivery systems. At § 441.313(a)(4), we proposed to require that States explain that assistance in accessing the required information on the website is available at no cost and include information on the availability of oral interpretation in all languages and written translation available in each prevalent non-English language, how to request auxiliary aids and services, and a toll-free and TTY/TDY telephone number. Further, we proposed to apply the proposed requirements at § 441.313 to sections 1915(j), (k), and (i) State plan services by finalizing §§ 441.486, 441.595, and 441.750, respectively.

We are finalizing the requirements without substantive changes. Our burden estimates are described below. The burden associated with the website transparency requirements at § 441.313 will affect the 48 States (including Washington, DC) that deliver HCBS under sections 1915(c), (i), (j), or (k) authorities. We are requiring at § 441.313(c) to apply the website transparency requirements to services delivered under FFS or managed care delivery systems, and we are providing States with the option to meet the requirements at § 441.313 by linking to the web pages of the managed care organization, prepaid ambulatory health plan, prepaid inpatient health plan, or primary care case management entity that are authorized to provide services. However, we are not requiring managed care plans to report the data and information required under § 441.311 on their website. As such, we estimate that there is no additional burden for managed care plans associated with the requirements to link to the web pages of the managed care organization, prepaid ambulatory health plan, prepaid inpatient health plan, or primary care case management entity that are authorized to provide services for § 441.313. Further, the burden associated with the requirements for managed care plans to report the data and information required under § 441.311 is estimated in the ICRs Regarding Compliance Reporting (§ 441.311(b)).

If a State opts to comply with the requirements at § 441.313 by linking to the web pages of the managed care organization, prepaid ambulatory health plan, prepaid inpatient health plan, or primary care case management entity that are authorized to provide services, the State will incur a burden. However, such burden will be less than the burden associated with posting the information required under § 441.311 on their own website. We are unable to estimate the number of States that may opt to comply with the requirements at § 441.313 by linking to the web pages of the managed care organization, prepaid ambulatory health plan, prepaid inpatient health plan, or primary care case management entity that are authorized to provide services. As a result, we do not take into account the option in our burden estimate and conservatively assume that all States subject to the requirements at § 441.313 by posting the information required under § 441.311 on their own website.

We estimate both a one-time and ongoing burden to implement these requirements at the State level.

a. One Time Website Transparency Requirements: States (§ 441.313)

The burden associated with the website transparency requirements at § 441.313 will affect the 48 States (including Washington DC) that deliver HCBS under sections 1915(c), (i), (j), or (k) authorities. We estimate both a one-time and ongoing burden to implement these requirements at the State level. In developing our burden estimate, we assumed that States will provide the data and information that States are required to report under newly proposed § 441.311 through an existing website, rather than develop a new website to meet this requirement.

With regard to the one-time burden, based on the website transparency requirements, we estimate it will take: 24 hours at $111.18/hr for an administrative services manager to determine the content of the website; 80 hours at $98.84/hr for a computer programmer or contractor to develop the website; 3 hours at $118.14/hr for a general and operations manager to review and approve the website; and 2 hours at $236.96/hr for a chief executive to review and approve the website. In aggregate, we estimate a one-time burden of 5,232 hours (48 States × 109 hr) at a cost of $547,385 (48 States × [(24 hr × $111.18/hr) + (80 hr × $98.84/hr) + (3 hr × $118.14/hr) + (2 hr × $236.96/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost will be $273,693 ($547,385 × 0.50) per year.

TABLE 31: Summary of the One-Time Burden for States for the Website Transparency Requirements at § 441.313

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)/year
Determine content of website	48	48	Once	24	1,152	111.18	128,080	64,040
Develop website	48	48	Once	80	3,840	98.84	379,546	189,773
Review and approve the website at the management level	48	48	Once	3	144	118.14	17,012	8,506
Review and approve the website at the executive level	48	48	Once	2	96	236.96	22,748	11,374
Total	48	48	Once	Varies	5,232	Varies	547,385	273,693

b. Ongoing Website Transparency Requirements: States (§ 441.313)

With regard to the State on-going burden related to the website transparency requirement, per quarter we estimate it will take: 8 hours at $111.18/hr for an administrative services manager to provide updated data and information for posting and to verify the accuracy of the website; 20 hours at $98.84/hr for a computer programmer or contractor to update the website; 3 hours at $118.14/hr for a general and operations manager to review and approve the website; and 2 hours at $236.96/hr for a chief executive to review and approve the website. In aggregate, we estimate an ongoing annual burden of 6,336 hours (33 hr × 48 States × 4 quarters) at a cost of $709,359 (48 States × 4 quarters × [(8 hr × $111.18/hr) + (20 hr × $98.84/hr) + (3 hr × $118.14/hr) + (2 hr × $236.96/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be $354,680 ($709,359 × 0.50) per year.

TABLE 32: Summary of the Ongoing Burden for States for the Website Transparency Requirements at § 441.313

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Provide updated data and information for posting and verify the accuracy of the website	48	192	Quarterly	8	1,536	111.18	170,772	85,386
Update website	48	192	Quarterly	20	3,840	98.84	379,546	189,773
Review and approve website at the management level	48	192	Quarterly	3	576	118.14	68,049	34,024
Review and approve website at the executive level	48	192	Quarterly	2	384	236.96	90,993	45,496
Total	48	192	Quarterly	Varies	6,336	Varies	709,359	354,680

11. ICRs Regarding HCBS Payment Adequacy (§ 441.302(k); Applied to Other HCBS Authorities at §§ 441.464(f), 441.570(f), 441.745(a)(1)(vi), and to Managed Care at § 438.72(b))

The following changes will be submitted to OMB for approval after this final rule is finalized and when our survey instrument has been developed. The survey instrument will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. In the meantime, we are setting out our burden figures (see below) as a means of scoring the impact of this rule's changes. The availability of the survey instrument and more definitive burden estimates will be announced in both **Federal Register** notices. The CMS ID number for that collection of information request is CMS–10854 (OMB control number 0938–TBD). Since this would be a new collection of information request, the OMB control number has yet to be determined (TBD) but will be issued by OMB upon their approval of the new collection of information request.

We proposed, and are finalizing, a new policy at § 441.302(k)(3)(i), which requires that 80 percent of Medicaid payments for the following services for homemaker services, home health aide services, and personal care services (as set forth in § 440.180(b)(2) through (4)) be spent on compensation for direct care workers. We proposed, and are finalizing, definitions for compensation and direct care workers at §§ 441.302(k)(1) and (2), respectively, which are discussed in greater detail in section II.B.5. of this final rule. As finalized, States must comply with the requirements in § 441.302(k) 6 years after this rule is finalized.

As discussed in greater detail in section II.B.5. of this final rule, we are finalizing this policy with additional modifications which have an impact on our burden estimates. We are finalizing a policy at § 441.302(k)(3)(ii) that allows States to apply a different minimum performance threshold for small providers. We are finalizing a requirement at § 441.302(k)(4)(i) that allows States to develop reasonable, objective criteria through a transparent process (which includes public notice and opportunities for comment from interested parties) to identify small providers that the State would require to meet this alternative minimum performance requirement. We are finalizing a requirement at § 441.302(k)(4)(ii) that the State must set the percentage for a small provider to meet the minimum performance level based on reasonable, objective criteria that it develops through a transparent process that includes public notice and opportunities for comment from interested parties. The costs associated with establishing the small provider threshold (including activities related to public notice and opportunities for comment) have been added to this burden estimate for States. We do not estimate an impact on managed care plans associated with the small provider threshold. We estimate a small impact on providers associated with this requirement; while we believe providers' activities would remain the same whether they were complying with the 80 percent threshold or a State-set small provider threshold, we also assume an additional activity associated with demonstrating eligibility for the State-set small provider threshold. We note that while we have not specified a process by which a State would have providers determine eligibility for a small provider threshold, we are calculating a burden based on the assumption that States would have such a process.

We are also finalizing at § 441.302(k)(5) a flexibility to allow States to offer certain providers temporary hardship exemptions. As finalized, this requirement would allow States to develop reasonable, objective criteria through a transparent process (which includes public notice and opportunities for comment from interested parties) to exempt from the minimum performance requirement at paragraphs (k)(3) of this section a reasonable number of providers determined by the State to be facing extraordinary circumstances that prevent their compliance with either the 80 percent threshold requirement or the State's small provider threshold. The costs associated with establishing the hardship exemption (including activities related to public notice and opportunities for comment) have been added to this burden estimate for States. We do not anticipate a specific impact on managed care plans as a result of this requirement. We do not estimate an impact on managed care plans associated with the hardship exemption. We estimate a small impact on providers associated with this requirement, as we assume an additional activity associated with demonstrating eligibility for the State-set hardship exemption. We note that while we have not specified a process by which a State would have providers determine eligibility for a hardship exemption, we are calculating a burden based on the assumption that States would have such a process.

We are finalizing at § 441.302(k)(6) reporting requirements for small provider minimum performance levels and hardship exemptions. Under this requirement, States that establish a small provider minimum performance level must report to CMS annually the following information, in the form and manner, and at a time, specified by CMS: the State's small provider criteria developed in accordance with paragraph (k)(4)(i) of this section; the State's small provider minimum performance level; the percentage of providers of services set forth at § 440.180(b)(2) through (4) that qualify for the small provider minimum performance level; and a plan, subject to CMS review and approval, for small providers to meet the minimum performance requirement at paragraph (k)(3)(i) of this section within a reasonable period of time. States that provide a hardship exemption must report to CMS annually the following information, in the form and manner, and at a time, specified by CMS: the State's hardship criteria; the percentage of providers of services set forth at § 440.180(b)(2) through (4) that qualify for a hardship exemption; and a plan, subject to CMS review and approval, for reducing the number of providers that qualify for a hardship exemption within a reasonable period of time. We also finalized a flexibility at § 441.302(k)(6)(iii) that CMS may waive the reporting requirements if the State demonstrates it has applied the small provider minimum performance level or the hardship exemption to less than 10 percent of the State's providers.

We have added the burden associated with the reporting requirement finalized at § 441.302(k)(6) to the burden estimate. We do not expect that all States will need to submit such a report (because some States will expect most, if not all, of their providers to comply with the minimum performance threshold); we also expect that over time, fewer States will need to submit such a report (again, as more States begin to require that more than 90 percent of their providers comply with the minimum performance threshold.) However, to avoid underestimating burden, we have calculated the burden of this requirement based on the assumption that all 48 States will submit such a report annually. We do not anticipate an impact on managed care plans or providers associated with this additional requirement.

We also finalized at § 441.302(k)(7) an exemption for the Indian Health Service and Tribal health programs subject to 25 U.S.C. 1641, which exempts these providers from the requirements in § 441.302(k). Based on internal data, we believe that about 100 providers would be eligible for this exclusion as § 441.302(k)(7) requires no additional action on the part of the State or providers impacted by this exemption) we did not calculate a change in the burden activities as a result of this exemption.

We are finalizing the application of these requirements to services delivered under FFS or managed care delivery systems. Further, we are finalizing the application of the finalized requirements sections 1915(j), (k), and (i) State plan services by cross-referencing at §§ 441.450(c), 441.540(c), and 441.725(c), respectively.

We are finalizing the requirements at §§ 441.302(k) with the substantive modifications as described above. Burden estimates for the finalized requirements are below. We note an additional change to the burden estimates. As presented in the proposed rule at 88 FR 28047, we had presented the burden estimate of both the HCBS payment adequacy provision at § 441.302(k) and the payment adequacy reporting requirement at § 441.311(e) in a single ICR. Since the publication of the NPRM, upon further consideration we have determined that as §§ 441.302(k) and 441.311(e) represent distinct sets of requirements, it is more appropriate to present the costs associated with § 441.311(e) under a separate ICR in this section IV. of the final rule.

However, while § 441.311(e) represents a distinct set of requirements from those in § 441.302(k), we also expect that States will employ certain efficiencies in complying with both §§ 441.302(k) and 441.311(e). In particular, we expect that States will build a single IT infrastructure and use the same processes both for collecting data for the reporting requirement at § 441.311(e) and for determining providers' compliance with the 80 percent threshold at § 441.302(k)(3)(i) or the small provider threshold at § 441.302(k)(3)(ii). The burden associated with States' development of infrastructure and processes to determine what percentage of HCBS providers' Medicaid payments for homemaker, home health aide, or personal care services is spent on direct care worker compensation, as well as providers' reporting of this information to the State, is included in the ICR for § 441.311(e) (ICR 5 of this section IV. of the final rule). We believe representing these costs under only one ICR avoids duplicative or inflated burden estimates.

The burden estimates below include costs associated specifically with § 441.302(k), namely: development and application of the small provider threshold under § 441.302(k)(3)(ii) and (4), development and application of the hardship exemption under § 441.302(k)(5), and the reporting on the small provider threshold and hardship exemption under § 441.302(k)(6).

a. States

The burden associated with the requirements at § 441.302(k) will affect the 48 States (including Washington DC) that deliver HCBS under sections 1915(c), (i), (j), or (k) authorities.[410] [411] We estimate both a one-time and ongoing burden to implement these requirements at the State level. Specifically, under §§ 441.302(k) States will have to: (1) draft new policy regarding the application of the 80 percent minimum performance level at

[410] Arizona, Rhode Island, and Vermont do not have HCBS programs under any of these authorities.

[411] For purposes of this burden analysis, we are not taking into consideration temporary wage increases or bonus payments that have been or are being made.

§ 441.302(k)(3), the small provider performance level and criteria described in § 441.302(k)(4), and the hardship exemptions described in § 441.302(k)(5) (one-time); (2) publish the proposed requirements for the small provider performance level described in § 441.302(k)(4) and threshold and the hardship exemption described in § 441.302(k)(5) through State notice and publication processes (one-time); (3) update provider manuals and other policy guidance regarding the performance levels described in § 441.302(k)(3) and (4) and the hardship exemption described in § 441.302(k)(5) for each of the services subject to the requirement (one-time); (4) inform providers of the process for demonstrating eligibility for the small provider performance level described at § 441.302(k)(4) or the hardship exemption described at § 441.302(k)(5) through State notification processes, both initially and annually (one-time and ongoing); (5) review providers' eligibility for the small provider performance level described at § 441.302(k)(4) or hardship exemption described in § 441.302(k)(5) (ongoing); and (6) provide the report on the small provider performance level and the hardship exemption required at § 441.302(k)(6) to us on an annual basis (ongoing).

i. One Time HCBS Payment Adequacy Requirements (§ 441.302(k)): State Burden

With regard to the one-time requirements, we estimate it will take 100 hours at $111.18/hr for an administrative services manager to: draft policy content; prepare notices and draft rules for publication, conduct public hearings on the small provider performance level and hardship exemptions in accordance with § 441.302(k)(4) and (5), respectively. We estimate it will take 50 hours at $100.64/hr for a management analyst to: update provider manuals for each of the affected services (explaining the policies for § 441.302(k) generally, and the policies and criteria related to the small provider performance level and hardship exemption described at § 441.302(k)(4) and (5), respectively; and draft provider agreement and managed care contract amendments regarding the requirements at § 441.302(k)(3), (4) and (5). We estimate it will take 8 hours at $98.84/hr for a computer programmer to build, design, and operationalize internal systems for identifying providers falling under § 441.302(k)(4) or (5). We estimate it will take 40 hours at $67.18/hr for a training and development specialist to: develop and conduct training for providers specific to the requirements associated with § 441.302(k)(3), (4), and (5). We estimate it will take 20 hours at $118.14/hr for a general and operations manager to: review and approve provider agreement amendment sand managed care contract modifications; and to review and approve policy guidance for publication. We estimate it will take 10 hours at $236.96/hr for a chief executive to review and approve all operations associated with these requirements.

In aggregate, we estimate a one-time burden of 10,944 hours (228 hr × 48 States) at a cost of $1,169,295 (48 States × [(100 hr × $111.18/hr) + (50 hr × $100.64/hr) + (8 hr × $98.84/hr) + (40 hr × $67.18/hr) + (20 hr × $118.14/hr) + (10 hr × $236.96/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be $584,648 ($1,169,295 × 0.50).

BILLING CODE 4120–01–P

TABLE 33: Summary of One-Time Burden for States for the HCBS Payment Adequacy Requirements at § 441.302(k)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Draft policy content; prepare notices and draft rules for publication, conduct public hearings for § 441.302(k)(4) and (5)	48	48	Once	100	4,800	111.18	533,664	266,832
Update provider manuals for each of the affected services (explaining the policies related to § 441.302(k) (4) and (5); and draft provider agreement and managed care contract amendments	48	48	Once	50	2,400	100.64	241,536	120,768
Build, design, and operationalize internal systems for marking providers identified as under § 441.302(k)(4) or (5)	48	48	Once	8	384	98.84	37,955	18,977
Develop and conduct training for providers for the requirements associated with § 441.302(k)	48	48	Once	40	1,920	67.18	128,986	64,493
Review, approve managed care contract modifications, provider agreement updates, policy and rules for publication, and training materials	48	48	Once	20	960	118.14	113,414	56,707
Review and approve all operations associated with this requirement	48	48	Once	10	480	236.96	113,740	56,780
Total	48	48	Once	Varies	10,944	varies	1,169,295	584,648

ii. Ongoing HCBS Payment Adequacy Requirements (§ 441.302(k)): State Burden

We also expect that States will have to review, on an ongoing basis, providers' requests to be considered under the small provider performance level at § 441.302(k)(4) or the hardship exemption at § 441.302(k)(5). As noted in the Collection of Information in the proposed rule at 88 FR 28049, we estimate that 11,555 HCBS providers provide homemaker, home health aide, or personal care services and thus are subject to the requirements at § 441.302(k). We estimate that around 15 percent of these providers will request consideration under either the

small provider performance level or hardship exemption; 10 percent is selected as we expect States will set criteria to apply to 10 percent or less of providers. Thus, we expect that States (collectively) will need to review 1,155 requests for flexibilities under § 441.302(k)(4) or (5) on an ongoing, annual basis; we expect that it will take 0.5 hours at $100.64/hr for a management analyst to review each request.

With regard to additional ongoing requirements, we estimate it will take 2 hours at $98.84/hr for a computer programmer to update providers' status in any system that tracks providers subject to the small provider performance level and hardship exemptions under § 441.302(k)(4) or (5), respectively, and calculate the percent of providers subject to 441.302(k)(4) or (5). We also estimate it will take 2 hours at $118.14/hr by a general and operations manager to generate the report required at § 441.302(k)(6) for submission to CMS. We estimate it will take 2 hours at $236.96/hr for a chief executive to review and approve all operations associated with these requirements.

In aggregate, we estimate an ongoing burden of 866 hours [(0.5 hr × 1,155 providers) + (6 hr × 48 States)] at a cost of $101,698 [1,155 providers × (0.5 hr × $100.65) + (48 States × [(2 hr × $98.84/hr) + (2 hr × $118.14/hr) + (2 hr × $236.96/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be $50,849 ($101,698 × 0.50) per year.

TABLE 34: Summary of Ongoing Burden for States for the HCBS Payment Adequacy Requirements at §§ 441.302(k)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Review providers' requests for classification under § 441.302(k)(4) or (5)	1,155	1,155	Annually	0.5	576	100.64	58,120	29,060
Collect information from providers; aggregate and stratify data as required; derive an overall percentage for each service; identify percentages for providers subject to flexibilities; and develop report annually	48	48	Annually	2	96	98.84	9,489	4,744
Review, verify and approve reporting as required in § 441.302(k) and § 441.311(e) -to CMS	48	48	Annually	2	96	118.14	11,341	5,671
Review and approve all operations associated with reporting requirements at § 441.302(k) and § 441.311(e)	48	48	Annually	2	96	236.96	22,748	11,374
Total	Varies	1,203 (1,155 + 48)	Annually	Varies	866	Varies	101,698	50,849

BILLING CODE 4120–01–C

b. Service Providers

The burden associated with § 441.302(k) being finalized in this final rule will affect service providers that provide the services listed at § 440.180(b)(2) through (4) and (6). We estimate an ongoing burden on providers to request, on an ongoing basis, either qualification as a small provider under the small provider criteria (in accordance with § 441.302(k)(4)) or eligibility for the hardship exemption (in accordance with § 441.302(k)(5)). (We do also expect there to be a burden on providers to implement the separate payment adequacy reporting requirement at § 441.311(e); these costs are addressed in a separate ICR.)

As noted above, we expect that annually, we estimate that 1,155 providers will request consideration for eligibility for the small provider performance level or the hardship exemption under § 441.302(k)(4) or (5), respectively.

With regard to the ongoing requirement, we estimate it would take: 1 hour at $118.14/hr for a general and operations manager to file the request for the State. In aggregate, we estimate an ongoing burden of 1,155 hours (1,155 providers × 1 hr) at a cost of $136,452 (1,155 providers × (1 hr × $118.14/hr).

TABLE 35: Summary of Ongoing Burden for Service Providers for the HCBS Payment Adequacy Requirements at § 442.302(k)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Request qualification under § 441.302(k)(4) or (5)	1,155	1,155	Once	1	1,155	118.14	136,452	n/a
Total	1,155	1,155	Once	1	1.155	118.14	136,452	n/a

12. ICRs Regarding Payment Rate Transparency (§ 447.203)

The following changes will be submitted to OMB for approval under control number 0938–1134 (CMS–10391).

This final rule will update documentation requirements in § 447.203. To develop the burden estimates associated with these changes, we account for the removal of existing information collection requirements in current § 447.203(b), and the introduction of new requirements at 447.203(b) and (c). As described later in this section, we estimate the impact of the revisions to § 447.203 will result in a net burden reduction. We do not anticipate any additional information collection burden from the conforming edits finalized in § 447.204, as the conforming edits merely alter the items submitted as part of an existing submission requirement, and the burden of producing those items is reflected in the estimates related to § 447.203, including instances where we move language from § 447.204 to § 447.203.

a. Removal of Access Monitoring Review Plan: States (§ 447.203(b)(1) Through (8))

The burden reduction associated with the removal of § 447.203(b)(1) through (8) consists of the removal of time and effort necessary to develop and publish AMRPs, perform ongoing monitoring, and corrective action plans.

Former § 447.203(b)(1) and (2) described the minimum factors that States must consider when developing an AMRP. Specifically, the AMRP must include: input from both Medicaid beneficiaries and Medicaid providers, an analysis of Medicaid payment data, and a description of the specific measures the State will use to analyze access to care. Section 447.203(b)(3) required that States include aggregate percentage comparisons of Medicaid payment rates to other public (including, as practical, provider payments rates in Medicaid managed care or Medicare rates) and private health coverage rates within geographic areas of the State. Section 447.203(b)(4) described the minimum content that must be included in the monitoring plan. States were required to describe: measures the State uses to analyze access to care issues, how the measures relate to the overarching framework, access issues that are discovered as a result of the review, and the State Medicaid agency's recommendations on the sufficiency of access to care based on the review. Section 447.203(b)(5) described the timeframe for States to develop the AMRP and complete the data review for the following categories of services: primary care, physician specialist services, behavioral health, pre- and post-natal obstetric services including labor and delivery, home health, any services for which the State has submitted a SPA to reduce or restructure provider payments which changes could result in diminished access, and additional services as determined necessary by the State or CMS based on complaints or as selected by the State. While the initial AMRPs have been completed, the plan had to be updated at least every 3 years, but no later than October 1 of the update year. Section 447.203(b)(6)(i) required that any time a State submits a SPA to reduce provider payment rates or restructure provider payments in a way that could diminish access, the State must submit an AMRP associated with the services affected by the payment rate reduction or payment restructuring that has been completed within the prior 12 months.

Former § 447.203(b)(6)(ii) required that States have procedures within the AMRP to monitor continued access after implementation of a SPA that reduces or restructures payment rates. The monitoring procedures were required to be in place for a period of at least 3 years following the effective date of the SPA. However, States were already required to submit information on compliance with section 1902(a)(30)(A) of the Act prior to the 2015 final rule with comment period. Therefore, removal of § 447.203(b)(6)(ii) results in a burden reduction.

Finally, we note that this section references the rescission of the AMRP process contained in § 447.203(b)(1) through (b)(8). However, the requirements of former paragraph (b)(7) are reflected in new paragraph (b)(4), and the requirements of former paragraph (b)(8) are reflected in new paragraph (c)(5). As such, there is not a change in impact related to the rescission of these specific aspects of the AMRP process and are not reflected in this section.

In our currently approved information collection request, we estimated that the requirements to develop and make the AMRPs publicly available for the specific categories of Medicaid services will affect each of the 50 State Medicaid programs and the District of Columbia

(51 total respondents). We will use that estimate here as well, although we note that the requirements may not be limited to solely those States, as some territories may not be exempt under waivers; however, because these figures fluctuate, we are maintaining the estimate for consistency. As such, for consistency, we will maintain the estimate of 51 respondents subject to this final rule. We further note that the one-time cost estimates have already been met for AMRPs, and the ongoing monitoring requirements are every 3 years. As such, the estimates in this section for burden reduction are for 17 respondents, which is one-third of the 51 affected respondents, to provide an annual estimate of the reduced burden.

We estimated that every 3 years, it would take: 80 hours at $55.54/hr for a social science research analyst to gather data, 80 hours at $106.30/hr for a computer and information analyst to analyze the data, 100 hours at $100.64/hr for a management analyst to develop the content of the AMRP, 40 hours at $80.08/hr for a business operations specialist to publish the AMRP, and 10 hours at $118.14/hr for a general and operations manager to review and approve the AMRP. In aggregate, and as shown in Table 36, we estimate the reduced annual burden of the rescission of the ongoing AMRP requirements would be minus 5,270 hours (17 States × 310 hr) and minus $465,729 (17 States × [(80 hr × $55.54/hr) + (80 hr × $106.30/hr) + (100 hr × $100.64/hr) + (40 hr × $80.08/hr) + (10 hr × $118.14/hr)]). Taking into account the 50 percent Federal contribution for administrative expenditures, the rescission represents a saving to States of minus $232,865 ($465,729 × 0.50).

The currently approved ongoing burden associated with the requirements under § 447.203(b)(6)(ii) is the time and effort it takes each of the State Medicaid programs to monitor continued access following the implementation of a SPA that reduces or restructures payment rates. In our currently approved information collection request, we estimated that in each SPA submission cycle, 22 States will submit SPAs to implement rate changes or restructure provider payments based on the number of submissions received in FY 2010. Using our currently approved burden estimates we estimate a reduction of: 40 hours at $100.64/hr for a management analyst to develop the monitoring procedures, 24 hours at $100.64/hr for a management analyst to periodically review the monitoring results, and 3 hours at $118.14/hr for a general and operations manager to review and approve the monitoring procedures. In aggregate, we estimate burden reduction of minus 1,474 hours (22 responses × 67 hr) and minus $149,498 (22 States × [(40 hr × $100.64/hr) + (24 hr × $100.64/hr) + (3 hr × $118.14/hr)]). Accounting for the 50 percent Federal administrative match, the total State cost reduction is adjusted to minus $74,749 ($149,498 × 0.50).

TABLE 36: Summary of Annual Burden Reduction Associated with Removal of Access Monitoring Review Plan Requirements (§ 447.203(b)(1) through (8))

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
Rescission of §447.203(b)(1) through (b)(6)(i)	17	17	Triennial (figures are annualized)	(310)	(5,270)	Varies	(465,729)	(232,865)
Rescission of § 447.203(b)(6)(ii)	22	22	Varies (figures are annualized)	(67)	(1,474)	Varies	(149,498)	(74,749)
TOTAL	39	39	Varies	Varies	(6,744)	Varies	(615,227)	(307,614)

b. Payment Rate Transparency (§ 447.203(b)(1) Through (5))

We proposed to replace the AMRP requirements with new payment rate transparency and analysis requirements at § 447.203(b)(1) through (5), which we are finalizing as proposed apart from minor technical adjustments. The burden associated with these requirements consists of the time and effort to develop and publish a Medicaid FFS provider payment rate information and analysis.

Section 447.203(b)(1) specifies that all FFS Medicaid payments must be published on a publicly accessible website that is maintained by the State. Section 447.203(b)(2) specifies the service types that are subject to the proposed payment analysis, which include: primary care services; obstetrical and gynecological services; outpatient mental health and substance use disorder services; and certain HCBS. Section 447.203(b)(3) describes the required components of the payment analysis to include, for services in § 447.203(b)(2)(i) through (iii), a percentage comparison of Medicaid payment rates to the most recently published Medicare payment rates effective for the time period for each of the service categories specified in paragraph (b)(2). We also specify that the payment analysis must include percentage comparisons made on the basis of Medicaid base payments. For HCBS described in § 447.203(b)(2)(iv), we require a State-based comparison of average hourly payment rates. Section 447.203(b)(4) details the payment analysis timeframe, with the first payment analysis required to be published by the State agency by July 1, 2026, which is a change from our proposed date of January 1, 2026, and updated every 2 years by July 1. Section 447.203(b)(5) describes our mechanism

for ensuring compliance and that we may take compliance action against a State that fails to meet the requirements of the payment rate transparency, comparative payment rate analysis, and payment rate disclosure provisions in preceding paragraphs in § 447.203(b), including a deferral or disallowance of certain of the State's administrative expenditures following the procedures described at part 430, subpart C.

We estimate that the requirements to complete and make publicly available all FFS Medicaid payments and the comparative payment rate analysis and payment rate disclosures under § 447.203(b)(1) through (5) for the specific categories of Medicaid services will affect 51 total respondents, based on the estimate in the prior section regarding the variation in States and territories subject to these requirements. We require applicable States and territories to publish all FFS Medicaid payments initially by July 1, 2026, while future updates to the payment rate transparency information would depend on when a State submits a SPA updating provider payments and we have approved that SPA. As such, we assume 51 one-time respondents for the initial rates publication. Because the comparative payment rate analysis and payment rate disclosure requirement is biennial, we assume 26 annual respondents in any given year, and we will assume this figure would account for the updates made following a rate reduction SPA or rate restructuring SPA approval. The comparative payment rate analysis will be similar to the prior requirement at § 447.203(b)(3) that required AMRPs to include a comparative payment rate analysis against public or private payers. The inclusion of levels of provider payment available from other payers is also one of five required components of the AMRP as specified by current § 447.203(b)(1). To estimate the burden associated with our comparative payment rate analysis and payment rate disclosure provisions, we assume this work will require approximately 25 percent of the ongoing labor hour burden that we previously estimated to be required by the entire AMRP, to account for the service categories subject to the comparative payment rate analysis and payment rate disclosure in § 447.203(b)(2) as decreased from the full body of AMRP service requirements. We invited comment on these estimated proportions. We are finalizing this requirement to include reporting on an additional service (habilitation services, as defined at § 440.180(b)(6)) in the payment rate disclosure. Below, we include in our burden calculations the minimal increased anticipated burden associated with the addition of reporting on habilitation services.

With regard to the developing and publishing the payment rate transparency data under § 447.203(b)(1), we estimate a low one-time and ongoing burden due to the data being available, and the main work required to meet the proposed requirement would be formatting and web publication. As such, we estimate it will initially take: 5 hours at $55.54/hr for a research assistant to gather the data, 5 hours at $80.08/hr for a business operations specialist to publish, and 1 hour at $118.14/hr for a general and operations manager to review and approve the rate transparency data. In aggregate, we estimate a one-time burden of 561 hours (51 responses × 11 hr) at a cost of $40,608 (51 responses × [(5 hr × $55.54/hr) + (5 hr × $80.08/hr) + (1 hr × $118.14/hr)]). Taking into account the Federal administrative match of 50 percent, the requirement will cost States $20,304 ($40,608 × 0.50).

For the ongoing cost to update assumed to take place every 2 years (although we proposed that updates would only be required as necessary to keep the data current, with any update made no later than 1 month following the date of CMS approval of the SPA or similar amendment providing for the change), we estimate an annualized impact on 26 respondents (51 respondents every 2 years) of: 2 hours at $55.54/hr for a research assistant to update the data, 1 hour at $80.08/hr for a business operations specialist to publish the updates, and 1 hour at $118.14/hr for a general and operations manager to review and approve the rate transparency update. In aggregate, we estimate an annualized burden of 104 hours (26 responses × 4 hr) at a cost of $8,042 (26 responses × [(2 hr × $55.54/hr) + (1 hr × $80.08/hr) + (1 hr × $118.14/hr)]). Taking into account the Federal administrative match of 50 percent, the requirement will cost States $4,021 ($8,042 × 0.50).

With regard to developing and publishing the comparative payment rate analysis and payment rate disclosure at § 447.203(b)(2), we estimate it will take: 22 hours at $55.54/hr for a research assistant to gather the data, 22 hours at $106.30/hr for an information analyst to analyze the data, 25 hours at $100.64/hr for a management analyst to design the comparative payment rate analysis, 11 hours at $80.08/hr for a business operations specialist to publish the comparative payment rate analysis and payment rate disclosure, and 3 hours at $118.14/hr for a general and operations manager to review and approve the comparative payment rate analysis and payment rate disclosure. In aggregate, we estimate an annualized burden, based on 51 respondents every 2 years, of 2,054 (26 responses × 79 hr) at a cost of $190,107 (26 States × [(22 hr × $55.54/hr) + (22 hr × $106.30/hr) + (25 hr × $100.64/hr) + (11 hr × $80.08/hr) + (3 hr × $118.14/hr)]). We then adjust the total cost to $95,053 ($190,107 × 0.50) to account for the 50 percent Federal administrative match. We have summarized the total burdens in Table 37.

TABLE 37: Summary of Burden Associated with Payment Rate Transparency Requirements (§ 447.203(b)(1) through (5))

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
§ 447.203(b)(1) Rate Transparency	51	51	One-time	11	561	Varies	40,608	20,304
§ 447.203(b)(1) Rate Transparency	26	26	Biannual (figures are annualized)	4	104	Varies	8,042	4,021
§ 447.203(b)(2) and (3) Rate Analysis	26	26	Biannual (figures are annualized)	79	2,054	Varies	190,107	95,053
TOTAL	51	103	Varies	Varies	2,719	Varies	238,757	119,378

c. Medicaid Payment Rate Interested Parties' Advisory Group (§ 447.203(b)(6))

The burden associated with the recordkeeping requirements at § 447.203(b)(6), specifically the online publication associated with the reporting and recommendations of the interested parties advisory group, will consist of the time and effort for all 50 States and the District of Columbia to:

- Appoint members to the interested parties' advisory group.
- Provide the group members with materials necessary to:
  - ++ Review current and proposed rates.
  - ++ Hold meetings.
  - ++ Provide a written recommendation to the State.
- Publish the group's recommendations to a website maintained by the single State agency.

The requirements will require varying levels of efforts for States depending on the existence of groups that may fulfil the requirements of this group. However, because it is unknown how many States will be able to leverage existing practices, and to what extent, this estimate does not account for those differences. We are finalizing the requirements at § 447.203(b)(6) with a modification to add habilitation services as defined at § 440.180(b)(6), in addition to the previously identified services, to the group's purview. However, this addition is not expected to create any additional burden. We estimate that it will take 40 hours at $140.14/hr for a human resources manager to recruit interested parties and provide the necessary materials for the group to meet. In aggregate, we estimate a one-time burden of 2,040 hours (51 responses × 40 hr) at a cost of $285,886 (2,040 hr × $140.14/hr). Taking into account the 50 percent administrative match, the total one-time State cost is estimated to be $142,943 ($285,886 × 0.50).

We believe the ongoing work to maintain the needs of this group will take a human resources manager 5 hours at $140.14/hr annually. Additionally, we estimate it will take 4 hours for the biennial requirement, or 2 hours annually at $118.14/hr for an operations manager to review and prepare the recommendation for publication. In aggregate, we estimate an ongoing annualized burden of 182 hours (26 responses × 7 hr) at a cost of $24,361 (26 Respondents × [(5 hr × $140.14/hr) + (2 hr × $118.14/hr)]). Accounting for the 50 percent Federal administrative match, the total State cost is adjusted to $12,181 ($24,361 × 0.50). We have summarized the total burden in Table 38.

TABLE 38: Summary of Burden for Medicaid Payment Rate Interested Parties' Advisory Group

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
§ 447.203(b)(6) (Establish advisory group)	51	51	One-time	40	2,040	140.14	285,886	142,943
§ 447.203(b)(6) (Support and publish recommendation)	51	26	Biennial (figures are annualized)	7	182	Varies	24,361	12,181
TOTAL	51	77	Varies	Varies	2,222	Varies	310,247	155,124

d. State Analysis Procedures for Payment Rate Reductions or Payment Restructuring (§ 447.203(c))

The State analysis procedures for payment rate reductions and payment restructurings at § 447.203(c)(1) through (3) within this final rule effectively will replace payment rate reduction or payment restructuring procedures in current § 447.203(b)(6). As noted, the burden reduction associated with the removal of § 447.203(b)(6)(i) has already been accounted for in the recurring burden reduction estimate shown in Table 36 for the removal of the AMRP requirements, and the burden reduction associated with the removal of monitoring requirements at current § 447.203(b)(6)(ii) has been accounted for in Table 36 as well. Our replacement procedures at § 447.203(c)(1) through (3) will introduce new requirements as follows.

i. Initial State Analysis for Rate Reduction or Restructuring (§ 447.203(c)(1))

Section 447.203(c)(1) will require that for States proposing to reduce or restructure provider payment rates, the State must document that their program and proposal meet all of the following requirements: (1) Medicaid rates in the aggregate for the service category following the proposed reduction(s) or restructurings are at or above 80 percent of most recent Medicare prices or rates for the same or a comparable set of services; (2) Proposed reductions or restructurings result in no more than a 4 percent reduction of overall spending for each service category affected by a proposed reduction or restructuring in a single State fiscal year; and (3) Public process yields no significant access concerns or the State can reasonably respond to concerns.

Section 447.203(c)(1) will apply to all States that submit a SPA that proposes to reduce or restructure provider payment rates. We limited our estimates for new information collection burden to the requirements at § 447.203(c)(1)(i) through (ii). Our estimates assume States will build off the comparative analysis required by § 447.203(b)(2) through (4) to complete the requirements by § 447.203(c)(1)(i), which will limit the additional information collection burden. We also assume no additional information collection burden posed by the public review process required by § 447.203(c)(1)(iii), as this burden is encapsulated by current public process requirements at § 447.204.

The requirements of § 447.203(c) apply to all 50 States and the District of Columbia, as well as US territories. We will again use the estimate of 51 utilized in preceding sections, although we note some territories may be subject to these requirements if not exempt under waivers, and these figures fluctuate. As such, for consistency, we will maintain the estimate of 51 respondents subject to this rule. While we cannot predict how many States will submit a rate reduction SPA or rate restructuring SPA in a given year, the figures from 2019 provide the best recent estimate, as the years during the COVID pandemic do not reflect typical behavior. In 2019, we approved rate reduction and rate restructuring SPAs from 17 unique State respondents. Therefore, to estimate the annualized number of respondents subject to this information collection burden, we will utilize a count of 17 respondents.

With regard to the burden associated with completing the required State analysis for rate reductions or restructurings at § 447.203(c)(1), we estimate that it will take: 20 hours at $100.64/hr for a management analyst to structure the rate reduction or restructuring analysis, 25 hours at $106.30/hr for an information analyst to complete the rate reduction or restructuring analysis, and 3 hours at $118.14/hr for a general and operations manager to review and approve the rate reduction or restructuring analysis. In aggregate, we estimate a burden of 816 hours (17 States × 48 hr) at a cost of $85,420 (17 States × [(20 hr × $100.64/hr) + (25 hr × $106.30/hr) + (3 hr × $118.14/hr)]). Accounting for the 50 percent Federal administrative reimbursement, this adjusts to a total State cost of $42,710 ($85,420 × 0.50).

TABLE 39: Burden Associated with Tier 1 State Analysis Procedures for Rate Reductions or Restructurings (§ 447.203(c)(1))

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
§ 447.203(c)(1)	17	17	Annual	48	816	Varies	85,420	42,710
TOTAL	17	17	Annual	48	816	Varies	85,420	42,710

We solicited public comment on these estimates as well as relevant State data to further refine the burden and time estimates. We did not receive public comments on this issue, and therefore, we are finalizing as proposed.

ii. Additional State Rate Analysis (§ 447.203(c)(2))

Section 447.203(c)(2) describes requirements for payment proposals that do not meet the requirements in paragraph (c)(1), requiring the State to provide the nature of the change and policy purpose, the rates compared to Medicare and/or other payers pre- and post-reduction or restructuring, counts/trends of actively participating providers by geographic areas, counts of FFS Medicaid beneficiaries residing in geographic areas/characteristics of the beneficiary population, service utilization trends, access to care complaints from beneficiaries, providers, and other interested parties, and the State's response to access to care complaints.

The information collection requirements at § 447.203(c)(2) applies to those States that submit rate reduction or restructuring SPAs that do not meet one or more of the criteria proposed by § 447.203(c)(1). Using 2019 rate reduction and restructuring SPA figures, we estimate that 17 States will submit rate reduction or restructuring SPAs per year. Then, a 2019 Urban Institute analysis [412] indicates that 22 States (or 43 percent) have rates that meet the 80 percent fee ratio threshold proposed in § 447.203(c)(1)(i) across all services. Although our proposal did not

[412] Zuckerman, S. et al. ''Medicaid Physician Fees Remained Substantially Below Fees Paid By Medicare in 2019.'', *Health Affairs,* Volume 40, Number 2, February 2021, p. 343–348, *https://www.healthaffairs.org/doi/10.1377/hlthaff.2020.00611,* accessed August 31, 2022.

include all services, using this all services amount is our best method to estimate how many States may fall below on any given service without knowing which. Because we cannot predict the amount a State may propose to reduce, once or cumulatively for the SFY, and because failure of any one criterion in § 447.203(c)(1) will require additional analysis under § 447.203(c)(2), we will use that percentage to assess how many States will need to perform additional analysis. Using this percentage, we estimate that 7 (43 percent × 17) of the estimated 17 unique State respondents may submit rate reduction or restructuring SPAs meet the criteria for the streamlined analysis process under proposed § 447.203(c)(1). Therefore, we assume that 10 out of 17 unique annual State respondents who submit rate reduction or restructuring SPAs will also need to perform the additional analysis § 447.203(c)(2).

The required components of the review and analysis in § 447.203(c)(2) are similar to the AMRP requirements found at current § 447.203(b)(1). However, due to the availability of a template for States to facilitate completion of the required analysis, as well as the lack of a requirement to publish the analysis, we anticipate a moderately reduced burden associated with § 447.203(c)(2) when compared to the burden estimated for the AMRPs.

With regard to our requirements, we estimate that it would take: 64 hours at $55.54/hr for a social science research assistant to gather data, 64 hours at $106.30/hr for a computer and information analyst to analyze data, 80 hours at $100.64/hr for a management analyst to structure the analyses and organize output, and 8 hours at $118.14/hr for a general and operations manager to review and approve the rate reduction or restructuring analysis. In aggregate, we estimate a burden of 2,160 hours (10 States × 216 hr) at a cost of $193,541 (10 States × [(64 hr × $55.54/hr) + (64 hr × $106.30/hr) + (80 hr × $100.64/hr) + (8 hr × $118.14/hr)]). The total cost is adjusted down to $96,771 ($193,541 × 0.50) for States after accounting for the 50 percent Federal administrative match. We solicited public comment on these estimates as well as relevant State data to further refine the burden and time estimates. We did not receive public comments on this issue, and therefore, we are finalizing as proposed.

We do not assume any additional information collection imposed by the compliance procedures at § 447.203(c)(3).

Table 40 shows our estimated combined annualized burden for § 447.203(c), which includes 17 States for § 447.203(c)(1) and 10 States for § 447.203(c)(2). In total, we estimate an annualized burden of 2,976 (816 hours + 2,160 hours) hours at a cost of $278,961 ($85,420 + $193,541). This cost to States is then adjusted to $139,481 after the 50 percent Federal administrative reimbursement is applied.

BILLING CODE 4120–01–P

TABLE 40: Summary of Burden Associated with State Analysis Procedures for Rate Reductions or Restructurings (§ 447.203(c))

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Share ($)
§ 447.203(c)(1) (initial State analysis)	17	17	Annual	48	816	Varies	85,420	42,710
§ 447.203(c)(2) (additional State analysis)	10	10	Annual	216	2,160	Varies	193,541	96,771
TOTAL	17	27	Annual	264	2,976	Varies	278,961	139,481

D. Burden Summary

TABLE 41: Summary of Annual Burden Estimates

Regulation Section(s) in Title 42 of the CFR	OMB Control Number (CMS ID Number)	# of Respondents	# of Responses	Time per Response (hr)	Total Time (hr)	Hourly Labor Rate ($/hr)	Total Labor Cost ($)	State Share ($)	Total Beneficiary Cost ($)
§431.12 (Table 3) (MACs & BACs)	0938-TBD (CMS-10845)	51 States	153	Varies	17,340	Varies	1,665,354	832,676	n/a
§441.301(c)(3) – One-time burden to States (Table 4) (Person-Centered Service Plans)	0938-TBD (CMS-10854)	48 States	48	Varies	528	Varies	65,409	32,704	n/a
§441.301(c)(3) – One-time burden to Managed Care Plans (Table 5) (Person-Centered Service Plans)	0938-TBD (CMS-10854)	161 Managed Care Plans	161	Varies	966	Varies	127,650	n/a	n/a
§441.301(c)(7) – One-time burden to States (Table 6) (Grievance Systems)	0938-TBD (CMS-10854)	48 States	48	Varies	24,960	Varies	2,596,493	1,298,246	n/a
§441.301(c)(7) – Ongoing burden to States (Table 7) (Grievance Systems)	0938-TBD (CMS-10854)	48 States	29,255	Varies	16,206	Varies	1,135,949	567,975	n/a
§441.302(a)(6) – One-time burden to States (Table 8) (Incident Management System)	0938-TBD (CMS-10854)	48 States	96	Varies	19,872	Varies	124,958,292	62,479,146	n/a
§441.302(a)(6) – Ongoing burden to States (Table 9) (Incident Management System)	0938-TBD (CMS-10854)	48 States	283,542	Varies	15,177	Varies	24,778,520	12,389,260	n/a
§441.302(a)(6) – Ongoing burden to Service Providers (Table 10) (Incident Management System)	0938-TBD (CMS-10854)	15,742 Providers	28,345	1	28,345	118.14	3,348,678	n/a	n/a
§441.302(a)(6) – One-time burden to Managed Care Plans (Table 11) (Incident Management System)	0938-TBD (CMS-10854)	161 Managed Care Plans	161	Varies	26,726	Varies	2,712,747	n/a	n/a
§441.302(a)(6) – Ongoing burden to Managed Care Plans (Table 12) (Incident Management System)	0938-TBD (CMS-10854)	161 Managed Care Plans	6,964	Varies	5,476	Varies	535,791	n/a	n/a
§441.311(b)(1) Ongoing burden to States (Table 25) (Incident Management System Assessment)	0938-1362 (CMS-10692)	48 States	48	Varies	96	Varies	8,326	4,163	n/a
§ 441.311(e) – One-time burden to States (Table 13) (Payment Adequacy Reporting)	0938-TBD (CMS-10854)	48 States	48	Varies	7,776	Varies	850,285	425,173	n/a

Regulation Section(s) in Title 42 of the CFR	OMB Control Number (CMS ID Number)	# of Respondents	# of Responses	Time per Response (hr)	Total Time (hr)	Hourly Labor Rate ($/hr)	Total Labor Cost ($)	State Share ($)	Total Beneficiary Cost ($)
§ 441.311(e) – Ongoing burden to States (Table 14) (Payment Adequacy Reporting)	0938-TBD (CMS-10854)	48 States	48	Varies	1,200	Varies	121,302	60,651	n/a
§ 441.311(e) – One-time burden to service providers (Table 15) (HCBS Payment Adequacy)	0938-TBD (CMS-10854)	15,642 Providers	15,642	Varies	1,298,286	Varies	116,591,088	n/a	n/a
§ 441.311(e) – Ongoing burden to service providers (Table 16) (Payment Adequacy Reporting)	0938-TBD (CMS-10854)	15,642 Providers	15,642	Varies	328,482	Varies	30,743,100	n/a	n/a
§ 441.311(e) – One-time burden to managed care plans (Table 17) (Payment Adequacy Reporting)	0938-TBD (CMS-10854)	161 Managed Care Plans	161	Varies	20,286	Varies	1,989,464	n/a	n/a
§ 441.311(e) – Ongoing burden to managed care plans (Table 18) (Payment Adequacy Reporting)	0938-TBD (CMS-10854)	161 Managed Care Plans	161	Varies	1,610	Varies	203,607	n/a	n/a
§ 441.302(k) One-time burden to States (Table 33) (HCBS Payment Adequacy)	0938-TBD (CMS-10854)	48 States	48	Varies	10,944	Varies	1,169,295	584,648	n/a
§ 441.302(k) Ongoing burden to States (Table 34) (HCBS Payment Adequacy)	0938-TBD (CMS-10854)	Varies	1,203	Varies	866	Varies	101,698	50,849	n/a
§441.303(f)(6), § 441.311(d)(1) – One-Time burden to States (Table 19) (Supporting Documentation for HCBS Access)	0938-TBD (CMS-10854)	39 States	39	Varies	1,599	Varies	178,777	89,388	n/a
§441.303(f)(6), § 441.311(d)(1) – Ongoing burden to States (Table 20) (Supporting Documentation for HCBS Access)	0938-TBD (CMS-10854)	39 States	39	Varies	585	Varies	72,778	36,389	n/a
§441.311(d)(2)(i) One-Time burden to States (Table 21) (Additional HCBS Access Reporting)	0938-TBD (CMS-10854)	48 States	48	Varies	8,016	Varies	839,954	419,977	n/a
§441.311(d)(2)(i) Ongoing burden to States (Table 22) (Additional HCBS Access Reporting)	0938-TBD (CMS-10854)	48 States	48	Varies	3,168	Varies	340,861	170,431	n/a
§441.311(d)(2)(i) One-Time burden to managed care plans (Table 23) (Additional HCBS Access Reporting)	0938-TBD (CMS-10854)	161 Managed Care Plans	161	Varies	12,397	Varies	1,305,923	n/a	n/a

Regulation Section(s) in Title 42 of the CFR	OMB Control Number (CMS ID Number)	# of Respondents	# of Responses	Time per Response (hr)	Total Time (hr)	Hourly Labor Rate ($/hr)	Total Labor Cost ($)	State Share ($)	Total Beneficiary Cost ($)
§441.311(d)(2)(i) Ongoing burden to managed care plans (Table 24) (Additional HCBS Access Reporting)	0938-TBD (CMS-10854)	161 Managed Care Plans	161	Varies	6,762	Varies	726,983	n/a	n/a
Removal of Current Form 372(S) Ongoing Reporting Information Collection (Table 26)	0938–0272 (CMS–372(S))	48 States	253	(44)	(11,132)	75.32	(891,451)	(445,725)	n/a
Form 372(S) Reporting Requirement to include Proposed § 441.311(b)(2)-(4) (Table 27)	0938-TBD (CMS-10854)	48 States	48	Varies	2,640	Varies	231,952	115,976	n/a
§441.311(c) One-time burden to States (Table 28) (HCBS Quality Measure Set)	0938-TBD (CMS-10854)	48 States	48	Varies	64,560	Varies	5,301,830	2,650,915	n/a
§441.311(c) Ongoing burden to States (Table 29) (HCBS Quality Measure Set)	0938-TBD (CMS-10854)	24 States	24	Varies	58,920	Varies	4,202,621	2,101,310	n/a
§441.311(c) Ongoing burden to beneficiaries (Table 30) (HCBS Quality Measure Set)	0938-TBD (CMS-10854)	48,000 Beneficiaries	24,000	0.75	18,000	20.71	n/a	n/a	372,780
§441.313 One-time burden to States (Table 31) (Website Transparency)	0938-TBD (CMS-10854)	48 States	48	Varies	5,232	Varies	547,385	273,693	n/a
§441.313 Ongoing burden to States (Table 32) (Website Transparency)	0938-TBD (CMS-10854)	48 States	192	Varies	6,336	Varies	709,359	354,680	n/a
Removal of § 447.203(b)(1)-(6)(i)) (Table 36) (Removal of AMRP)	0938–1134 (CMS–10391)	51 States and Territories	17	(310)	(5,270)	*varies*	(465,729)	(232,865)	n/a
Removal of § 447.203(b)(6)(ii) (Table 36) (Removal of AMRP)	0938–1134 (CMS–10391)	51 States and Territories	22	(67)	(1,474)	*varies*	(149,498)	(74,749)	n/a
§ 447.203(b)(1) (Table 37) (Rate transparency)	0938–1134 (CMS–10391)	51 States and Territories	26	4	104	*varies*	8,042	4,021	n/a
§ 447.203(b)(2) (Table 37) (Rate analysis)	0938–1134 (CMS–10391)	51 States and Territories	26	83	2,158	*varies*	190,107	95,053	n/a

Regulation Section(s) in Title 42 of the CFR	OMB Control Number (CMS ID Number)	# of Respondents	# of Responses	Time per Response (hr)	Total Time (hr)	Hourly Labor Rate ($/hr)	Total Labor Cost ($)	State Share ($)	Total Beneficiary Cost ($)
§ 447.203(b)(6) (Table 38) (advisory group)	0938–1134 (CMS–10391)	51 States and Territories	26	7	182	*varies*	24,361	12,181	n/a
§ 447.203(c)(1) (Table 39) (initial State analysis)	0938–1134 (CMS–10391)	51 States and Territories	17	48	816	*varies*	85,420	42,710	n/a
§ 447.203(c)(2) (Table 39) (additional State analysis)	0938–1134 (CMS–10391)	51 States and Territories	12	216	2,160	*varies*	193,541	96,771	n/a
TOTAL		Varies	407,029	Varies	2,200,901	Varies	327,156,264	84,435,647	372,380

BILLING CODE 4120–01–C

IV. Regulatory Impact Analysis

A. Statement of Need

1. Medicaid Advisory Committee

The changes to § 431.12 are intended to provide beneficiaries a greater voice in State Medicaid programs. In making policy and program decisions, it is vital for States to include the perspective and experience of those served by the Medicaid program. States are currently required to operate a MCAC, made up of health professionals, consumers, and State representatives to ''advise the Medicaid agency about health and medical care services.'' This rule establishes new requirements for a MAC in place of the MCAC, with additional membership requirements to include a broader group of interested parties, to advise the State Medicaid agency on matters related to the effective administration of the Medicaid program. We seek to expand the viewpoints represented on the MAC, to provider States with richer feedback on Medicaid program and policy issues. States are already required to set up and use MCACs. The changes will result in the State also setting up a smaller group, the BAC, which will likely have a cost implication. The additional cost will depend on whether or not States already have a beneficiary committee—we know that many States already do. This smaller group which feeds into the larger MAC will benefit the Medicaid program by creating a forum for beneficiaries to weigh in on key topics and share their unique views as Medicaid program participants. The new provisions of § 431.12 also enhance transparency and accountability through public reporting requirements related to the operation and activities of the MAC and BAC, and guidelines for operation of both bodies.

2. Home and Community-Based Services (HCBS)

The proposed changes at part 441, subpart G, seek to amend and add new Federal requirements, which are intended to improve access to care, quality of care, and health outcomes, and strengthen necessary safeguards that are in place to ensure health and welfare, and promote health equity for people receiving Medicaid-covered HCBS. The provisions in this final rule are intended to achieve a more consistent and coordinated approach to the administration of policies and procedures across Medicaid HCBS programs in accordance with section 2402(a) of the Affordable Care Act, and is made applicable to part 441, subparts J, K, and M, as well as part 438 to achieve these goals.

Specifically, the proposed rule seeks to: strengthen person-centered services planning and incident management systems in HCBS; require minimum percentages of Medicaid payments for certain HCBS to be spent on compensation for the direct care workforce; require States to establish grievance systems in FFS HCBS programs; report on waiver waiting lists in section 1915(c) waiver programs, service delivery timeframes for certain HCBS, and a standardized set of HCBS quality measures; and promote public transparency related to the administration of Medicaid-covered HCBS through public reporting on measures related to incident management systems, critical incidents, person-centered planning, quality, access, and payment adequacy.

In 2014, we released guidance [413] for section 1915(c) waiver programs, which described a process in which States were to report on State-developed performance measures to demonstrate that they meet the six assurances that are required for section 1915(c) waiver programs. Those six assurances include the following:

1. *Level of Care:* The State demonstrates that it implements the processes and instrument(s) specified in its approved waiver for evaluating/reevaluating an applicant's/waiver participant's level of care consistent with care provided in a hospital, nursing facility, or Intermediate Care Facilities for Individuals with Intellectual Disabilities.

2. *Service Plan:* The State demonstrates it has designed and implemented an effective system for reviewing the adequacy of service plans for waiver participants.

3. *Qualified Providers:* The State demonstrates that it has designed and implemented an adequate system for assuring that all waiver services are provided by qualified providers.

4. *Health and Welfare:* The State demonstrates it has designed and implemented an effective system for assuring waiver participant health and welfare.

[413] *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/3-cmcs-quality-memo-narrative_0_71.pdf.*

5. *Financial Accountability:* The State demonstrates that it has designed and implemented an adequate system for insuring financial accountability of the waiver program.

6. *Administrative Authority:* The Medicaid Agency retains ultimate administrative authority and responsibility for the operation of the waiver program by exercising oversight of the performance of waiver functions by other State and local/regional non-State agencies (if appropriate) and contracted entities.

Despite these assurances, there is evidence that State HCBS systems still need to be strengthened and that there are gaps in existing reporting requirements. We believe that this final rule is necessary to address these concerns and strengthen HCBS systems. The requirements in this final rule are intended to supersede and fully replace reporting and performance expectations described in the 2014 guidance for section 1915(c) waiver programs. They are also intended to promote consistency and alignment across HCBS programs, as well as delivery systems, by applying the requirements (where applicable) to sections 1915(i), (j), and (k) authorities State plan benefits and to both FFS and managed care delivery systems.

3. Fee-for-Service (FFS)

Provisions under § 447.203 from this final rule will impact States' required documentation of compliance with section 1902(a)(30)(A) of the Act to ''assure that payments are . . . sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.'' We have received comments from State agencies that the existing AMRP requirement first established by the 2015 final rule with comment period imposes excessive administrative burden for its corresponding value in demonstrating compliance with section 1902(a)(30)(A) of the Act.

This final rule will replace the existing AMRP requirement with a more limited payment rate transparency requirement under proposed § 447.203(b), while requiring a more detailed access impact analysis (as described at proposed § 447.203(c)(2)) when a State proposes provider rate reductions or restructurings that exceed certain thresholds for a streamlined analysis process under proposed § 447.203(c)(1). By limiting the data collection and publication requirements imposed on all States, while targeting certain provider rate reductions or restructuring proposals for a more detailed analysis, this final rule will provide administrative burden relief to States while maintaining a transparent and data-driven process to assure State compliance with section 1902(a)(30)(A) of the Act.

B. Overall Impact

We have examined the impacts of this rule as required by E.O. 12866 on Regulatory Planning and Review (September 30, 1993), E.O. 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), E.O. 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)). Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act, 5 U.S.C. 801 *et seq.*), OMB's Office of Information and Regulatory Affairs has determined that this final rule does meet the criteria set forth in 5 U.S.C. 804(2).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 as amended by Executive Order 14094 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) having an annual effect on the economy of $200 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising legal or policy issues for which centralized review would meaningfully further the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for rules that meet section 3(f)(1) of the Executive Order. This final rule does meet that criterion as the aggregate amount of benefits and costs may meet the $200 million threshold in at least 1 year.

Based on our estimates using a ''no action'' baseline in accordance with OMB Circular A–4, (available at *https://www.whitehouse.gov/wpcontent/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf*), OMB's Office of Information and Regulatory Affairs has determined that this rulemaking is significant or otherwise meets section 3(f)(1). Therefore, OMB has reviewed these proposed regulations, and the Departments have provided the following assessment of their impact.

C. Detailed Economic Analysis

As mentioned in the prior section, and in accordance with OMB Circular A–4, the following estimates were determined using a ''no action'' baseline. That is, our analytical baseline for impact is a direct comparison between the provisions and not proposing them at all.

1. Benefits

a. Medicaid Advisory Committees (MAC)

We believe the changes to § 431.12 will benefit State Medicaid programs and those they serve by ensuring that beneficiaries have a significant role in advising States on the experience of receiving health care and services through Medicaid. These benefits cannot be quantified. However, the BAC and a more diverse and transparent MAC will provide opportunities for richer interested parties feedback and expertise to positively impact State decision making on Medicaid program and policy chances. For example, beneficiary feedback on accessing health care services and the quality of those services can inform decisions on provider networks and networks adequacy requirements. Issues that States need to address, like cultural competency of providers, language accessibility, health equity, and disparities and biases in the Medicaid program, can be revealed through beneficiary experiences. The MAC falls into the Public Administration 921 Executive, Legislative, and Other General Government Support.

b. Person-Centered Service Plans, Grievance Systems, Incident Management Systems

The changes benefit Medicaid beneficiaries and States by requiring States to demonstrate through reporting requirements that they provide safeguards to assure eligibility for Medicaid-covered care and services is determined and provided in a manner that is in the Medicaid beneficiaries'

best interest, although these potential benefits cannot be monetarily quantified at this time. The changes will provide further safeguards that ensure health and welfare by strengthening the person-centered service plan requirements, establishing grievance systems, amending requirements for incident management systems, and establishing new reporting requirements for States, and contracted managed care plans identified by the North American Industry Classification System (NAICS) industry code (Direct Health and Medical Insurance Carriers (524114).

These changes will benefit individuals on HCBS waiver wait lists, and individuals who receive homemaker, home health aide, personal care, and habilitation services under the finalized regulations found at §§ 441.301(c), 441.302(a)(6), 441.302(h), 441.303(f), 441.311, 441.725, and amended regulations in §§ 441.464, 441.474, 441.540, 441.555, 441.570, 441.580, and 441.745. These benefits cannot be monetarily quantified at this time.

c. Home and Community-Based Services (HCBS) Payment Adequacy and Payment Adequacy Reporting

This final rule adds a new reporting requirement at § 441.311(e) (and amends §§ 441.474(c), 441.580(i), and 441.745(a)(1)(vii)) to require States to demonstrate through reporting what percent of payments to providers of certain HCBS (homemaker, home health aide, personal care, and habilitation services) are spent on compensation to direct care workers. The goal of this requirement is to promote transparency and to assure that payments are consistent with efficiency, economy, and quality of care, in accordance with section 1902(a)(30)(A) of the Act. This final rule seeks to address access to care that is being affected by direct care workforce shortages. States will be required to report annually and will be required to separately report on payments for services that are self-directed and services that include facility costs. benefit from reporting in the aggregate for each service subject to the requirement across HCBS programs and delivery systems, which minimizes administrative burden while providing us better oversight of compensation of the direct care workforce. These potential benefits cannot be monetarily quantified at this time due to the variety of State data collection approaches.

Additionally, through this final rule, we are finalizing § 441.302(k), which establishes certain minimum thresholds for the percent of Medicaid payments for certain HCBS must be spent on compensation for direct care workers. We believe this requirement will help to ensure that payments to workers are sufficient to provide access to care that is at least comparable to that of the general population in the same geographic location, in accordance with section 1902(a)(30)(A) of the Act. We are also finalizing a number of flexibilities to allow States to address needs of specific providers, such as providers that are small or rural, or are experiencing particular hardship that would temporarily prevent the provider for adhering to the minimum payment level. Through this requirement, we can better ensure payment adequacy to a provider population experiencing worker shortages that impact beneficiary access. While we believe this requirement will promote increases in direct care worker compensation in some regions, these potential benefits cannot be monetarily quantified at this time due to the variety of State data collection approaches.

d. Home and Community-Based Services (HCBS) Quality Measure Set Reporting

As described in section II.B.8. of this final rule, on July 21, 2022, we issued State Medicaid Director Letter (SMDL) #22–003 [414] to release the first official version of the HCBS Quality Measure Set. This final rule provides definitions and sets forth requirements at § 441.312 that expand on the HCBS Quality Measure Set described in the SMDL. By expanding and codifying aspects of the SMDL, we can better drive improvement in quality of care and health outcomes for beneficiaries receiving HCBS. States will also benefit from the clarity afforded by this final rule, and from the assurance that other States they may be looking to for comparison are adhering to the same requirements. The clarity and assurance, at this time, cannot be measured.

e. Fee-for-Service (FFS) Payment Transparency

The changes to § 447.203 will update requirements placed on States to document access to care and service payment rates. The updates create a systematic framework through which we can assess compliance with section 1902(a)(30)(A) of the Act, while reducing existing burden on States and maximizing the value of their efforts, as described in section III.C.11.a. of this rule.

The payment rate transparency provisions at § 447.203(b) create a process that will facilitate transparent oversight by us and other interested parties. By requiring States to calculate Medicaid payment rates as a percent of corresponding Medicare payment rates, this provision offers a uniform benchmark through which CMS and interested parties can assess payment rate sufficiency. When compared to the existing AMRP requirement, the rate analysis proposed by § 447.203(b) should improve the utility of the reporting, while reducing the associated administrative burden, as reflected in the Burden Estimate Summary Table 38. Updates at § 447.203(c) specify required documentation and analysis when States propose to reduce or restructure provider payment rates. By establishing thresholds at § 447.203(c)(1), this final rule will generally limit the more extensive access review prescribed by § 447.203(c)(2) to those SPAs that we believe more likely to cause access concerns. In doing so, these proposed updates reduce the State administrative burden imposed by existing documentation requirements for proposed rate reductions or restructurings, without impeding our ability to ensure proposed rate reduction and restructuring SPAs comply with section 1902(a)(30)(A) of the Act. These burden reductions are reflected in the Collection of Information section of this rule.

When considering the benefits of these regulatory updates, we considered the possibility that the improved transparency required by § 447.203(b) could create upward pressure on provider payment rates, and that the tiered nature of documentation requirements set by § 447.203(c) could create an incentive for States to moderate proposed payment reductions or restructurings that were near the proposed thresholds that would trigger additional analysis and documentation requirements. If either of these rate impacts were to occur, existing literature implies there could be follow-on benefits to Medicaid beneficiaries, including but not limited to increased physician acceptance rates,[415] increased appointment availability,[416] and even improved self-reported health.[417] However, nothing in this final rule will require States to directly adjust payment

[414] *https://www.medicaid.gov/federal-policy-guidance/downloads/smd22003.pdf.*

[415] Holgash, K. and Martha Heberlein, *Health Affairs,* April 10, 2019.

[416] Candon, M., et al. *JAMA Internal Medicine,* January 2018, p. 145–146.

[417] Alexander, D., and Molly Schnell. ''The Impacts of Physician Payments on Patient Access, Use, and Health'', National Bureau of Economic Research, Working Paper 26095, July 2019 (revised August 2020), p. 1–74. *https://www.nber.org/papers/w26095.* Accessed June 16, 2022.

rates, and we recognize that multiple factors influence State rate-setting proposals, including State budgetary pressures, legislative priorities, and other forces. These competing influences create substantial uncertainty about the specific impact of the provisions at § 447.203 on provider payment rate-setting and beneficiary access. Rather, the specific intent and anticipated outcome of these provisions is the creation of a more uniform, transparent, and less burdensome process through which States can conduct required payment rate and access analyses and we can perform our oversight role related to provider payment rate sufficiency.

2. Costs

a. Medicaid Advisory Committee (MAC)

In addition to the costs reflected in section III.C.1 of this final rule, States will incur additional ongoing costs (estimated below in Table 42) in appointing and recruiting members to the MAC and BAC and, also developing and publishing bylaws, membership lists, and meeting minutes for the MAC and BAC. All of these costs can be categorized under the NAICS Code 921 (Executive, Legislative, and Other General Government Support) since States are the only entity accounted for in the MAC and BAC. How often these costs occur will also vary in how often the State chooses to make changes such as add or replace members of the MAC and BAC or change its bylaws. Additionally, there will be new, ongoing costs, estimated below, for States related to meeting logistics and administration for the BAC. All of these new costs can also be categorized under the NAICS Code 921 (Executive, Legislative, and Other General Government Support). To derive average costs, as in the previous section of this final rule, we used data from the U.S. Bureau of Labor Statistics' (BLS') May 2022 National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes/2022/may/oes_nat.htm*). Costs include our estimated cost of fringe benefits and other indirect costs, calculated at 100 percent of salary, in our adjusted hourly wage.

Since most States are already holding MAC meetings under current regulatory requirements, any new costs related to MAC requirements would likely be minimal. In terms of the MAC and BAC meeting costs, we estimate a total cost for 5 years of $3.414 million or $682,821 annually for States. We estimate it will take a business operations specialist 10 hours to plan and execute each BAC meeting, at a total cost of $162,180 ($79.50/hour × 10 hours × 4 meetings/year) × 51 States and the District of Columbia). To satisfy the requirements of § 431.12(h)(3)(i), a public relations specialist will spend an estimated 80 hours/year supporting Medicaid beneficiary MAC and BAC members at a total cost of $308,122 ($75.50/hour × 80 hours) × 51 States and the District of Columbia). A chief executive in State government, as required by § 431.12(h)(3)(iii) will spend a total of 8 hours a year attending BAC meetings, which we estimate will be 2 hours in duration, 4 times a year at a total cost of $ 49,319 ($120.88/hour × 2 hours/meeting × 4 meetings) × 51 States and the District of Columbia). Each meeting of the BAC will cost States an estimated $200 in meeting costs and telecommunication, at an annual total cost of $40,800 ($200 × 4 meetings) × 51 States and the District of Columbia). The meeting costs are estimated by adding the average cost for telecommunications (approximately $130[418] per meeting) to the average cost of meeting supplies (approximately $70 per meeting for photocopies, name tags, etc.). While we cannot estimate precisely the costs for meeting materials and additional items to support meetings, we are including a nominal estimate of $70 per meeting to acknowledge these costs.

There will also be a per meeting cost to States for financial support for beneficiary members participating in MAC and BAC meetings, as described in § 431.12(h)(3)(ii). We estimate a cost of $75/beneficiary/meeting in the form of transportation vouchers, childcare reimbursement, meals, and/or other financial compensation. Assuming 4 meetings per year (with BAC and MAC meetings co-located and occurring on the same day) and an average of 8 beneficiary members on the BAC and MAC, the cost of financial support for beneficiary members across States is estimated to cost approximately $122,400 annually (($75/beneficiary × 8 beneficiaries × 4 meetings/year) × 51 States and the District of Columbia). This cost will vary depending on the decisions States make around financial support, the number of beneficiary members of the BAC and MAC, and the number of meetings per year. We solicited comment on the costs associated with planning, execution, and participation in the MAC and BAC meetings.

We did not receive public comments specifically on these estimates, and therefore, we are finalizing as proposed.

[418] Sources: *https://www.usnews.com/360-reviews/business/best-conference-calling-services; https://money.com/best-conference-calling-services/.*

TABLE 42: Projected Ten Year Costs for Proposed Updates

Provision	Year										Total CY 2024-2033 ($ in millions)
	Year One ($ in millions)	Year Two ($ in millions)	Year Three ($ in millions)	Year Four ($ in millions)	Year Five ($ in millions)	Year Six ($ in millions)	Year Seven ($ in millions)	Year Eight ($ in millions)	Year Nine ($ in millions)	Year Ten ($ in millions)	
§ 431.12 MAC & BAC logistic and admin support	0.560	0.560	0.560	0.560	0.560	0.560	0.560	0.560	0.560	0.560	5.6
§ 431.12 Financial support to MAC/BAC beneficiary members (cost will range per State)	0.122	0.122	0.122	0.122	0.122	0.122	0.122	0.122	0.122	0.122	1.22
Total	0.682	0.682	0.682	0.682	0.682	0.682	0.682	0.682	0.682	0.682	6.82
Costs will vary depending by State, on how many in person meetings are held, and how many Medicaid beneficiaries are selected for the MAC and BAC											

b. Home and Community-Based Services (HCBS)

Costs displayed in Table 43 are inclusive of both one-time and ongoing costs. One-time costs are split evenly over the years leading up to the provision's applicability date. For example, if a finalized provision is applicable 3 years after the final rule's publication, the one-time costs would be split evenly across each of the years leading to that applicability date. Please note the following applicability dates (beginning after the effective date of this final rule): 2 years for the grievance process requirements finalized at § 441.302(c)(7); 3 years for the person-centered planning, incident management, changes to Form 372(S), access reporting, and website transparency requirements finalized at §§ 441.301(c)(3), 441.302(a)(6), 441.311(b), 441.311(d) and 441.313, respectively; 4 years for the reporting requirements for the HCBS Quality Measure Set and for payment adequacy reporting finalized at § 441.311(c) and (e), respectively; 5 years for the electronic incident management system requirement at § 441.302(a)(6); and 6 years for the HCBS payment adequacy requirements finalized at § 441.302(k). The estimates below do not account for higher costs associated with medical care, as the costs are related exclusively to reporting costs. Costs to States, the Federal government, and managed care plans do not account for enrollment fluctuations, as they assume a stable number of States operating HCBS programs and managed care plans delivering services through these programs. Similarly, costs to providers and beneficiaries do not account for enrollment fluctuations. In the COI section, costs are based on a projected range of HCBS providers and beneficiaries. Given this uncertainty, here, we based cost estimates on the mid-point of the respective ranges and kept those assumptions consistent over the course of the 5-year projection. Per OMB guidelines, the projected estimates for future years do not include ordinary inflation. (that is, they are reported in constant-year dollars).

Table 44 summarizes the estimated ongoing costs for States, managed care plans (Direct Health and Medical Insurance Carriers (NAICS 524114)), and providers (Services for the Elderly and Persons with Disabilities (NAICS 624120) and Home Health Care Services (NAICS 621610)) from the Collection of Information section (section III. of this final rule) of the HCBS provisions of the final rule projected over 10 years. This comprises the entirety of anticipated quantifiable costs associated with changes to part 441, subpart G. It is also possible that increasing the threshold from 86 percent to 90 percent for compliance reporting at § 441.311(b)(2) through (3) may lead to additional costs to remediate issues pertaining to critical incidents or person-centered planning. However, the various avenues through which States could address these concerns creates substantial uncertainty as to what those costs may be. While we acknowledge the potential for increased costs in a limited number of States that may fall within the gap between the existing and the compliance thresholds, we do not quantify them here.

BILLING CODE 4120–01–P

TABLE 43: Projected 10-Year Costs for Updates to 441 Subparts G, J, K, and M

Provision Costs (in millions)	**Year 1**	**Year 2**	**Year 3**	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	Projected 10-year total*
§ 441.301(c)(3) (Person-Centered Service Plans)	0.06	0.06	0.06	-	-	-	-	-	-	-	0.19
§ 441.301(c)(7) (Grievance Systems)	1.30	1.30	1.14	1.14	1.14	1.14	1.14	1.14	1.14	1.14	11.68
§ 441.302(a)(6) (Incident Management System)	1.56	1.56	1.56	28.66	28.66	28.66	28.66	28.66	28.66	28.66	205.31
§ 441.302(a)(6) (Incident Management System – Electronic Incident Management System)	24.60	24.60	24.60	24.60	24.60	0	0	0	0	0	123.00
§ 441.311(b)(1)(Incident Management System Assessment)	-	-	-	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.06
§ 441.311(e) (Payment Adequacy Reporting)	29.86	29.86	29.86	29.86	31.07	31.07	31.07	31.07	31.07	31.07	305.84
§ 441.302(k) (HCBS Payment Adequacy)	0.19	0.19	0.19	0.19	0.19	0.19	0.24	0.24	0.24	0.24	2.12
§441.303(f)(6), § 441.311(d)(1) (Supporting Documentation for HCBS Access)	0.06	0.06	0.06	0.07	0.07	0.07	0.07	0.07	0.07	0.07	0.69
§441.311(d)(2)(i) (Additional HCBS Access Reporting)	0.71	0.71	0.71	1.07	1.07	1.07	1.07	1.07	1.07	1.07	9.62
Removal of Current Form 372(S) Ongoing Reporting Information Collection	-	-	-	(0.89)	(0.89)	(0.89)	(0.89)	(0.89)	(0.89)	(0.89)	(6.24)
Form 372(S) Reporting Requirement to include § 441.311(b)(2)-(4)	-	-	-	0.23	0.23	0.23	0.23	0.23	0.23	0.23	1.62
§441.311(c) (HCBS Quality Measure Set)	1.33	1.33	1.33	1.33	4.58	4.58	4.58	4.58	4.58	4.58	32.75
§441.313 (Website Transparency)	0.18	0.18	0.18	0.71	0.71	0.71	0.71	0.71	0.71	0.71	5.51
Total*	59.85	59.85	59.69	87.00	91.44	66.84	66.88	66.88	66.88	66.88	692.17

* Totals were calculated based on actual figures, so the total row and projected 10-year total column may appear slightly different than had they been calculated based on estimates to the nearest million.

The costs displayed in Table 44 are inclusive of costs anticipated to be incurred by State Medicaid agencies, the Federal government, providers, managed care plans, and beneficiaries.

Table 44 distributes those costs across these respective entities.

TABLE 44: Projected Distribution of Costs for Updates to 42 CFR 441 Subpart G, J, K, and M

Costs (in millions)	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	Projected 10-year total*
State Costs	14.41	14.41	14.34	26.36	27.75	15.45	15.41	15.41	15.41	15.41	175.35
Federal Government Costs	14.41	14.41	14.34	26.36	27.75	15.45	15.41	15.41	15.41	15.41	175.35
Managed Care Plan Costs	1.88	1.88	1.88	1.76	1.47	1.47	1.47	1.47	1.47	1.47	16.20
HCBS Provider Costs	29.15	29.15	29.15	32.50	34.09	34.09	34.23	34.23	34.23	34.23	325.03
Beneficiary costs	0	0	0	0	0.37	0.37	0.37	0.37	0.37	0.37	2.24
Total*	59.86	59.86	59.70	91.44	66.84	66.88	66.88	66.88	66.88	66.88	692.17

* Totals were calculated based on actual figures, so the total row and projected 10-year total column may appear slightly different than had they been calculated based on estimates to the nearest million.

c. Fee-for-Service (FFS) Payment Rate Transparency

The costs associated with the payment rate transparency proposals are wholly associated with information collection requirements, and as such those impacts are reflected in the COI section of this rule. For ease of reference, and for projection purposes, we are including those costs here in Table 45.

TABLE 45: Projected 5-Year State Costs for Updates to 42 CFR 447.203

Provision	Calendar year (CY)					Total CY 2024-2028 ($ in millions)
	2024 ($ in millions)	2025 ($ in millions)	2026 ($ in millions)	2027 ($ in millions)	2028 ($ in millions)	
Removal of current § 447.203 (AMRPs)	-0.615	-0.615	-0.615	-0.615	-0.615	-3.075
§ 447.203(b)	0.516	0.254	0.254	0.254	0.254	1.532
§ 447.203(c)(SPAs)	0.279	0.279	0.279	0.279	0.279	1.395
Total	**0.18**	**-0.082**	**-0.082**	**-0.082**	**-0.082**	**-0.148**

TABLE 46: NAICS Classification of Services and Their Distribution of Costs

Services	NAICS	Percentage of Costs
Managed Care Plans	Direct Health and Medical Insurance Carriers (524114)	100 Percent
Home and Community-Based Services (HCBS)	Elderly and Persons with Disabilities (624120)	67 Percent
Home and Community-Based Services (HCBS)	Home Health Care Services (621610)	37 Percent

TABLE 47: One Time and Annual Costs Detailed

	Cost to States ($)	Cost to Beneficiaries ($)	Cost to Providers ($)	Cost to Managed Care Plans ($)	Costs to Federal Government ($)	One Time Burden Overall Total ($)	Annual Burden Overall Total ($)
Regulatory Review	19,587.06	39,174.12	-	61,833.66	-	120,594.84	0
§ 431.12 Medical Care Advisory Committee Requirements	790,795	-	-		790,795	-	1,581,590
§ 441.301(c)(3) (Person-Centered Service Plans) (One-time Costs) (Tables 4, 5)	32,704	-	-	127,650	32,704	193,059	-
§ 441.301(c)(7) (Grievance Systems) (One-time Costs) (Table 6)	1,298,246	-	-	-	1,298,246	2,596,493	-
§441.301(c)(7) (Grievance Systems) (Ongoing Costs) (Table 7)	567,975	-	-	-	567,975	-	1,135,949
§ 441.302(a)(6) (Incident Management System) (One-time Costs) (Tables 8, 11)	62,479,146	-	-	2,712,747	62,479,146	127,671,039	-
§ 441.302(a)(6) (Incident Management System) (Ongoing Costs) (Tables 9, 10, 12)	12,389,260	-	3,348,678	535,791	12,389,260	-	28,662,989
§ 441.311(b)(1) (Incident Management System Assessment) (Ongoing Costs) (Table 25)	4,163	-	-	-	4,163	-	
§ 441.311(e) (Payment Adequacy Reporting) (One-time Costs) (Tables 13, 15, 17)	425,173	-	116,591,088	1,989,464	425,173	119,430,837	-
§ 441.311(e) (Payment Adequacy	60,651	-	30,743,100	203,607	60,652	-	31,068,009

Reporting) (Ongoing) (Tables 15, 16, 18)							
§ 441.302(k) (HCBS Payment Adequacy) (One-time Costs) (Table 33)	584,648	-	-	-	584,648	1,169,295	-
§ 441.302(k) (HCBS Payment Adequacy) (Ongoing Costs) (Tables 34, 36)	50,849	-	136,452	-	50,849	-	238,150
§§ 441.303(f)(6) and 441.311(d)(1) (Supporting Documentation for HCBS Access) (One-time Costs) (Table 19)	89,388	-	-	-	89,388	178,777	-
§§ 441.303(f)(6) and 441.311(d)(1) (Supporting Documentation for HCBS Access) (Ongoing Costs) (Table 20)	36,389	-	-	-	36,389	-	72,778
§ 441.311(d)(2)(i) (HCBS Access Reporting) (One-time Costs) (Tables 21, 23)	419,977	-	-	1,305,923	419,977	2,140,427	-
§ 441.311(d)(2)(i) (HCBS Access Reporting) (Ongoing Costs) (Tables 22, 24)	170,431	-	-	726,983	170,431	-	1,067,845
Removal of Current Form 372(S) Ongoing Reporting Information Collection (Ongoing Costs) (Table 26)	(445,725)	-	-	-	(445,725)	-	(891,450)

Form 372(S) Reporting Requirement to include § 441.311(b)(2) through (4) (Ongoing Costs) (Table 27)	115,976	-	-	-	115,976	-	231,952
§ 441.311(c) (HCBS Quality Measure Set) (One-time Costs) (Table 28)	2,650,915	-	-	-	2,650,915	5,302,480	-
§ 441.311(c) (HCBS Quality Measure Set) (Ongoing Costs) (Tables 29, 30)	2,101,310	372,780	-	-	2,101,310	-	4,575,400
§ 441.313 (Website Transparency) (One-time Costs) (Table 31)	273,693	-	-	-	273,693	547,385	-
§ 441.313 (Website Transparency) (Ongoing Costs) (Table 32)	354,680	-	-	-	354,680	-	709,359
Removal of § 447.203(b)(1) through (6) (Removal of AMRP) (Table 36)	(307,614)	-	-	-	307,614)	(615,228)	-
§ 447.203(b)(1) (Rate transparency) (Table 36)	23,453	-	-	-	23,453	39,195	7,712
§ 447.203(b)(2) (Rate analysis) (Table 37)	87,103	-	-	-	87,103	-	174,206
§ 447.203(b)(6) (advisory group) (Table 38)	145,386	-	-	-	145,386	267,934	22,837
§ 447.203(c)(1) (initial State analysis) (Table 40)	40,678	-	-	-	40,678	-	81,356
§ 447.203(c)(2) (additional State analysis) (Table 40)	92,716	-	-	-	92,716	-	185,432

BILLING CODE 4120–01–C

3. Transfers

Transfers are payments between persons or groups that do not directly affect the total resources available to society. They are a benefit to recipients and a cost to payers, with zero net effects. Because this rule proposes changes to requirements to State agencies without changes to payments from Federal to State governments, the transfer impact is null, and cost impacts are reflected in the other sections of this rule.

4. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed or final rule, we should estimate the cost associated with regulatory review. There is uncertainty involved with accurately quantifying the number of entities that will review the rule. However, for the purposes of this final rule we assume that on average, each of the 51 affected State Medicaid agencies will have one contractor per State review this final rule. This average assumes that some State Medicaid agencies may use the same contractor, others may use multiple contractors to address the various provisions within this final rule, and some State Medicaid agencies may perform the review in-house. We also assume that each affected managed care plan (estimated in the COI section to be 161 managed care plans) will review the final rule. Lastly, we assume that an average of two advocacy or interest group representatives from each State will review this final rule. In total, we are estimating that 314 entities (51 State Contractors + 161 Managed Care Plans + 102 Advocacy and Interest Groups) will review this final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. We did not receive public comment on this issue.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this final rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We solicited comments on this assumption.

We did not receive public comments on this provision, and therefore, we are finalizing as proposed.

Using the wage information from the Bureau of Labor Statistics, *https://www.bls.gov/oes/current/oes_nat.htm,* we are considering medical and health service managers (Code 11–9111), as including the 51 State Contractors, 161 Managed Care Plans and 102 Advocacy and Interest Groups identified in this final rule, and we estimate that the cost of reviewing this rule is $123.06 per hour, including fringe benefits and other indirect costs. Assuming an average reading speed of 250 words per minute, we estimate that it will take approximately 6.67 hours for each individual to review half of this final rule ([200,000 words × 0.5]/250 words per minute/60 minutes per hour). For each entity that reviews the rule, the estimated cost is $820.40 (6.67 hours × $123.06). Therefore, we estimate that the total one-time cost of reviewing this regulation is $257,605.60 ($820.40 per individual review × 314 reviewers).

D. Alternatives Considered

1. Medicaid Advisory Committee (MAC)

In determining the best way to promote beneficiary and interested parties' voices in State Medicaid program decision making and administration, we considered several ways of revising the MCAC structure and administration. We considered setting minimum benchmarks for each category of all types of MAC members, but we viewed it as too restrictive. We ultimately concluded that only setting minimum benchmarks (at least 25 percent) for beneficiary representation on the MAC and requiring representation from the other MAC categories would give States maximum flexibility in determining the exact composition of their MAC. However, we understand that some States may want us to set specific thresholds for each MAC category rather than determine those categories on their own.

We also considered having not having a separate BAC, but we ultimately determined that requiring States to establish a separate BAC assures that there is a dedicated forum for States to receive beneficiary input outside of the MAC. In the MAC setting, a beneficiary might not feel as comfortable speaking up among other Medicaid program interested parties. The BAC also provides an opportunity for beneficiaries to focus on the issues that are most important to them, and bring those issues to the MAC.

Finally, we also considered setting specific topics for the MAC to provide feedback. However, due to the range of issues specific to each State's Medicaid program, we determined it was most conducive to allow States work with their MAC to identify which topics and priority issues would benefit from interested parties' input.

2. Home and Community-Based Services (HCBS)

a. Person-Centered Service Plans, Grievance Systems, Incident Management Systems

We considered whether to codify the existing 86 percent performance level that was outlined in the 2014 guidance for both person-centered service plans and incident management systems. We did not choose this alternative due to feedback from States and other interested parties of the importance of these requirements, as well as concerns that an 86 percent performance level may not be sufficient to demonstrate that a State has met the requirements.

We considered whether to apply these requirements to section 1905(a) ''medical assistance'' State Plan personal care, home health, and case management services. We decided against this alternative based on State feedback that they do not have the same data collection and reporting capabilities for these services as they do for HCBS delivered under sections 1915(c), (i), (j), and (k) of the Act and because of differences between the requirements of those authorities and section 1905(a) State Plan benefits.

Finally, we considered allowing a good cause exception to the minimum performance level reporting requirements to both the person-centered service plan and the incident management system. We decided against this alternative because the 90 percent performance level is intended to account for various scenarios that might impact a State's ability to achieve these performance levels. Furthermore, there are existing disaster authorities that States could utilize to request a waiver of these requirements in the event of a public health emergency or a disaster.

b. HCBS Payment Adequacy and Payment Adequacy Reporting

We considered several alternatives to this final rule. We considered whether the requirements at § 441.302(k) relating to the percent of payments going to the direct care workforce should apply to other services, such as adult day health, habilitation, day treatment or other partial hospitalization services, psychosocial rehabilitation services, and clinic services for individuals with mental illness. As discussed in section II.B.5, we decided against these alternatives because the services (homemaker, home health aide, and personal care) are those for which the vast majority of payment should be comprised of compensation for direct care workers and for which there will be low facility or other indirect costs. We

also did not include other services for which the percentage might be variable due to the diversity of services included or for which worker compensation will be reasonably expected to comprise only a small percentage of the payment.

As an alternative to the payment adequacy reporting requirement finalized at § 441.311(e), we considered whether other reporting requirements such as a State assurance or attestation or an alternative frequency of reporting could be used to collect data from States regarding the percent of Medicaid payments is spent on compensation to direct care workers. We determined, upon reviewing public comment, that collecting the data is necessary to promote transparency and inform future policymaking. We considered whether to require reporting at the delivery system, HCBS waiver program, or population level but decided against additional levels of reporting because it will increase reporting burden for States without providing additional information necessary for demonstrating that Medicaid payments are being allocated efficiently in accordance with section 1902(a)(30)(A) of the Act.

We considered whether to apply both § 441.302(k) and the reporting requirements finalized at § 441.311 to section 1905(a) ''medical assistance'' State Plan personal care and home health services, but decided not to, largely due to concerns that the statutory and regulatory requirements for section 1905(a) services are different from the statutory and regulatory requirements for section 1915 services; these differences will require additional consideration and rulemaking should the requirements be applied to section 1905(a) services. States also provided feedback that, for the purposes of § 441.311, they do not have the same data collection and reporting capabilities for these services as they do for sections 1915(c), (i), (j), and (k) HCBS.

c. Supporting Documentation Requirements

No alternatives were considered.

d. HCBS Quality Measure Set Reporting

We considered giving States the flexibility to choose which measures they will stratify and by what factors but decided against this alternative as discussed in the Mandatory Medicaid and CHIP Core Set Reporting proposed rule (see 87 FR 51313). We believe that consistent measurement of differences in health outcomes between different groups of beneficiaries is essential to identifying areas for intervention and evaluation of those interventions.[419] Consistency could not be achieved if each State made its own decisions about which data, it would stratify and by what factors.

3. Payment Rate Transparency

In developing this final rule, we considered multiple alternatives. We considered not proposing this rule and maintaining the status quo under current regulations at § 447.203 and 204. However, as noted throughout the Background and Provisions sections of this rule, since the 2011 proposed rule, we have received concerns from interested parties, including State agencies, about the administrative burden of completing AMRPs and questioning whether they are the most efficient way to determine access to care. These comments expressed particular concern about the AMRPs' value when they are required to accompany a proposed nominal rate reduction or restructuring, or where proposed rate changes are made via application of a previously approved rate methodology. At the same time, and as we have discussed, in *Armstrong* v. *Exceptional Child Care, Inc.,* 575 U.S. 320 (2015), the Supreme Court held that Medicaid providers and beneficiaries do not have private right of action against States to challenge State-determined Medicaid payment rates in Federal courts. This decision made our administrative review of SPAs proposing to reduce or restructure payment rates all the more important. For both of these reasons, this rule includes requirements that will create an alternative process that both reduces the administrative burden on States and standardizes and strengthens our review of payment rate reductions or payment restructurings to ensure compliance with section 1902(a)(30)(A) of the Act.

We considered, but did not propose, adopting a complaint-driven process or developing a Federal review process for assessing access to care concerns. Although such processes could further our goals of ensuring compliance with the access requirement in section 1902(a)(30)(A) of the Act, we concluded similar effects can be achieved through methods that did not require the significant amount of Federal effort that will be necessary to develop either or both of these processes. Additionally, a complaint-driven process will not necessarily ensure a balanced review of State-proposed payment rate or payment structure changes, and it is possible that a large volume of complaints could be submitted with the intended or unintended effect of hampering State Medicaid program operations. Therefore, the impact of adopting a complaint-driven process or developing a Federal review process for assessing access to care concerns may be negligible given existing processes. Instead, we believe that relying on existing processes that States are already engaged in, such as the ongoing provider and beneficiary feedback channels under paragraph (b)(7) in § 447.203 and the public process requirement for States submitting a SPA that are required to reduce or restructure Medicaid service payments in § 447.204, will be more effective than creating a new process. While we are relying on existing public feedback channels and processes that States are already engaged in, we solicited public comment regarding our alternative consideration to adopting a complaint driven process or developing a Federal review process for assessing access to care concerns.

We also considered numerous variations of the individual provisions of the final rule. We considered, but did not propose, maintaining the benefits outlined in the current § 447.203(b)(5)(ii)(A) through (H) or requiring all mandatory Medicaid benefit categories be included in the comparative payment rate analysis proposed under § 447.203(b)(2). We also considered, but did not propose, including inpatient hospital behavioral health services and covered outpatient drugs including professional dispensing fees as additional categories of services subject to the comparative payment rate analysis proposed under § 447.203(b)(2). We considered, but did not propose, requiring States whose Medicaid payment rates vary by provider type, calculate an average Medicaid payment rate of all providers for each E/M CPT code subject to the comparative payment rate analysis. We also considered, but did not propose, different points of comparison other than Medicare under the comparative payment rate analysis proposed under § 447.203(b)(2) or using a peer payment rate benchmarking approach for benefit categories where Medicaid is the only or primary payer, or there is no comparable Medicare rate under the comparative payment rate analysis proposed under § 447.203(b)(2) and (3). We considered, but did not propose, varying timeframes for the comparative payment rate analysis proposed under § 447.203(b)(2). We also considered not

[419] Schlotthauer AE, Badler A, Cook SC, Perez DJ, Chin MH. Evaluating Interventions to Reduce Health Care Disparities: An RWJF Program. Health Aff (Millwood). 2008;27(2):568–573.

proposing the payment rate transparency aspect of this rule proposed under § 447.203(b)(1), leaving the comparative payment rate analysis to replace the AMRP process as proposed under § 447.203(b)(2). With regard to the proposal in § 447.203(c), we considered, but did not propose, establishing alternative circumstances from those described in the 2017 SMDL for identifying nominal payment rate adjustments, establishing a minimum set of required data for States above 80 percent of the most recent Medicare payment rates after the proposed reduction or restructuring, using measures that are different from the proposed measures that would be reflected in the forthcoming template, allowing States to use their own unstructured data for States that fail to meet all three criteria in § 447.203(c)(1), and CMS producing and publishing the comparative payment rate analysis proposed in § 447.203(b).

We considered, but did not propose, maintaining the benefits outlined in the current § 447.203(b)(5)(ii)(A) through (H) or requiring all mandatory Medicaid benefit categories be included in the comparative payment rate analysis proposed under § 447.203(b)(2). Maintaining the benefits in previous § 447.203(b)(5)(ii)(A) through (H) might have simplified the transition from the AMRP process to the payment rate transparency and comparative payment rate analysis requirements. However, our experience implementing the 2015 final rule with comment period, as well as interested parties' and States' feedback about the AMRP process, encouraged us to review and reconsider the current list of benefits subject to the AMRP process under current regulations § 447.203(b)(5)(ii)(A) through (H) to determine where we could decrease the level of effort required from States while still allowing ourselves an opportunity to review for access concerns. During our review of the current list of benefits under § 447.203(b)(5)(ii)(A) through (H), we considered, but did not propose, requiring all mandatory Medicaid benefit categories be included in the comparative payment rate analysis. However, when considering the existing burden of the AMRP process under current § 447.203)(b), we believed that expanding the list of benefits to include under proposed § 447.203(b) and (c) would not support our goal to develop a new access strategy that aims to balance Federal and State administrative burden with our shared obligation to ensure compliance with section 1902(a)(30)(A) of the Act. As previously noted in section II. of this rule, we solicited public comment on primary care services, obstetrical and gynecological services, outpatient behavioral health services, and personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency as the proposed categories of services subject to the comparative payment rate analysis requirements in proposed § 447.203(b)(2)(i). Additionally, we solicited public comment regarding our alternative consideration to propose maintaining the benefits outlined in the current § 447.203(b)(5)(ii)(A) through (H) or propose requiring all mandatory Medicaid benefit categories.

We considered, but did not propose, requiring States whose Medicaid payment rates vary by provider type to calculate an average Medicaid payment rate of all provider types for each E/M CPT code subject to the comparative payment rate analysis. Rather than proposing States distinguish their Medicaid payment rates by each provider type in the comparative payment rate analysis, we considered proposing States calculate an average Medicaid payment rate of all providers for each E/M CPT code. This consideration would have simplified the comparative payment rate analysis because States would include a single, average Medicaid payment rate amount and only need to separately analyze their Medicaid payment rates for services delivered to pediatric and adult populations, if they varied. However, calculating an average for the Medicaid payment rate has limitations, including sensitivity to extreme values and inconsistent characterizations of the payment rate between Medicaid and Medicare. In this rule, we propose to characterize the Medicare payment rate as the non-facility payment rate listed on the Medicare PFS for the E/M CPT/HCPCS codes subject to the comparative payment rate analysis. If we were to propose the Medicaid payment rate be calculated as an average Medicaid payment rate of all provider types for the same E/M CPT/HCPCS code, then States' calculated average Medicaid payment rate could include a wide variety of provider types, from a single payment rate for physicians to an average of three payment rates for physicians, physician assistants, and nurse practitioners. This wide variation in how the Medicaid payment rate is calculated among States would provide a less meaningful comparative payment rate analysis to Medicare. The extremes and outliers that would be diluted by using an average are not necessarily the same for both Medicaid and Medicare, so even if both sides of the comparison used an average, we would not be able to look more closely at specific large differences between the respective rates. As previously noted in section II. of this final rule, we solicited public comment on the proposed characterization of the Medicaid payment rate, which accounts for variation in payment rates for pediatric and adult populations and distinguishes payment rates by provider type, in the comparative payment rate analysis. Additionally, we solicited public comment regarding our alternative consideration to propose requiring States whose Medicaid payment rates vary by provider type to calculate an average Medicaid payment rate of all provider types for each E/M CPT code subject to the comparative payment rate analysis.

We considered, but did not propose, requiring States to use a different point of comparison, other than Medicare, for certain services where Medicare is not a consistent or primary payer, such as pediatric dental services or HCBS. The impact of requiring a different point of comparison, other than Medicare, would have carried forward the current regulation requiring States to ''include an analysis of the percentage comparison of Medicaid payment rates to other public (including, as practical, provider payment rates in Medicaid managed care) and private health insurer payment rates within geographic areas of the State'' in their AMRPs. As previously discussed in this rule, FFS States expressed concerns following the 2015 final rule with comment period that private payer payment rates were proprietary information and not available to them, therefore, the challenges to comply with current regulations would be carried forward into the proposed rule. Therefore, we also considered, but did not propose, using various payment rate benchmarking approaches for benefit categories where Medicaid is the only or primary payer, or there is no comparable Medicare rate. As previously noted in section II. of this final rule, we considered benchmarks based on national Medicaid payment averages for certain services included within the LTSS benefit category, benchmarks that use average daily rates for certain HCBS that can be compared to other State Medicaid programs, and benchmarks that use payment data specific to the State's Medicaid program for similarly situated services so that the service payments may be benchmarked to national average. Notwithstanding the

previously described limitations of the alternative considered for situations where differences between Medicaid and Medicare coverage and payment exists, we solicited public comment regarding our alternative consideration to propose States use a different point of comparison, other than Medicare, for certain services where Medicare is not a consistent or primary payer or States use a payment rate benchmarking approach for benefit categories where Medicaid is the only or primary payer, or there is no comparable Medicare rate. Specifically, we solicited public comment on the feasibility and burden on States to implement these alternatives considered for the proposed comparative payment rate analysis. For any comparison to other State Medicaid programs or to a national benchmark, we also solicited public comment on the appropriate role for such a comparison in the context of the statutory requirement to consider beneficiary access relative to the general population in the geographic area.

We considered, but did not propose, various timeframes for the comparative payment rate analysis, including annual (every year), triennial (every 3 years), or quinquennial (every 5 years) updates after the initial effective date of January 1, 2026. As noted in section II. of this final rule, we did not propose an annual timeframe as we believed that an annual update requirement was too frequent due to many States' biennial legislative sessions that provide the Medicaid agency with authority it make Medicaid payment rate changes as well as create more or maintain a similar level of administrative burden of the AMRPs. While some States do have annual legislative sessions and may have annual Medicaid payment rate changes, we believed that proposing annual updates solely for the purpose of capturing payment rate changes in States that with annual legislative sessions would be overly burdensome and duplicative for States with biennial legislative sessions who do not have new, updated Medicaid payment rates to update in their comparative payment rate analysis. Therefore, for numerous States with biennial legislative sessions, the resulting analysis would likely not vary significantly from year to year. Additionally, the comparative payment rate analysis proposes to use the most recently published Medicare payment rates and we are cognizant that Medicare payment rate updates often occur on a quarterly basis. While Medicare often increases rates by the market basket inflation amount, as well as through rulemaking, it does not always result in payment increases for providers.[420] [421] We also considered, but did not propose, maintaining the triennial (every 3 years) timeframe currently in regulation, because we thought it necessary to make significant changes to the non-SPA-related reported in § 447.203(b) that would represent a significant departure from the initial AMRP process in the 2015 final rule with comment in the current § 447.203(b)(1) and this new proposed approach did not lend itself to the triennial timeframe of the current AMRP process. Lastly, we considered, but did not propose, the comparative payment rate analysis be published on a quinquennial basis (every 5 years), because this timeframe was too infrequent for the comparative payment rate analysis to provide meaningful, actionable information. As previously noted in section II. of this rule, we are solicited public comment on the proposed timeframe for the initial publication and biennial update requirements of the comparative payment rate analysis as proposed in § 447.203(b)(4). Additionally, we solicited public comment regarding our alternative consideration to propose an annual, triennial, or quinquennial timeframe for the updating the comparative payment rate analysis after the initial effective date.

We considered, but did not propose, requiring the comparative payment rate analysis be submitted directly to us, as this would not achieve the public transparency goal of the proposed rule. As proposed in § 447.203(b)(3), we are requiring States develop and publish their Medicaid comparative payment rate analysis on the State's website in an accessible and easily understandable format. This proposal is methodologically similar to the current regulation, which requires AMRPs be submitted to us and publicly published by the State and CMS. We found this aspect of the rule to be an effective method of publicly sharing access to care information, as well as ensuring State compliance. As previously noted in section II. of this rule, we solicited public comment on the proposed requirement for States to publish their Medicaid FFS payment rates for all services and comparative payment rate analysis and payment rate disclosure information on the State's website under the proposed § 447.203(b)(1) and (3), respectively. Additionally, we solicited public comment regarding our alternative consideration to propose requiring the comparative payment rate analysis be submitted directly to us and not publicly published.

We considered, but did not propose, that we produce and publish the comparative payment rate analysis proposed in § 447.203(b)(2) through (3) whereby we would develop reports for all States demonstrating Medicaid payment rates for all services or a subset for Medicaid services as a percentage of Medicare payment rates. Shifting responsibility for this analysis would remove some burden from States and allow us to do a full cross-comparison of State Medicaid payment rates to Medicare payment rates, while ensuring a consistent rate analysis across States. However, this approach would rely on T–MSIS data, which would increase the lag in available data due to the need for CMS to prepare it, and introduce uncertainty into the results due to ongoing variation in State T–MSIS data quality and completeness. Although our proposed approach still relies on State-supplied data, they are able to perform the comparisons on their own regardless of the readiness and compliance of any other State. Furthermore, we would need to validate its results with States and work through any discrepancies. Ultimately, we determined the increased lag time and uncertainty in results would diminish the utility of the rate analyses proposed in § 447.203(b), if performed by us instead of the States, to support our oversight of State compliance with section 1902(a)(30)(A) of the Act. As previously noted in section II. of this rule, we solicited public comment on our proposal to require States to develop and publish a comparative payment rate analysis and payment rate disclosure as proposed in § 447.203(b)(2) and (3). Additionally, we solicited public comment regarding our alternative consideration to propose that we produce and publish the comparative payment rate analysis and payment rate disclosure proposed in § 447.203(b)(2) and (3) for all States.

We considered, but did not propose, establishing alternative circumstances

[420] Although ''market basket'' technically describes the mix of goods and services used in providing health care, this term is also commonly used to denote the input price index (that is, cost category weights and price proxies combined) derived from that market basket. Accordingly, the term ''market basket'' as used in this document refers to the various CMS input price indexes. A CMS market basket is described as a fixed-weight, Laspeyres-type index because it measures the change in price, over time, of the same mix of goods and services purchased in the base period. FAQ—Medicare Market Basket Definitions and General Information, updated May 2022. *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/Downloads/info.pdf* Accessed January 4, 2023.

[421] Medicare Unit Cost Increases Reported as of April 2022. *https://www.cms.gov/files/document/ffs-trends-2021-2023-april-2022.pdf.* Accessed January 4, 2023.

from the 2017 SMDL for identifying nominal payment rate adjustments when States propose a rate reduction or restructuring. We previously outlined in SMDL #17–004 several circumstances where Medicaid payment rate reductions generally would not be expected to diminish access: reductions necessary to implement CMS Federal Medicaid payment requirements; reductions that will be implemented as a decrease to all codes within a service category or targeted to certain codes, but for services where the payment rates continue to be at or above Medicare and/or average commercial rates; and reductions that result from changes implemented through the Medicare program, where a State's service payment methodology adheres to the Medicare methodology. This final rule will not codify this list of policies that may produce payment rate reductions unlikely to diminish access to Medicaid-covered services. We considered, but did not propose, setting a different percentage for the criteria that State Medicaid rates for each benefit category affected by the reductions or restructurings must, in the aggregate, be at or above 80 percent of the most recent comparable Medicare payment rates after the proposed reduction or restructuring as a threshold. We considered setting the threshold at 100 percent of Medicare to remain consistent with the 2017 SMDL. However, after conducting a literature review, we determined that 80 percent of the most recently published Medicare payment rates is currently the most reliable benchmark of whether a rate reduction or restructuring is likely to diminish access to care. We also considered, but did not propose, setting a different percentage for the criteria that proposed reductions or restructurings result in no more than 4 percent reduction of overall FFS Medicaid expenditures for a benefit category. We considered a variety of percentages, but determined that codifying the 4 percent threshold from the 2017 SMDL and proposed in the 2018 proposed rule [422] was the best option based on our experience implementing this established policy after the publication of the 2017 SMDL. Additionally, we received a significant number of comments in the 2018 proposed rule from State Medicaid agencies that signaled strong support for this percentage threshold as a meaningful threshold for future rate changes.[423] [424] [425] Lastly, we considered, but did not propose, defining what is meant by ''significant'' access concerns received through the public process described in § 447.204 when a State proposes a rate reduction or restructuring. As proposed, we expect State Medicaid agencies to make reasonable determinations about which access concerns are significant when raised through the public process, and as part of our SPA review, may request additional information from the State to better understand any access concerns that have been raised through public processes and whether they are significant. Based on our experience implementing the policies outlined in the 2017 SMDL and a literature review of relevant research about payment rate sufficiency, we proposed criteria for States proposing rate reductions or restructurings that would reduce the SPA submission requirements when those criteria are met. Additionally, each of these thresholds is one of a three-part test where States must meet all three, or else it will trigger a requirement for additional State analysis of the rate reduction or restructuring. As previously noted in section II. of this rule, we solicited public comment on the streamlined criteria proposed in § 447.203(c)(1). Additionally, we solicited public comment regarding our alternative consideration to propose establishing alternative circumstances from the 2017 SMDL for identifying nominal payment rate adjustments when States propose a rate reduction or restructuring.

We considered, but did not propose, establishing a minimum set of required data for States above 80 percent of the most recent Medicare payment rates after the proposed reduction or restructuring regardless of the remaining criteria. This requirement would minimize administrative burden on States by not requiring States submit all items in § 447.203(c)(2) and establish a baseline for comparison if future rate reductions or restructurings are proposed that may lower the State's payment rates below 80 percent of the most recent Medicare payment rates. However, we determined that, while we believe 80 percent to be an effective threshold point, we did not want that to serve as the only trigger for additional analysis. As proposed, only States that do not meet all of the proposed requirements in § 447.203(c)(1) will have to submit the required data outlined in § 447.203(c)(2). As previously noted in section II. of this rule, we solicited public comment on our proposal to require all three criteria described in § 447.203(c)(1)(i) through (iii) for assessing the effect of a proposed payment rate reduction or payment restructuring on access to care. Additionally, we solicited public comment regarding our alternative consideration to propose establishing alternative circumstances from the 2017 SMDL for identifying nominal payment rate adjustments when States propose a rate reduction or restructuring.

We considered, but did not propose, allowing States to use their own unstructured data, similar to the AMRP process, for States that fail to meet all three criteria in § 447.203(c)(1), thereby eliminating the need for us to develop a template for States proposing rate reductions or restructurings. While this would reduce administrative burden on us and provide States with flexibility in determining relevant data for complying with statutory and regulatory requirements, we received feedback after the 2015 final rule with comment period that States found developing an AMRP from scratch with minimal Federal guidelines a challenging task and other interested parties noted that States had too much discretion in documenting sufficient access to care. Therefore, we proposed developing a template to support State analyses of rate reduction or restructuring SPAs that fail to meet the criteria in § 447.203(c)(1). As noted elsewhere in the preamble, we are releasing subregulatory guidance, including a template to support completion of the analysis that would be required under paragraph (c)(2), alongside this final rule. We also anticipate working directly with States through the SPA review process to ensure compliance with section 1902(a)(30)(A) of the Act. Additionally, we solicited public comment regarding our alternative consideration to propose allowing States to use their own unstructured data, similar to the AMRP process, for States that fail to meet all three criteria in § 447.203(c)(1).

After careful consideration, we ultimately determined that the requirements in proposed § 447.203(b) and (c) would strike a more optimal balance between alleviating State and Federal administrative burden, while ensuring a transparent, data-driven, and consistent approach to States' implementation and our oversight of

[422] 83 FR 12696 at 12705.

[423] Connecticut Department of Social Services, Comment Letter on 2018 Proposed Rule (May 21, 2018), *https://downloads.regulations.gov/CMS-2018-0031-0021/attachment_1.pdf.*

[424] California Department of Health Care Services, Comment Letter on 2018 Proposed Rule (May 24, 2018), *https://downloads.regulations.gov/CMS-2018-0031-0090/attachment_1.pdf.*

[425] Florida Agency for Health Care Administration, Comment Letter on 2018 Proposed Rule (May 24, 2018), *https://downloads.regulations.gov/CMS-2018-0031-0083/attachment_1.pdf.*

State compliance with the access requirement in section 1902(a)(30)(A) of the Act.

We considered finalizing the payment rate transparency provisions under 447.203(b)(1) as proposed, but in response to commenter concerns about the requirement to breakdown bundled payment rates into constituent services and rates, we added regulatory language to provide States with flexibility in complying with the payment rate transparency publication requirements when individual rates for constituent services within a State's bundle payment rate do not exist. Specifically, we added the following language: ''unless this information is not reasonably available'' to the requirement that ''in the case of a bundled or similar payment methodology'' States must ''identify each constituent service included within the rate and how much of the bundled payment is allocated to each constituent service under the State's methodology.'' We also clarified in this final rule through a previous comment response that facility payment rates (for example, provider-specific rates and per diem rates) are not considered to be bundled payment rates and are not subject to the payment rate transparency provisions. We believe this additional regulatory language and clarification will reduce administrative burden on States by narrowing the scope of bundled payment rates subject to the payment rate transparency requirements. While we still believe this requirement is necessary to ensure maximum transparency of payment rates in the case of bundled fee schedule payment rates, it is also necessary to account for circumstances where a State does not have information available to comply with this regulatory requirement.

We considered finalizing the payment rate transparency provisions under 447.203(b)(1) as proposed, but in response to commenter concerns about requiring States with prospective effective dates to publish rates that are not yet in effect, we added regulatory language to address this circumstance. Specifically, the regulation now states that the agency is required to include the date the payment rates were last updated on the State Medicaid agency's website and to ensure these data are kept current, where any necessary update must be made no later than either 1 month following the date of CMS approval of the State plan amendment, section 1915(c) HCBS waiver amendment, or similar amendment revising the provider payment rate or methodology, or 1 month following the effective date of the approved amendment, whichever date occurs latest. If we finalized the regulatory language as proposed, then States would be required to update their payment rate transparency publications with payment rates that are not yet in effect, and this would not align with our transparency efforts to ensure a States' payment rate transparency publication is as current as possible, and accurate once published.

We considered finalizing the payment rate transparency provisions under § 447.203(b)(1) with a requirement to organize the payment rate transparency publication by CPT/HCPCS code, similar to the comparative payment rate analysis, but in response to commenter concerns about administrative burden on States to comply with the provisions as proposed, we did not require the payment rate transparency publication to be organized in this manner. While we still require both the payment rate transparency publication and comparative payment rate analysis to be organized in such a way that a member of the public can readily determine the amount that Medicaid would pay for the service, requiring the publication to be organized by CPT/HCPCS code would create substantial burden for States that do not current organize their payment rates in this manner as all fee schedule payment rates are subject to this provision. By not requiring the payment rate transparency publication to be organized a particular way, we are providing States with the flexibility to use existing fee schedule publications for compliance with the regulations finalized in this rule.

We considered, but did not finalize, an increase to the 80 percent of Medicare threshold in § 447.203(c)(1)(i) to 100 percent of Medicare as suggested by some of the commenters. Taking such an action would have increased the threshold for States to qualify for the streamlined review process and increased administrative burden on the States. We ultimately decided not to pursue this alternative because this threshold was not intended to provide absolute assurance that a provider would participate in the Medicaid program. Instead, we are using 80 percent as a threshold to determine the level of analysis and information a State must provide to CMS to support consistency with section 1902(a)(30)(A) of the Act and allow CMS to focus its review efforts on proposals at the highest risk of access concerns. We also note that the 80 percent threshold was just one of three criteria that must be met for a streamlined review. Our stated intention in this rule was that we were intending this to provide States with relief from the more burdensome AMRP process defined in the 2015 final rule with comment period, and establishing a higher threshold would not fit within that stated purpose.

We received public comments on several of these alternatives, but many of those comments blended with discussion of the relevant provisions, so in general our responses to those comments are contained in section II.C. However, we did receive some comments on alternatives not already addressed in this final rule.

Comment: One commenter responded to our decision not to propose adopting a complaint-driven process or developing a Federal review process for assessing access to care concerns. That commenter stated that CMS' reliance on existing State processes, such as the ongoing provider and beneficiary feedback channels and the public process requirement for States submitting a SPA that proposed to reduce or restructure Medicaid services would be acceptable if the existing processes are responsive and delivered timely action when concerns are raised.

Response: We agree with the commenter regarding existing processes being responsive and timely. As described in the proposed rule, these processes must meet requirements under newly finalized § 447.203(c)(4) (which includes existing requirements from the 2015 final rule with comment period that was relocated from § 447.203(b)(7)), as well as § 447.204 (which includes existing requirements from the 2015 final rule with comment period with confirming changes to align with this final rule). These existing regulatory requirements require States have ongoing mechanisms for beneficiary and provider input on access to care in which they promptly respond to public input and maintain a record the public input, as well as how the State responded. While this is a general requirement for ensuring States have a method for collecting access to care issues from the public, these requirements also specifically apply to States proposing a rate reduction or restructuring.

Comment: One commenter agreed with CMS' decision to exclude outpatient drugs from the proposed comparative payment rate analysis under § 447.203(b)(2) noting that, in addition to the reasons CMS outlined in the proposed rule, the cost of outpatient drugs can change weekly and there are anticipated cost differences compared to other payers, such as Medicare or States. The commenter recommended that, if CMS decides to subject outpatient drugs to the comparative payment rate

analysis, then CMS should develop a unique methodology for States to follow in making the comparison to another payer.

Response: We appreciate the commenter's support for our decision, as well as their recommendation for how we could subject outpatient drugs to the comparative payment rate analysis if we did end up deciding to include them. We are not changing the services subject to the analysis in this final rule, although we note we have updated ''outpatient behavioral health services'' to ''outpatient mental health and substance use disorder services.''

E. Accounting Statement and Table

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf*), we have prepared an accounting statement in Table 48 showing the classification of the impact associated with the provisions of this final rule. Note, Table 47 shown previously in this final rule provides a summary of the one-time and annual costs estimates.

TABLE 48: Accounting Table

Category	Estimates	Units		
		Year Dollar	Discount Rate	Period Covered
Regulatory Review Costs				
Annualized Monetized	.112	2023	7%	2024 - 2028
($million/year)	.117	2023	3%	2024 - 2028
Costs to States				
Annualized Monetized	72.12	2023	7%	2024 - 2028
($million/year)	75.22	2023	3%	2024 - 2028
Costs to Beneficiaries				
Annualized Monetized	0.47	2023	7%	2024 - 2028
($million/year)	0.49	2023	3%	2024 - 2028
Costs to Providers				
Annualized Monetized	102.05	2023	7%	2024 - 2028
($million/year)	106.44	2023	3%	2024 - 2028
Costs to Managed Care Plans				
Annualized Monetized	6.84	2023	7%	2024 - 2028
($million/year)	7.13	2023	3%	2024 - 2028

F. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that *almost all* of Home Health Care Services, Services for the Elderly and Persons with Disabilities, and Direct Health and Medical Insurance Carriers are small entities as that term is used in the RFA (include small businesses, nonprofit organizations, and small governmental jurisdictions). The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $9.0 million to $47 million in any 1 year).

For purposes of the RFA, approximately 95 percent of the health care industries impacted are considered small businesses according to the Small Business Administration's size standards with total revenues of $47 million or less in any 1 year.

According to the SBA's website at *http://www.sba.gov/content/small-business-size-standards* HCBS Provider Costs and Managed care Plan fall in the North American Industrial Classification System 621610 Home Health Care Services, 624120 Services for the Elderly and Persons with Disabilities, and 524114 Direct Health and Medical Insurance Carriers.

BILLING CODE 4120–01–P

TABLE 49: HCBS Providers Costs and Managed Care Plan Size Standards

NAICS (6-digit)	Industry Subsector Description	SBA Size Standard/ Small Entity Threshold	Total Small Businesses
621610	Home Health Care Services	$19 Million	22,840
624120	Services for the Elderly and Persons with Disabilities	$15 Million	26,051
524114	Direct Health and Medical Insurance Carriers	$47 Million	455

Source: 2017 Statistics of U.S. Businesses

TABLE 50: NAICS 62160 Home Health Care Servies ($19 Million Size Standard)

Firm Size (by Receipts)	Firm Count	% of Small Firms	Avg. Revenue
SMALL FIRMS	**22,840**	**100%**	**$ 5,320,704.31**
<$100K	5,861	26%	$ 35,948.98
$100K -$499K	5,687	25%	$ 256,725.47
$500 - $999K	3,342	15%	$ 414,742.71
$1M - $2.49M	4,434	19%	$ 1,201,189.90
$2.5M - $4.9M	1,951	9%	$ 1,135,879.03
$5M - $7.5M	672	3%	$ 667,476.88
$7.6M - $9.9M	356	2%	$ 496,663.20
$10M - $14.9M	346	2%	$ 642,844.22
$15M - $19.9M	191	1%	$ 469,233.92
LARGE FIRMS			
Receipts > $20M	961	N/A	$ 6,451,412.39 (for firms > $100M

Source: 2017 Statistics of U.S. Businesses

TABLE 51: NAICS 624120 Services for the Elderly and Persons with Disabilities ($15 Million Size Standard)

Firm Size (by Receipts)	Firm Count	% of Small Firms	Avg. Revenue
SMALL FIRMS	**26,051**	**100%**	**$ 3,117,267.70**
<$100K	8,293	32%	$ 31,953.45
$100K -$499K	6,864	26%	$ 215,283.61
$500 - $999K	3,449	13%	$ 298,760.76
$1M - $2.49M	4,093	16%	$ 764,108.16
$2.5M - $4.9M	1,827	7%	$ 705,634.63
$5M - $7.5M	695	3%	$ 404,539.85
$7.6M - $9.9M	401	2%	$ 295,453.88
$10M - $14.9M	429	2%	$ 401,533.34
LARGE FIRMS			
Receipts > $15M	1,211	N/A	$57,136,066.67 (for firms > $100M

Source: 2017 Statistics of U.S. Businesses

TABLE F52: NAICS 524114 Direct Health and Medical Insurance Carriers ($47 Million Size Standard)

Firm Size (by Receipts)	Firm Count	% of Small Firms	Avg. Revenue
SMALL FIRMS	**455**	**100%**	**$25,087,240.51**
<$100K	79	17%	$ 52,101.27
$100K -$499K	170	37%	$ 542,278.48
$500 - $999K	42	9%	$ 388,329.11
$1M - $2.49M	48	11%	$ 946,037.97
$2.5M - $4.9M	31	7%	$ 1,371,468.35
$5M - $7.5M	12	3%	$ 939,797.47
$7.6M - $9.9M	10	2%	$ 1,126,303.80
$10M - $14.9M	14	3%	$ 2,033,645.57
$15M - $19.9M	13	3%	$ 2,802,481.01
$20M- $24.9M	5	1%	$ 1,389,189.87
$25M- $29.9M	4	1%	$ 1,523,012.66
$30M - $34.9M	9	2%	$ 3,417,797.47
$35M- $39.9M	6	1%	$ 2,599,443.04
$40M- $49.9M	12	3%	$ 5,955,354.43
LARGE FIRMS			
Receipts > 50M	290	N/A	$ 3,244,413,424.12 (for firms > $100M

Tables 50, 51, and 52 aid in showing the distribution of firms and revenues at their 6 digits NAICS code level. These tables aim to provide an understanding of the disproportionate impacts among firms, between small and large firms.

Individuals and States are not included in the definition of a small entity. This rule will not have a significant impact measured change in revenue of 3 to 5 percent on a substantial number of small businesses or other small entities. All the industries combined, according to the 2017 Economic Census, earned approximately $46,771,961,000.00. Hence, all the costs combined, amounts to about 1 percent.

TABLE 53: NAICS Classification of Services, the Distribution of Costs, Annualized Cost per Industry, Average Annual Revenue for Small Firms, and Revenue Test

Services	NAICS	Percentage of Costs	Annualized Cost* per Industry	Avg. Annual Revenue for Small Firms	Revenue Test
Managed Care Plans	Direct Health and Medical Insurance Carriers (524114)	100 Percent	$370,989,000	**$5,320,704.31**	**1.4%**
Home and Community-Based Services (HCBS)	Elderly and Persons with Disabilities (624120)	67 Percent	$248,562,630.00	**$3,117,267.70**	**1.3%**
Home and Community-Based Services (HCBS)	Home Health Care Services (621610)	37 Percent	$137,265,930.00	**$25,087,240.51**	**18%**

*Annualized Cost per Industry was determined from the Accounting Table 7.

BILLING CODE 4120–01–C

Therefore, as its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent.

According to Table 12, for Direct Health and Medical Insurance Carriers (524114) and Elderly and Persons with Disabilities (624120), we do not believe that the 3 to 5 percent threshold will be reached by the requirements in this final rule. However, Home Health Care Services (621610) has a substantial effect on its small businesses.

Therefore, the Secretary has certified that this final rule will not have a significant economic impact on a substantial number of small entities in

the Direct Health and Medical Insurance Carriers (524114) and Elderly and Persons with Disabilities (624120) industries. However, the Secretary cannot certify that this final rule will not have a significant economic impact on the Home Health Care Services (621610) industry.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the Act. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This final rule will not have a significant impact on the operations of small rural hospitals since small hospitals are not affected by the proposed rule. Therefore, the Secretary has certified that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

G. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2023, that threshold is approximately $177 million. This final rule will impose a mandate that will result in the expenditure by the private sector, of more than $177 million in at least 1 year.

Several of the provisions in this final rule address gaps in existing regulations. In these cases, the costs for States to implement the changes to existing processes will likely be minimal. For the remaining areas of the rule, we have sought to minimize burden whenever possible, while still achieving the goals of this rulemaking, as reflected in the burden analyses and estimates described in sections III. and IV. of this final rule. We further note that, as reflected in those sections, States would be able to claim administrative match for the work required to implement the proposals.

We have described the projected paperwork costs to providers, as well as to States, the Federal Government, and managed care plans (as applicable) in the Collection of Information section (section III. of this final rule.) We note that the requirements finalized at § 441.302(k) regarding the HCBS payment adequacy requirements represent the biggest impact on small entities. We have not calculated an additional financial impact on providers beyond what is reflected in the Collection of Information (in section III.) and the Regulatory Impact Analysis (section (this section, section IV. of the final rule.) The requirements finalized at § 441.302(k) may require that a number of HCBS providers ensure that they allocate more of their Medicaid payments to direct care workers than they had prior to the implementation of § 441.302(k); this does not reflect a change in the Medicaid payments. The underlying assumption of this requirement is that providers are capable of allocating 80 percent their Medicaid payments to direct care workers by ensuring that payments are allocated efficiently and that overhead is kept to a minimum. Additionally, as discussed in II.B.5. of this final rule, we have provided States with several flexibilities for certain providers that would be unable to operate successfully under this requirement. While we received anecdotal data from public commenters regarding current Medicaid rates, workforce shortages, and survey responses from providers regarding their reaction to the proposal in the proposed rule, we did not receive data (nor do we have other sources of data) on which to estimate additional costs associated with § 441.302(k) aside from what is presented in the Collection of Information and Regulatory Impact Analysis sections above.

H. Federalism

E.O. 13132 establishes certain requirements that an agency must meet when it issues a proposed rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This rule does not impose substantial direct costs on State or local governments, preempt State law, or otherwise have Federalism implications. As mentioned in the previous section of this rule, the costs to States by our estimate do not rise to the level of specified thresholds for significant burden to States. In addition, many proposals amend existing requirements or further requirements that already exist in statute, and as such would not create any new conflict with State law.

I. Conclusion

The policies in this final rule, will enable us to implement enhanced access to health care services for Medicaid beneficiaries across FFS, managed care, and HCBS delivery systems.

The analysis in section IV. of this final rule, together with the rest of this preamble, provides a regulatory impact analysis. In accordance with the provisions of E.O. 12866, this final rule was reviewed by the Office of Management and Budget.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on April 11, 2024.

List of Subjects

42 CFR Part 431

Administrative practice and procedure, Consumer protection, Grant programs—health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirement.

42 CFR Part 438

Administrative practice and procedure, Grant programs—health, Health professions, Medicaid, Older adults, People with Disabilities, Reporting and recordkeeping requirements.

42 CFR Part 441

Administrative practice and procedure, Consumer protection, Grant programs—health, Health professions, Medicaid, Older adults, People with Disabilities, Reporting and recordkeeping requirements.

42 CFR Part 447

Accounting, Administrative practice and procedure, Drugs, Grant programs—health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, and Rural areas.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR Chapter IV as set forth below:

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

■ 1. The authority citation for part 431 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 2. Section 431.12 is revised to read as follows:

§ 431.12 Medicaid Advisory Committee and Beneficiary Advisory Council.

(a) *Basis and purpose.* This section, based on section 1902(a)(4) of the Act, prescribes State Plan requirements for establishment and ongoing operation of a public Medicaid Advisory Committee

(MAC) with a dedicated Beneficiary Advisory Council (BAC) comprised of current and former Medicaid beneficiaries, their family members, and caregivers, to advise the State Medicaid agency on matters of concern related to policy development, and matters related to the effective administration of the Medicaid program.

(b) *State plan requirement.* The State plan must provide for a MAC and a BAC that will advise the director of the single State Agency for the Medicaid program on matters of concern related to policy development and matters related to the effective administration of the Medicaid program.

(c) *Selection of members.* The Director of the single State Agency for the Medicaid program must select members for the MAC and BAC for a term of length determined by the State, which may not be followed immediately by a consecutive term for the same member, on a rotating and continuous basis. The State must create a process for recruitment and selection of members and publish this information on the State's website as specified in paragraph (f).

(d) *MAC membership and composition.* The membership of the MAC must be composed of the following percentage and representative categories of interested parties in the State:

(1) For the period from July 9, 2024 through July 9, 2025, 10 percent of the MAC members must come from the BAC; for the period from July 10, 2025 through July 9, 2026, 20 percent of MAC members must come from the BAC; and thereafter, 25 percent of MAC members must come from the BAC.

(2) The remaining committee members must include representation of at least one from each of the following categories:

(A) State or local consumer advocacy groups or other community-based organizations that represent the interests of, or provide direct service, to Medicaid beneficiaries.

(B) Clinical providers or administrators who are familiar with the health and social needs of Medicaid beneficiaries and with the resources available and required for their care. This includes providers or administrators of primary care, specialty care, and long-term care.

(C) As applicable, participating Medicaid MCOs, PIHPs, PAHPs, PCCM entities or PCCMs as defined in § 438.2, or a health plan association representing more than one such plans; and

(D) Other State agencies that serve Medicaid beneficiaries (for example, foster care agency, mental health agency, health department, State agencies delegated to conduct eligibility determinations for Medicaid, State Unit on Aging), as ex-officio, non-voting members.

(e) *Beneficiary Advisory Council.* The State must form and support a BAC, which can be an existing beneficiary group, that is comprised of: individuals who are currently or have been Medicaid beneficiaries and individuals with direct experience supporting Medicaid beneficiaries (family members and paid or unpaid caregivers of those enrolled in Medicaid), to advise the State regarding their experience with the Medicaid program, on matters of concern related to policy development and matters related to the effective administration of the Medicaid program.

(1) The MAC members described in paragraph (d)(1) of this section must also be members of the BAC.

(2) The BAC must meet separately from the MAC, on a regular basis, and in advance of each MAC meeting to ensure BAC member preparation for each MAC meeting.

(f) *MAC and BAC administration.* The State agency must create standardized processes and practices for the administration of the MAC and the BAC that are available for public review on the State website. The State agency must—

(1) Develop and publish, by posting publicly on its website, bylaws for governance of the MAC and BAC along with a current list of members. States will also post publicly the past meeting minutes of the MAC and BAC meetings, including a list of meeting attendees. States will give BAC members the option to include their names in the membership list and meeting minutes that will be posted publicly.

(2) Develop and publish by posting publicly on its website a process for MAC and BAC member recruitment and selection along with a process for selection of MAC and BAC leadership;

(3) Develop, publish by posting publicly on its website, and implement a regular meeting schedule for the MAC and BAC; the MAC and BAC must each meet at least once per quarter and hold off-cycle meetings as needed. Each MAC and BAC meeting agenda must include a time for members and the public (if applicable) to disclose conflicts of interest.

(4) Make at least two MAC meetings per year open to the public and those meetings must include a dedicated time during the meeting for the public to make comments. BAC meetings are not required to be open to the public, unless the State's BAC members decide otherwise. The public must be adequately notified of the date, location, and time of each public MAC meeting and any public BAC meeting at least 30 calendar days in advance of the date of the meeting.

(5) Offer a rotating, variety of meeting attendance options. These meeting options are: all in-person attendance, all virtual attendance, and hybrid (in person and virtual) attendance options. Regardless of which attendance type of meeting it is, States are required to always have, at a minimum, telephone dial-in option at the MAC and BAC meetings for its members. If the MAC or BAC meeting is deemed open to the public, the State must offer at a minimum a telephone dial-in option for members of the public;

(6) Ensure that the meeting times and locations for MAC and BAC meetings are selected to maximize member attendance and may vary by meeting; and

(7) Facilitate participation of beneficiaries by ensuring that that meetings are accessible to people with disabilities, that reasonable modifications are provided when necessary to ensure access and enable meaningful participation, and communications with individuals with disabilities are as effective as with others, that reasonable steps are taken to provide meaningful access to individuals with Limited English Proficiency, and that meetings comply with the requirements at § 435.905(b) of this chapter and applicable regulations implementing the ADA, Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act, and section 1557 of the Affordable Care Act at 28 CFR part 35 and 45 CFR parts 80, 84 and 92, respectively.

(g) *MAC and BAC participation and scope.* The MAC and BAC participants must have the opportunity to advise the director of the single State Agency for the Medicaid program on matters related to policy development and matters related to the effective administration of the Medicaid program. At a minimum, the MAC and BAC must determine, in collaboration with the State, which topics to provide advice on related to—

(1) Additions and changes to services;

(2) Coordination of care;

(3) Quality of services;

(4) Eligibility, enrollment, and renewal processes;

(5) Beneficiary and provider communications by State Medicaid agency and Medicaid MCOs, PIHPs, PAHPs, PCCM entities or PCCMs as defined in § 438.2;

(6) Cultural competency, language access, health equity, and disparities and biases in the Medicaid program;

(7) Access to services; and

(8) Other issues that impact the provision or outcomes of health and medical care services in the Medicaid program as determined by the MAC, BAC, or State.

(h) *State agency staff assistance, participation, and financial help.* The single State Agency for the Medicaid program must provide staff to support planning and execution of the MAC and the BAC to include—

(1) Recruitment of MAC and BAC members;

(2) Planning and execution of all MAC and BAC meetings and the production of meeting minutes that include actions taken or anticipated actions by the State in response to interested parties' feedback provided during the meeting. The minutes are to be posted on the State's website within 30 calendar days following each meeting. Additionally, the State must produce and post on its website an annual report as specified in paragraph (i) of this section; and

(3) The provision of appropriate support and preparation (providing research or other information needed) to the MAC and BAC members who are Medicaid beneficiaries to ensure meaningful participation. These tasks include—

(i) Providing staff whose responsibilities are to facilitate MAC and BAC member engagement;

(ii) Providing financial support, if necessary, to facilitate Medicaid beneficiary engagement in the MAC and the BAC; and

(iii) Attendance by at least one staff member from the single State Agency for the Medicaid program's executive staff at all MAC and BAC meetings.

(i) *Annual report.* The MAC, with support from the State, must submit an annual report describing its activities, topics discussed, and recommendations. The State must review the report and include responses to the recommended actions. The State agency must then—

(1) Provide MAC members with final review of the report;

(2) Ensure that the annual report of the MAC includes a section describing the activities, topics discussed, and recommendations of the BAC, as well as the State's responses to the recommendations; and

(3) Post the report to the State's website. States have 2 years from July 9, 2024 to finalize the first annual MAC report. After the report has been finalized, States will have 30 days to post the annual report.

(j) *Federal financial participation.* FFP is available at 50 percent of expenditures for the MAC and BAC activities.

(k) *Applicability dates.* Except as noted in paragraphs (d)(1) and (i)(3) of this section, the requirements in paragraphs (a) through (j) of this section are applicable July 9, 2025.

■ 3. Section 431.408 is amended by revising paragraph (a)(3)(i) to read as follows:

§ 431.408 State public notice process.

(a) * * *

(3) * * *

(i) The Medicaid Advisory Committee and Beneficiary Advisory Council that operate in accordance with § 431.12 of this subpart; or

* * * * *

PART 438—MANAGED CARE

■ 4. The authority citation for part 438 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 5. Section 438.72 is added to subpart B to read as follows:

§ 438.72 Additional requirements for long-term services and supports.

(a) [Reserved]

(b) *Services authorized under section 1915(c) waivers and section 1915(i), (j), and (k) State plan authorities.* The State must comply with the requirements at §§ 441.301(c)(1) through (3), 441.302(a)(6), 441.302(k), 441.311, and 441.313 for services authorized under section 1915(c) waivers and section 1915(i), (j), and (k) State plan authorities.

PART 441—SERVICES: REQUIREMENTS AND LIMITS APPLICABLE TO SPECIFIC SERVICES

■ 6. The authority citation for part 441 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 7. Section 441.301 is amended by revising paragraphs (c)(1) introductory text and (c)(3), and adding paragraph (c)(7) to read as follows:

§ 441.301 Contents of request for a waiver.

* * * * *

(c) * * *

(1) *Person-centered planning process.* The individual, or if applicable, the individual and the individual's authorized representative, will lead the person-centered planning process. When the term ''individual'' is used throughout § 441.301(c)(1) through (3), it includes the individual's authorized representative if applicable. In addition, the person-centered planning process:

* * * * *

(3) *Review of the person-centered service plan*—(i) *Requirement.* The State must ensure that the person-centered service plan for every individual is reviewed, and revised as appropriate, based upon the reassessment of functional need at least every 12 months, when the individual's circumstances or needs change significantly, or at the request of the individual.

(ii) *Minimum performance at the State level.* The State must demonstrate, through the reporting requirements at § 441.311(b)(3), that it ensures the following minimum performance levels are met:

(A) Complete a reassessment of functional need at least every 12 months for no less than 90 percent of the individuals continuously enrolled in the waiver for at least 365 days; and

(B) Review, and revise as appropriate, the person-centered service plan, based upon the reassessment of functional need, at least every 12 months, for no less than 90 percent of the individuals continuously enrolled in the waiver for at least 365 days.

(iii) *Applicability date.* States must comply with the performance levels described in paragraph (c)(3)(ii) of this section beginning 3 years after July 9, 2024; and in the case of the State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes HCBS in the MCO's, PIHP's, or PAHP's contract, the first rating period for contracts with the MCO, PIHP, or PAHP beginning on or after the date that is 3 years after July 9, 2024.

* * * * *

(7) *Grievance system*—(i) *Purpose.* The State must establish a procedure under which a beneficiary may file a grievance related to the State's or a provider's performance of the activities described in paragraphs (c)(1) through (6) of this section. This requirement does not apply to a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act. The State may have activities described in paragraph (c)(7) of this section performed by contractors or other government entities, provided, however, that the State retains responsibility for ensuring performance of and compliance with these provisions.

(ii) *Definitions.* As used in this section:

Grievance means an expression of dissatisfaction or complaint related to

the State's or a provider's performance of the activities described in paragraphs (c)(1) through (6) of this section, regardless of whether remedial action is requested.

Grievance system means the processes the State implements to handle grievances, as well as the processes to collect and track information about them.

(iii) *General requirements.* (A) The beneficiary or a beneficiary's authorized representative, if applicable, may file a grievance. All references to beneficiary include the role of the beneficiary's representative, if applicable.

(*1*) Another individual or entity may file a grievance on behalf of the beneficiary, or provide the beneficiary with assistance or representation throughout the grievance process, with the written consent of the beneficiary or authorized representative.

(*2*) A provider cannot file a grievance that would violate the State's conflict of interest guidelines, as required in § 441.540(a)(5).

(B) The State must:

(*1*) Base its grievance processes on written policies and procedures that, at a minimum, meet the conditions set forth in this paragraph (c)(7);

(*2*) Provide beneficiaries reasonable assistance in ensuring grievances are appropriately filed with the grievance system, completing forms and taking other procedural steps related to a grievance. This includes, but is not limited to, ensuring the grievance system is accessible to individuals with disabilities and providing meaningful access to individuals with Limited English Proficiency, consistent with § 435.905(b) of this chapter, and includes auxiliary aids and services where necessary to ensure effective communication, such as providing interpreter services and toll-free numbers that have adequate TTY/TTD and interpreter capability;

(*3*) Ensure that punitive or retaliatory action is neither threatened nor taken against an individual filing a grievance or who has had a grievance filed on their behalf;

(*4*) Accept grievances and requests for extension of timeframes from the beneficiary;

(*5*) Provide to the beneficiary the notices and information required under this subsection, including information on their rights under the grievance system and on how to file grievances, and ensure that such information is accessible for individuals with disabilities and individuals with Limited English Proficiency in accordance with § 435.905(b);

(*6*) Review any grievance resolution with which the beneficiary is dissatisfied; and

(*7*) Provide information about the grievance system to all providers and subcontractors approved to deliver services.

(C) The process for handling grievances must:

(*1*) Allow the beneficiary to file a grievance with the State either orally or in writing;

(*2*) Acknowledge receipt of each grievance;

(*3*) Ensure that the individuals who make decisions on grievances are individuals:

(*i*) Who were neither involved in any previous level of review or decision-making related to the grievance nor a subordinate of any such individual;

(*ii*) Who are individuals who have the appropriate clinical and non-clinical expertise, as determined by the State; and

(*iii*) Who consider all comments, documents, records, and other information submitted by the beneficiary without regard to whether such information was submitted to or considered previously by the State;

(*4*) Provide the beneficiary a reasonable opportunity, face-to-face (including through the use of audio or video technology) and in writing, to present evidence and testimony and make legal and factual arguments related to their grievance. The State must inform the beneficiary of the limited time available for this sufficiently in advance of the resolution timeframe for grievances as specified in paragraph (c)(7)(v) of this section;

(*5*) Provide the beneficiary their case file, including medical records in compliance with the HIPAA Privacy Rule (45 CFR part 160 and part 164 subparts A and E), other documents and records, and any new or additional evidence considered, relied upon, or generated by the State related to the grievance. This information must be provided free of charge and sufficiently in advance of the resolution timeframe for grievances as specified in paragraph (c)(7)(v) of this section; and

(*6*) Provide beneficiaries, free of charge, with language services, including written translation and interpreter services in accordance with § 435.905(b), to support their participation in grievance processes and their use of the grievance system.

(iv) *Filing timeframes.* A beneficiary may file a grievance at any time.

(v) *Resolution and notification*—(A) *Basic rule.* The State must resolve each grievance, and provide notice, as expeditiously as the beneficiary's health condition requires, within State-established timeframes that may not exceed the timeframes specified in this section.

(B) *Resolution timeframes.* For resolution of a grievance and notice to the affected parties, the timeframe may not exceed 90 calendar days from the day the State receives the grievance. This timeframe may be extended under paragraph (c)(7)(v)(C) of this section.

(C) *Extension of timeframes.* The States may extend the timeframe from that in paragraph (c)(7)(v)(B) of this section by up to 14 calendar days if –

(*1*) The beneficiary requests the extension; or

(*2*) The State documents that there is need for additional information and how the delay is in the beneficiary's interest.

(D) *Requirements following extension.* If the State extends the timeframe not at the request of the beneficiary, it must complete all of the following:

(*1*) Make reasonable efforts to give the beneficiary prompt oral notice of the delay;

(*2*) Within 2 calendar days of determining a need for a delay, but no later than the timeframes in paragraph (c)(7)(v)(B) of this section, give the beneficiary written notice of the reason for the decision to extend the timeframe; and

(*3*) Resolve the grievance as expeditiously as the beneficiary's health condition requires and no later than the date the extension expires.

(vi) *Format of notice.* The State must establish a method to notify a beneficiary of the resolution of a grievance and ensure that such methods meet, at a minimum, the standards described at § 435.905(b) of this chapter.

(vii) *Recordkeeping.* (A) The State must maintain records of grievances and must review the information as part of its ongoing monitoring procedures.

(B) The record of each grievance must contain, at a minimum, all of the following information:

(*1*) A general description of the reason for the grievance;

(*2*) The date received;

(*3*) The date of each review or, if applicable, review meeting;

(*4*) Resolution of the grievance, as applicable;

(*5*) Date of resolution, if applicable; and

(*6*) Name of the beneficiary for whom the grievance was filed.

(C) The record must be accurately maintained in a manner available upon request to CMS.

(viii) *Applicability date.* States must comply with the requirement at paragraph (c)(7) of this section beginning 2 years after July 9, 2024.

■ 8. Section 441.302 is amended by—
■ a. Adding paragraph (a)(6);
■ b. Revising paragraph (h); and
■ c. Adding paragraph (k).

The additions and revision read as follows:

§ 441.302 State assurances.

* * * * *

(a) * * *

(6) Assurance that the State operates and maintains an incident management system that identifies, reports, triages, investigates, resolves, tracks, and trends critical incidents.

(i) *Requirements.* The State must:

(A) Define critical incident to include, at a minimum—

(*1*) Verbal, physical, sexual, psychological, or emotional abuse;

(*2*) Neglect;

(*3*) Exploitation including financial exploitation;

(*4*) Misuse or unauthorized use of restrictive interventions or seclusion;

(*5*) A medication error resulting in a telephone call to, or a consultation with, a poison control center, an emergency department visit, an urgent care visit, a hospitalization, or death; or

(*6*) An unexplained or unanticipated death, including but not limited to a death caused by abuse or neglect;

(B) Use an information system, as defined in 45 CFR 164.304 and compliant with 45 CFR part 164, that, at a minimum, enables—

(*1*) Electronic critical incident data collection;

(*2*) Tracking (including of the status and resolution of investigations); and

(*3*) Trending;

(C) Require providers to report to the State, within State-established timeframes and procedures, any critical incident that occurs during the delivery of services authorized under section 1915(c) of the Act and as specified in the beneficiary's person-centered service plan, or occurs as a result of the failure to deliver services authorized under section 1915(c) of the Act and as specified in the beneficiary's person-centered service plan;

(D) Use claims data, Medicaid fraud control unit data, and data from other State agencies, such as Adult Protective Services or Child Protective Services, to the extent permissible under applicable State law to identify critical incidents that are unreported by providers and occur during the delivery of services authorized under section 1915(c) of the Act and as specified in the beneficiary's person-centered service plan, or occur as a result of the failure to deliver services authorized under section 1915(c) of the Act and as specified in the beneficiary's person-centered service plan;

(E) Ensure that there is information sharing on the status and resolution of investigations, such as through the use of information sharing agreements, between the State and the entity or entities responsible in the State for investigating critical incidents as defined in paragraph (a)(6)(i)(A) of this section if the State refers critical incidents to other entities for investigation;

(F) Separately investigate critical incidents if the investigative agency fails to report the resolution of an investigation within State-specified timeframes; and

(G) Demonstrate that it meets the requirements in paragraph (a)(6) of this section through the reporting requirement at § 441.311(b)(1).

(ii) *Minimum performance at the State level.* The State must demonstrate, through the reporting requirements at § 441.311(b)(2), that it meets the following minimum performance levels:

(A) Initiate an investigation, within State-specified timeframes, for no less than 90 percent of critical incidents;

(B) Complete an investigation and determine the resolution of the investigation, within State-specified timeframes, for no less than 90 percent of critical incidents; and

(C) Ensure that corrective action has been completed within State-specified timeframes, for no less than 90 percent of critical incidents that require corrective action.

(iii) *Applicability date.* States must comply with the requirements in paragraph (a)(6) of this section beginning 3 years after July 9, 2024; except for the requirement at paragraph (a)(6)(i)(B) of this section, with which the State must comply beginning 5 years after July 9, 2024; and in the case of the State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes HCBS in the MCO's, PIHP's, or PAHP's contract, the first rating period for contracts with the MCO, PIHP, or PAHP beginning on or after 3 years after July 9, 2024, except for the requirement at paragraph (a)(6)(i)(B) of this section, with which the first rating period for contracts with the MCO, PIHP or PAHP beginning on or after 5 years after July 9, 2024.

* * * * *

(h) *Reporting.* Assurance that the agency will provide CMS with information on the waiver's impact, including the data and information as required in § 441.311.

* * * * *

(k) *HCBS payment adequacy.* Assurance that payment rates are adequate to ensure a sufficient direct care workforce to meet the needs of beneficiaries and provide access to services in the amount, duration, and scope specified in beneficiaries' person-centered service plans.

(1) *Definitions.* As used in this paragraph—

(i) *Compensation* means:

(A) Salary, wages, and other remuneration as defined by the Fair Labor Standards Act and implementing regulations (29 U.S.C. 201 *et seq.,* 29 CFR parts 531 and 778);

(B) Benefits (such as health and dental benefits, life and disability insurance, paid leave, retirement, and tuition reimbursement); and

(C) The employer share of payroll taxes for direct care workers delivering services authorized under section 1915(c) of the Act.

(ii) *Direct care worker* means any of the following individuals who may be employed by a Medicaid provider, State agency, or third party; contracted with a Medicaid provider, State agency, or third party; or delivering services under a self-directed services delivery model:

(A) A registered nurse, licensed practical nurse, nurse practitioner, or clinical nurse specialist who provides nursing services to Medicaid beneficiaries receiving home and community-based services available under this subpart;

(B) A licensed or certified nursing assistant who provides such services under the supervision of a registered nurse, licensed practical nurse, nurse practitioner, or clinical nurse specialist;

(C) A direct support professional;

(D) A personal care attendant;

(E) A home health aide; or

(F) Other individuals who are paid to provide services to address activities of daily living or instrumental activities of daily living, behavioral supports, employment supports, or other services to promote community integration directly to Medicaid beneficiaries receiving home and community-based services available under this subpart, including nurses and other staff providing clinical supervision.

(iii) *Excluded costs* means costs that are not included in the calculation of the percentage of Medicaid payments to providers that is spent on compensation for direct care workers. Such costs are limited to:

(A) Costs of required trainings for direct care workers (such as costs for qualified trainers and training materials);

(B) Travel costs for direct care workers (such as mileage reimbursement or public transportation subsidies); and

(C) Costs of personal protective equipment for direct care workers.

(2) *Requirement.* (i) Except as provided in paragraph (k)(2)(ii) of this section, the State must demonstrate annually, through the reporting requirements at paragraph (k)(6) of this section and § 441.311(e), that it meets the minimum performance levels in paragraph (k)(3) of this section for furnishing homemaker, home health aide, or personal care services, as set forth at § 440.180(b)(2) through (4), that are delivered by direct care workers and authorized under section 1915(c) of the Act.

(ii) *Treatment of certain payment data under self-directed services delivery models.* If the State provides that homemaker, home health aide, or personal care services, as set forth at § 440.180(b)(2) through (4), may be furnished under a self-directed services delivery model in which the beneficiary directing the services sets the direct care worker's payment rate, then the State does not include such payment data in its calculation of the State's compliance with the minimum performance levels at paragraph (k)(3) of this section.

(3) *Minimum performance at the provider level.* Except as provided in paragraphs (k)(5) and (7) of this section, the State must meet the following minimum performance level as applicable, calculated as the percentage of total payment (not including excluded costs) to a provider for furnishing homemaker, home health aide, or personal care services, as set forth at § 440.180(b)(2) through (4), represented by the provider's total compensation to direct care workers:

(i) Except as provided in paragraph (k)(3)(ii) of this section, the State must ensure that each provider spends 80 percent of total payments the provider receives for services it furnishes as described in paragraph (k)(3) of this section on total compensation for direct care workers who furnish those services.

(ii) At the State's option, for providers determined by the State to meet its State-defined small provider criteria in paragraph (k)(4)(i) of this section, the State must ensure that each provider spends the percentage set by the State in accordance with paragraph (k)(4)(ii) of this section of total payments the provider receives for services it furnishes as described in paragraph (k)(3) of this section on total compensation for direct care workers who furnish those services.

(4) *Small provider minimum performance level*—(i) *Small provider criteria.* The State may develop reasonable, objective criteria through a transparent process to identify small providers that the State would require to meet the minimum performance requirement at paragraph (k)(3)(ii) of this section. The transparent process for developing criteria to identify providers that qualify for the minimum performance requirement in paragraph (k)(3)(ii) of this section must include public notice and opportunities for comment from interested parties.

(ii) *Small provider minimum performance level.* The State must set the percentage for a small provider to meet the minimum performance level at paragraph (k)(3)(ii) of this section based on reasonable, objective criteria it develops through a transparent process that includes public notice and opportunities for comment from interested parties.

(5) *Hardship exemption.* The State may develop reasonable, objective criteria through a transparent process to exempt from the minimum performance requirement at paragraph (k)(3) of this section a reasonable number of providers determined by the State to be facing extraordinary circumstances that prevent their compliance with paragraph (k)(3) of this section. The State must develop these criteria through a transparent process that includes public notice and opportunities for comment from interested parties. If a provider meets the State's hardship exemption criteria, then the State does not include that provider in its calculation of the State's compliance with the minimum performance level at paragraph (k)(3) of this section.

(6) Reporting on small provider minimum performance level and hardship exemption.

(i) States that establish a small provider minimum performance level under paragraph (k)(4) of this section must report to CMS annually the following information, in the form and manner, and at a time, specified by CMS:

(A) The State's small provider criteria developed in accordance with paragraph (k)(4)(i) of this section;

(B) The State's small provider minimum performance level developed in accordance with paragraph (k)(4)(ii) of this section;

(C) The percentage of providers of services set forth at § 440.180(b)(2) through (4) that qualify for the small provider minimum performance level at paragraph (k)(4) of this section; and

(D) A plan, subject to CMS review and approval, for small providers to meet the minimum performance requirement at paragraph (k)(3)(i) of this section within a reasonable period of time.

(ii) States that provide a hardship exemption in accordance with paragraph (k)(5) of this section must report to CMS annually the following information, in the form and manner, and at a time, specified by CMS:

(A) The State's hardship criteria developed in accordance with paragraph (k)(5) of this section;

(B) The percentage of providers of services set forth at § 440.180(b)(2) through (4) that qualify for a hardship exemption as provided in paragraph (k)(5) of this section; and

(C) A plan, subject to CMS review and approval, for reducing the number of providers that qualify for a hardship exemption within a reasonable period of time.

(iii) CMS may waive the reporting requirements in paragraphs (k)(6)(i)(D) or (k)(6)(ii)(C) of this section, as applicable, if the State demonstrates it has applied the small provider minimum performance level at paragraph (k)(4)(ii) of this section or the hardship exemption at paragraph (k)(5) of this section to less than 10 percent of the State's providers.

(7) *Exemption for the Indian Health Service and Tribal health programs subject to 25 U.S.C. 1641.* The Indian Health Service and Tribal health programs subject to the requirements at 25 U.S.C. 1641 are exempt from the requirements at paragraph (k) of this section.

(8) *Applicability date.* States must comply with the requirements set forth in paragraph (k) of this section beginning 6 years after July 9, 2024; and in the case of the State that implements a managed care delivery system under the authority of section 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes homemaker, home health aide, or personal care services, as set forth at § 440.180(b)(2) through (4) in the MCO's, PIHP's, or PAHP's contract, the first rating period for contracts with the MCO, PIHP, or PAHP beginning on or after the date that is 6 years after July 9, 2024.

■ 9. Section 441.303 is amended by revising paragraph (f)(6) to read as follows:

§ 441.303 Supporting documentation required.

* * * * *

(f) * * *

(6) The State must indicate the number of unduplicated beneficiaries to which it intends to provide waiver services in each year of its program. This number will constitute a limit on the size of the waiver program unless the State requests and the Secretary approves a greater number of waiver

participants in a waiver amendment. If the State has a limit on the size of the waiver program and maintains a list of individuals who are waiting to enroll in the waiver program, the State must meet the reporting requirements at § 441.311(d)(1).

* * * * *

■ 10. Section 441.311 is added to subpart G to read as follows:

§ 441.311 Reporting requirements.

(a) *Basis and scope.* Section 1902(a)(6) of the Act requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports. Section 1902(a)(19) of the Act requires States to provide safeguards to assure that eligibility for Medicaid-covered care and services will be determined and provided in a manner that is consistent with simplicity of administration and the best interests of Medicaid beneficiaries. This section describes the reporting requirements for States for section 1915(c) waiver programs, under the authority at section 1902(a)(6) and (a)(19) of the Act.

(b) *Compliance reporting*—(1) *Incident management system.* As described in § 441.302(a)(6)—

(i) The State must report, every 24 months, in the form and manner, and at a time, specified by CMS, on the results of an incident management system assessment to demonstrate that it meets the requirements in § 441.302(a)(6).

(ii) CMS may reduce the frequency of reporting to up to once every 60 months for States with incident management systems that are determined by CMS to meet the requirements in § 441.302(a)(6).

(2) *Critical incidents.* The State must report to CMS annually on the following information regarding critical incidents as defined in § 441.302(a)(6)(i)(A), in the form and manner, and at a time, specified by CMS:

(i) Number and percent of critical incidents for which an investigation was initiated within State-specified timeframes;

(ii) Number and percent of critical incidents that are investigated and for which the State determines the resolution within State-specified timeframes;

(iii) Number and percent of critical incidents requiring corrective action, as determined by the State, for which the required corrective action has been completed within State-specified timeframes.

(3) *Person-centered planning.* To demonstrate that the State meets the requirements at § 441.301(c)(3)(ii) regarding person-centered planning (as described in § 441.301(c)(1) through (3)), the State must report to CMS annually on the following, in the form and manner, and at a time, specified by CMS—

(i) Percent of beneficiaries continuously enrolled for at least 365 days for whom a reassessment of functional need was completed within the past 12 months. The State may report this metric using statistically valid random sampling of beneficiaries.

(ii) Percent of beneficiaries continuously enrolled for at least 365 days who had a service plan updated as a result of a re-assessment of functional need within the past 12 months. The State may report this metric using statistically valid random sampling of beneficiaries.

(4) Annually, the State will provide CMS with information on the waiver's impact on the type, amount, and cost of services provided under the State plan, in the form and manner, and at a time, specified by CMS.

(c) *Reporting on the Home and Community-Based Services Quality Measure Set,* as described in § 441.312.

(1) *General rules.* The State—

(i) Must report every other year, according to the format and schedule prescribed by the Secretary through the process for developing and updating the measure set described in § 441.312(d), on all measures in the Home and Community-Based Services Quality Measure Set that are identified by the Secretary pursuant to § 441.312(d)(1)(ii) of this subpart.

(ii) May report on all other measures in the Home and Community-Based Services Quality Measure Set that are not described in § 441.312(d)(1)(ii) and (iii) of this subpart.

(iii) Must establish, subject to CMS review and approval, State performance targets for each of the measures in the Home and Community-Based Services Quality Measure Set that are identified by the Secretary pursuant to § 441.312(d)(1)(ii) and (iii) of this subpart and describe the quality improvement strategies that the State will pursue to achieve the performance targets.

(iv) May establish State performance targets for each of the measures in the Home and Community-Based Services Quality Measure Set that are not identified by the Secretary pursuant to § 441.312(d)(1)(ii) and (iii) of this subpart and describe the quality improvement strategies that the State will pursue to achieve the performance targets.

(2) Measures identified per § 441.312(d)(1)(iii) of this subpart will be reported by the Secretary on behalf of the State.

(3) In reporting on Home and Community-Based Services Quality Measure Set measures, the State may, but is not required to:

(i) Report on the measures identified by the Secretary pursuant to § 441.312(c) of this subpart for which reporting will be, but is not yet required (that is, reporting has not yet been phased-in).

(ii) Report on the populations identified by the Secretary pursuant to § 441.312(c) of this subpart for whom reporting will be, but is not yet required.

(d) *Access reporting.* The State must report to CMS annually on the following, in the form and manner, and at a time, specified by CMS:

(1) *Waiver waiting lists.* (i) A description of how the State maintains the list of individuals who are waiting to enroll in the waiver program, if the State has a limit on the size of the waiver program, as described in § 441.303(f)(6), and maintains a list of individuals who are waiting to enroll in the waiver program. This description must include, but is not limited to:

(A) Information on whether the State screens individuals on the list for eligibility for the waiver program;

(B) Whether the State periodically re-screens individuals on the list for eligibility; and

(C) The frequency of re-screening, if applicable.

(ii) Number of people on the list of individuals who are waiting to enroll in the waiver program, if applicable.

(iii) Average amount of time that individuals newly enrolled in the waiver program in the past 12 months were on the list of individuals waiting to enroll in the waiver program, if applicable.

(2) *Access to homemaker, home health aide, personal care, and habilitation services.* (i) Average amount of time from when homemaker services, home health aide services, personal care services, and habilitation services, as set forth in § 440.180(b)(2) through (4) and (6), are initially approved to when services began, for individuals newly receiving services within the past 12 months. The State may report this metric using statistically valid random sampling of beneficiaries.

(ii) Percent of authorized hours for homemaker services, home health aide services, personal care services, and habilitation services, as set forth in § 440.180(b)(2) through (4) and (6), that

are provided within the past 12 months. The State may report this metric using statistically valid random sampling of beneficiaries.

(e) *Payment adequacy*—(1) *Definitions.* As used in this paragraph (e)-

(i) *Compensation* means:

(A) Salary, wages, and other remuneration as defined by the Fair Labor Standards Act and implementing regulations (29 U.S.C. 201 *et seq.,* 29 CFR parts 531 and 778);

(B) Benefits (such as health and dental benefits, life and disability insurance, paid leave, retirement, and tuition reimbursement); and

(C) The employer share of payroll taxes for direct care workers delivering services authorized under section 1915(c) of the Act.

(ii) *Direct care worker* means any of the following individuals who may be employed by a Medicaid provider, State agency, or third party; contracted with a Medicaid provider, State agency, or third party; or delivering services under a self-directed services delivery model:

(A) A registered nurse, licensed practical nurse, nurse practitioner, or clinical nurse specialist who provides nursing services to Medicaid beneficiaries receiving home and community-based services available under this subpart;

(B) A licensed or certified nursing assistant who provides such services under the supervision of a registered nurse, licensed practical nurse, nurse practitioner, or clinical nurse specialist;

(C) A direct support professional;

(D) A personal care attendant;

(E) A home health aide; or

(F) Other individuals who are paid to provide services to address activities of daily living or instrumental activities of daily living, behavioral supports, employment supports, or other services to promote community integration directly to Medicaid beneficiaries receiving home and community-based services available under this subpart, including nurses and other staff providing clinical supervision.

(iii) *Excluded costs* means costs that are not included in the calculation of the percentage of Medicaid payments to providers that are spent on compensation for direct care workers. Such costs are limited to:

(A) Costs of required trainings for direct care workers (such as costs for qualified trainers and training materials);

(B) Travel costs for direct care workers (such as mileage reimbursement or public transportation subsidies); and

(C) Cost of personal protective equipment for direct care workers.

(2) *Payment adequacy reporting.* (i) Except as provided in paragraphs (e)(2)(ii) and (e)(4) of this section, the State must report to CMS annually on the percentage of total payments (not including excluded costs) for furnishing homemaker services, home health aide services, personal care, and habilitation services, as set forth in § 440.180(b)(2) through (4) and (6), that is spent on compensation for direct care workers, at the time and in the form and manner specified by CMS. The State must report separately for each service and, within each service, must separately report services that are self-directed and services delivered in a provider-operated physical location for which facility-related costs are included in the payment rate.

(ii) If *the* State provides that homemaker, home *health* aide, personal care services, or habilitation services, as set forth at § 440.180(b)(2) through (4) and (6), may be furnished under a self-directed services delivery model in which the beneficiary directing the services sets the direct care worker's payment rate, then the State must exclude such payment data from the reporting required in paragraph (e) of this section.

(3) *Payment adequacy reporting readiness.* One year prior to the applicability date for paragraph (e)(2)(i) of this section, the State must report on its readiness to comply with the reporting requirement in (e)(2)(i) of this section.

(4) *Exclusion of data from the Indian Health Service and Tribal health programs that are subject to 25 U.S.C. 1641.* States must exclude the Indian Health Service and Tribal health programs subject to the requirements at 25 U.S.C. 1641 from the reporting required in paragraph (e) of this section, and not require submission of data by, or include any data from, the Indian Health Service or Tribal health programs subject to the requirements at 25 U.S.C. 1641 for the State's reporting required under paragraph (e)(2) of this section.

(f) *Applicability dates.* (1) The State must comply with the reporting requirements at paragraphs (b) and (d) of this section beginning 3 years after July 9, 2024; and in the case of a State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes HCBS in the MCO's, PIHP's, or PAHP's contract, the first rating period for contracts with the MCO, PIHP, or PAHP beginning on or after the date that is 3 years after July 9, 2024.

(2) The State must comply with the reporting requirements at paragraphs (c) and (e) of this section beginning 4 years after July 9, 2024; and in the case of a State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes HCBS in the MCO's, PIHP's, or PAHP's contract, the first rating period for contracts with the MCO, PIHP or PAHP beginning on or after the date that is 4 years after July 9, 2024.

■ 11. Section 441.312 is added to subpart G to read as follows:

§ 441.312 Home and community-based services quality measure set.

(a) *Basis and scope.* Section 1102(a) of the Act provides the Secretary of HHS with authority to make and publish rules and regulations that are necessary for the efficient administration of the Medicaid program. Section 1902(a)(6) of the Act requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports. This section describes the Home and Community-Based Services Quality Measure Set, which States are required to use in section 1915(c) waiver programs to promote public transparency related to the administration of Medicaid-covered HCBS, under the authority at sections 1102(a) and 1902(a)(6) of the Act.

(b) *Definitions.* As used in this subpart—

(1) *Attribution rules* means the process States use to assign beneficiaries to a specific health care program or delivery system for the purpose of calculating the measures on the Home and Community-Based Services Quality Measure Set.

(2) *Home and Community-Based Services Quality Measure Set* means the Home and Community-Based Services Quality Measures for Medicaid established and updated by the Secretary through a process that allows for public input and comment, including through the **Federal Register**, as described in paragraph (d) of this section.

(c) *Responsibilities of the Secretary.* The Secretary shall—

(1) Identify, and update no more frequently than every other year, beginning no later than December 31, 2026, the quality measures to be included in the Home and Community-Based Services Quality Measure Set as defined in paragraph (b) of this section.

(2) Make technical updates and corrections to the Home and Community-Based Services Quality Measure Set annually as appropriate.

(3) Consult at least every other year with States and other interested parties identified in paragraph (g) of this section to—

(i) Establish priorities for the development and advancement of the Home and Community-Based Services Quality Measure Set;

(ii) Identify newly developed or other measures which should be added including to address any gaps in the measures included in the Home and Community-Based Services Quality Measure Set;

(iii) Identify measures which should be removed as they no longer strengthen the Home and Community-Based Services Quality Measure Set; and

(iv) Ensure that all measures included in the Home and Community-Based Quality Measure Set reflect an evidenced-based process including testing, validation, and consensus among interested parties; are meaningful for States; and are feasible for State-level, program-level, or provider-level reporting as appropriate.

(4) In consultation with States, develop and update, no more frequently than every other year, the Home and Community-Based Services Quality Measure Set Quality Measure Set using a process that allows for public input and comment as described in paragraph (d) of this section.

(d) *Process for developing and updating the HCBS Quality Measure Set.* The process for developing and updating the Home and Community-Based Services Quality Measure Set Quality Measure Set will address all of the following:

(1) Identification of all measures in the Home and Community-Based Services Quality Measure Set, including:

(i) Measures newly added and measures removed from the prior version of the Home and Community-Based Services Quality Measure Set;

(ii) The specific measures for which reporting is mandatory;

(iii) The measures for which the Secretary will complete reporting on behalf of States and the measures for which States may elect to have the Secretary report on their behalf; and

(iv) The measures, if any, for which the Secretary will provide States with additional time to report, as well as how much additional time the Secretary will provide, in accordance with paragraph (c) of this section.

(2) Technical information to States on how to collect and calculate the data on the Home and Community-Based Services Quality Measure Set.

(3) Standardized format and reporting schedule for reporting measure data required under this section.

(4) Procedures that State agencies must follow in reporting measure data required under this section.

(5) Identification of the populations for which States must report the measures identified by the Secretary under paragraph (e) of this section, which may include, but is not limited to beneficiaries—

(i) Receiving services through specified delivery systems, such as those enrolled in a MCO, PIHP, or PAHP as defined in § 438.2 or receiving services on a fee-for-service basis;

(ii) Who are dually eligible for Medicare and Medicaid, including beneficiaries whose medical assistance is limited to payment of Medicare premiums or cost sharing;

(iii) Who are older adults;

(iv) Who have physical disabilities;

(v) Who have intellectual and development disabilities;

(vi) Who have serious mental illness; and

(vii) Who have other health conditions.

(6) Technical information on attribution rules for determining how States must report on measures for beneficiaries who are included in more than one population, as described in paragraph (d)(5) of this section, during the reporting period.

(7) The subset of measures among the measures in the Home and Community-Based Services Quality Measure Set that must be stratified by race, ethnicity, sex, age, rural/urban status, disability, language, or such other factors as may be specified by the Secretary and informed by consultation every other year with States and interested parties in accordance with paragraphs (b)(2) and (g) of this section.

(8) Describe how to establish State performance targets for each of the measures in the Home and Community-Based Services Quality Measure Set.

(e) *Phasing in of certain reporting.* As part of the process that allows for developing and updating the Home and Community-Based Services Quality Measure Set described in paragraph (d) of this section, the Secretary may provide that mandatory State reporting for certain measures and reporting for certain populations of beneficiaries will be phased in over a specified period of time, taking into account the level of complexity required for such State reporting.

(f) *Selection of measures for stratification.* In specifying which measures, and by which factors, States must report stratified measures consistent with paragraph (d)(7) of this section, the Secretary will take into account whether stratification can be accomplished based on valid statistical methods and without risking a violation of beneficiary privacy and, for measures obtained from surveys, whether the original survey instrument collects the variables necessary to stratify the measures, and such other factors as the Secretary determines appropriate; the Secretary will require stratification of 25 percent of the measures in the Home and Community-Based Services Quality Measure Set for which the Secretary has specified that reporting should be stratified by 4 years after July 9, 2024, 50 percent of such measures by 6 years after July 9, 2024, and 100 percent of measures by 8 years after July 9, 2024.

(g) *Consultation with interested parties.* For purposes of paragraph (c)(2) of this section, the Secretary must consult with interested parties as described in this paragraph to include the following:

(1) State Medicaid Agencies and agencies that administer Medicaid-covered home and community-based services.

(2) Health care and home and community-based services professionals, including members of the allied health professions who specialize in the care and treatment of older adults, children and adults with disabilities, and individuals with complex medical needs.

(3) Health care and home and community-based services professionals (including members of the allied health professions), providers, and direct care workers who provide services to older adults, children and adults with disabilities, and individuals with complex medical and behavioral health care needs who live in urban and rural medically underserved communities or who are members of distinct population sub-groups at heightened risk for poor outcomes.

(4) Providers of home and community-based services.

(5) Direct care workers and national organizations representing direct care workers.

(6) Consumers and national organizations representing older adults, children and adults with disabilities, and individuals with complex medical needs.

(7) National organizations and individuals with expertise in home and community-based services quality measurement.

(8) Voluntary consensus standards setting organizations and other

organizations involved in the advancement of evidence-based measures of health care.

(9) Measure development experts.

(10) Such other interested parties as the Secretary may determine appropriate.

■ 12. Section 441.313 is added to subpart G to read as follows:

§ 441.313 Website transparency.

(a) The State must operate a website consistent with § 435.905(b) of this chapter that provides the results of the reporting requirements specified at §§ 441.302(k)(6) and 441.311. The State must:

(1) Include all content on one website, either directly or by linking to websites of individual MCO's, PIHP's, or PAHP's, as defined in § 438.2 of this chapter;

(2) Include clear and easy to understand labels on documents and links;

(3) Verify no less than quarterly, the accurate function of the website and the timeliness of the information and links; and

(4) Include prominent language on the website explaining that assistance in accessing the required information on the website is available at no cost and include information on the availability of oral interpretation in all languages and written translation available in each non-English language, how to request auxiliary aids and services, and a toll-free and TTY/TDY telephone number.

(b) CMS must report on its website the results of the reporting requirements specified at §§ 441.302(k)(6) and 441.311 that the State reports to CMS.

(c) The State must comply with these requirements beginning 3 years after July 9, 2024; and in the case of the State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), and 1115(a) of the Act and includes HCBS in the MCO's, PIHP's, or PAHP's contract, the first rating period for contracts with the MCO, PIHP, or PAHP beginning on or after the date that is 3 years after July 9, 2024.

■ 13. Section 441.450 is amended in paragraph (c) by revising the definition of ''Service plan'' to read as follows:

§ 441.450 Basis, scope, and definitions.

* * * * *

(c) * * *

Service plan means the written document that specifies the services and supports (regardless of funding source) that are to be furnished to meet the needs of a participant in the self-directed PAS option and to assist the participant to direct the PAS and to live in the community. The service plan is developed based on the assessment of need using a person-centered and directed process. The service plan supports the participant's engagement in community life and respects the participant's preferences, choices, and abilities. The participant's representative, if any, families, friends, and professionals, as desired or required by the participant, will be involved in the service-planning process. Service plans must meet the requirements of § 441.301(c)(3), except that the references to section 1915(c) of the Act are instead references to section 1915(j) of the Act.

* * * * *

■ 14. Section 441.464 is amended by—

■ a. Adding paragraph (d)(5);

■ b. Redesignating paragraphs (e) and (f) as paragraphs (g) and (h); and

■ c. Adding new paragraphs (e) and (f).

The revisions and additions read as follows:

§ 441.464 State assurances.

* * * * *

(d) * * *

(5) Implement and maintain a grievance process in accordance with § 441.301(c)(7), except that the references to section 1915(c) of the Act are instead references to section 1915(j) of the Act.

(e) *Incident management system.* The State operates and maintains an incident management system that identifies, reports, triages, investigates, resolves, tracks, and trends critical incidents and adheres to requirements of § 441.302(a)(6), except that the references to section 1915(c) of the Act are instead references to section 1915(j) of the Act.

(f) *Payment rates. Payment rates* are adequate to ensure a sufficient direct care workforce to meet the needs of beneficiaries and provide access to services in the amount, duration, and scope specified in beneficiaries' person-centered service plans, in accordance with § 441.302(k), except that the references to section 1915(c) of the Act are instead references to section 1915(j) of the Act.

* * * * *

■ 15. Section 441.474 is amended by adding paragraph (c) to read as follows:

§ 441.474 Quality assurance and improvement plan.

* * * * *

(c) The quality assurance and improvement plan must comply with all components of §§ 441.302(k)(6), 441.311 and 441.312 and related reporting requirements relevant to the State's self-directed PAS program, except that the references to section 1915(c) of the Act are instead references to section 1915(j) of the Act.

■ 16. Section 441.486 is added to subpart J to read as follows:

§ 441.486 Website transparency.

For States subject to the requirements of subpart J, the State must operate a website consistent with § 441.313, except that the references to section 1915(c) of the Act are instead references to section 1915(j) of the Act.

■ 17. Section 441.540 is amended by revising paragraph (c) to read as follows:

§ 441.540 Person-centered service plan.

* * * * *

(c) *Reviewing the person-centered service plan.* The State must ensure that the person-centered service plan for every individual is reviewed, and revised as appropriate, based upon the reassessment of functional need at least every 12 months, when the individual's circumstances or needs change significantly, and at the request of the individual. States must adhere to the requirements of § 441.301(c)(3), except that the references to section 1915(c) of the Act are instead references to section 1915(k) of the Act.

■ 18. Section 441.555 is amended by adding paragraph (e) to read as follows:

§ 441.555 Support system.

* * * * *

(e) Implement and maintain a grievance process, in accordance with § 441.301(c)(7), except that the references to section 1915(c) of the Act are instead references to section 1915(k) of the Act.

■ 19. Section 441.570 is amended by adding paragraphs (e) and (f) to read as follows:

§ 441.570 State assurances.

* * * * *

(e) An incident management system in accordance with § 441.302(a)(6) is implemented, except that the references to section 1915(c) of the Act are instead references to section 1915(k) of the Act.

(f) Payment rates are adequate to ensure a sufficient direct care workforce to meet the needs of beneficiaries and provide access to services in the amount, duration, and scope specified in beneficiaries' person-centered service plans, in accordance with § 441.302(k), except that the references to section 1915(c) of the Act are instead references to section 1915(k) of the Act.

■ 20. Section 441.580 is amended by redesignating paragraph (i) as (j), and adding a new paragraph (i) to read as follows:

§ 441.580 Data collection.

* * * * *

(i) Data and information as required in §§ 441.302(k)(6) and 441.311, except that the references to section 1915(c) of the Act are instead references to section 1915(k) of the Act.

* * * * *

■ 21. Section 441.585 is amended by adding paragraph (d) to read as follows:

§ 441.585 Quality assurance system.

* * * * *

(d) The State must implement the Home and Community-Based Services Quality Measure Set in accordance with § 441.312, except that the references to section 1915(c) of the Act are instead references to section 1915(k) of the Act.

■ 22. Section 441.595 is added to subpart K to read as follows-

§ 441.595 Website transparency.

For States subject to the requirements of subpart K, the State must operate a website consistent with § 441.313, except that the references to section 1915(c) of the Act are instead references to section 1915(k) of the Act.

■ 23. Section 441.725 is amended by revising paragraph (c) to read as follows:

§ 441.725 Person-centered service plan.

* * * * *

(c) Reviewing the person-centered service plan. The State must ensure that the person-centered service plan for every individual is reviewed, and revised as appropriate, based upon the reassessment of functional need as required in § 441.720, at least every 12 months, when the individual's circumstances or needs change significantly, and at the request of the individual. States must adhere to the requirements of § 441.301(c)(3), except that the references to section 1915(c) of the Act are instead references to section 1915(i) of the Act.

■ 24. Section 441.745 is amended by–

■ a. Revising paragraph (a)(1)(iii) and adding (a)(1)(iv) through (vii);

■ b. Revising paragraph (b)(1)(i); and

■ c. Adding paragraph (b)(1)(v).

The revision and additions read as follows:

§ 441.745 State plan HCBS administration: State responsibilities and quality improvement.

* * * * *

(a) * * *

(1) * * *

(iii) *Grievances.* A State must implement and maintain a grievance process in accordance with § 441.301(c)(7), except that the references to section 1915(c) of the Act are instead references to section 1915(i) of the Act.

(iv) *Appeals.* A State must provide individuals with advance notice of and the right to appeal terminations, suspensions, or reductions of Medicaid eligibility or covered services as described in part 431, subpart E, of this chapter.

(v) A State must implement an incident management system in accordance with § 441.302(a)(6), except that the references to section 1915(c) of the Act are instead references to section 1915(i) of the Act.

(vi) A State must assure payment rates are adequate to ensure a sufficient direct care workforce to meet the needs of beneficiaries and provide access to services in the amount, duration, and scope specified in beneficiaries' person-centered service plans, in accordance with § 441.302(k), except that the references to section 1915(c) of the Act are instead references to section 1915(i) of the Act.

(vii) A State must assure the submission of data and information as required in § 441.302(k)(6) and § 441.311, except that the references to section 1915(c) of the Act are instead references to section 1915(i) of the Act.

* * * * *

(b) * * *

(1) * * *

(i) Incorporate a continuous quality improvement process that includes monitoring, remediation, and quality improvement, including recognizing and reporting critical incidents, as defined in § 441.302(a)(6)(i)(A), except that the references to section 1915(c) of the Act are instead references to section 1915(i) of the Act.

* * * * *

(v) Implementation of the Home and Community-Based Services Quality Measure Set in accordance with § 441.312, except that the references to section 1915(c) of the Act are instead references to section 1915(i) of the Act.

* * * * *

■ 25. Section 441.750 is added to subpart M to read as follows—

§ 441.750 Website transparency.

For States subject to the requirements of subpart M, the State must operate a website consistent with § 441.313, except that the references to section 1915(c) of the Act are instead references to section 1915(i) of the Act.

PART 447—PAYMENT FOR SERVICES

■ 26. The authority citation for part 447 is revised to read as follows:

Authority: 42 U.S.C. 1302, and 1396r–8, and Pub. L. 111–148.

■ 27. Section 447.203 is amended by revising paragraph (b) and adding paragraph (c) to read as follows:

§ 447.203 Documentation of access to care and service payment rates.

* * * * *

(b)(1) *Payment rate transparency.* The State agency is required to publish all Medicaid fee-for-service fee schedule payment rates on a website that is accessible to the general public.

(i) For purposes of this paragraph (b)(1), the payment rates that the State agency is required to publish are Medicaid fee-for-service fee schedule payment rates made to providers delivering Medicaid services to Medicaid beneficiaries through a fee-for-service delivery system.

(ii) The website where the State agency publishes its Medicaid fee-for-service payment rates must be easily reached from a hyperlink on the State Medicaid agency's website.

(iii) Medicaid fee-for-service payment rates must be organized in such a way that a member of the public can readily determine the amount that Medicaid would pay for a given service.

(iv) In the case of a bundled payment methodology, the State must publish the Medicaid fee-for-service bundled payment rate and, where the bundled payment rate is based on fee schedule payment rates for each constituent service, must identify each constituent service included within the rate and how much of the bundled payment is allocated to each constituent service under the State's methodology.

(v) If the rates vary, the State must separately identify the Medicaid fee-for-service payment rates by population (pediatric and adult), provider type, and geographical location, as applicable.

(vi) The initial publication of the Medicaid fee-for-service payment rates shall occur no later than July 1, 2026 and include approved Medicaid fee-for-service payment rates in effect as of July 1, 2026. The agency is required to include the date the payment rates were last updated on the State Medicaid agency's website and to ensure these data are kept current where any necessary update must be made no later than 1 month following the latter of the date of CMS approval of the State plan amendment, section 1915(c) HCBS waiver amendment, or similar amendment revising the provider payment rate or methodology, or the effective date of the approved amendment. In the event of a payment rate change that occurs in accordance with a previously approved rate methodology, the State will ensure that its payment rate transparency

publication is updated no later than 1 month after the effective date of the most recent update to the payment rate.

(2) *Comparative payment rate analysis and payment rate disclosure.* The State agency is required to develop and publish a comparative payment rate analysis of Medicaid fee-for-service fee schedule payment rates for each of the categories of services in paragraphs (b)(2)(i) through (iii) of this section. If the rates vary, the State must separately identify the payment rates by population (pediatric and adult), provider type, and geographical location, as applicable. The State agency is further required to develop and publish a payment rate disclosure of the average hourly Medicaid fee-for-service fee schedule payment rates for each of the categories of services in paragraph (b)(2)(iv) of this section, as specified in paragraph (b)(3) of this section. If the rates vary, the State must separately identify the payment rates by population (pediatric and adult), provider type, geographical location, and whether the payment rate includes facility-related costs, as applicable.

(i) Primary care services.

(ii) Obstetrical and gynecological services.

(iii) Outpatient mental health and substance use disorder services.

(iv) Personal care, home health aide, homemaker, and habilitation services, as specified in § 440.180(b)(2) through (4) and (6), provided by individual providers and provider agencies.

(3) *Comparative payment rate analysis and payment rate disclosure requirements.* The State agency must develop and publish, consistent with the publication requirements described in paragraphs (b)(1) through (b)(1)(ii) of this section, a comparative payment rate analysis and a payment rate disclosure.

(i) For the categories of services described in paragraph (b)(2)(i) through (iii) of this section, the comparative payment rate analysis must compare the State agency's Medicaid fee-for-service fee schedule payment rates to the most recently published Medicare payment rates effective for the same time period for the evaluation and management (E/M) codes applicable to the category of service. The State must conduct the comparative payment rate analysis at the Current Procedural Terminology (CPT) or Healthcare Common Procedure Coding System (HCPCS) code level, as applicable, using the most current set of codes published by CMS, and the analysis must meet the following requirements:

(A) The State must organize the analysis by category of service as described in paragraphs (b)(2)(i) through (iii) of this section.

(B) The analysis must clearly identify the base Medicaid fee-for-service fee schedule payment rates for each E/M CPT/HCPCS code identified by CMS under the applicable category of service, including, if the rates vary, separate identification of the payment rates by population (pediatric and adult), provider type, and geographical location, as applicable.

(C) The analysis must clearly identify the Medicare non-facility payment rates as established in the annual Medicare Physician Fee Schedule final rule effective for the same time period for the same set of E/M CPT/HCPCS codes, and for the same geographical location as the base Medicaid fee-for-service fee schedule payment rates, that correspond to the base Medicaid fee-for-service fee schedule payment rates identified under paragraph (b)(3)(i)(B) of this section, including separate identification of the payment rates by provider type.

(D) The analysis must specify the base Medicaid fee-for-service fee schedule payment rate identified under paragraph (b)(3)(i)(B) of this section as a percentage of the Medicare non-facility payment rate as established in the annual Medicare Physician Fee Schedule final rule identified under paragraph (b)(3)(i)(C) of this section for each of the services for which the base Medicaid fee-for-service fee schedule payment rate is published pursuant to paragraph (b)(3)(i)(B) of this section.

(E) The analysis must specify the number of Medicaid-paid claims and the number of Medicaid enrolled beneficiaries who received a service within a calendar year for each of the services for which the base Medicaid fee-for-service fee schedule payment rate is published pursuant to paragraph (b)(3)(i)(B) of this section.

(ii) For each category of services specified in paragraph (b)(2)(iv) of this section, the State agency is required to publish a payment rate disclosure that expresses the State's payment rates as the average hourly Medicaid fee-for-service fee schedule payment rates, separately identified for payments made to individual providers and provider agencies, if the rates vary. The payment rate disclosure must meet the following requirements:

(A) The State must organize the payment rate disclosure by category of service as specified in paragraph (b)(2)(iv) of this section.

(B) The disclosure must identify the average hourly Medicaid fee-for-service fee schedule payment rates by applicable category of service, including, if the rates vary, separate identification of the average hourly Medicaid fee-for-service fee schedule payment rates for payments made to individual providers and provider agencies, by population (pediatric and adult), provider type, geographical location, and whether the payment rate includes facility-related costs, as applicable.

(C) The disclosure must identify the number of Medicaid-paid claims and the number of Medicaid enrolled beneficiaries who received a service within a calendar year for each of the services for which the average hourly Medicaid fee-for-service fee schedule payment rates are published pursuant to paragraph (b)(3)(ii)(B) of this section.

(4) *Comparative payment rate analysis and payment rate disclosure timeframe.* The State agency must publish the initial comparative payment rate analysis and payment rate disclosure of its Medicaid fee-for-service fee schedule payment rates in effect as of July 1, 2025 as required under paragraphs (b)(2) and (b)(3) of this section, by no later than July 1, 2026. Thereafter, the State agency must update the comparative payment rate analysis and payment rate disclosure no less than every 2 years, by no later than July 1 of the second year following the most recent update. The comparative payment rate analysis and payment rate disclosure must be published consistent with the publication requirements described in paragraphs (b)(1)introductory text, (b)(1)(i) and (b)(1)(ii) of this section.

(5) *Compliance with payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements.* If a State fails to comply with the payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements in paragraphs (b)(1) through (b)(4) of this section, including requirements for the time and manner of publication, future grant awards may be reduced under the procedures set forth at 42 CFR part 430, subparts C and D by the amount of FFP CMS estimates is attributable to the State's administrative expenditures relative to the total expenditures for the categories of services specified in paragraph (b)(2) of this section for which the State has failed to comply with applicable requirements, until such time as the State complies with the requirements. Unless otherwise prohibited by law, deferred FFP for those expenditures will be released after the State has fully complied with all applicable requirements.

(6) *Interested parties advisory group for rates paid for certain services.* (i) The State agency must establish an advisory

group for interested parties to advise and consult on provider rates with respect to service categories under the Medicaid State plan, 1915(c) waiver, and demonstration programs, as applicable, where payments are made to the direct care workers specified in § 441.311(e)(1)(ii) for the self-directed or agency-directed services found at § 440.180(b)(2) through (4), and (6).

(ii) The interested parties advisory group must include, at a minimum, direct care workers, beneficiaries, beneficiaries' authorized representatives, and other interested parties impacted by the services rates in question, as determined by the State.

(iii) The interested parties advisory group will advise and consult with the Medicaid agency on current and proposed payment rates, HCBS payment adequacy data as required at § 441.311(e), and access to care metrics described in § 441.311(d)(2), associated with services found at § 440.180(b)(2) through (4) and (6), to ensure the relevant Medicaid payment rates are sufficient to ensure access to personal care, home health aide, homemaker, and habilitation services for Medicaid beneficiaries at least as great as available to the general population in the geographic area and to ensure an adequate number of qualified direct care workers to provide self-directed personal assistance services.

(iv) The interested parties advisory group shall meet at least every 2 years and make recommendations to the Medicaid agency on the sufficiency of State plan, 1915(c) waiver, and demonstration direct care worker payment rates, as applicable. The State agency will ensure the group has access to current and proposed payment rates, HCBS provider payment adequacy reporting information as described in § 441.311(e), and applicable access to care metrics as described in § 441.311(d)(2) for HCBS in order to produce these recommendations. The process by which the State selects interested party advisory group members and convenes its meetings must be made publicly available.

(v) The Medicaid agency must publish the recommendations produced under paragraph (b)(6)(iv) of the interested parties advisory group consistent with the publication requirements described in paragraph (b)(1) through (b)(1)(ii) of this section, within 1 month of when the group provides the recommendation to the agency.

(c)(1) *Initial State analysis for rate reduction or restructuring.* For any State plan amendment that proposes to reduce provider payment rates or restructure provider payments in circumstances when the changes could result in diminished access where the criteria in paragraphs (c)(1)(i) through (iii) of this section are met, the State agency must provide written assurance and relevant supporting documentation that the following conditions are met as well as a description of the State's procedures for monitoring continued compliance with section 1902(a)(30)(A) of the Act, as part of the State plan amendment submission in a format prescribed by CMS as a condition of approval:

(i) Medicaid payment rates in the aggregate (including base and supplemental payments) following the proposed reduction or restructuring for each benefit category affected by the proposed reduction or restructuring would be at or above 80 percent of the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services.

(ii) The proposed reduction or restructuring, including the cumulative effect of all reductions or restructurings taken throughout the current State fiscal year, would be likely to result in no more than a 4 percent reduction in aggregate fee-for-service Medicaid expenditures for each benefit category affected by proposed reduction or restructuring within a State fiscal year.

(iii) The public processes described in paragraph (c)(4) of this section and § 447.204 yielded no significant access to care concerns from beneficiaries, providers, or other interested parties regarding the service(s) for which the payment rate reduction or payment restructuring is proposed, or if such processes did yield concerns, the State can reasonably respond to or mitigate the concerns, as appropriate, as documented in the analysis provided by the State pursuant to § 447.204(b)(3).

(2) *Additional State rate analysis.* For any State plan amendment that proposes to reduce provider payment rates or restructure provider payments in circumstances when the changes could result in diminished access where the requirements in paragraphs (c)(1)(i) through (iii) of this section are not met, the State must also provide the following to CMS as part of the State plan amendment submission as a condition of approval, in addition to the information required under paragraph (c)(1) of this section, in a format prescribed by CMS:

(i) A summary of the proposed payment change, including the State's reason for the proposal and a description of any policy purpose for the proposed change, including the cumulative effect of all reductions or restructurings taken throughout the current State fiscal year in aggregate fee-for-service Medicaid expenditures for each benefit category affected by proposed reduction or restructuring within a State fiscal year.

(ii) Medicaid payment rates in the aggregate (including base and supplemental payments) before and after the proposed reduction or restructuring for each benefit category affected by proposed reduction or restructuring, and a comparison of each (aggregate Medicaid payment before and after the reduction or restructuring) to the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services and, as reasonably feasible, to the most recently available payment rates of other health care payers in the State or the geographic area for the same or a comparable set of covered services.

(iii) Information about the number of actively participating providers of services in each benefit category affected by the proposed reduction or restructuring. For this purpose, an actively participating provider is a provider that is participating in the Medicaid program and actively seeing and providing services to Medicaid beneficiaries or accepting Medicaid beneficiaries as new patients. The State must provide the number of actively participating providers of services in each affected benefit category for each of the 3 years immediately preceding the State plan amendment submission date, by State-specified geographic area (for example, by county or parish), provider type, and site of service. The State must document observed trends in the number of actively participating providers in each geographic area over this period. The State may provide estimates of the anticipated effect on the number of actively participating providers of services in each benefit category affected by the proposed reduction or restructuring, by geographic area.

(iv) Information about the number of Medicaid beneficiaries receiving services through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring. The State must provide the number of beneficiaries receiving services in each affected benefit category for each of the 3 years immediately preceding the State plan amendment submission date, by State-specified geographic area (for example, by county or parish). The State must document observed trends in the number of Medicaid beneficiaries receiving services in each affected benefit category in each geographic area

over this period. The State must provide quantitative and qualitative information about the beneficiary populations receiving services in the affected benefit categories over this period, including the number and proportion of beneficiaries who are adults and children and who are living with disabilities, and a description of the State's consideration of the how the proposed payment changes may affect access to care and service delivery for beneficiaries in various populations. The State must provide estimates of the anticipated effect on the number of Medicaid beneficiaries receiving services through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring, by geographic area.

(v) Information about the number of Medicaid services furnished through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring. The State must provide the number of Medicaid services furnished in each affected benefit category for each of the 3 years immediately preceding the State plan amendment submission date, by State-specified geographic area (for example, by county or parish), provider type, and site of service. The State must document observed trends in the number of Medicaid services furnished in each affected benefit category in each geographic area over this period. The State must provide quantitative and qualitative information about the Medicaid services furnished in the affected benefit categories over this period, including the number and proportion of Medicaid services furnished to adults and children and who are living with disabilities, and a description of the State's consideration of the how the proposed payment changes may affect access to care and service delivery. The State must provide estimates of the anticipated effect on the number of Medicaid services furnished through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring, by geographic area.

(vi) A summary of, and the State's response to, any access to care concerns or complaints received from beneficiaries, providers, and other interested parties regarding the service(s) for which the payment rate reduction or restructuring is proposed as required under § 447.204(a)(2).

(3) *Compliance with requirements for State analysis for rate reduction or restructuring.* A State that submits a State plan amendment that proposes to reduce provider payment rates or restructure provider payments in circumstances when the changes could result in diminished access that fails to provide the information and analysis to support approval as specified in paragraphs (c)(1) and (2) of this section, as applicable, may be subject to State plan amendment disapproval under § 430.15(c) of this chapter. Additionally, States that submit relevant information, but where there are unresolved access to care concerns related to the proposed State plan amendment, including any raised by CMS in its review of the proposal and any raised through the public process as specified in paragraph (c)(4) of this section or under § 447.204(a)(2), may be subject to State plan amendment disapproval. If State monitoring of beneficiary access after the payment rate reduction or restructuring takes effect shows a decrease in Medicaid access to care, such as a decrease in the provider-to-beneficiary ratio for any affected service, or the State or CMS experiences an increase in beneficiary or provider complaints or concerns about access to care that suggests possible noncompliance with the access requirements in section 1902(a)(30)(A) of the Act, CMS may take a compliance action using the procedures described in § 430.35 of this chapter.

(4) *Mechanisms for ongoing beneficiary and provider input.* (i) States must have ongoing mechanisms for beneficiary and provider input on access to care (through hotlines, surveys, ombudsman, review of grievance and appeals data, or another equivalent mechanism), consistent with the access requirements and public process described in § 447.204.

(ii) States should promptly respond to public input through these mechanisms citing specific access problems, with an appropriate investigation, analysis, and response.

(iii) States must maintain a record of data on public input and how the State responded to this input. This record will be made available to CMS upon request.

(5) *Addressing access questions and remediation of inadequate access to care.* When access deficiencies are identified, the State must, within 90 days after discovery, submit a corrective action plan with specific steps and timelines to address those issues. While the corrective action plan may include longer-term objectives, remediation of the access deficiency should take place within 12 months.

(i) The State's corrective actions may address the access deficiencies through a variety of approaches, including, but not limited to: Increasing payment rates, improving outreach to providers, reducing barriers to provider enrollment, providing additional transportation to services, providing for telemedicine delivery and telehealth, or improving care coordination.

(ii) The resulting improvements in access must be measured and sustainable.

(6) *Compliance actions for access deficiencies.* To remedy an access deficiency, CMS may take a compliance action using the procedures described at § 430.35 of this chapter.

■ 28. Section 447.204 is amended by—

■ a. Revising paragraphs (a)(1) and (b); and

■ b. Removing paragraph (d).

The revisions read as follows:

§ 447.204 Medicaid provider participation and public process to inform access to care.

(a) * * *

(1) The data collected, and the State analysis performed, under § 447.203(c).

* * * * *

(b) The State must submit to CMS with any such proposed State plan amendment affecting payment rates documentation of the information and analysis required under § 447.203(c) of this chapter.

* * * * *

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2024–08363 Filed 4–22–24; 4:15 pm]

BILLING CODE 4120–01–P

Ensuring Access to Medicaid Services (CMS-2442-F)
Provisions and Relevant Timing Information and Dates*

Updated September 9, 2024

Regulation Section(s) in Title 42 of the CFR	Applicability Dates**
Medicaid Advisory Committee (MAC) & Beneficiary Advisory Council (BAC) § 431.12	§ 431.12 MAC & BAC: Except as noted in paragraphs (d)(l) and (i)(3), the requirements in paragraphs (a) through (j) are applicable 1 year after the effective date of the final rule.
Medicaid Advisory Committee (MAC) & Beneficiary Advisory Council (BAC) § 431.12	§ 431.12 (d)(l) BAC crossover on MAC: For the period from 1 year after the effective date of the final rule through 2 years after the effective date of the final rule, 10 percent; for the period from 2 years plus one day after the effective date of the final rule through 3 years after the effective date of the final rule, 20 percent; and thereafter, 25 percent of committee members must be from the BAC.
Medicaid Advisory Committee (MAC) & Beneficiary Advisory Council (BAC) § 431.12	§ 431.12 (i)(3) Annual report: States have 2 years from the effective date of the final rule to finalize the first annual report. After the report has been finalized, States will have 30 days to post the annual report.
Person-Centered Service Plans §§ 441.301(c)(1) and (3), 441.450(c), 441.540(c), and 441.725(c)	Beginning 3 years after the effective date of the final rule***
Grievance Systems §§ 441.301(c)(7), 441.464(d)(5), 441.555(e), and 441.745(a)(1)(iii)	Beginning 2 years after the effective date of the final rule
Incident Management System §§ 441.302(a)(6), 441.464(e), 441.570(e), 441.745(a)(1)(v), and (b)(1)(i)	Beginning 3 years after the effective date of the final rule***; except for the requirement at § 441.302(a)(6)(i)(B) (electronic incident management system), which begins 5 years after the effective date of the final rule***
HCBS Payment Adequacy §§ 441.302(k), 441.464(f), 441.570(f), and 441.745(a)(1)(vi)	Beginning 6 years after the effective date of the final rule***
Reporting Requirements §§ 441.311, 441.474(c), 441.580(i), and 441.745(a)(1)(vii)	Beginning 3 years after the effective date of the final rule*** for § 441.311(b) (compliance reporting) and § 441.311(d) (access reporting) Beginning 4 years after the effective date of the final rule*** for § 441.311(c) (reporting on the HCBS Quality Measure Set) and (e) (HCBS payment adequacy reporting)
HCBS Quality Measure Set §§ 441.312, 441.474(c), 441.585(d), and 441.745(b)(1)(v)	HHS Secretary begins identifying quality measures no later than December 31, 2026, and no more frequently than every other year. HHS Secretary shall make technical updates and corrections to the HCBS Quality Measure Set annually as appropriate.
Website Transparency §§ 441.313, 441.486, 441.595, and 441.750	Beginning 3 years after the effective date of the final rule***
Payment Rate Transparency Publication § 447.203(b)(1)	July 1, 2026, then updated within 30 days of a payment rate change.
Comparative Payment Rate Analysis Publication § 447.203(b)(2) to (4)	July 1, 2026, then every 2 years
Payment Rate Disclosure § 447.203(b)(2) to (4)	July 1, 2026, then every 2 years
Interested Parties Advisory Group § 447.203(b)(6)	The first meeting must be held within 2 years after effective date of the final rule (then at least every 2 years).
Rate Reduction and Restructuring SPA procedures § 447.203(c)(1) and (2)	Effective date of the final rule

* Regulatory provisions in this table are applicable at the time this rule becomes effective.

** In this final rule, including the regulations being finalized herein, we use the term “applicability date” to indicate when a new regulatory requirement will be applicable and when States must begin compliance with the requirements as specified in that regulation.
*** In the case of the State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes HCBS in the managed care organization’s (MCO), prepaid inpatient health plan’s (PIHP), or prepaid ambulatory health plan’s (PAHP) contract, the applicability date is the first rating period for contracts with the MCO, PIHP or PAHP beginning on or after the applicability date specified in the chart.

Pennsylvania Homecare Association

MEMORANDUM

To: Members of the Pennsylvania Senate and House of Representatives

Date: May 1, 2024

Subject: CMS Final Rule on Medicaid Access Threatens the Longevity of Home-Based Care

In May 2023, the Centers for Medicare & Medicaid Services (CMS) proposed a rule requiring Home and Community-Based Services (HCBS) agencies to allocate at least 80% of Medicaid payments for direct care worker compensation, known as the 80/20 Rule. Despite concerns from providers and Medicaid agencies about burdensome reporting and lack of flexibility for implementation, CMS finalized the "Ensuring Access to Medicaid Services" rule with the problematic provisions still in place.

The Pennsylvania Homecare Association (PHA) has significant concerns with the final rule and its impact on the over 700 home-based care providers we represent. The proposed rule introduces a nationwide Medicaid pass-through requirement, mandating that 80% of all HCBS Medicaid payments be directed towards compensating direct care workers (DCWs), with the remaining 20% allocated for other operational expenses. While this rule aims to enhance care quality, it lacks substantiated evidence and threatens access for vulnerable individuals.

PHA strongly opposes the 80/20 provision of this mandate, as it will exacerbate challenges in homecare services rather than improving them. Our industry is already facing underinvestment in critical support services, leading to workforce shortages and a crisis in care quality.

Pennsylvania's Medicaid fee-for-service reimbursement rates for personal assistance services (PAS) are among the lowest regionally with an average regional rate of $20.63. Before implementing arbitrary standards for direct and indirect costs of administering services, we must evaluate the impact on care access and quality. PHA advocates for higher wages for caregivers but opposes efforts that dictate how employers invest Medicaid funds, hindering innovation and patient outcomes.

While the rule aims to improve access to care and promote health equity, the home care community has significant concerns regarding statutory authority, inequities across states, and the need for actuarial studies coupled with further data to support the 80/20 division. PHA continues to push for better DCW compensation through increased Medicaid reimbursement rates. Additionally, PHA supports elements of the rule that seek to address Medicaid Payment Adequacy and improve access to care and health outcomes for Medicaid beneficiaries.

In conclusion, federal processes like the 80/20 provision that overreach and extend a one size fits all model to state operations risk undermining the long-term sustainability of our healthcare systems and detract from the overarching objective of establishing a system that effectively supports individuals as they age.

Thank you for your attention to this critical matter. We look forward to your continued support in providing a system that offers quality, home-based care for all Pennsylvania residents.

Policy Update

CMS Releases Final Rule: Medicaid Program; Ensuring Access to Medicaid Services

Summary

On April 22, 2024 the Centers for Medicare & Medicaid Services (CMS) published the final rule Medicaid Program; Ensuring Access to Medicaid Services. The rule has a particular focus on home- and community-based services (HCBS), including direct care worker compensation requirements, HCBS waitlists, grievance process development, critical incident reporting definitions and HCBS quality reporting. The final rule also seeks to increase transparency in payment rates.

The rule is effective 60 days after publication, but many provisions have an effective date that widely differs from the overarching effective date. CMS also released a fact sheet on the regulation and timeline for the various effective dates.

Key Takeaways

The Medicaid; Ensuring Access to Medicaid Services final rule includes the following key proposals:

- CMS requires that at least 80% of Medicaid payments for personal care, homemaker and home health aide services be spent on compensation for direct care workers (as opposed to administrative overhead). CMS also made many modifications in the proposed rule which altered the applicability of the provision.
- States will be required to establish a grievance process for fee-for-service HCBS beneficiaries to submit complaints.
- CMS establishes a minimum definition of “critical incident” and minimum state performance and reporting requirements for investigation and action related to critical incidents, as well as requires states to operate and maintain an electronic incident management system.
- The final rule requires states to ensure that the person-centered service plan is reviewed and revised, at least every 12 months for at least 90% of individuals continuously enrolled in a state’s HCBS programs.
- CMS is requiring states to report on waiting lists in section 1915(c) waiver programs and on service delivery timeliness for personal care, homemaker, home health aide services, and habilitation services.
- CMS requires states to report every other year on the HCBS Quality Measure Set and establishes a process for updating the measure set.
- The final rule requires states to publish all fee-for-service (FFS) Medicaid fee schedule payment rates on a publicly available and accessible website. It also requires states to compare their FFS payment rates for primary care, obstetrical and gynecological care, and outpatient mental health and substance use disorder services to Medicare rates, and publish the analysis every two years, and also requires states to publish the average hourly rate paid for personal care, home health aide, homemaker, and habilitation services, and publish the disclosure every two years.
- States will be required to establish and operate the newly named Medicaid Advisory Committee (MAC) and a Beneficiary Advisory Council (BAC) one year after the rule’s effective date.

Home and Community Based Services

Compensation to HCBS Direct Care Workers

Key Takeaway: CMS requires that at least 80% of Medicaid payments for personal care, homemaker and home health aide services be spent on compensation for direct care workers (as opposed to administrative overhead). CMS also made many modifications in the proposed rule which altered the applicability of the provision.

One of the most controversial provisions in the final rule is the requirement that at least 80% of Medicaid payments for homemaker, home health aide and personal care services be spent on compensation for direct care workers. As in the proposed rule, this proposal would apply to both Medicaid fee-for-service (FFS) and managed care delivery systems. In particular, it applies to these homemaker, home health aide and personal care services provided through section 1915(c), (j), (k) and (i) authorities, and applicable to managed care delivery systems authorized by section 1915(a), 1915(b), 1932(a), or 1115(a).

Although the services and authorities did not change from the proposed rule to the final rule, CMS made several definitional changes that impact this provision.

First, CMS changed the definition of compensation in the final rule. Compensation is defined to include: salary, wages, and other remuneration defined by the Fair Labor Standards Act, benefits, and the employer share of payroll taxes. In the final rule, CMS updated the definition of "benefits" within compensation. CMS noted that benefits are inclusive of health and dental benefits, life and disability insurance, paid leave, retirement, and tuition reimbursement. However, in the final rule "sick leave" was changed to "paid leave," life and disability insurance" was added, and "retirement" was added as a blanket term for retirement plans and contributions. In the final rule, CMS also created a new definition of "excluded costs" which are costs not included in the state's calculation of the percentage of Medicaid payment that is spent on compensation. Excluded costs are "training costs (such as costs for training materials or payment to qualified trainers); travel costs for direct care workers (such as mileage reimbursement or public transportation subsidies); and costs of personal protective equipment for direct care workers."

CMS modified and expanded the definition direct care workers to include clinical supervisors in the definition of direct care workers in the final rule. Under the final rule, direct care workers include individuals who may be employed by a Medicaid provider, State agency, or third party; contracted with a Medicaid provider, State agency, or third party; or delivering services under a self-directed services delivery model:

- A registered nurse, licensed practical nurse, nurse practitioner, or clinical nurse specialist who provides nursing services to Medicaid beneficiaries receiving home and community-based services available under this subpart;
- A licensed or certified nursing assistant who provides such services under the supervision of a registered nurse, licensed practical nurse, nurse practitioner, or clinical nurse specialist;
- A direct support professional;
- A personal care attendant;
- A home health aide; or
- Other individuals who are paid to provide services to address activities of daily living or instrumental activities of daily living, behavioral supports, employment supports, or other services to promote community integration directly to Medicaid beneficiaries receiving home and community-based services available under this subpart, including nurses and other staff providing clinical supervision.

Also, of note, in the final rule, CMS specified that for self-directed services, when the beneficiary is directing the services sets the direct care worker's payment rate, then the State does not include such payment data in its calculation of the State's compliance with the 80% requirement.

However, the final rule makes some modifications to allow states to exclude certain providers and provide some state flexibilities from the requirement. First, CMS is allowing states to set a separate minimum performance level for small providers, and allowing states the option to develop "reasonable, objective criteria to identify small providers" to meet this small provider minimum performance level set by the state. Second, the final rule also allows state to develop a "hardship exemption" for some providers determined by the state "to be facing extraordinary circumstances" that prevent them from meeting the 80% pass through requirement. An finally, CMS is exempting Indian Health Service and Tribal health programs from the 80% pass through requirement.

As it relates to reporting requirements, in three years, states will be required to report on their readiness to collect data regarding the percentage of Medicaid payments for homemaker, home health aide, personal care, and habilitation services spent on compensation to the direct care workers furnishing these services. While in four years, states must report to CMS annually on the percentage of total payments (not including excluded costs) for furnishing homemaker services, home health aide services, personal care, and habilitation services, that is spent on compensation for direct care workers. In addition, the state must report separately for each service and, within each service, must separately report services that are self-directed and services delivered in a provider-operated physical location for which facility-related costs are included in the payment rate.

Also in the final rule, CMS notes that they intend that this policy apply to the provider level and that states must ensure that each provider spends 80% of Medicaid payments they receive for certain HCBS on direct care worker compensation.

CMS proposes that these payment and transparency requirements would be effective six years after the effective date of the final rule for FFS, and would apply to the first managed care plan contract rating period that begins on or after the date six years following the final rule's effective date of the final rule. This represents a delay in effective date as compared to the proposed rule, which was a four year effective timeframe.

As it relates to enforcement of this provision, CMS notes it will "continue to use our standard enforcement tools and discretion, as appropriate." However, no specific enforcement actions are outlined in the final rule.

HCBS Grievance Procedures

Key Takeaway: States will be required to establish a grievance process for FFS HCBS beneficiaries to submit complaints.

Beginning 2 years after the effective date of the final rule, states will be required to establish grievance procedures for Medicaid beneficiaries who receive FFS HCBS through Section 1915(c) and in the final rule made the requirements applicable to section 1915(j), (k) and (i) authorities. The grievance process gives beneficiaries (or an authorized representative) an opportunity to file an expression of dissatisfaction or complaint, related to the State's or a provider's performance of the person-centered service plan and HCBS settings requirements. The rule outlines requirements for the grievance procedures, including recordkeeping, timelines for acknowledgments and procedures, notices to beneficiaries and protocols for handling grievance submissions. The finalized rule also specifies that States must provide beneficiaries with reasonable assistance in ensuring grievances are appropriately filed with the grievance system.

Definition of Critical Incident

Key Takeaway: CMS establishes a minimum definition of "critical incident" and minimum state performance and reporting requirements for investigation and action related to critical incidents, as well as requires states to operate and maintain an electronic incident management system.

As in the proposed rule, CMS finalized a new standard definition of a critical incident to include, at a minimum, "verbal, physical, sexual, psychological, or emotional abuse; neglect; exploitation including financial exploitation; misuse or unauthorized use of restrictive interventions or seclusion; a medication error resulting in

a telephone call to or a consultation with a poison control center, an emergency department visit, an urgent care visit, a hospitalization, or death; or an unexplained or unanticipated death, including but not limited to a death caused by abuse or neglect." No such standardized federal definition currently exists.

In the final rule, CMS requires that states operate and maintain an electronic incident management system that identifies, reports, triages, investigates, resolves, tracks and trends critical incidents. CMS requires that states report to CMS every 24 months on the results of an incident management system assessment.

States need to identify critical incidents through required provider reporting and other data sources (*e.g.*, claims, Medicaid Fraud Control Units, Adult Protective Services, Child Protective Services, law enforcement) and have information sharing agreements with those entities for investigations.

CMS proposes that these requirements would be effective three years after the effective date of the final rule for FFS. However, CMS is allowing for five years for states to implement the electronic incident management system.

HCBS Person-Centered Planning

Key Takeaway: The final rule requires states to ensure that the person-centered service plan is reviewed and revised, at least every 12 months for at least 90% of individuals continuously enrolled in a state's HCBS programs.

Under the final rule, states are required to demonstrate that an assessment of functional need is conducted annually for at least 90% of individuals continuously enrolled in a state's HCBS programs. States are required to demonstrate that they reviewed the person-centered service plan and revised the plan as appropriate based on the results of this required reassessment of functional need every 12 months, for at least 90% of individuals continuously enrolled in the state's HCBS programs. These requirements will be applied across section 1915(c), (i), (j) and (k) waiver authorities. They will not apply to section 1905(a) "medical assistance" state plan personal care, home health and case management services.

The rule also requires states to report on the percentage of beneficiaries continuously enrolled in the state's HCBS programs for 365 days or longer who had a service plan updated as a result of a reassessment of functional need within the past 12 months.

A person-centered plan includes six elements: level of care, service plan, qualified providers, health and welfare, financial accountability and administrative authority. States are required to conduct systemic remediation and implement a quality improvement project when they score below 90 percent on any of these performance measures, as proposed.

Wait List Reporting

Key Takeaway: CMS is requiring states to report on waiting lists in section 1915(c) waiver programs and on service delivery timeliness for personal care, homemaker, home health aide services, and habilitation services.

States have the option to cap the number of people enrolled in HCBS waivers. As a result, there are often waiting lists for individuals to receive HCBS. Under this final rule, CMS is requiring states to report on waiting lists in section 1915(c) waiver programs and on service delivery timeliness for personal care, homemaker, home health aide services, and habilitation services. As compared to the proposed rule, the final rule is an expansion of services with the inclusion of habilitation services in this reporting requirement.

Specific reporting requirements for the state include:

- A description of how the State maintains the list of individuals who are waiting to enroll in the waiver program, if the State has a limit on the size of the waiver program, and maintains a list of individuals who are waiting to enroll in the waiver program.

- Average amount of time from when homemaker services, home health aide services, personal care services, and habilitation services are initially approved to when services began, for individuals newly receiving services within the past 12 months.
- Percent of authorized hours for homemaker services, home health aide services, personal care services, and habilitation services that are provided within the past 12 months.

HCBS Quality Measurement Set

Key Takeaway: CMS requires states to report every other year on the HCBS Quality Measure Set and establishes a process for updating the measure set.

The HCBS Quality Measure Set is a set of nationally standardized quality measures for Medicaid-covered HCBS. The final rule requires that states report every other year on measures identified in the HCBS Quality Measure Set as mandatory measures. The rule also creates a process to regularly update and maintain the required measure set.

Specifically, beginning December 31, 2026, CMS will solicit comments on the HCBS Quality Measure Set no more frequently than every other year in order to do the following:

- Establish priorities for the development and advancement of the HCBS quality measure set,
- Identify newly developed or other measures that should be added, including to address gaps in the HCBS quality measure set,
- Identify measures that should be removed because they no longer strengthen the HCBS quality measures, and
- Ensure that all measures included in the HCBS quality measure set are evidence-based, meaningful for states, and feasible for state-level and program-level reporting as appropriate.

The final rule, also establishes a process for updating the HCBS quality measurement set, which includes the following steps:

- Identify all measures in the HCBS quality measure set, including newly added measures, measures that have been removed, mandatory measures, measures that the Secretary will report on states' behalf, measures that states can elect to have the Secretary report on their behalf, and measures for which the Secretary will provide states additional time to report,
- Inform states how to collect and calculate data on the measures,
- Provide a standardized format and schedule for reporting the measures,
- Provide procedures that states must follow in reporting the measure data,
- Identify specific populations for which states must report the measures,
- Identify the subset of measures that must be stratified by race, ethnicity, sex, age, rural/urban status, disability, language or other factors as may be specified by the Secretary, and
- Describe how to establish state performance targets for each of the measures.

The requirements will be effective four years after the final rule's effective date (rather than three as proposed).

Payment Rate Transparency

Key Takeaway: The final rule requires states to publish all FFS Medicaid fee schedule payment rates on a publicly available and accessible website. It also requires states to compare their FFS payment rates for primary care, obstetrical and gynecological care, and outpatient mental health and substance use disorder services to Medicare rates, and publish the analysis every two years, and also requires states to publish the average hourly rate paid for personal care, home health aide, homemaker, and

habilitation services, and publish the disclosure every two years.

State Medicaid programs are required to ensure that payments to providers are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available to beneficiaries at least to the extent as to the general population in the same geographic area. However, there are currently no specific requirements for how much a state Medicaid program is required to pay a provider. Moreover, in *Armstrong v. Exceptional Child Center*, the Supreme Court of the United States ruled that Medicaid providers and beneficiaries do not have a private right of action to challenge Medicaid payment rates in federal courts. As a result, there is significant variation across states in payment rates for services rendered. Medicaid payment rates are historically lower than Medicare payment rates across provider types.

Currently, there are no requirements for states to publicly post payment rate information, and if information is made available, it often is not easily accessible or understandable. States are required to conduct access monitoring review plans (AMRPs) to analyze data and supporting information to reach conclusions on sufficient access for covered services provided under fee-for-service. When states submit a state plan amendment to reduce or restructure provider payment rates, they must consider the data collected through the AMRP and undertake a public process that solicits input on the potential impact of the final reduction or restructuring of Medicaid FFS payment rates on beneficiary access to care.

This final rule rescinds the AMRP requirements and instead requires states to publish all Medicaid FFS payment rates in a clearly accessible location on a public website. The final rule requires Medicaid payment rates to be organized such that a member of the public could readily determine the amount that Medicaid would pay for a service and, in the case of a bundled or similar payment methodology, identify each constituent service included within the rate and how much of the bundled payment is allocated to each constituent service under the state's methodology. If the rates vary, the state would be required to separately identify the Medicaid FFS payment rates by population (pediatric and adult), provider type (*e.g.*, physician, advanced practice nurse, physician assistant) and geographical location, as applicable. States also have to date when the payment rates were last updated on the state Medicaid agency's website. In addition, states are now required to publish payment rates no later than July 1, 2026, including approved Medicaid FFS payment rates in effect as of July 1, 2026. (Of note, the Medicaid managed care rule that was released in coordination with this final rule includes requirements for publishing Medicaid managed care payment rates.)

CMS is also finalizing its proposal to require states to conduct a comparative payment rate analysis between their Medicaid payment rates and Medicare rates for primary care services, obstetrical and gynecological services, and outpatient mental health and substance use disorder services." If the rates vary, the State must separately identify the payment rates by population (pediatric and adult), provider type, and geographical location, as applicable.

For HCBS services – personal care, home health aide, homemaker, and habilitation services – states are required to develop and publish a payment rate disclosure of the average hourly Medicaid fee-for-service fee schedule payment rates. (The addition of habilitation services to this requirement is new and an expansion.) For HCBS, if rates vary, states need separate identification of the average hourly Medicaid fee-for-service fee schedule payment rates for payments made to individual providers and provider agencies:

- by population (pediatric and adult),
- provider type,
- geographical location,
- and whether the payment rate includes facility-related costs, as applicable. (Adding the requirement for states to include facility related costs is new to the final rule.)

The State agency must publish the initial comparative payment rate analysis and payment rate disclosure of its

Medicaid fee-for-service fee schedule payment rates in effect as of July 1, 2025, by no later than July 1, 2026. Thereafter, the State agency must update the comparative payment rate analysis and payment rate disclosure no less than every 2 years, by no later than July 1 of the second year following the most recent update.

In the final rule, CMS is requiring states to establish an interested parties' advisory group to advise and consult with the state on payment rates for direct care workers for personal care, home health aide, homemaker, and habilitation services. The addition of habilitation services to this group's purview is an addition and expansion in the final rule. This group would include, at a minimum, direct care workers, beneficiaries and their authorized representatives, and other interested parties. There appears to no explicit mention of providers in the group. The interested parties advisory group shall meet at least every 2 years and make recommendations to the Medicaid agency on the sufficiency of State plan, 1915(c) waiver, and demonstration direct care worker payment rates.

Finally, states are required to conduct an "excess access review" if payment reduction or restructuring results in any of the following scenarios:

- Aggregate Medicaid payment rates are lower than 80% of the most recently published Medicare payment rates.
- Changes to Medicaid payment rates are more than a 4% reduction in aggregate FFS Medicaid expenditures for each affected benefit category during the state fiscal year.
- The public processes raise significant access-to-care concerns from beneficiaries, providers or other interested parties.

Medical Care Advisory Committees

Key Takeaway: States will be required to establish and operate the newly named Medicaid Advisory Committee (MAC) and a Beneficiary Advisory Council (BAC) one year after the rule's effective date.

Currently, states are required to have a Medical Care Advisory Committee (MCAC) in place to advise the state Medicaid agency about health and medical care services. However, current laws include very little specificity regarding how states should use MCACs to ensure the proper and efficient administration of the Medicaid program and promote beneficiary perspectives. As a result, MCAC membership, transparency, meeting frequency, and meeting structure varies significantly across states. The final rule seeks to increase transparency and uniformity while also improving committee effectiveness.

The final rule would rename the MCAC to the Medicaid Advisory Committee (MAC) and create a separate Beneficiary Advisory Council (BAC). In the proposed rule, this was referred to as the Beneficiary Advisory Group, or BAG. The MAC and BAC will serve as vehicles for bi-directional feedback between interested parties and the state on matters related to the effective administration of the Medicaid program. Federal matching funds for Medicaid administrative activities would remain available to states in the same manner as the former MCAC.

The MAC and its corresponding BAC will advise the state on issues related to health and medical services, matters related to policy development, and the effective administration of the Medicaid program, consistent with the requirement that a state plan must meaningfully engage Medicaid beneficiaries and other low-income people in the administration of the plan.

Every state would vary in the size and make-up of its committees and the topics that would benefit from interested parties' feedback. Members of the MAC and BAC would be selected by the state Medicaid director on a rotating, continuous basis. The MAC and BAC must each meet at least once per quarter with off-cycle meetings as needed, and at least two MAC meetings per year must be opened to the public. CMS also proposes an administrative framework for the MAC and BAC to ensure transparency and a meaningful feedback loop with the public and among MAC and BAC members.

CMS also finalized that at least 10 to 25 percent of MAC members must be individuals from the BAC with lived Medicaid beneficiary experience (*e.g.*, they are currently or have been a Medicaid beneficiary or the family member/care giver of a Medicaid beneficiary). Instead of the 25 percent minimum threshold coming into effect right away as proposed, 10 percent of the MAC members must come from the BAC through July 9, 2025; for the period from July 10, 2025 through July 9, 2026, 20 percent of MAC members must come from the BAC; and thereafter, 25 percent of MAC members must come from the BAC.

The rest of the MAC membership should include representation from each of the following categories:

- Members of state or local consumer advocacy groups or other community-based organizations that represent the interests of, or provide direct service, to Medicaid beneficiaries
- Clinical providers or administrators who are familiar with the health and social needs of Medicaid beneficiaries and with the resources available and required for their care
- Representatives from participating Medicaid managed care plans or the state health plan association representing such plans, as applicable
- Representatives from other state agencies serving Medicaid beneficiaries as *ex officio* members.

Conclusion

As noted above, the rule is effective 60 days after publication, but many provisions have an effective date that widely differs from the overarching effective date. Stakeholders should review the final rule to assess the changes and its implications for their business lines.

Of note, CMS also clarifies in the rule that if any provision of this final rule is held to be invalid or unenforceable by its terms, or stayed pending further State action, it shall be severable from this final rule, and not affect the remainder of other provisions.

Should you have any questions regarding the Medicaid Access final rule, please contact the McDermottPlus team.

Key Messages/Talking Points:
Medicaid Access Rule

High Level Messages:

- We all recognize the value that direct care workers provide as well as the need to pay them more. We want to do so, but this policy is counterproductive and would have opposite effect.
- NAHC and our partners have been willing and repeatedly offering to engage in constructive problem solving with CMS and remain ready to do so.
- There are many great things in this rule; however, the pass-through will undermine all other positive policies.
- Any Federally required pass through is unallowable under law, regardless of the percentage.

Specific Items to Discuss:

- Survey data from PMHC, ANCOR, HCAOA, and NAHC consistently showed that this policy would lead to provider closures & exits from Medicaid.
- The restrictive threshold definitions will serve to limit resources for caregiver support and other enhanced care-focused operations, resulting in reduced quality, health and safety, and oversight in HCBS.
- This provision will reduce, not increase, access. Individuals who rely on HCBS to live their lives in home-based settings will lose services, particularly if providers cannot meet these new requirements or are forced to restrict innovative, value-added care supports.
- States across the political spectrum, including California, Washington State, Colorado, Florida, Missouri, Tennessee, and many others, opposed the policy because it is unworkable in the Medicaid program.
- Multiple law firm analyses found that there is no statutory authority for the provision – i.e. CMS is acting outside of its legal authority.
- The provision appears to have been arbitrarily created and not based on data or an explained rationale.
- The blanket approach undermines state autonomy, creates stark inequities across and within states, limits the ability to modify program requirements, and penalizes providers and states that have more regulation and oversight.
- State programs are all extremely different and this rule tries to apply a blanket policy that does not fit within the framework of the 56 unique Medicaid programs.
- Analyses of over a dozen state ratesetting methodology and regulations found that none of these states would meet the threshold due to requirements such as supervision, physical building locations, quality oversight, travel time, and other non-negotiable expenses.
- Smaller providers will be impacted the most, including rural and culturally-specific companies, further exacerbating the stark access challenges their clients face.

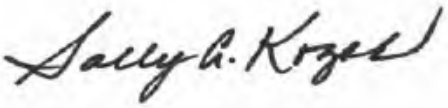
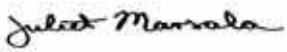
- The provision seeks to establish precedent that CMS/HHS has the authority to dictate how providers spend Medicaid revenue, which would not only devastate HCBS access but also place other providers at risk of arbitrary limits on the use of their Medicaid revenue in the future.
- The proposal places a massive unfunded mandate on both states and providers.
    - Analyses of current state rate structures show that states, on average, would need to raise rates by over 45% to meet the mandate without requiring massive cuts to quality, health and safety, and other required activities.
    - Without rate increases, providers would need to cut their non-caregiver wage expenses by over 2/3rds.
- The biggest issue is inadequate payment rates, and no amount of mandating how existing reimbursement is allocated will solve that. We need a holistic solution to ensure direct care providers are well cared for and well compensated.

Pennsylvania
Department of Human Services

Medical Assistance BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
August 23, 2024	August 23, 2024	05-24-01, 07-24-01, 54-24-05, 59-24-05, 00-24-02

SUBJECT
Updated Electronic Visit Verification Manual Edits Compliance Percentage Requirements in the Fee-for-Service Delivery and Managed Care Delivery Systems

BY	BY	BY
 Sally A. Kozak, Deputy Secretary Office of Medical Assistance Programs	 Juliet Marsala, Deputy Secretary Office of Long-Term Living	 Kristin Ahrens, Deputy Secretary Office of Developmental Programs

IMPORTANT REMINDER: All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISe to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at: https://www.pa.gov/en/agencies/dhs/resources/for-providers/promise/promise-provider-enrollment.html.

PURPOSE:

The purpose of this Medical Assistance (MA) bulletin is to advise providers of changes to the manual edit thresholds for Electronic Visit Verification (EVV) records in both personal care services (PCS) and home health care services (HHCS), effective with dates of service on and after January 1, 2025.

SCOPE:

This bulletin applies to providers enrolled in the MA Program who render PCS and HHCS to beneficiaries or participants (beneficiaries) in the MA fee-for-service (FFS) delivery system, including through home and community-based services waivers, and the managed care delivery system via Physical HealthChoices or Community HealthChoices. Beneficiaries may receive services within the following programs:

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

Fee-for-service provider service center: 1-800-537-8862

Physical and Community HealthChoices providers should address any questions regarding EVV to the applicable MCO.

Visit the Office of Medical Assistance Programs Website at: https://www.pa.gov/en/agencies/dhs/resources/for-providers/ma-for-providers/contact-information-for-ma-providers.html

- Office of Developmental Programs (ODP): Adult Autism Waiver, Community Living Waiver, Consolidated Waiver, Person/Family Directed Support Waiver, and Base Funded Program;

- Office of Long-Term Living (OLTL): OBRA Waiver, Act 150, and Community HealthChoices; or,

- Office of Medical Assistance Programs (OMAP): MA FFS and Physical HealthChoices.

Providers in the managed care delivery system are to address any provider EVV-related interface, billing, and payment questions with the applicable managed care organization (MCO).

BACKGROUND:

On August 26, 2020, the Department of Human Services (Department) issued MA Bulletin 05-20-03, titled "Electronic Visit Verification for Personal Care Services Provided in the Fee-for-Service Delivery System," which advised OMAP providers that it was expected that no more than 50% of their PCS claims billed have manual edits, beginning November 20, 2020 (https://www.pa.gov/content/dam/copapwp-pagov/en/dhs/documents/docs/publications/documents/forms-and-pubs-omap/MAB2020082601.pdf).

On September 10, 2020, the Department issued MA Bulletin 07-20-04 et. al, titled "Electronic Visit Verification (EVV) for Personal Care Services (PCS)," which advised OLTL and ODP providers that it was expected that no more than 50% of their PCS EVV records have manual edits within a federal fiscal year quarter, beginning January 1, 2021 (https://www.pa.gov/content/dam/copapwp-pagov/en/dhs/documents/docs/publications/documents/forms-and-pubs-omap/MAB2020091001.pdf).

On August 10, 2022, the Department issued MA Bulletin 05-22-09 et. al, titled "Electronic Visit Verification Requirements for Home Health Care Services in the Fee-for-Service Delivery and Managed Care Delivery Systems," which advised OLTL, ODP, and OMAP providers that to meet federal compliance requirements no more than 50% of their HHCS records could contain manual edits within a federal fiscal year quarter, beginning January 1, 2023, and also contained a note that the percentage would be periodically updated and move to no more than 15% of claims on a federal fiscal year quarterly basis by January 1, 2025 (https://www.pa.gov/content/dam/copapwp-pagov/en/dhs/documents/docs/publications/documents/forms-and-pubs-omap/MAB2022081001.pdf).

DISCUSSION:

Beginning with dates of service on and after January 1, 2025, in order to meet federal EVV compliance requirements, providers must achieve 85% of EVV records for verified visits

without manual edits for PCS and HHCS. This includes all participants/Common Law Employers in Participant-Directed Services, as they will be disenrolled from Participant-Directed Services if there is continued non-compliance. Providers rendering services to beneficiaries across multiple programs must achieve 85% of records without manual edits in each program to be considered fully compliant.

Additional information on timelines related to monitoring, technical assistance, corrective action plans, and penalties for not meeting manual edit thresholds will be provided in a future MA Bulletin before January 1, 2025.

PROCEDURE:

Effective with dates of services on and after January 1, 2025, providers must achieve 85% of EVV records for verified visits without manual edits for PCS and HHCS on a federal fiscal year quarterly basis. The EVV Compliance report is currently available in the EVV Aggregator. To access the EVV Compliance Report, providers need to log into the Aggregator and perform the following steps: 1) Choose Reports from the menu on the left; 2) In the Report Type drop down, choose Date Range Reports; 3) In the Report Name drop down, choose EVV Compliance; and 4) Choose Run Report. Providers have the ability to choose dates to run the report and can also narrow the report down by Account (if you have more than one), Client Name or Employee Name. The report provides detail information based on visit date, client, and employee for each account. The last page of the report shows summary information including the percentages of compliance.

For further PCS and HHCS information and updates, providers and MCOs should refer to the Department's EVV web page at: https://www.pa.gov/en/agencies/dhs/resources/for-providers/evv.html.

DEFINITIONS:

Verified Visit – A visit which contains all six of the service elements required by the 21st Century Cures Act. These service elements are the type of service provided, the name of the individual receiving service, the date of service delivery, the location of service delivery, the name of the individual providing the service, and the time the service begins and ends. A visit without these elements is considered incomplete.

Manual Visit – Any verified visit which has been manually entered or edited after the point of service. Manual Visits include both Manual Entries and Manual Edits.

Manual Entry – A verified visit that has been manually entered into a provider's EVV software after the point of service.

Manual Edit – A verified visit in which visit information was entered incorrectly and requires any type of edit or correction. If a provider has to manipulate data or add missing data or change data in any way after the service is delivered, even if a visit was originally captured using a visit modality that captures in real-time; this is deemed a manual edit.

SUPERSEDED BULLETINS:

This MA Bulletin supersedes, in part, MA Bulletins 05-20-03, 07-20-04 et. al, and 05-22-09 et. al.

Department of Human Services Updates

Electronic Visit Verification for Personal Care Services and Home Health Care Services

General Information

Q: Where can I find more information on how to implement EVV (Electronic Visit Verification)? Where do I go to get started?

A: The Pennsylvania (PA) Department of Human Services' (DHS) website with Electronic Visit Verification (EVV) information and guidance can be found at https://www.dhs.pa.gov/providers/Billing-Info/Pages/EVV.aspx.

Q: How does DHS communicate significant changes related to EVV?

A: DHS uses its website, Medical Assistance Bulletins, public meeting, listserv communications, and operations memorandums when necessary to communicate EVV changes.

Home Health Care Services (HHCS)

pennsylvania
DEPARTMENT OF HUMAN SERVICES

Q: What Home Health Care services are subject to EVV?

A: The procedure codes subject to Home Health Care Services EVV are located DHS website at https://www.dhs.pa.gov/providers/Billing-Info/Pages/EVV-HHCS.aspx.

Medicaid as Secondary Payor

pennsylvania
DEPARTMENT OF HUMAN SERVICES

Q: Is EVV required when commercial insurance is the primary and Medicaid is the secondary payor?

A: Claims and encounters submitted to Medicaid that do not have any cost sharing with Medicare or Medicare Advantage are subject to EVV error status codes in PROMISe.

Q: Is EVV required when Medicare is the primary and Medicaid is the secondary payor?

A: Claims and encounters submitted to Medicaid by Medicare are not submitted to EVV processing since Medicare performs the EVV validation.

Q: Is EVV required when Medicare Advantage is the primary and Medicaid is the secondary payor?

A: Claims and encounters submitted to Medicaid by Medicare Advantage are not submitted to EVV processing since Medicare Advantage performs the EVV validation.

GPS Range

pennsylvania
DEPARTMENT OF HUMAN SERVICES

Q: What is the current required GPS range in feet?

A: In the fee-for-service (FFS) delivery system, the perimeter for locations is set at 1/4-mile in the PA-DHS EVV System; however, even if the recorded location is outside the 1/4-mile perimeter, this will not cause an exception in the PA-DHS EVV System. The provider will be able to enter multiple addresses where services are provided, and these addresses can be updated as needed. If an error occurs, any system errors may be corrected through the web portal by the administrator.

Although location is a required element and must be submitted as part of the EVV record, PA-DHS is not currently validating against the location for billing purposes. In essence, PA-DHS validates that a location is captured, but does not validate whether the location matches any location on file. If this policy changes in the future, PA-DHS will communicate that to providers.

GPS Range

Q: What is the current required GPS range in feet? (Cont'd)

In the managed care delivery system, your managed care organizations (MCO) may have different requirements. Please inquire with your MCO about their policy regarding location, utilizing the MCO Directory at https://www.dhs.pa.gov/providers/Providers/Documents/Managed%20Care%20Information/MCO%20Directory.pdf.

Manual Edit Compliance

pennsylvania
DEPARTMENT OF HUMAN SERVICES

Q: What is the current target for EVV compliance percentage?

A: The thresholds and timeframes are specified in Medical Assistance Bulletin 05-22-09 and Medical Assistance Bulletin 07-20-04.

Medical Assistance Bulletin 05-22-09:
https://www.dhs.pa.gov/docs/Publications/Documents/FORMS%20AND%20PUBS%20OMAP/MAB2022081001.pdf)

Medical Assistance Bulletin 05-22-09:
https://www.dhs.pa.gov/docs/Publications/Documents/FORMS%20AND%20PUBS%20OMAP/MAB2020091001.pdf

Manual Edit Compliance

pennsylvania
DEPARTMENT OF HUMAN SERVICES

Q: What is the current target for EVV compliance percentage? (Cont'd)

To meet federal EVV compliance requirements, providers must achieve 50% of EVV records. DHS will review manual edit data on the fiscal year quarterly basis for providers providing services through a FFS program and will both provide technical assistance to those providers that do not achieve the 50% threshold for manual edits and develop corrective action plans as part of the standard monitoring process when necessary.

For providers rendering services in the managed care delivery system, the MCOs and DHS will conduct the review of manual edit data on a fiscal year quarterly basis and contact the provider regarding any needed quality improvement plan.

NOTE: The Office of Developmental Programs (ODP), the Office of Long-Term Living (OLTL), and the Office of Medical Assistance Programs (OMAP) will conduct their own program office manual edit reviews. Any changes to DHS offices responsible for manual edit reviews will be communicated on the DHS' EVV web page at https://www.dhs.pa.gov/providers/Billing-Info/Pages/EVV-HHCS.aspx.

Manual Edit Compliance

pennsylvania
DEPARTMENT OF HUMAN SERVICES

Q: Is the state still planning to increase the compliance rate to 85%? If so, when does this change take effect?

By January 1, 2025, each provider must have manual edits to no more than 15% of claims on a quarterly basis. Threshold percentages may change over time until January 1, 2025. Percentages and deadlines will be communicated to providers on the DHS EVV web page at https://www.dhs.pa.gov/providers/Billing-Info/Pages/EVV-HHCS.aspx.

Manual Edit Compliance

pennsylvania
DEPARTMENT OF HUMAN SERVICES

Q: What compliance percentage are providers at today (aggregate)?

A: DHS calculates manual edit compliance by provider, not by aggregate.

- OLTL FFS: In January of 2024, 62% of claims were auto-verified, and 38% were manual visits.
- ODP FFS: In January of 2024, 70% of claims were auto-verified, and 30% were manual visits.
- OMAP FFS: In January of 2024, 76% of claims were auto-verified, and 24% were manual visits.
- MCO: In January of 2024, 69% of claims were auto-verified, and 31% were manual visits.

Manual Edit Compliance

pennsylvania
DEPARTMENT OF HUMAN SERVICES

Q: How does DHS calculate compliance percentages? If using HHAeXchange, can you please reference the exact report location and name?

A: The total number of manually verified visits divided by the total number of verified visits equals the percentage of manual visits. Your manual visit percentage should be less than 50%. If 50% or more of your visits per quarter are manual, you are non-compliant.

DHS utilizes a report generated by a business intelligence tool that mirrors the DHS aggregator to identify compliance percentages.

Providers should reach out to their own vendor for assistance with EVV reports. Providers should reach out to their MCOs, if applicable, for compliance guidance.

Manual Edit Compliance

pennsylvania
DEPARTMENT OF HUMAN SERVICES

Q: How often does DHS assess compliance percentages?

A: DHS reviews manual edit data on a fiscal year quarterly basis for providers rendering services through a FFS program. For providers rendering services in the managed care delivery system, the MCOs and DHS will conduct the review of manual edit data on a fiscal year quarterly basis and contact the provider regarding any needed quality improvement plan.

Providers should continually be monitoring their own compliance via their own vendor's reports and within the DHS Aggregator. To view your agency's compliance within the DHS Aggregator, click on **Reports** > **Date Range Reports** > **EVV Compliance**.

Manual Edit Compliance

pennsylvania
DEPARTMENT OF HUMAN SERVICES

Q: What happens if providers do not meet the compliance percentage requirement?

A: OLTL: Currently, OLTL's Quality Management Efficiency Team (QMET) monitors EVV compliance for FFS providers. QMETs are primarily verifying that providers are keeping the proper hard-copy documentation for manual visits and are providing technical assistance and guidance to agencies who are near or below the threshold percentage.

ODP: Currently, ODP sends out letters through their EVV mailbox.

OMAP: OMAP continue to monitor EVV manual edit compliance rates each calendar quarter. The expectation is that manual edit compliance rates should be less than 25% of the DHS-established threshold, and OMAP would like to show manual edit percentage improvements each subsequent calendar quarter. If you have any concerns regarding technical issues, please contact the Provider Assistance Center (PAC) Help Line at 1-800-248-2152.

Participant Cell Phone Use

pennsylvania
DEPARTMENT OF HUMAN SERVICES

Q: Can a direct care worker clock in and clock out using a client's cell phone? Does that count as an EVV compliant visit?

A: A participant's cell phone can be used under the following conditions:

- The participant has given consent to the caregiver to use their electronic device.
- The visit is captured via Mobile Visit Verification (MVV) or Fixed Visit Verification (FVV) visit modalities (Not Telephony).

Providers should not have a written policy that implies the agency will rely solely on participant cell phone use. It is the agency's responsibility to ensure caregivers are able to clock in and out to comply with EVV.

1:2 Services

Q: If you have a 1:2 ratio (1 employee to 2 customers), what is the recommendation for collection of EVV data? Does the employee have to clock in to 2 customers at the same time (and does Sandata allow an employee to clock in twice for 2 different customers) OR does the second customer always require a manual edit?

A: DSPs/SSPs that provide support services to more than one individual concurrently must clock-in/clock-out for each individual for the service to be accurately captured and stored in the EVV aggregator. If a DSP/SSP fails to check-in/check-out for each individual, related claims will deny during EVV validation as no record will be found in the aggregator.

The employee can clock in and out for two (2), or more, individuals, and manual edits are not necessary.

ODP is editing a third version of technical guidance. The current version can be found here: https://www.dhs.pa.gov/providers/Documents/EVV/ODP%20EVV%20Guidance_Version%202.0.pdf.

2:1 Services

pennsylvania
DEPARTMENT OF HUMAN SERVICES

Q: If you have a 2:1 ratio (2 employees to 1 customer), each employee would clock in to the one customer, but the bill rate is combined. What is the recommendation for capture of the service code in this scenario so that billing is not duplicated due to the 2 clock ins? How do Sandata and DHS recommend we address these scenarios?

A: For personal care services with 2:1 staff to individual ratios, at least two (2) instances (records) for the same service/same individual/same date of service/same provider must be present in the EVV aggregator to pass EVV validation. The total unit calculation for the service itself is based on logic that is designed in the system to look at the earliest common time and the latest common time between both DSPs/SSPs. The minutes associated with this time will then be converted to units, stored in the aggregator and compared to the units found on the claim. While there are two (2) visits present in the Sandata aggregator, it is only necessary to bill one (1) claim in PROMISe.

Late/Missing Authorizations

pennsylvania
DEPARTMENT OF HUMAN SERVICES

Q: For payors who utilize HHAeXchange for billing, if the authorization is not in the system, the provider cannot bill. However, in many circumstances, we have evidence of authorization from the plan, but the authorization is not in HHAX. Thus, billing is held up and there is potential disruption to EVV compliance. How should providers address this issue?

A: Late authorizations do not and should not affect EVV manual edit compliance. HHAeXchange has informed the DHS that authorizations, clients, schedules, etc. can be linked after a visit has been completed. As with any alternate EVV (AltEVV) software questions or issues, you should reach out to your AltEVV vendor for assistance.

Provider billing issues should be addressed with the applicable payor. Reach out to your MCO or the Service Coordinator for assistance with missing authorizations.

Submitting Data from Different Source Systems

pennsylvania
DEPARTMENT OF HUMAN SERVICES

Q: Is there a known limitation that one provider (with one EIN [Employer Identification Number]) cannot submit data on the same client from two different source systems (ex: one from HHAeXchange and one from Alaya Care)?

A: DHS does not currently allow for one provider to submit data for the same client from two different source systems as this can have negative impacts on data feeds.

Typically, when a provider is switching vendors there is a cutoff date set for when they will stop using the old system and begin using the new system. There may be some overlap, but the Alternate EVV team closely monitors those situations and limits the time that can occur for.

pennsylvania
DEPARTMENT OF HUMAN SERVICES

Q: For Highmark Wholecare, which requires the use of Netsmart, our providers are being told that they must capture an electronic signature at point of care but are not being required to capture GPS location. Can you please clarify what is required and why signatures would not be required by the plan? Also, can you share best practices on universal precautions and keeping electronic devices clean between uses if this is required?

A: DHS does not require the use of electronic signatures; however, payors can have additional requirements that go beyond DHS requirements. Please reach out to your contracted MCO for guidance.

OLTL Contact Information

pennsylvania
DEPARTMENT OF HUMAN SERVICES

To update contact information within PROMISe™, please reach out to our enrollment team at RA-HCBSEnProv@pa.gov or 1-800-932-0939 (option 1).

For questions related to manual edit compliance, please contact our EVV compliance team at RA-PWOLTLEVVcomplnce@pa.gov

Any OLTL specific EVV questions can be directed to RA-PWOLTL_EVV@pa.gov

Other Contact Information

pennsylvania
DEPARTMENT OF HUMAN SERVICES

ODP EVV Claim Inquiries: ODP EVV claim inquiries should be made to the ODP Claims Resolution Section: ra-odpclaimsres@state.pa.us, 1-866-386-8880
Hours of operation: Monday - Thursday, 8:30 AM -12 PM & 1 PM - 3:30PM

For technical issues such as DHS Sandata account assistance, Welcome Kit reissuance, account unlock issues for DHS Sandata EVV, please contact Provider Assistance Center (PAC) – papac1@gainwelltechnologies.com or 1-800-248-2152.

For general EVV program issues or requests to be added to the EVV Listserv, please contact EVV Resource Account at: RA-PWEVVNOTICE@pa.gov

Providers with technical issues reaching out to PAC or Sandata Alternate EVV team should copy DHS on those emails at the following email address: RA-PWEVVISSUES@pa.gov

Providers with support ticket numbers they wish to escalate with DHS should reach out to DHS at the following email address: RA-PWEVVISSUES@pa.gov

pennsylvania
DEPARTMENT OF HUMAN SERVICES

Additional Q&A

Department of Human Services (DHS) Compliance Information

Electronic Visit Verification (EVV) for Personal Care Services and Home Health Care Services

Manual Edit Compliance History

pennsylvania
DEPARTMENT OF HUMAN SERVICES

On August 26, 2020, Medical Assistance Bulletin 05-20-03 advised Office of Medical Assistance Programs (OMAP) providers that it was expected that no more than 50% of personal care services (PCS) claims billed have manual edits, beginning November 20, 2020. - https://www.pa.gov/content/dam/copapwp-pagov/en/dhs/documents/docs/publications/documents/forms-and-pubs-omap/MAB2020082601.pdf

On September 10, 2020, Medical Assistance Bulletin 07-20-04 et. al advised Office of Long-Term Living (OLTL) and Office of Developmental Programs (ODP) providers that it was expected that no more than 50% of PCS claims billed have manual edits within a federal fiscal quarter, beginning January 1, 2021. - https://www.pa.gov/content/dam/copapwp-pagov/en/dhs/documents/docs/publications/documents/forms-and-pubs-omap/MAB2020091001.pdf

Manual Edit Compliance History

pennsylvania
DEPARTMENT OF HUMAN SERVICES

On August 10, 2022, Medical Assistance Bulletin 05-22-09 et. al advised OLTL, ODP, and OMAP providers that to meet federal compliance requirements no more than 50% of their home health care services (HHCS) records could contain manual edits within a federal fiscal year quarter, beginning January 1, 2023. The bulletin also contained a note that the percentage would be periodically updated and move to no more than 15% of claims on a federal fiscal year quarterly basis by January 1, 2025. - https://www.pa.gov/content/dam/copapwp-pagov/en/dhs/documents/docs/publications/documents/forms-and-pubs-omap/MAB2022081001.pdf

Updated Manual Edit Requirements

pennsylvania
DEPARTMENT OF HUMAN SERVICES

On August 23, 2024, Medical Assistance Bulletin 05-24-01 et. al advised OLTL, ODP, and OMAP providers that to meet federal compliance requirements providers must achieve 85% of their PCS and HHCS verified visits without manual edits on a federal fiscal year quarterly basis, beginning January 1, 2025. - https://www.pa.gov/content/dam/copapwp-pagov/en/dhs/documents/docs/publications/documents/forms-and-pubs-omap/MAB2024082301.pdf

This bulletin includes Participant-Directed Services and includes a definitions section that is universal across program offices.

There will be no incremental changes to the percentage requirement before the end of Calendar Year 2024.

Fee-for-Service Compliance Review

pennsylvania
DEPARTMENT OF HUMAN SERVICES

DHS reviews manual edit data on the fiscal year quarterly basis for providers rendering services through a Fee-for-Service program and in Calendar Year 2025 will both provide technical assistance to those providers that do not achieve the 15% threshold for manual edits and develop corrective action plans as part of the standard monitoring process when necessary.

DHS is currently exploring how to standardize processes across program offices. Additional information on timelines related to monitoring, technical assistance, corrective action plans, and penalties beginning in Calendar Year 2026 for not meeting manual edit thresholds will be provided in a future Medical Assistance Bulletin.

Managed Care Compliance Review

pennsylvania
DEPARTMENT OF HUMAN SERVICES

For providers rendering services in the managed care delivery system, the Managed Care Organizations and DHS conduct the review of manual edit data on a fiscal year quarterly basis and contact the provider regarding any needed quality improvement plan. Providers with questions regarding beneficiaries in the managed care delivery system should contact their contracted MCO(s) for information.

Physical HealthChoices and Community HealthChoices Directory - https://www.pa.gov/content/dam/copapwp-pagov/en/dhs/documents/providers/providers/documents/managed-care-information/MCO%20Directory.pdf

Manual Edit Compliance

pennsylvania
DEPARTMENT OF HUMAN SERVICES

Average Auto-Verified Percentage by Program*:

Program	Avg % Auto-Verified Visits
PH MCOs	68%
OMAP Fee For Service	74%
CHC MCOs	71%
OLTL Fee for Service	59%
ODP	65%

*Percentages based on visit data from 4/1/2024 - 6/30/2024

Manual Edit Compliance

pennsylvania
DEPARTMENT OF HUMAN SERVICES

Average Auto-Verified Percentage by Program Office:

Program Office	Avg % Auto-Verified Visits
PH MCOs and OMAP FFS	68%
CHC MCOs and OLTL FFS	68%
ODP	65%

*Percentages based on visit data from 4/1/2024 - 6/30/2024

Manual Edit Compliance

pennsylvania
DEPARTMENT OF HUMAN SERVICES

Percentage of Providers Meeting the Current Threshold (50%):

Program	% of Compliant Providers	% Non-Compliant Providers
PH MCOs	73%	27%
OMAP FFS	75%	25%
CHC MCOs	87%	13%
OLTL FFS	65%	35%
ODP	74%	26%

*Percentages based on visit data from 4/1/2024 - 6/30/2024

Manual Edit Compliance

pennsylvania
DEPARTMENT OF HUMAN SERVICES

Percentage of Providers Meeting the 1/1/25 Threshold (15%):

Program	% of Compliant Providers	% Non-Compliant Providers
PH MCOs	48%	52%
OMAP FFS	63%	37%
CHC MCOs	27%	73%
OLTL FFS	36%	64%
ODP	35%	65%

*Percentages based on visit data from 4/1/2024 - 6/30/2024

DHS Resources

pennsylvania
DEPARTMENT OF HUMAN SERVICES

DHS uses its website, Medical Assistance Bulletins, public meeting, listserv communications, and operations memorandums when necessary to provide guidance and communicate EVV changes. - https://www.pa.gov/en/agencies/dhs/resources/for-providers/evv.html

DHS' Bulletin Search page has been updated and can be searched by keywords and numbers - https://www.pa.gov/en/agencies/dhs/resources/for-providers/bulletin-search.html#sortCriteria=%40copapwpissuedate%20descending

Contact Information

pennsylvania
DEPARTMENT OF HUMAN SERVICES

For general EVV program issues or requests to be added to the EVV Listserv, please contact EVV Resource Account at: RA-PWEVVNOTICE@pa.gov

Any OLTL-specific EVV questions can be directed to RA-PWOLTL_EVV@pa.gov

OMAP-related question can be directed to the Provider Inquiry Line at 1-800-537-8862 (options 2-6-1).

ODP EVV Claim Inquiries: ODP EVV claim inquiries should be made to the ODP Claims Resolution Section: ra-odpclaimsres@state.pa.us, 1-866-386-8880 (Hours of operation: Monday - Thursday, 8:30 AM -12 PM & 1 PM - 3:30PM)

Technical Issue Information

pennsylvania
DEPARTMENT OF HUMAN SERVICES

For technical issues such as DHS Sandata account assistance, Welcome Kit reissuance, account unlock issues for DHS Sandata EVV, please contact Provider Assistance Center (PAC) – papac1@gainwelltechnologies.com or 1-800-248-2152.

Providers with technical issues reaching out to PAC or Sandata Alternate EVV team should copy DHS on those emails at the following email address: RA-PWEVVISSUES@pa.gov

Providers with support ticket numbers they wish to escalate with DHS should reach out to DHS at the following email address: RA-PWEVVISSUES@pa.gov

Manual Edit Compliance

pennsylvania
DEPARTMENT OF HUMAN SERVICES

Q&A

pennsylvania
DEPARTMENT OF HUMAN SERVICES

Office of Developmental Programs

Comprehensive Guide to Electronic Visit Verification

VERSION 3.0

This resource provides Office of Developmental Programs (ODP) specific Electronic Visit Verification (EVV) information for stakeholders

Contents

***New** – added to this version of guidance

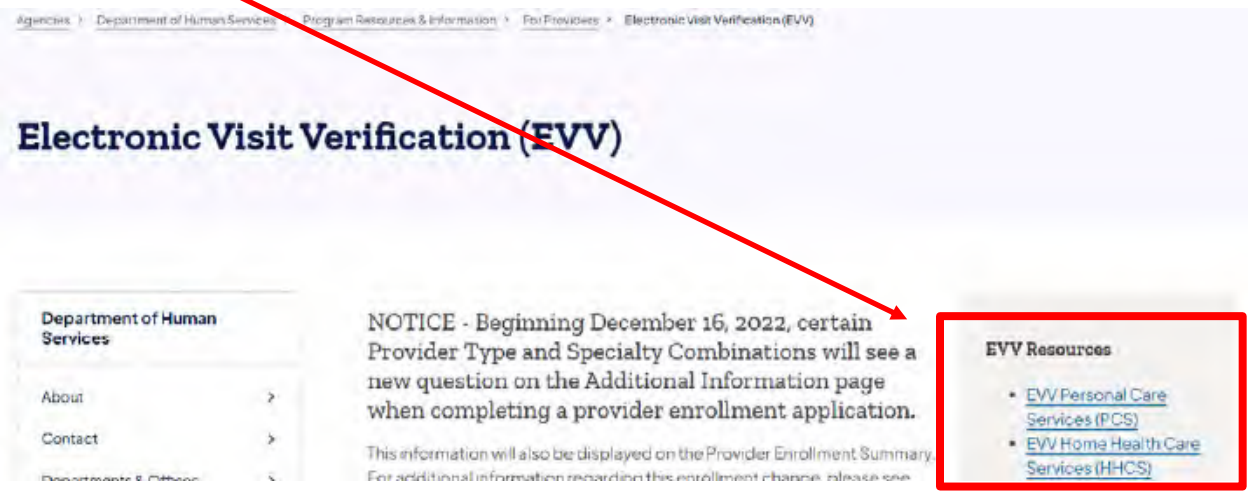
INTRODUCTION

This document is technical in nature and provides detailed information to support EVV (billing/claims, EVV errors and EVV calculation logic). The DHS EVV website contains the majority of other information that IS NOT contained in this document including public meeting notices, EVV listserv communications, contact information, training and Frequently Asked Questions (FAQs) that address general, provider, technology, and training questions: EVV Provider Billing

Effective January 1, 2020, Section 12006 of the 21st Century Cures Act required that care workers, providers, provider agencies, Agency with Choice (AWC) and Vendor Fiscal (VF)/Employer Agents (EAs) use an EVV system to electronically capture Personal Care Service (PCS) visits and corresponding visit data. Pennsylvania also requires these provider entities to electronically send these captured visits to the DHS EVV aggregator as the source of record and for them to be validated against during claims processing. On January 1, 2021, EVV for PCS was fully implemented to be in compliance with the 21st Century Cures Act.

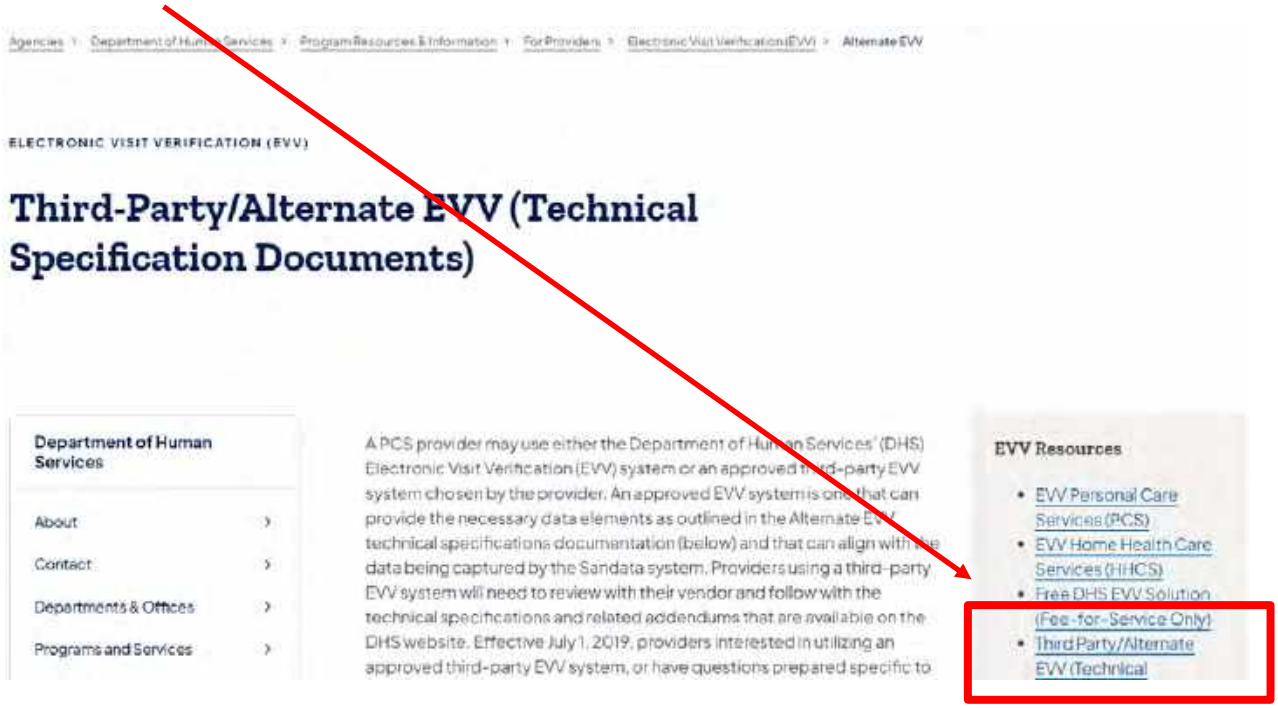
In addition, Section 12006 of the 21st Century Cures Act requires that DHS implement a statewide EVV system for providers rendering Home Health Care Services (HHCS) by January 1, 2023.

For a list of ODP personal care and home healthcare services subject to EVV, visit the DHS EVV website at: DHS EVV Website under EVV Resources



Pennsylvania uses an open EVV system model. This means that providers, provider agencies, AWCs and VF/EAs may choose to use the DHS EVV system, at no cost to the provider, **OR** they may utilize an alternate EVV vendor system to capture the six data elements required under the 21st Century Cures Act. Alternate EVV users are required to meet the EVV technical

specifications for interfacing with the DHS Aggregator. To view this document, go to: Alternate EVV Webpage under EVV Resources.



The Consolidated Waiver, Person Family Directed Supports (P/FDS) Waiver, Community Living Waiver, Adult Autism Waiver and the Base program all offer personal care and home health care services that are subject to EVV. All EVV systems must capture the following data points:

- Type of service(s)
- Individual receiving the service(s)
- Date of the service(s)
- Location of the service(s) delivery
- Care worker(s) providing the service(s)
- Time the service(s) begins and ends.

In addition to the six (6) required data points, providers, provider agencies, AWCs, VF/EAs using a third party/alternate EVV vendor system, are required to transmit additional visit related data elements to the EVV aggregator[1] for the record to successfully be accepted into and be stored in the DHS EVV aggregator for claims validation. For providers using an alternate EVV solution, see the Alternate EVV Technical specifications on the DHS EVV website (see screenshot above for document web location).

[1] The DHS EVV Aggregator is a system that receives and stores data from third-party systems (also referred to as Alternate EVV) and the DHS EVV system into a single uniform platform to facilitate payments of claims. The DHS Aggregator allows providers to use a third-party system (also referred to as Alternate EVV) for visit verification. The DHS EVV aggregator **DOES NOT** submit claims.

NOTE:

- The DHS EVV aggregator only stores EVV data captured during the visit and is validated against during claims processing when an EVV service is found on a claim transaction. No edits/visit changes can physically be performed by the provider in the aggregator environment. In other words, the aggregator does not allow providers to physically go into it and make changes to previously captured EVV visits. Edits to previously captured visits can only be made in the EVV source system where the visit was captured. The DHS EVV aggregator is view only and DOES NOT submit claims.

- If an EVV record is sent by an alternate EVV vendor system to the DHS EVV aggregator and is missing required data or the format is incorrect, as specified in the Alternate EVV technical specifications, the record will be rejected and, therefore, the record will not be stored in the DHS EVV aggregator. Rejected and missing records in the DHS EVV aggregator will set an EVV claim validation edit error status code (ESC) 928, *"NO MATCHING PCS EVV VISIT FOUND" or ESC 938, "NO MATCHING EVV HHCS VISIT FOUND"), when this scenario presents itself and the claim detail line will deny. Providers should ensure that errors and exceptions are corrected in the EVV source system they use and resubmitted to the EVV aggregator as an update to an existing visit BEFORE claim transactions are submitted to the Medicaid Management Information System (MMIS), currently referred to as PROMISe™.

ODP PERSONAL CARE SERVICES (PCS) SUBJECT TO EVV

The Centers for Medicare & Medicaid Services (CMS) states that PCS consists of services supporting activities of daily living (ADL), such as movement, bathing, toileting, transferring, and personal hygiene or services that offer support for instrumental activities of daily living (IADL), such as meal preparation, money management, shopping, and telephone use.

There are six ODP services that are considered personal care services and are subject to EVV. The DHS EVV system and EVV aggregator, provided by Sandata, will ONLY support the six ODP services below.

PCS Services Subject to EVV for
Consolidated Waiver, Person/Family Directed Support Waiver (P/FDS), Community Living Waiver (CLW), and Base Services
(Applies to Care workers, Provider, Provider Agency, AWC and VF/EA)

- Companion
- In-Home and Community Support
- Unlicensed Respite (excludes respite camp)
- Homemaker

PCS Services Subject to EVV for Adult Autism Waiver (AAW)

- Community Support
- Unlicensed Respite (In-Home Only)

ODP HOME HEALTH CARE SERVICES (HHCS) SUBJECT TO EVV

There are five ODP services considered HHCS and are subject to EVV. The DHS EVV system and EVV aggregator will ONLY support the five ODP HHCS below.

HHCS Services Subject to EVV for Consolidated Waiver, Person/Family Directed Support Waiver (P/FDS), Community Living Waiver (CLW), and Base Services (Applies to Provider, Provider Agency, AWC and VF/EA)

- Shift Nursing (1:1 and 2:1)
- Physical Therapy
- Occupational Therapy
- Speech/Language Therapy

HHCS Services Subject to EVV for Adult Autism Waiver (AAW)

- Therapy – Speech

IMPORTANT DATES AND EXPECTED ACTION

Per the 21st Century Cures Act mandate, Pennsylvania first implemented EVV for personal care services (PCS) on January 1, 2020, and again for Home Health Care Services (HHCS) on January 1, 2024.

DHS EVV Sandata Solution Users

Providers, Provider Agencies and AWCs who are new to EVV and are interested in using the DHS Sandata EVV solution to electronically capture visits for PCS or HHCS should reach out to the Provider Assistance Center papac1@gainwelltechnologies.com or 1-800-248-2152 to express interest, obtain more information and request a Welcome Kit. Please note, that Providers, Provider Agencies and AWCs will be instructed by the PAC line to attend self-paced mandatory training first to use and access the DHS Sandata EVV system. The training may be accessed at https://sandatalearn.com/?KeyName=PAEVVAgency.

Alternate EVV System Users

Providers, Provider Agencies, AWCs and VF/EAs who choose to use an Alternate (Third Party) EVV system for either PCS or HHCS should go to the DHS EVV website to understand the requirements for using an alternate EVV system. To locate this information, go to the main landing page of the DHS EVV website, find and click on the hyperlink in the red box shown in the screenshot on the following page.

EVV MANUAL THRESHOLD COMPLIANCE AND MONITORING

ODP and OLTL's EVV Bulletin (Electronic Visit Verification (EVV) for Personal Care Services (PCS), number 07-20-04, 54-20-04, 59-20-04, 00-20-03), issued September 10, 2020, contains information about manual edits and compliance rate expectations that begins on page 6 of the Bulletin and can be found here: ODP and OLTL EVV Bulletin.

*Medical Assistance Bulletin number 05-22-09, 07-22-03, 54-22-01, 59-22-01, 00-22-06," Electronic Visit Verification Requirements for Home Health Care Services in the Fee-for-Service Delivery and Managed Care Delivery Systems", was issued on August 10, 2022. This bulletin applies to OMAP, ODP and OLTL. It contains information about manual edits and compliance rate expectations that begins on page 6 of the Bulletin. This information is consistent with the information communicated in the aforementioned Bulletin number 07-20-04, 54-20-04, 59-20-04, 00-20-03 and can be found here: MAB2022081001.pdf (pa.gov).

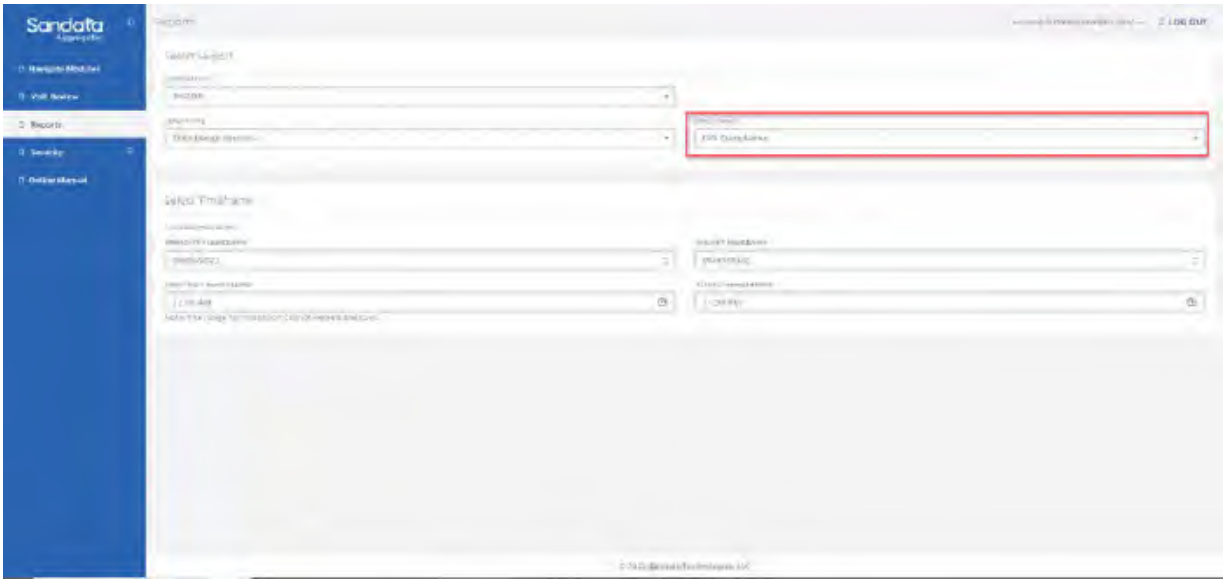
CMS requires that states actively assess EVV manual compliance. ODP Electronic Visit Verification team regularly monitors EVV manual compliance rates and emails quarterly progress notices from the ODP EVV resource account, ra-pwodpevvissues@pa.gov.

It is a sound business practice and strongly encouraged that the providers, provider agencies, AWCs and VF/EA ensure they have documentation demonstrating the service was rendered as specified in the waivers, that the service rendered meets the anticipated needs of the individual, as defined in the ISP, and any manual updates made to the EVV record corroborates with any claims submitted.

The EVV Compliance report is currently available in the EVV Aggregator. To access the EVV Compliance Report you need to log into the Aggregator and perform the following steps:

1. Choose Reports from the menu on the left.
2. In the Report Type drop down, choose Date Range Reports.
3. In the Report Name drop down, choose EVV Compliance.
4. Choose Run Report.

You will have the ability to choose dates to run the report. You can also narrow the report down by Account (if you have more than one), Client Name or Employee Name. The report provides detail information based on visit date, client, and employee for each account. The last page of the report shows summary information including the percentages of compliance.



ODP has incorporated EVV Manual Threshold compliance into their Claims Documentation review process, which is a component of ODP's Quality Assessment and Improvement (QA&I) process. For more information on claim documentation requirements see Bulletin 00-02-03, Technical Guidance for Claim and Service Documentation.

EVV ASSISTANCE/CONTACT INFORMATION

ODP EVV Claim Inquiries: ODP EVV claim inquiries should be made to the ODP Claims Resolution Section: ra-odpclaimsres@pa.gov 1-866-386-8880
Hours of operation: Monday - Thursday, 8:30 AM -12 PM & 1 PM - 3:30PM

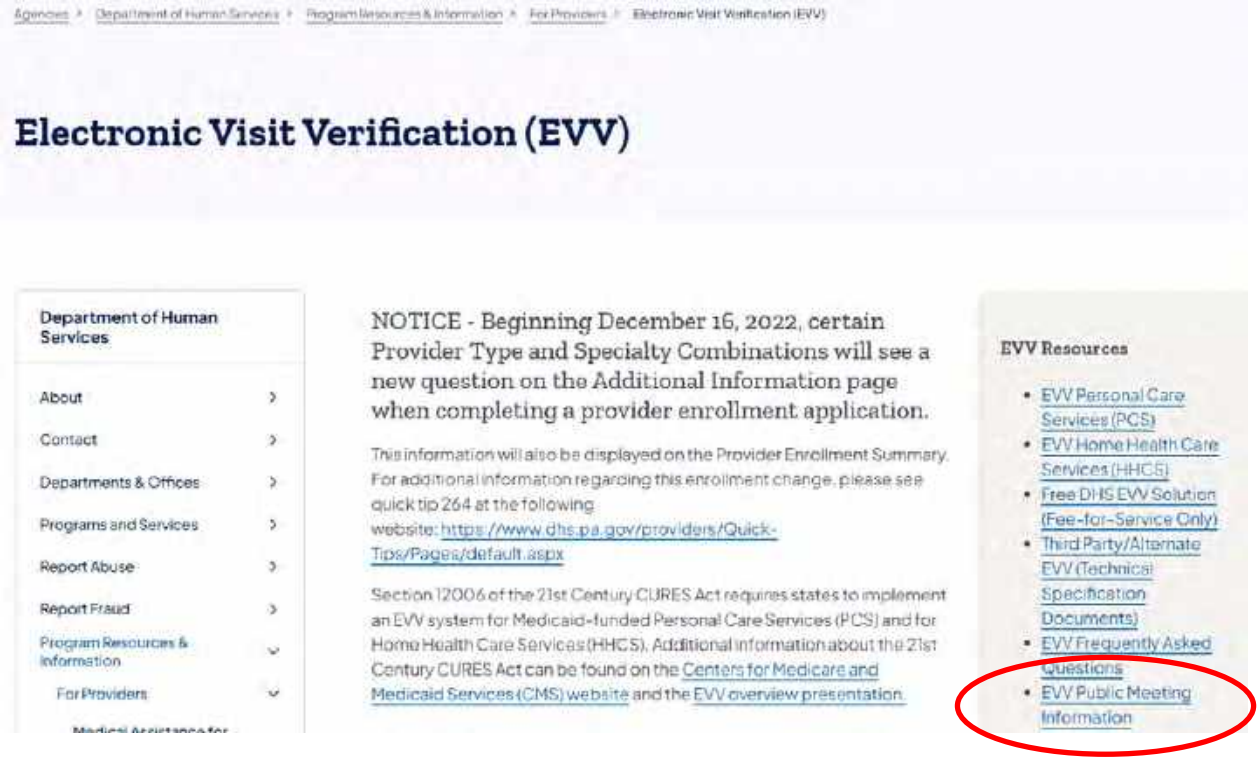
For technical issues such as DHS Sandata account assistance, Welcome Kit reissuance, account unlock issues for DHS Sandata EVV, please contact Provider Assistance Center (PAC) – papac1@gainwelltechnologies.com or 1-800-248-2152.

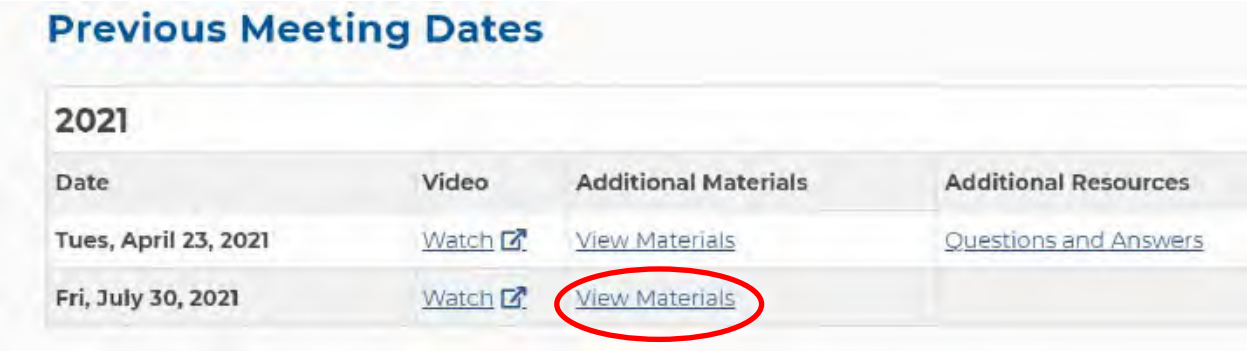
For general EVV program issues or requests to be added to the EVV Listserv, please contact EVV Resource Account at: RA-PWEVVNOTICE@pa.gov

Providers with technical issues reaching out to PAC or Sandata Alternate EVV team should copy DHS on those emails at the following email address: RA-PWEVVISSUES@pa.gov
Providers with support ticket numbers they wish to escalate with DHS should reach out to DHS at the following email address: RA-PWEVVISSUES@pa.gov

The Sandata Online Customer Service/Ticket Portal (also referred to as the Knowledge Center) is available as a resource for providers experiencing EVV issues. For information on how to access this portal and the EVV resources within it, go to the slide deck from the July 30, 2021

Public Meeting. See the first and second screen shot below for the resource location that explains how to access the Sandata Online Customer Service portal.





EVV AGGREGATOR

The DHS EVV Aggregator is a system that receives and stores data from third-party EVV systems and the DHS EVV Sandata system into a single uniform platform to facilitate payments of claims. The DHS EVV aggregator allows providers to use a third-party system (also referred to as Alternate EVV) for visit verification. The DHS EVV aggregator **DOES NOT** submit claims.

If a claim detail line passes EVV validation, the Internal Control Number (ICN) associated with the claim is passed to and stored in the DHS EVV aggregator. When viewing EVV records in the DHS EVV aggregator, please note that the presence of an ICN does not mean the claim was paid. It only means that the claim passed EVV validation and was allowed to continue through the usual claim's adjudication process. After EVV validation occurs against the DHS EVV aggregator, the claim will still need to go through HCSIS plan validation and may set edits during this process. An EVV record in the DHS EVV aggregator will show a "Processed" status after EVV validation occurs and passes while a "Verified" status in the aggregator means EVV claims validation has not yet occurred against the visit record.

The DHS EVV Aggregator is a read-only web portal for the provider, provider agency, AWC or VF/EA to view their EVV data, search and run reports. Aggregator reports are downloadable in Excel or CSV format.

VISIT SIGN OFF/SIGNATURE

Provider Agency Using the DHS Sandata EVV System: If the provider agency is using the DHS Sandata EVV system, this system does not require sign-off/signature on the visit. This feature was disabled in the DHS Sandata EVV system.

Provider Agency Using an Alternative EVV System: If the provider agency is using an alternative EVV system, then the provider agency may require a signature.

If a signature is required by the provider agency and if the participant is unable to sign or voice verify for EVV, the Supports Coordinator should:

a. Document the reason the participant cannot verify EVV in the Individual's care plan.

b. Document who, if anyone, will verify the service for the participant.

VF/FMS Model: If the participant is using the ODP Vendor Fiscal/Financial Management Service model, currently managed by Public Partnership LLC (PPL) the EVV system PPL uses requires a signature. The Common Law Employer, NOT the participant, is required to sign the timesheet.

AWC Model: If the participant is in the Agency with Choice (AWC) model, regardless of whether the AWC is using the DHS Sandata EVV system or an alternate EVV system, the Managing Employer (ME) is NOT required to approve time sheets for services subject to EVV, however, the AWC provider is still required to ensure service delivery was provided.

CHECK-IN/CHECK-OUT REQUIREMENTS

EVV does not affect or change access to care or the policy and provision of services. Service provision should support/align with the service definition found in the approved waiver(s) and the services' duration, frequency and scope as described in the individual's approved plan.

There will be no change in service delivery as a result of EVV. However, it is the responsibility of the provider, provider agency, AWC and VF/EA to ensure DSPs (Direct Support Professionals)/SSPs (Support Service Professionals):

- Are informed of which EVV solution they are required to use to capture PCS and HHCS visit information,
- Are trained on the agency's EVV system or DHS's EVV solution, and
- Understand and comply with the organization's expectations regarding their business practices to support EVV.

COMBINING PARTIAL UNITS

NOTE: <u>ODP is a fee-for-service program that does not round time or individual units of service.</u> The rate methodology for ODP personal care and home health care services is designed to take into consideration the time differential that may occur normally with service delivery.

ODP PCS and HHCS EVV services are associated with the following units of service:

- Respite (unlicensed and agency managed), In-Home and Community Supports, Companion and Specialized Skill Development (Adult Autism Waiver), Nursing: 15 minutes
- Homemaker Services: 1 Hour
- Respite (unlicensed): 24 Hours/Day Unit. (Does not include respite camp and respite in a Life Sharing setting)

ODP rounding rules for 15-minute units of service that are applied in the EVV Aggregator:

- 14 minutes = 0 units
- 15 minutes to 29 minutes = 1 unit
- 30 minutes to 44 minutes = 2 units
- 45 minutes to 59 minutes = 3 units

ODP rounding rules for 1-hour units of service that are applied in the EVV Aggregator:

- 59 minutes = 0 Units
- 1 hour to 1 hour and 59 minutes = 1 unit
- 2 hours to 2 hours and 59 minutes = 2 units

ODP rounding rules for 24 hours/day units of service that are applied in the EVV Aggregator:

- 16 hours = 0 units
- 16 hours and 1 minute to 40 hours = 1 unit
- 40 hours and 1 minute to 64 hours = 2 units
- 64 hours and 1 minute to 72 hours = 3 units
- 72 hours and 1 minute to 96 hours = 4 units

This section is intended to provide additional clarification on combining partial units when billing for Personal Care and Home Health Care Services subject to EVV. The ODP announcement can be found here: ODP Announcement 22-098

All ODP PCS and HHCS subject to EVV are permitted to bill units on one claim detail line that are based on the total accumulated continuous or non-continuous service time across an individual calendar day or across multiple calendar days not to exceed 31 days. The 31-day restriction is based on a limitation associated with the EVV aggregator. If 31 days are exceeded, error status code (ESC) 933 will set and deny the claim detail line.

The begin and end date submitted on a claim detail line informs the system what date range to use when locating visit time in the EVV Aggregator that will be used by the system to calculate units for the same provider, same individual and same service, regardless if the service delivery time was rendered continuous or non-continuously. Once all service time in the aggregator is located, the system totals all the time found and use the total time to calculate units. The total calculated units in the EVV aggregator are then assessed against the units submitted on the claim when determining to pass or fail the claim detail line.

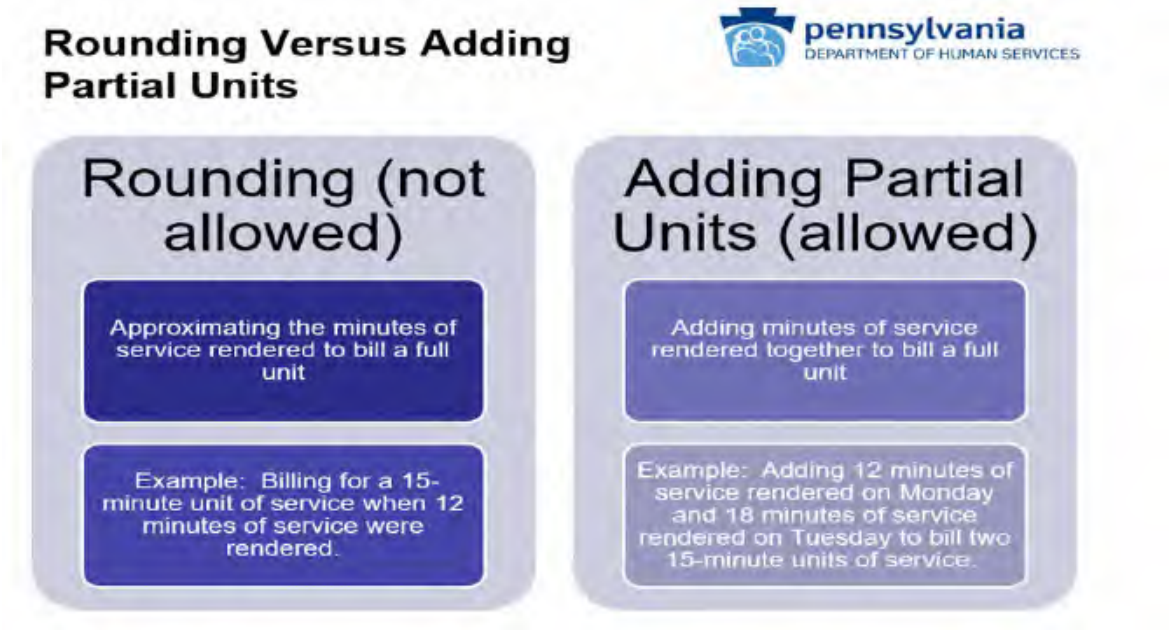
As long as the total calculated units found in the EVV aggregator ***is equal to or greater than*** the units submitted on the claim detail line, the claim will pass EVV validation and continue moving through the claims adjudication process where it is subject to individual support plan validation and additional Medical Assistance and ODP specific edits and audits in the Medicaid Management Information System (PROMIS*e*™).

ROUNDING

ODP issued Bulletin 00-22-05 Individual Support Plans on August 9, 2022. Please refer to the most recent update found here Individual Support Plan Manual.pdf (pa.gov) to review how ODP defines units of service. Rounding is not permitted.

ODP conforms with the Office of Medical Assistance Fee for Service Programs regarding rounding. The rate methodology for ODP personal care and home health care services is designed to take into consideration the time differential that may occur normally with service delivery.

Please note that seconds electronically captured during a visit are not considered in the unit calculation. In other words, if a service delivery visit is 7 minutes and 55 seconds, the EVV system would consider this visit 7 minutes in duration.



PLACE OF SERVICE CODES (POS)

Several data points represent the "location of service delivery".

- The first point is the place of service code (POS) on a claim transaction. During normal claims processing, the POS code on the claim detail line is always validated to ensure the location in which the service was rendered is permissible as specified in the waiver. All valid POS codes for each service are in the ISP Manual.

  ODP EVV services are associated with four (4) place of service codes:

  - 99: Other (Community)
  - 12: Home
  - 11: Office
  - *02: Telehealth (only applies to HHCS which includes Physical Therapy, Occupational Therapy and Speech/Language Therapy)

- The second data point that represents the location of service delivery is on the EVV record itself. For DHS Sandata EVV users, the "VisitLocationType" is anticipated to be enforced/required when submitting EVV transactions. The user will be required to select either "Home" or "Community" for the record to be considered complete. If the service

is/will be rendered in both the home and community during the service visit period, the user should select the value where the service was primarily rendered.

- When a third-party/alternate vendor EVV transaction is submitted to the EVV aggregator, the aggregator will validate that the "location of service delivery" is present in the transaction. If it is not present in the alternate EVV transaction or the field is blank, the EVV record will be rejected and will need to be resubmitted to the Aggregator with the "location of service delivery" included.

For PCS and HHCS, the GPS location where service delivery was provided is stored in the EVV aggregator. This information is accessible to AWC, VF/EA, provider, provider agencies and DHS who may review this information or perform audits as needed. While in the community, DSPs/SSPs have the option to turn off GPS to alleviate any privacy concerns about tracking community locations.

If the same service was rendered consecutively in multiple places within a 24-hour period, the visit may be electronically captured as one visit or two separate visits each representing a different place of service. It is at the discretion of the provider, provider agency, AWC and VF/AE to prescribe business rules as it applies to checking-in/checking-out when the same service is delivered consecutively during a 24-hour period in different locations. Billing should align with the check-in/check-out rules defined by the provider/provider agency.

Visit Capture Guidance When Location Changes Within a 24-hour Period: *In-home and community supports* services were rendered in the home from 8am – 12:00pm then in the community from 12:00pm - 2:00pm. For DHS EVV compliance, the location is only required to be captured at check-in and check-out for each service provided to the individual. The service may start at one location and end at another location; however, the locations visited by the caregiver and the individuals receiving support in-between check-in and check-out for the service are not required to be captured. In the noted example, the caregiver would need to check in at 8:00 am and check out at 2:00 pm, with the location being captured at check-in as the home and the location for the check-out captured as the community. Agencies may establish policies to capture the location where the service was rendered, including check-in and check-out based more accurately on when the service delivery location changes. Agencies are encouraged to instruct DSPs/SSPs on their rules for checking-in/checking-out when the same service is delivered in different settings consecutively in a 24-hour period.

Place of Service Billing Instructions:

Option 1: For the above scenario, if the DSP/SSP checked-in/checked-out for each location in which the same service was delivered to the same individual within a 24-hour period, the provider has two (2) billing options:

1. Bill one claim detail with units that reflect the period 8am – 2pm and use the place of service code that was most prominent during the time span of service delivery.
2. Bill two (2) claim detail lines with **different place of service codes** while entering the same service, date of service and same recipient ID. If this method is used, Error Status Code (ESC) 5000, "Detail is a suspected duplicate-modifier", will set for informational purposes only and the claim detail line will be approved for payment, assuming no other edits set for other reasons. No additional action is needed by the provider when ESC 5000 sets.

Option 2: If the same service was delivered consecutively in different settings from 8am to 2pm and the DSP/SSP checked-in at 8am and checked-out at 2pm, the provider would bill one (1) claim detail line, enter units that reflect the period 8am – 2pm and enter the place of service code that was most prominent during the time span of service delivery.

Choosing a place of service code to enter on a claim detail line when billing the same service that is rendered non-consecutively in multiple locations (i.e., home and community) during a 24-hour period. If there is a break in service and the setting changed for the same provider, same service, and same consumer during a 24-hour period, the service's visit check-in/check-out time and locations should be individually captured by the EVV application and will be stored as multiple records in the EVV aggregator. When billing, the claim detail line(s) should align with the date, service (procedure code and modifier(s), if applicable), location and number of units stored in the EVV records. If the same service was rendered non-consecutively in different locations throughout a calendar day and the visits were electronically captured in this manner, all accumulated units rendered in the community should be entered on one claim detail line while all accumulated units rendered in the home should be entered on a second claim detail line.

A claim with multiple claim detail lines that contain different place of service codes, will cause Error Status Code (ESC) 5000 to set, "Detail is a suspected duplicate-modifier". This ESC is an informational edit and will not prevent the claim from continuing to process. No additional action is needed by the provider when this ESC sets.

Place of Service Billing Rule: The place of service code is a required field on a claim and only one code is permitted on each claim detail line to specify where the service was rendered.

2:1 STAFFING RATIOS

2:1 Staff to Individual Ratio (Applies to Respite and In-Home and Community Supports Services)

For Personal Care Services subject to EVV with 2:1 staff to individual ratios, **both** DSPs/SSPs **MUST** check-in/check-out for the same individual/same service/same date/time and same location. ODP recognizes that it may sometimes be challenging for both DSPs/SSPs to check-in/check-out at the exact same time and has designed system logic to account for potential check-in/check-out time differences associated with 2:1 staff to individual ratios. It is important to understand this logic to train staff appropriately and minimize/eliminate claim payment issues.

For personal care services with 2:1 staff to individual ratios, at least two (2) instances (records) for the same service/same individual/same date of service/same provider must be present in the EVV aggregator in order for the claim to pass EVV validation. The total unit calculation for the service itself is based on logic that is designed in the system to look at the earliest common time and the latest common time between both DSPs/SSPs. The minutes associated with this time will then be converted to units, stored in the aggregator and compared to the units found on the claim.

For example, DSP/SSP "A" checks in at 4:55 PM and checks out at 5:10 PM, and DSP/SSP "B" checks in at 5:00 PM and checks out at 5:15 PM. The common check-in time between both DSPs/SSPs is 5:00 PM, and the common check-out time between both DSPs/SSPs is 5:10 PM. In this example, only 10 minutes will be calculated as the common time in which the service was delivered by both DSPs/SSPs, which equates to zero (0) units. For this example, if a claim is billed for 1 unit, it will deny in the system.

*If a check-in or check-out time was not accurately captured or not electronically captured at all for one or both care workers, EVV systems allow for the visit to be manually entered or manually adjusted to reflect the time-of-service delivery. If there are time disparities between the care workers rendering a 2:1 service due to device or connectivity at the point of care limitations and both care workers were, in fact, present at the exact same time to render services, a manual adjustment to the EVV record is justified. Manual adjustments should always contain notes documenting why the adjustment was made.

*RULE: For 2:1 services, the DHS EVV System expectation is that only two caregivers are clocked in at the same time. **IF** a 2:1 service has more than two caregivers at the point of care at the same time, this results in overlapping check in times for the same provider, participant, service, and date of service. This scenario will cause ESC 927 to set and the claim will be denied. To correct this issue, it is recommended the provider manually adjusts the EVV record of the third caregiver, whose shift overlaps with the original two caregivers who began the visit then resubmit the EVV record to the DHS Aggregator. When making the manual EVV record adjustment, the start time of the third caregiver's visit should be no earlier than the exact time the shift is intended to begin. To avoid this issue altogether and prevent the need for a manual EVV record adjustment, it is recommended that the third care worker not check in until after the care worker they are replacing checks out.

Linking 2 to 1 visits with the Group Code Field

AltEVV- According to our PA-DHS Alternate EVV Technical Specifications, the "GroupCode" field is optional.

DHS EVV- For those using the Sandata system and capturing visits using the SMC app (as opposed to a telephony visit)

- If the service being rendered is a group service which is a 2:1 service, then, the Group Code must be assigned otherwise the claim would deny once billed in PROMIS*e*™.
- If the service being rendered is a 1: Many service (e.g., 1:2, 1:3, 1:4), then the Group Code is optional (lack of the code would not cause a claim to deny once billed in PROMIS*e*™.

1:2, 1:3 and 1:4 STAFFING RATIOS

DSPs/SSPs that provide support services to more than one individual concurrently, must check-in/check-out for each individual for the service/visit to be accurately captured and stored in the EVV aggregator. If a DSP/SSP fails to check-in/check-out for each individual, related claims will deny during EVV validation because no record will be found in the Sandata aggregator.

VALIDATE HCSIS AUTHORIZATION PRIOR TO EVV AND BILLING

Providers, provider agencies, AWCs and VFs/AEs should regularly review Service Authorization Notices and/or the Provider Service Detail Report in HCSIS prior to service delivery and billing to ensure the service(s), date span associated with the authorized service line on the plan (service begin and end-date), the provider authorized on the plan is accurate and sufficient units and dollars are authorized on the individual's plan. Service Authorization Notices can be run and re-run to view changes made to the plan within a specific period by entering a date in the "*Date Last Changed From:*" field and "To:" field.

Regularly reviewing Service Authorization Notices and/or the Provider Service Detail report will minimize and/or prevent claim/claim detail line denials.

BILLING FOR 15 MINUTE SERVICES

Same logic applies for 1-hour units of service.

1. **Bill a single date of service delivery (that does not cross midnight) on one calendar day for the same service, same participant, and same provider/provider agency.**

Bill Single Visit on Single Calendar Day				
Date	**Time In**	**Time Out**	**Total Time**	**Total Units**
01/01/2019	**11:00 am**	**11:50 am**	**50 min**	**3**

From DOS	To DOS	POS	Proc Code	Modifiers 1	2	3	4	Diag XRef	Units Billed	Units Alwd
2019/01/01	2019/01/01	12	W1726					1	3.00	3.00

- **Claim 1:** If "Units Alwd" on claim are less than or equal to the units found in the EVV aggregator, the claim detail line will pass EVV validation in the aggregator and continue processing.

From DOS	To DOS	POS	Proc Code	Modifiers 1	2	3	4	Diag XRef	Units Billed	Units Alwd
2019/01/01	2019/01/01	12	W1726					1	2.00	2.00

- **Claim 2:** If "Units Alwd" on claim are greater than the units in the EVV aggregator, the claim detail line will be denied and stop processing.

2. **Bill two non-consecutive visits (that do not cross midnight) in one calendar day by the same or two different DSPs/SSPs for the same service, same participant (RID) and same provider/provider agency.**

Bill Two Visits on the Same Day				
Date	**Time In**	**Time Out**	**Total Time**	**Total Units**
01/01/2019	**11:00 am**	**11:16 am**	**16 minutes**	**1**
01/01/2019	**11:00 pm**	**11:18 pm**	**18 minutes**	**1**

From DOS	To DOS	POS	Proc Code	Modifiers 1	2	3	4	Diag XRef	Units Billed	Units Alwd
2019/01/01	2019/01/01	12	W1726					1	2.00	2.00

- **Claim 1:** Detail line will pass EVV validation and continue processing because "Units Alwd" are equal to units found in the EVV aggregator records.

3. **Bill a single date of service delivery (that does not cross midnight) over two calendar days by the same or two different DSPs/SSPs for the same service, same participant, and same provider/provider agency. The provider can bill 2 separate detail line, one for each day OR span bill.**

Bill Two Claim Detail Lines One for Each Day				
Date	**Time In**	**Time Out**	**Total Time**	**Total Units**
01/01/2019	**11:00 am**	**11:16 am**	**20 minutes**	**1**
01/03/2019	**11:00 am**	**11:40 am**	**40 minutes**	**2**

From DOS	To DOS	POS	Proc Code	Modifiers 1	2	3	4	Diag XRef	Units Billed	Units Alwd
2019/01/01	2019/01/01	12	W1726					1	1.00	1.00
2019/01/03	2019/01/03	12	W1726					1	2.00	2.00

- Claim 1: Two separate claim detail lines where the EVV aggregator would calculate units strictly with no rounding applied for each day. In other words, one unit would be calculated for 01/01 and two units calculated for 01/03.

Bill One Claim Detail Line and Date Span				
Date	**Time In**	**Time Out**	**Total Time**	**Total Units**
01/01/2019	**11:00 am**	**11:55 am**	**55 minutes**	**3**
01/03/2019	**1:00 pm**	**1:40 pm**	**20 minutes**	**1**
Total accumulated time for date span 1/1/2019 - 1/3/2019			**75 minutes**	**5**

From DOS	To DOS	POS	Proc Code	Modifiers 1	2	3	4	Diag XRef	Units Billed	Units Alwd
2019/01/01	2019/01/02	99	W1726					1	5.00	5.00

- Claim 2: one claim detail line for both dates of service using span dating on one claim detail line. The EVV aggregator will add up all the minutes for the two dates of service then convert the total accumulated minutes to units.

4. **Bill multiple non-consecutive service deliveries (that do not cross midnight) over two calendar days by the same or two different DSPs/SSPs for the same service, same participant and same provider/provider agency. The provider can bill 2 separate detail line, one for each day OR span bill.**

Bill Two Claim Detail Lines One for Each Day						
Date	**Time In**	**Time Out**	**Time In**	**Time Out**	**Total Time**	**Total Units**
01/01/2019	11:00 am	11:09 am	1:00 pm	1:07 pm	16 minutes	1
01/03/2019	11:00 am	11:25 am	1:00 pm	1:15 pm	40 minutes	2

From DOS	To DOS	POS	Proc Code	Modifiers 1	2	3	4	Diag XRef	Units Billed	Units Alwd
2019/01/01	2019/01/01	12	W1726					1	1.00	1.00
2019/01/03	2019/01/03	12	W1726					1	2.00	2.00

- Billing two claim detail lines where the EVV aggregator would calculate units strictly with no rounding applied for each day. In other words, one unit would be calculated for 01/01 and two units calculated for 01/03.

Bill ONE Claim Detail Line and Span Date						
Date	**Time In**	**Time Out**	**Time In**	**Time Out**	**Total Time**	**Total Units**
01/01/2019	11:00 am	11:20 am	1:00 pm	1:20 pm	40 minutes	2
01/02/2019	11:00 am	11:20 am	1:00 pm	1:20 pm	40 minutes	2
Total accumulated time for date span 1/1/2019 - 1/3/2019					**80 minutes**	**5**

From DOS	To DOS	POS	Proc Code	Modifiers 1	2	3	4	Diag XRef	Units Billed	Units Alwd
2019/01/01	2019/01/02	99	W1726					1	5.00	5.00

- Billing one claim detail line for both dates of service using span dating on one claim detail line. The EVV aggregator will add up all the minutes for the two dates of service then convert the total accumulated minutes to units.

5. **Bill a single date of service delivery that DOES cross midnight on one calendar day for the same service, same participant, and same provider/provider agency (when service delivery is less than 24 hours)**

Bill Single Visit that Crosses Midnight and is LESS THAN 24 hours				
Date	**Time In**	**Time Out**	**Total Time**	**Total Units**
01/01/2019	**11:50 pm**	**12:40 am**	**50 min**	**3 units**

From DOS	To DOS	POS	Proc Code	Modifiers 1	2	3	4	Diag XRef	Units Billed	Units Alwd
2019/01/01	2019/01/01	12	W1726					1	3.00	3.00

- **<u>Claim 1</u>:** For this scenario to pass EVV validation against the aggregator, the claim MUST have a "From DOS" and "To DOS" that is equal and reflects the date in which the service began.

Bill Single Visit that Crosses Midnight and is GREATER THAN 24 hours				
Date	**Time In**	**Time Out**	**Total Time**	**Total Units**
01/01/2019	**11:00 pm**	**11:30 pm**	**24 hours 30 min**	**98 units**

From DOS	To DOS	POS	Proc Code	Modifiers 1	2	3	4	Diag XRef
2019/01/01	2019/01/02	99	W1726					1

- **<u>Claim 2</u>**: For this scenario to pass EVV validation against the aggregator, the claim MUST have a "From DOS" and "To DOS" that reflects the actual start date and end date of service delivery.

6. **Bill multiple non-consecutive service deliveries that DO cross midnight over two calendar days but less than 24 hours by the same or two different DSPs/SSPs for the same service, same participant, and same provider/provider agency.**

Bill Multiple Visits that Cross Midnight LESS THAN 24 hours				
Date	**Time In**	**Time Out**	**Total Time**	**Total Units**
01/01/2019	**11:30 pm**	**12:22 am**	**52 Minutes**	**3**
01/02/2019	**10:00 am**	**10:30 am**	**30 Minutes**	**2**

From DOS	To DOS	POS	Proc Code	Modifiers 1	2	3	4	Diag XRef	Units Billed	Units Alwd
2019/01/01	2019/01/01	12	W1726					1	3.00	3.00
2019/01/02	2019/01/02	99	W1726					1	2.00	2.00

- **Claim 1**: Bill 2 individual lines considering less than 24 hours for visit occurring over midnight in which "From DOS" and "To DOS" that is equal and reflects the date in which the service began.

From DOS	To DOS	POS	Proc Code	Modifiers 1	2	3	4	Diag XRef	Units Billed	Units Alwd
2019/01/01	2019/01/02	99	W1726					1	5.00	5.00

- **<u>Claim 2:</u>** Span bill in which the EVV aggregator will add up all the minutes for the two dates of service then convert the total accumulated minutes to units.

7. **Bill multiple consecutive service deliveries for same service event over two consecutive calendar days in excess of 24 hours by the same or two different DSPs/SSPs for the same service, same participant and same provider/provider agency.**

Bill Multiple Visits that Cross Midnight GREATER THAN 24 hours				
Date	**Time In**	**Time Out**	**Total Time**	**Total Units**
01/02/2021	**10:00 am**	**9:00 pm**	**11 Hours**	**44 Units**
01/02/2021	**8:47 pm**	**7:01 pm**	**22 Hours 14 Min**	**88 Units**
			33 Hours 14 Minutes	**132 Units (> 96 Units so dates on claim should reflect 1/2/2021 - 1/3/2021)**

BILLING FOR UNLICENSED RESPITE DAY SERVICES

For unlicensed respite day services, providers/provider agencies should ensure the visit record in the EVV aggregator shows at least 16 hours and one minute of continuous service delivery to align with the ISP Manual, which indicates that "day respite must be provided for periods of more than 16 hours". From a visit capture perspective, DSPs/SSPs should ensure that their clock-in and clock-out time reflects at least 16 hours and one minute of consecutive service delivery. Please remember that seconds captured are not considered when calculating units in the system so the care worker should ensure they capture at least an additional minute either at check-in or check-out to ensure more than 16 hours is captured. For unlicensed respite day services, there cannot be a break in service for a single service delivery event. For this service, the provider/provider agency has the option to bill for a single care event or multiple care events (span dating) on one claim detail line.

1. **Bill a single continuous care event by the same service, same provider, same DSP on one claim detail line that was rendered within one calendar day for unlicensed respite day 1:1, 1:2, 1:3 and 1:4 staff to individual ratios.**

   - To bill for unlicensed respite day services delivered continuously for at least 16 hours within one calendar day, the "From DOS" and "To DOS" on a single claim detail line should reflect the same date with "Units Billed" as "1".

Single Respite Day Visit				
Date	**Time In**	**Time Out**	**Total Time**	**Total Units**
01/01/2019	**6:00 am**	**11:00 pm**	**17 hours**	**1**

From DOS	To DOS	POS	Proc Code	Modifiers 1	2	3	4	Diag XRef	Units Billed	Units Alwd
2019/01/01	2019/01/01	11	W9799					1	1.00	1.00

2. **Bill multiple nonconsecutive visits for the same service, same provider, same (or multiple) DSPs on one claim detail line that was rendered within one calendar day for unlicensed respite day 1:1, 1:2, 1:3 and 1:4 staff to individual ratios.**
   - As long as the total time of service delivery is greater than 16 hours the claim will pass EVV validation and continue processing.

Multiple Non-Consecutive Visits Within a Day				
Date	**Time In**	**Time Out**	**Total Time**	**Total Units**
01/01/2019	**5:00 am**	**2:00 pm**	**9 hours**	**1**
01/01/2019	**3:00 pm**	**11:00 pm**	**8 hours**	

From DOS	To DOS	POS	Proc Code	Modifiers 1	2	3	4	Diag XRef	Units Billed	Units Alwd
2019/01/01	2019/01/01	11	W9799					1	1.00	1.00

3. **Bill a single continuous service event on one claim detail line that overlaps into another calendar day (crosses midnight) for unlicensed respite day 1:1, 1:2, 1:3 and 1:4 staff to individual ratios:**
   - For this billing scenario, the "From DOS" and "To DOS" of service on the single claim detail line should reflect the same date. This scenario assumes the care worker **did not** check-in and out at midnight and one EVV record is stored in the EVV aggregator reflecting this care event.

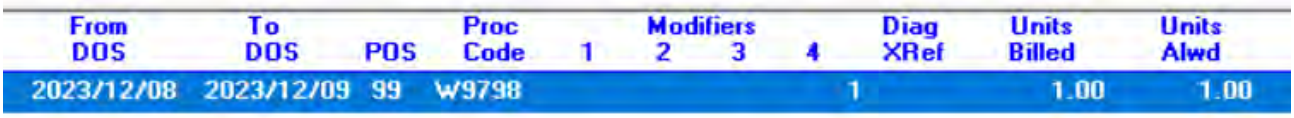
Single Respite Day Visit Across Midnight				
Date	**Time In**	**Time Out**	**Total Time**	**Total Unit**
01/01/2019	6:00 pm	11:00 am	17 hours	1

From DOS	To DOS	POS	Proc Code	Modifiers 1	2	3	4	Diag XRef	Units Billed	Units Alwd
2019/01/01	2019/01/01	11	W9799					1	1.00	1.00

4. **Bill a single service event on one claim detail line that crosses midnight where the provider/provider agency required the care worker(s) to check-out at midnight and check-in after midnight for unlicensed respite day 1:1, 1:2, 1:3 and 1:4 staff to individual ratios:**

    - Because the provider/provider agency requires the care worker to check-out and check back in at midnight, this creates two (2) EVV records in the EVV aggregator that represents one continuous care event. To account for this, the "From DOS" should reflect the date the service began and the "To DOS" should reflect the date the service was completed with "Units Billed" as "1". This will tell the system to look for and add up all time found in the aggregator that is associated with the same service/same individual/same provider for all dates in the date range submitted on the claim detail line then the system will use the total time found that is tied to those EVV records to calculate units.

Single Respite Day Visit Clock Out/In at Midnight				
Date	**Time In**	**Time Out**	**Total Time**	**Total Units**
12/08/2023	**6:00 pm**	**12:00am**	**6 hours**	1
12/09/2023	**12:00am**	**11:00am**	**11 hours**	



From DOS	To DOS	POS	Proc Code	Modifiers 1	2	3	4	Diag XRef	Units Billed	Units Alwd
2023/12/08	2023/12/09	99	W9798					1	1.00	1.00

5. **Bill multiple nonconsecutive visits for the same service, same provider, same (or multiple) DSPs on one claim detail line that crosses two different calendar days in excess of a 24-hour period unlicensed respite day 1:1, 1:2, 1:3 and 1:4 staff to individual ratios.**
    - When billing for services associated with a day unit that are rendered overnight and cross calendar days (**even if period exceeds 24 hours**), the claim detail line **MUST** contain only one date of service. The "From DOS" and "To DOS" **MUST** be the same and equal the first day the service was delivered in order to pass EVV validation and continue processing, as seen below.

Single Respite Day Visit Across 2 Calendar Days				
Date(s) of Service	**Time In**	**Time Out**	**Total Time**	**Total Unit(s)**
01/01/2019	**6:00 am**	**2:00 pm**	**8 hours**	**1**
01/01/19 – 01/02/19	**11:00 pm**	**8:00 am**	**9 hours**	

From DOS	To DOS	POS	Proc Code	Modifiers 1	2	3	4	Diag XRef	Units Billed	Units Alwd
2019/01/01	2019/01/01	11	W9799					1	1.00	1.00

6. **Bill a single service event on one claim detail line that was rendered within one calendar day for unlicensed respite day <u>2:1 staff</u> to individual ratio:**

- To bill for unlicensed respite day services delivered by two care workers within a calendar day, the "From DOS" and "To DOS" on the single claim detail line should reflect the same date.
- During claims validation against the EVV aggregator for 2:1 day unit services, the system will look for at least two (2) EVV records that contain the same service/same individual/same date of service/same provider for the claim to pass EVV validation. The total unit calculation for the service itself looks at the earliest common time and the latest common time between both care workers. The common minutes associated with this time are then converted to units and compared to the units found on the claim.

Single Respite Day Visit 2:1					
Employee	**Date**	**Time In**	**Time Out**	**Total Time**	**Total Units**
Care worker A	**01/26/2024**	**6:00 am***	**12:00am**	**18 hours**	**1**
Care worker B	**01/26/2024**	**5:45am**	**11:45pm***	**18 hours**	

*Common time begins when Care Worker A clocks in at 6:00am and ends when Care Worker B clocks out at 11:45pm. The common time is 17 hours and 45 minutes which passes the verification for an unlicensed respite day unit of 16 hours and 1 minute.

Detail No	Stat	From DOS	To DOS	POS	Proc Code	Modifiers 1	2	3	4	Diag XRef	Units Billed	Units Alwd
001	P	2024/01/26	2024/01/26	99	W9801					1	1.00	1.00

7. **Bill a single continuous service event <u>with no break in service</u> that overlaps into another calendar day (crosses midnight) on one claim detail line for unlicensed respite day services with a <u>2:1</u> staff to individual ratio:**

- For this billing scenario, the "From DOS" and "To DOS" of service on the single claim detail line should reflect the same date. This scenario assumes the care worker **<u>did not</u>** check-in and out at midnight and one EVV record is stored in the EVV aggregator reflecting this care event.
- During claims validation against the EVV aggregator for 2:1 unlicensed respite day service, the system looks for at least two (2) EVV records that contain the same service/same individual/same date of service/same provider for the claim to pass EVV validation. The total unit calculation for the service itself looks at the earliest common time and the latest common time between both

care workers. The minutes associated with the common time are then converted to units and compared to the units found on the claim.

Single Respite Day Visit 2 to 1 Across Midnight					
Employee	**Date**	**Time In**	**Time Out**	**Total Time**	**Total Units**
Care worker A	01/26/2024	6:00 pm	12:00 pm	18 hours	1
Care worker B	01/26/2024	6:00 pm	12:00 pm	18 hours	

Detail No.	Stat	From DOS	To DOS	POS	Proc Code	Modifiers 1	2	3	4	Diag XRef	Units Billed	Units Alwd
001	P	2024/01/26	2024/01/26	99	W9801					1	1.00	1.00

8. Bill a single continuous service event with a break in service on one claim detail line that overlaps into another calendar day (clock out/in at midnight) for unlicensed respite day <u>2:1</u> staff to individual ratio:

- Because the provider/provider agency required the care worker(s) to check-out and check back in at midnight amid a continuous service delivery, this action generated and stored four EVV records (and possibly more if shift changes also occurred) in the EVV aggregator that actually represents one continuous care event. To account for this, the "From DOS" should reflect the date the service began and the "To DOS" should reflect the date the service was completed with "Units Billed" as "1". This will tell the system to look for and add up all common time found in the aggregator that is associated with the same service/same individual/same provider and same dates in the date range submitted on the claim detail line then use the total common time found that is tied to those EVV records to calculate units.

- During claims validation against the EVV aggregator for 2:1 unlicensed respite day services, the system looks for at least two (2) EVV records that contain the same service/same individual/same date of service/same provider for the claim to pass EVV validation. The total unit calculation for the service itself looks at the earliest common time and the latest common time between both care workers. The minutes associated with this time are then converted to units and compared to the units found on the claim.

Single Respite Day Visit 2: 1 Clock Out/In at Midnight					
Employee	**Date**	**Time In**	**Time Out**	**Total Time**	**Total Unit**
Care worker A	**12/08/2023**	**6:00pm**	**12:00am**	**6 hours**	**1**
Care worker B	**12/08/2023**	**6:00pm**	**12:00am**	**6 hours**	
Care worker A	**12/09/2023**	**12:00am**	**11:00am**	**11 hours**	
Care worker B	**12/09/2023**	**12:00am**	**11:00am**	**11 hours**	

From DOS	To DOS	POS	Proc Code	Modifiers 1	2	3	4	Diag XRef	Units Billed	Units Alwd
2023/12/08	2023/12/09	99	W9798					1	1.00	1.00

A special note on Shift Changes: For 2:1 unlicensed respite day services, if the aggregator contains overlapping time for three or more care workers, the system is unable to determine which care worker visit time to use when calculating units; and as a result, the claim detail line will deny. While this scenario can occur for other EVV services, it occurs most frequently when multiple DSPs are providing care to one individual. This typically occurs during shift changes:

Overlapping Shifts					
Employee	**Date**	**Time In**	**Time Out**	**Total Unit**	**Total Time**
Care worker A	**06/30/2023**	**6:00 pm**	**12:00 pm**		**18 hours**
Care worker B	**06/30/2023**	**6:00 pm**	**11:06 pm***	**?**	**5 hours**
Care worker C	**06/30/2023**	**11:00 pm***	**12:00 pm**		**13 hours**

*To resolve this issue, the provider should the manually adjust the new shift care worker's EVV visit time to a time that does not overlap with the care worker's time whose shift is ending. Due to this system limitation, a manual edit for this scenario is acceptable by DHS.

9. **Bill for multiple care events on one claim detail line (span dating) rendered over two or more calendar days for unlicensed respite day 1:1, 1:2, 1:3 or 1:4 services where each care event occurred within a calendar day and did not cross midnight.**

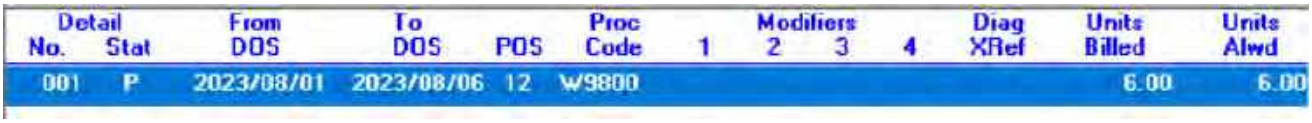
    - To bill for multiple unlicensed respite day service care events that crossed into one or more calendar days (referred to as span dating), the claim detail line must show a date span with a "From DOS" that reflects a date when the first service began and a "To DOS" that reflects a date when the last service delivery ended.

Multiple Respite Days Span Date				
Date	**Time In**	**Time Out**	**Total Unit**	**Total Time**
12/17/2023	6:00am	10:30pm	1	16.5 hours
12/23/2023	6:00am	10:15pm	1	16.15 hours

Detail No.	Stat	From DOS	To DOS	POS	Proc Code	Modifiers 1	2	3	4	Diag XRef	Units Billed	Units Alwd
001	P	2023/12/17	2023/12/23	99	W9798					1	2.00	2.00

10. **Billing for multiple care events on one claim detail line (<u>span dating</u>) for unlicensed respite day <u>2:1</u> services where each care event occurred within a calendar day and did not cross midnight.**

Multiple 2:1 Respite Days Span Date					
Employee	**Date**	**Time In**	**Time Out**	**Total Unit**	**Total Time**
Care worker A	08/01/2023	6:00am	11:00pm		17 hours
Care worker B	08/01/2023	6:00am	12:00am		18 hours
Care worker A	08/02/2023	2:00am	07:00pm		17 hours
Care worker B	08/02/2023	2:00am	07:00pm		17 hours
Care worker A	08/03/2023	6:00am	11:00pm		17 hours
Care worker B	08/03/2023	6:00am	12:00am		18 hours
Care worker A	08/04/2023	6:00am	11:00pm		17 hours
Care worker B	08/04/2023	6:00am	12:00am		18 hours
Care worker A	08/05/2023	6:00am	11:00pm		17 hours
Care worker B	08/05/2023	6:00am	12:00am		18 hours
Care worker A	08/0/2023	2:00am	07:00pm		17 hours
Care worker B	08/06/2023	2:00am	07:00pm		17 hours



Detail No.	Stat	From DOS	To DOS	POS	Proc Code	Modifiers 1	2	3	4	Diag XRef	Units Billed	Units Alwd
001	P	2023/08/01	2023/08/06	12	W9800						6.00	6.00

Please note: When date spanning, a claim detail line should not contain any more than 31 days in a date span. In other words, the "From DOS" and "To DOS" should not exceed 31 days. The 31-day restriction is based on a limitation associated with the EVV aggregator. If 31 days are exceeded, error status code (ESC) 933 will set and deny the claim detail line.

APPENDIX A: EVV Error Status Codes (ESCs)

The claims adjudication process will flow as it currently does today, EXCEPT when an EVV service is found on the claim, PROMISe™ will make a "call" to the EVV aggregator to validate a record(s) is present and ensures the EVV record(s) found in the EVV aggregator matches what is specified on the claim. If the claim detail line passes EVV validation, the claim will continue processing and next validate against the plan in HCSIS before completing the claims processing adjudication cycle. No EVV validation call will be made when a claim is voided. The ESCs below describe the EVV validation logic. **All error resolution corrections should be made in the original system. Once a correction is made, the corrected EVV record should be resent to the aggregator before a claim is resubmitted**. No corrections can be made in the EVV aggregator itself. The EVV aggregator is read only.

EVV ERROR STATUS CODES (ESC)			
EVV ESC CODE	**EVV ESC DESCRIPTION**	**WHY IS THIS ESC SETTING?**	**RESOLUTION ACTIVITY**
ESC 925	EVV PCS Visit Verified	Providers will see these ESCs each time PROMISe™ determines a service subject to EVV is found on the claim and the claim detail line passed EVV validation against the EVV Aggregator record(s).	These two edits set for informational purposes only. They serve to inform the provider, provider agency, AWC, and VF/EA, that the claim passed EVV validation in the Aggregator. No action is needed by the provider. When a claim passes EVV validation, it continues processing through the claims adjudication process as it currently does today.
ESC 935	EVV HHCS Visit Verified		
ESC 926	Duplicate Matching EVV PCS Visits Found	A duplicate EVV record exists in the aggregator.	When two exact EVV records exist in the aggregator, the claim validation call does not know which record to match with, so it will set either ESC 926 or ESC 936 and deny.

EVV ERROR STATUS CODES (ESC)			
EVV ESC CODE	**EVV ESC DESCRIPTION**	**WHY IS THIS ESC SETTING?**	**RESOLUTION ACTIVITY**
ESC 936	Duplicate Matching EVV HHCS Visits Found		To correct this issue for alternate EVV users, the EVV record should contain "BillVisit" set to "False". This will tell the aggregator to set the duplicate record to "Omit" so it is not considered during EVV validation against the aggregator. In addition, alternate EVV users should ensure when sending records for omission that they submit the same "VisitOtherID" that was assigned to the original record they wish to omit/remove.
ESC 927	PCS Units Billed Exceed Units Verified in EVV	When the provider sees either ESC set, the claim detail line denied because the **allowed** units on the claim detail line are greater than the units found on the EVV record in the Aggregator.	Provider, provider agencies, AWC and VF/EA, should determine if the units on the claim detail line or the units found in the EVV record need to be corrected. PROMISe™ is not designed to cut back units on the claim for an EVV service if the allowed units on the claim are greater than the total units found in the Aggregator. Providers should make corrections as applicable and resubmit the claim, ensuring the units found in the EVV Aggregator are equal to or greater than the units submitted on the claim. While performing claims resolution analysis, providers are encouraged to review the rounding rules and/or the calculation rules, make corrections accordingly and resubmit claim. Note: "Allowed" units on a claim detail line are not always equal to the exact units submitted on the claim because other edits/audits are performed before the units on the claim are validated against the units found in the EVV Aggregator record. Example: Fiscal year unit limitations or weekly unit limitations may "cutback" units submitted on a claim which would make the units on the claim less than what was submitted on the actual claim.
ESC 937	HHCS Units Billed Exceed Units Verified in EVV		
ESC 928	No Matching PCS EVV Visit Found	When the provider sees either ESC set, the claim detail line denied for one of the following reasons: 1. No EVV record was found in the Aggregator, OR	1. Submit EVV record to the Aggregator then resubmit the claim. 2. Verify if the claim was submitted and processed BEFORE the visit information was successfully sent to the EVV Aggregator. If not, resubmit claim. 3. If the EVV record in the Aggregator is in an "Incomplete" status, there is an exception(s) associated with the record that will need a manual update made. Go

EVV ERROR STATUS CODES (ESC)			
EVV ESC CODE	**EVV ESC DESCRIPTION**	**WHY IS THIS ESC SETTING?**	**RESOLUTION ACTIVITY**
ESC 938	No Matching HHCS EVV Visit Found	2. The EVV record was submitted to the aggregator AFTER the claim was submitted and processed, OR 3. The status of the EVV record in the EVV Aggregator is in an "Incomplete" status OR 4. Mismatch was found between either the date of service, RID (10 digits), procedure code/modifier and/or MPI (9 digit) code that is found on the claim versus what is found in the EVV record, OR 5. 2:1 service with overlapping time in the aggregator for 3 or more care workers (typically due to shift changes)	into the source EVV system you use, correct the data, ensure the record is in a "Verified" status then resubmit the visit to the EVV Aggregator. Resubmit the claim once you are sure the EVV record status has been sent to the Aggregator and in a "Verified" status. 4. If the EVV record that is found in the Aggregator contains a mismatch between one or more data elements on the claim, review the EVV record in the Aggregator and manually validate if the data elements found in the Aggregator record(s) contains the appropriate values as specified in the Alternate EVV technical specifications found on the DHS EVV website. A frequently seen error is when the EVV record contains a 9-digit MA ID # instead of the 10-digit Recipient ID number (RID) that is contained on the claim. If you experience this issue, update your client/participant number from 9 to 10-digits in your source system that feeds the alternate EVV system records that are sent to the aggregator. 5. For 2:1 services specifically, the system is unable to determine which care worker visit to use when calculating units if the aggregator contains overlapping time for 3 or more care workers. This scenario will typically occur during shift changes. To resolve this issue, the provider should manually adjust the 3rd care worker's EVV visit to a time that does not overlap with the care worker's time whose shift is ending. Due to this system limitation, a manual edit for this scenario is acceptable by DHS.
ESC 929	EVV Web Service Timeout	When this ESC sets, PROMISe™ received a web service timeout when communicating with the EVV Aggregator.	When this ESC sets, the claim will suspend and the PROMISe™ technical vendor, Gainwell, will resolve the error and reprocess the claim within a 24-hour period. **No action is needed by the provider.** If a provider, provider agency, AWC or VF/EA sees this ESC while performing claims reconciliation activities, DO NOTHING to the claim and check back later in the day or the following day to confirm the claim was reprocessed on its own.

EVV ERROR STATUS CODES (ESC)			
EVV ESC CODE	**EVV ESC DESCRIPTION**	**WHY IS THIS ESC SETTING?**	**RESOLUTION ACTIVITY**
ESC 930	EVV Internal Error	When this ESC sets, PROMISe™ received an internal error when communicating with the EVV Aggregator.	When this ESC sets, the claim will suspend and the PROMISe™ technical vendor, Gainwell, will resolve the error and reprocess the claim within a 24-hour period. **No action is needed by the provider.** If a provider, provider agency, AWC or VF/EA sees this ESC while performing claims reconciliation activities, DO NOTHING to the claim and check back later in the day or the following day to confirm the claim was reprocessed on its own. If this ESC continues to be present 24 hours after claim submission, contact the Provider Assistance Center (PAC).
ESC 931	EVV-PROMISe Internal Error	ESC sets when there is a technical issue related to the interface.	When this ESC sets, the claim will suspend and the PROMISe™ technical vendor, Gainwell, will resolve the error and reprocess the claim within a 24-hour period. **No action is needed by the provider.**

EVV ERROR STATUS CODES (ESC)			
EVV ESC CODE	**EVV ESC DESCRIPTION**	**WHY IS THIS ESC SETTING?**	**RESOLUTION ACTIVITY**
ESC 933 (Previously ESC 926)	EVV Internal Record Format Error	This ESC will set when PROMISe™ sends an incorrectly formatted record to the EVV Aggregator during the EVV record validation process **OR** when a provider bills a claim with a date span on one claim detail lines that is equal to or greater than 31 calendar days.	This ESC sets and will suspend the claim detail line for one of two reasons: 1. If an incorrectly formatted record is sent to the aggregator during the claim's validation process, this ESC sets, the claim will suspend and the PROMISe™ technical vendor, Gainwell, will resolve the error and reprocess the claim within a 24-hour period. **No action is needed by the provider**. If an AWC, VF/EA, provider or provider agency sees this ESC while performing claims reconciliation activities, DO NOTHING to the claim and check back later in the day or the following day to confirm the claim was reprocessed on its own. 2. This ESC will also set if a claim detail line is billed with a date span that is equal to or greater than 31 days. To resolve this issue, the date span on the claim detail line will either need to be split onto two separate claim detail lines and resubmitted or split and resubmitted on two separate claims.

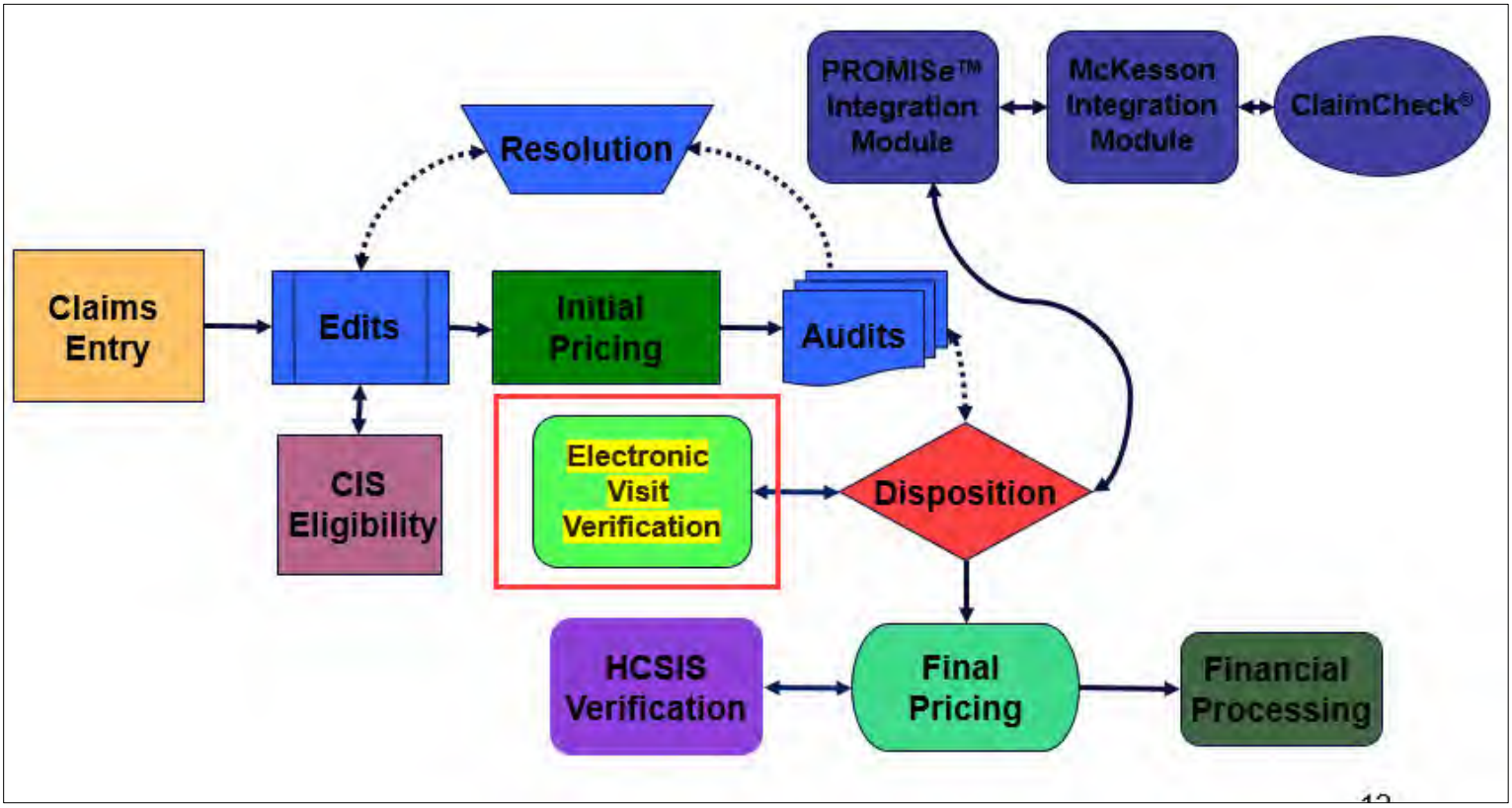
APPENDIX B: ABBREVIATIONS/DEFINITION OF TERMS

ACRONYM/ABBREVIATION/ TERM	DEFINITION/TRANSLATION
AAW	Adult Autism Waiver
Aggregator	The DHS EVV Aggregator is a system that integrates data from third-party systems (also referred to as Alternate EVV systems) and the DHS EVV system into a single uniform platform to facilitate payments of claims. The DHS Aggregator allows providers to use a third-party system (also referred to as Alternate EVV) for visit verification.
AWC	An Agency with Choice is one option a participant can use when self-directing their own services.
Claim	A transaction submitted requesting provider-rendered service payment. ODP providers use the 837 Professional format for claim transactions/billing.
CMS	Federal entity that translates to the Centers for Medicare and Medicaid Services
Community Support	An AAW service that assists a participant to gain skills needed to live in the community. The intent of this service is to reduce the need for direct assistance by improving a participant's ability to live independently in the community.
Companion	A service offered by the Consolidated, P/FDS, Community Living Waiver and Base program to provide supervision and assistance focused on health and safety of the individual. Not available to those in licensed residential settings.
DHS	Pennsylvania Department of Human Services
DOS	Date of Service abbreviation in PROMISe™
DSP/SSP	Direct Service Professional/Support Service Professional
ESC	Stands for Error Status Code. ESCs set during claims processing to inform the biller of what action took place while processing a claims transaction. When an ESC sets, it will either deny, pay or suspend an entire claim or just a claim detail line.
EVV	Electronic Visit Verification
FAQs	Frequently Asked Questions
HCSIS	Home and Community Services Information System
HHS	Home Healthcare Services
Homemaker	A service offered by the Consolidated, P/FDS, Community Living Waiver and Base program. Service includes household cleaning/maintenance and homemaker activities such as meal preparation, laundry, or services to keep the home clean and in safe condition.
IHCS	**In-Home and Community Supports:** A service offered by the Consolidated, P/FDS, Community Living Waiver and Base program. This service assists individuals with acquiring, retaining, and improving self-help, socialization, and adaptive skills. Service can be provided in home and community settings. This service may be made available

APPENDIX B: ABBREVIATIONS/DEFINITION OF TERMS

ACRONYM/ABBREVIATION/ TERM	DEFINITION/TRANSLATION
	to individuals in their own home or in other residential of community settings not subject to licensing regulations. Recreation is not an eligible service. Camp day or overnight can only be provided under respite/family aid. Entrance fees to events are not covered.
MMIS	Medicaid Management Information System (currently known as PROMISe™)
ODP	Office of Developmental Programs
OLTL	Office of Long-Term Living
OMAP	Office of Medical Assistance Programs
PCS	Personal Care Services
POS	Place of Service terminology used in PROMISe™
PROMISe™	Claims processing and management information system for the Commonwealth of Pennsylvania, Department of Human Services.
QA and I	Quality Assessment and Improvement. ODP Quality Assessment process designed to conduct a comprehensive quality management review of providers delivering services and supports to individuals with intellectual disabilities and autism spectrum disorders
Respite	A service offered by the Adult Autism Waiver, Consolidated, P/FDS, Community Living Waivers and Base program. This service is provided on a short-term basis to relieve those persons normally providing care to the individual.
Sandata	DHS EVV solution
VF/EA	Vendor Fiscal/Employer Agent

APPENDIX C: DETAILED PROCESS FLOW OF PROMISe™ CLAIMS ENGINE



APPENDIX D: Sandata Service ID Crosswalk to Procedure Code/Modifier Combo and Service Description

Payer	Program	Sandata Service	HCPCS Code	Modifier1	Modifier2	Modifier3	Modifier4	Service Description
PAODP	ODP	T2025_02	T2025	TD				Nursing - (1:1) RN-15 Mins
PAODP	ODP	T2025_03	T2025	TD	UN			Nursing (1:2) RN
PAODP	ODP	T2025_06	T2025	TE				Nursing - (1:1) LPN-15 Mins
PAODP	ODP	T2025_07	T2025	TE	UN			Nursing (1:2) LPN
PAODP	ODP	T2025_10	T2025	GN				Speech/Language Therapy-15 Mins
PAODP	ODP	T2025_11	T2025	GN	U2			Speech/Language Therapy - 15 Mins - AAW
PAODP	ODP	T2025_13	T2025	GO				Occupational Therapy-15 Mins
PAODP	ODP	T2025_18	T2025	GP				Physical Therapy-15 Mins
PAODP	ODP	W1724	W1724					Companion Basic (1:3)
PAODP	ODP	W1725	W1725					Companion Level 1 (1:2)
PAODP	ODP	W1726	W1726					Companion Level 2 (1:1)
PAODP	ODP	W7058	W7058					IHCS Basic (1:3)
PAODP	ODP	W7059	W7059					IHCS Level 1 (1:2)
PAODP	ODP	W7060	W7060					IHCS Level 2 (1:1)
PAODP	ODP	W7061	W7061					IHCS Level 2 (1:1) Enhanced
PAODP	ODP	W7068	W7068					IHCS Level 3 (2:1)
PAODP	ODP	W7069	W7069					IHCS Level 3 (2:1) Enhanced
PAODP	ODP	W7201	W7201					Specialized Skill Development (1:1)
PAODP	ODP	W7204	W7204					Specialized Skill Development (1:2)
PAODP	ODP	W7205	W7205					Specialized Skill Development (1:3)
PAODP	ODP	W7213	W7213					Respite - Agency Managed In Home
PAODP	ODP	W7283	W7283					Homemaker-1 Hour
PAODP	ODP	W8095	W8095					Respite Unlicensed Level 4 (2:1) Enhanced-15 Mins
PAODP	ODP	W8096	W8096					Respite -15 Mins Basic (1:4)
PAODP	ODP	W9596	W9596					Respite - Agency Managed Out of Home - 15 Mins

PAODP	ODP	W9795	W9795					Respite Unlicensed Basic (1:4)-Day
PAODP	ODP	W9796	W9796					Respite Unlicensed Level 1 (1:3)-Day
PAODP	ODP	W9797	W9797					Respite Unlicensed Level 2 (1:2)-Day
PAODP	ODP	W9798	W9798					Respite Unlicensed Level 3 (1:1)-Day
PAODP	ODP	W9799	W9799					Respite Unlicensed Level 3 (1:1) Enhanced-Day
PAODP	ODP	W9800	W9800					Respite Unlicensed Level 4 (2:1)-Day
PAODP	ODP	W9801	W9801					Respite Unlicensed Level 4 (2:1) Enhanced-Day
PAODP	ODP	W9860	W9860					Respite Unlicensed Level 1 (1:3)-15 Mins
PAODP	ODP	W9861	W9861					Respite Unlicensed Level 2 (1:2)-15 Mins
PAODP	ODP	W9862	W9862					Respite Unlicensed Level 3 (1:1)-15 Mins
PAODP	ODP	W9863	W9863					Respite Unlicensed Level 3 (1:1) Enhanced-15 Mins
PAODP	ODP	W9864	W9864					Respite Unlicensed Level 4 (2:1)-15 Mins
PAODP	ODP	T2025_02	T2025	TD				Nursing - (1:1) RN-15 Mins
PAODP	ODP	T2025_03	T2025	TD	UN			Nursing (1:2) RN
PAODP	ODP	T2025_04	T2025	TD	UN	U1		Nursing (1:2) RN - ECS
PAODP	ODP	T2025_05	T2025	TD	U1			Nursing - (1:1) RN-15 Mins -ECS
PAODP	ODP	T2025_06	T2025	TE				Nursing - (1:1) LPN-15 Mins
PAODP	ODP	T2025_07	T2025	TE	UN			Nursing (1:2) LPN
PAODP	ODP	T2025_08	T2025	TE	UN	U1		Nursing (1:2) LPN - ECS
PAODP	ODP	T2025_09	T2025	TE	U1			Nursing - (1:1) LPN-15 Mins - ECS
PAODP	ODP	T2025_10	T2025	GN				Speech/Language Therapy-15 Mins
PAODP	ODP	T2025_11	T2025	GN	U2			Speech/Language Therapy - 15 mins - AAW
PAODP	ODP	T2025_12	T2025	GN	U1			Speech/Language Therapy-15 Mins - ECS
PAODP	ODP	T2025_13	T2025	GO				Occupational Therapy-15 Mins
PAODP	ODP	T2025_14	T2025	GO	U1			Occupational Therapy-15 Mins - ECS
PAODP	ODP	T2025_18	T2025	GP				Physical Therapy-15 Mins
PAODP	ODP	T2025_19	T2025	GP	U1			Physical Therapy-15 Mins - ECS

PAODP	ODP	W1724	W1724					Companion Basic (1:3)
PAODP	ODP	W1724_02	W1724	U1				Companion Basic (1:3) - ECS
PAODP	ODP	W1725	W1725					Companion Level 1 (1:2)
PAODP	ODP	W1725_02	W1725	U1				Companion Level 1 (1:2) - ECS
PAODP	ODP	W1726	W1726					Companion Level 2 (1:1)
PAODP	ODP	W1726_02	W1726	U1				Companion Level 2 (1:1) - ECS
PAODP	ODP	W1726_03	W1726	U4				Companion Level 2 (1:1) – No Benefit Allowance
PAODP	ODP	W1726_04	W1726	U4	U1			Companion Level 2 (1:1) - No Benefit Allowance - ECS
PAODP	ODP	W7058_01	W7058					IHCS Basic (1:3)
PAODP	ODP	W7058_02	W7058	U1				IHCS Basic (1:3) - ECS
PAODP	ODP	W7059_01	W7059					IHCS Level 1 (1:2)
PAODP	ODP	W7059_02	W7059	U1				IHCS Level 1 (1:2) - ECS
PAODP	ODP	W7060_01	W7060					IHCS Level 2 (1:1)
PAODP	ODP	W7060_02	W7060	U1				IHCS Level 2 (1:1) - ECS
PAODP	ODP	W7060_03	W7060	U4				IHCS Level 2 (1:1) - No Benefit Allowance
PAODP	ODP	W7060_04	W7060	U4	U1			IHCS Level 2 (1:1) - No Benefit Allowance - ECS
PAODP	ODP	W7061_01	W7061					IHCS Level 2 (1:1) Enhanced
PAODP	ODP	W7061_02	W7061	U1				IHCS Level 2 (1:1) Enhanced - ECS
PAODP	ODP	W7061_03	W7061	TE				IHCS Level 2 (1:1) Enhanced - LPN
PAODP	ODP	W7061_04	W7061	TE	U1			IHCS Level 2 (1:1) Enhanced - LPN - ECS
PAODP	ODP	W7061_05	W7061	TE	U4			IHCS Level 2 (1:1) Enhanced - LPN - No Benefit Allowance
PAODP	ODP	W7061_06	W7061	TD				IHCS Level 2 (1:1) Enhanced - RN
PAODP	ODP	W7061_07	W7061	TD	U1			IHCS Level 2 (1:1) Enhanced - RN - ECS
PAODP	ODP	W7061_08	W7061	TD	U4			IHCS Level 2 (1:1) Enhanced - RN - No Benefit Allowance
PAODP	ODP	W7061_09	W7061	U4				IHCS Level 2 (1:1) Enhanced - No Benefit Allowance

PAODP	ODP	W7061_10	W7061	U4	U1			IHCS Level 2 (1:1) Enhanced - No Benefit Allowance - ECS
PAODP	ODP	W7061_11	W7061	TE	U4	U1		IHCS Level 2 (1:1) Enhanced - LPN - No Benefit Allowance - ECS
PAODP	ODP	W7061_12	W7061	TD	U4	U1		IHCS Level 2 (1:1) Enhanced - RN - No Benefit Allowance - ECS
PAODP	ODP	W7068_01	W7068					IHCS Level 3 (2:1)
PAODP	ODP	W7068_02	W7068	U1				IHCS Level 3 (2:1) - ECS
PAODP	ODP	W7068_03	W7068	U4				IHCS Level 3 (2:1) - No Benefit Allowance
PAODP	ODP	W7068_04	W7068	U4	U1			IHCS Level 3 (2:1) - No Benefit Allowance - ECS
PAODP	ODP	W7069	W7069					IHCS Level 3 (2:1) Enhanced
PAODP	ODP	W7069_02	W7069	U1				IHCS Level 3 (2:1) Enhanced - ECS
PAODP	ODP	W7069_03	W7069	TE				IHCS Level 3 (2:1) Enhanced - LPN
PAODP	ODP	W7069_04	W7069	TE	U1			IHCS Level 3 (2:1) Enhanced - LPN - ECS
PAODP	ODP	W7069_05	W7069	TE	U4			IHCS Level 3 (2:1) Enhanced - LPN - No Benefit Allowance
PAODP	ODP	W7069_06	W7069	TD				IHCS Level 3 (2:1) Enhanced - RN
PAODP	ODP	W7069_07	W7069	TD	U1			IHCS Level 3 (2:1) Enhanced - RN - ECS
PAODP	ODP	W7069_08	W7069	TD	U4			IHCS Level 3 (2:1) Enhanced - RN - No Benefit Allowance
PAODP	ODP	W7069_09	W7069	U4				IHCS Level 3 (2:1) Enhanced - No Benefit Allowance
PAODP	ODP	W7069_10	W7069	U4	U1			IHCS Level 3 (2:1) Enhanced - No Benefit Allowance - ECS
PAODP	ODP	W7069_11	W7069	TE	U4	U1		IHCS Level 3 (2:1) Enhanced - LPN - No Benefit Allowance - ECS
PAODP	ODP	W7069_12	W7069	TD	U4	U1		IHCS Level 3 (2:1) Enhanced - RN - No Benefit Allowance - ECS
PAODP	ODP	W7201	W7201					Specialized Skill Development (1:1)
PAODP	ODP	W7204	W7204					Specialized Skill Development (1:2)
PAODP	ODP	W7205	W7205					Specialized Skill Development (1:3)
PAODP	ODP	W7213	W7213					Respite - Agency Managed In Home

PAODP	ODP	W7283_01	W7283					Homemaker-1 Hour
PAODP	ODP	W7283_02	W7283	U4				Homemaker - Permanent - 1 Hour - No Benefit Allowance
PAODP	ODP	W7283_03	W7283	UA				Homemaker - Temporary - 1 Hour
PAODP	ODP	W7283_04	W7283	UA	U4			Homemaker - Temporary - 1 Hour - No Benefit Allowance
PAODP	ODP	W8095_01	W8095	U4				Respite-Unlic Level 4 (2:1) Enh-No Benefit Allowance-15 Mins
PAODP	ODP	W8095_02	W8095					Respite Unlicensed Level 4 (2:1) Enhanced-15 Mins
PAODP	ODP	W8095_03	W8095	U1				Respite – Unlicensed Level 4 (2:1) Enhanced) – ECS – 15 Mins
PAODP	ODP	W8095_04	W8095	U4	U1			Respite–Unlic Level 4 (2:1) Enh-No Benefit Allow–ECS–15 Mins
PAODP	ODP	W8095_05	W8095	TD	U1			Respite Unlicensed Level 4 (2:1) RN ECS-15 Mins
PAODP	ODP	W8095_06	W8095	TD	U4	U1		Respite Unlicensed Level 4 (2:1) RN-No Benefit Allowance-ECS-15 Mins
PAODP	ODP	W8095_07	W8095	TD	U4			Respite Unlicensed Level 4 (2:1) RN-No Benefit Allowance-15 Mins
PAODP	ODP	W8095_08	W8095	TD				Respite Unlicensed Level 4 (2:1) RN-15 Mins
PAODP	ODP	W8095_09	W8095	TE	U1			Respite Unlicensed Level 4 (2:1) LPN-ECS-15 Mins
PAODP	ODP	W8095_10	W8095	TE	U4	U1		Respite Unlic Level 4 (2:1) LPN-No Benefit Allowance-ECS-15 Mins
PAODP	ODP	W8095_11	W8095	TE	U4			Respite Unlic Level 4 (2:1) LPN-No Benefit Allowance-15 Mins
PAODP	ODP	W8095_12	W8095	TE				Respite Unlicensed Level 4 (2:1) LPN-15 Mins
PAODP	ODP	W8096_01	W8096					Respite -15 Mins Basic (1:4)
PAODP	ODP	W8096_02	W8096	U1				Respite -15 Mins Basic (1:4) - ECS
PAODP	ODP	W9596	W9596					Respite - Agency Managed Out of Home - 15 Mins
PAODP	ODP	W9795_01	W9795					Respite Unlicensed Basic (1:4)-Day
PAODP	ODP	W9795_02	W9795	U1				Respite Unlicensed Basic (1:4)-ECS-Day

PAODP	ODP	W9796_01	W9796					Respite Unlicensed Level 1 (1:3)-Day
PAODP	ODP	W9796_02	W9796	U1				Respite Unlicensed Level 1 (1:3)-ECS-Day
PAODP	ODP	W9797_01	W9797					Respite Unlicensed Level 2 (1:2)-Day
PAODP	ODP	W9797_02	W9797	U1				Respite Unlicensed Level 2 (1:2)-ECS-Day
PAODP	ODP	W9798_01	W9798					Respite Unlicensed Level 3 (1:1)-Day
PAODP	ODP	W9798_02	W9798	U1				Respite Unlicensed Level 3 (1:1)-ECS-Day
PAODP	ODP	W9798_03	W9798	U4				Respite Unlicensed Level 3 (1:1)-No Benefit Allowance-Day
PAODP	ODP	W9798_04	W9798	U4	U1			Respite Unlicensed Level 3 (1:1)-No Benefit Allowance-ECS-Day
PAODP	ODP	W9799_01	W9799					Respite Unlicensed Level 3 (1:1) Enhanced-Day
PAODP	ODP	W9799_02	W9799	U1				Respite Unlicensed Level 3 (1:1) Enhanced-ECS-Day
PAODP	ODP	W9799_03	W9799	U4				Respite Unlic Level 3 (1:1) Enhanced-No Benefit Allowance-Day
PAODP	ODP	W9799_04	W9799	U4	U1			Respite Unlic Level 3 (1:1) Enhanced-No Benefit Allowance-ECS-Day
PAODP	ODP	W9799_05	W9799	TD	U1			Respite Unlicensed Level 3 (1:1) - Enhanced - RN - ECS - Day
PAODP	ODP	W9799_06	W9799	TD	U4	U1		Respite Unlic Level 3 (1:1) Enh-RN-No Benefit Allowance-ECS-Day
PAODP	ODP	W9799_07	W9799	TD	U4			Respite Unlicensed Level 3 (1:1) -Enh-RN-No Benefit Allowance-Day
PAODP	ODP	W9799_08	W9799	TD				Respite Unlicensed Level 3 (1:1) - Enhanced - RN - Day
PAODP	ODP	W9799_09	W9799	TE	U1			Respite Unlicensed Level 3 (1:1) - Enhanced - LPN - ECS - Day
PAODP	ODP	W9799_10	W9799	TE	U4	U1		Respite Unlic Level 3 (1:1) Enh-LPN-No Benefit Allowance-ECS-Day
PAODP	ODP	W9799_11	W9799	TE	U4			Respite Unlicensed Level 3 (1:1) Enh-LPN-No Benefit Allowance-Day
PAODP	ODP	W9799_12	W9799	TE				Respite Unlicensed Level 3 (1:1) - Enhanced - LPN - Day
PAODP	ODP	W9800_01	W9800					Respite Unlicensed Level 4 (2:1)-Day

PAODP	ODP	W9800_02	W9800	U1				Respite Unlicensed Level 4 (2:1) ECS-Day
PAODP	ODP	W9800_03	W9800	U4				Respite Unlicensed Level 4 (2:1) No Benefit Allowance-Day
PAODP	ODP	W9800_04	W9800	U4	U1			Respite Unlicensed Level 4 (2:1) No Benefit Allowance-ECS-Day
PAODP	ODP	W9801_01	W9801					Respite Unlicensed Level 4 (2:1) Enhanced-Day
PAODP	ODP	W9801_02	W9801	U1				Respite Unlicensed Level 4 (2:1) Enhanced - ECS - Day
PAODP	ODP	W9801_03	W9801	U4				Respite Unlic Level 4 (2:1) Enhanced-No Benefit Allowance-Day
PAODP	ODP	W9801_04	W9801	U4	U1			Respite Unlic Level 4 (2:1) Enhanced-No Benefit Allowance-ECS-Day
PAODP	ODP	W9801_05	W9801	TD	U1			Respite Unlicensed Level 4 (2:1) Enhanced - RN - ECS - Day
PAODP	ODP	W9801_06	W9801	TD	U4	U1		Respite Unlic Level 4 (2:1) Enh - RN-No Benefit Allowance-ECS-Day
PAODP	ODP	W9801_07	W9801	TD	U4			Respite Unlic Level 4 (2:1) Enh – RN - No Benefit Allowance - Day
PAODP	ODP	W9801_08	W9801	TD				Respite Unlicensed Level 4 (2:1) Enhanced - RN - Day
PAODP	ODP	W9801_09	W9801	TE	U1			Respite Unlicensed Level 4 (2:1) - Enhanced - LPN - ECS - Day
PAODP	ODP	W9801_10	W9801	TE	U4	U1		Respite Unlic Level 4 (2:1) Enh-LPN-No Benefit Allowance-ECS-Day
PAODP	ODP	W9801_11	W9801	TE	U4			Respite Unlic Level 4 (2:1) - Enh - LPN-No Benefit Allowance-Day
PAODP	ODP	W9801_12	W9801	TE				Respite Unlicensed Level 4 (2:1) - Enhanced - LPN - Day
PAODP	ODP	W9860_01	W9860					Respite Unlicensed Level 1 (1:3)-15 Mins
PAODP	ODP	W9860_02	W9860	U1				Respite Unlicensed Level 1 (1:3)-ECS-15 Mins
PAODP	ODP	W9861_01	W9861					Respite Unlicensed Level 2 (1:2)-15 Mins
PAODP	ODP	W9861_02	W9861	U1				Respite Unlicensed Level 2 (1:2)-ECS-15 Mins
PAODP	ODP	W9862_01	W9862					Respite Unlicensed Level 3 (1:1)-15 Mins

PAODP	ODP	W9862_02	W9862	U1				Respite Unlicensed Level 3 (1:1)-ECS-15 Mins
PAODP	ODP	W9862_03	W9862	U4				Respite Unlicensed Level 3 (1:1)-No Benefit Allowance-15 Mins
PAODP	ODP	W9862_04	W9862	U4	U1			Respite Unlicensed Level 3 (1:1)-No Benefit Allowance-ECS-15 Mins
PAODP	ODP	W9863_01	W9863					Respite Unlicensed Level 3 (1:1) Enhanced-15 Mins
PAODP	ODP	W9863_02	W9863	U1				Respite Unlicensed Level 3 (1:1) Enhanced-ECS-15 Mins
PAODP	ODP	W9863_03	W9863	U4				Respite Unlic Level 3 (1:1) Enhanced-No Benefit Allowance-15 Mins
PAODP	ODP	W9863_04	W9863	U4	U1			Respite Unlic Level 3 (1:1) Enh-No Benefit Allowance-ECS-15 Mins
PAODP	ODP	W9863_05	W9863	TD	U1			Respite Unlicensed Level 3 (1:1) Enhanced RN-ECS-15 Mins
PAODP	ODP	W9863_06	W9863	TD	U4	U1		Respite Unlic Level 3(1:1)Enh-RN-No Benefit Allowance-ECS-15 Mins
PAODP	ODP	W9863_07	W9863	TD	U4			Respite Unlic Level 3 (1:1) Enh-RN-No Benefit Allowance-15 Mins
PAODP	ODP	W9863_08	W9863	TD				Respite Unlicensed Level 3 (1:1) Enhanced – RN - 15 Mins
PAODP	ODP	W9863_09	W9863	TE	U1			Respite Unlicensed Level 3 (1:1) Enhanced – LPN -ECS -15 Mins
PAODP	ODP	W9863_10	W9863	TE	U4	U1		Respite Unlic Level 3(1:1)Enh-LPN-No Benefit Allow-ECS-15 Mins
PAODP	ODP	W9863_11	W9863	TE	U4			Respite Unlic Level 3(1:1)Enh-LPN-No Benefit Allowance-15 Mins
PAODP	ODP	W9863_12	W9863	TE				Respite Unlicensed Level 3 (1:1) Enhanced-LPN-15 Mins
PAODP	ODP	W9864_01	W9864	U4				Respite Unlicensed Level 4 (2:1)-No Benefit Allowance-15 Mins
PAODP	ODP	W9864_02	W9864	U4	U1			Respite Unlic Level 4 (2:1)-No Benefit Allowance-ECS-15 Mins
PAODP	ODP	W9864_03	W9864					Respite Unlicensed Level 4 (2:1)-15 Mins

PAODP	ODP	W9864_04	W9864	U1				Respite Unlicensed Level 4 (2:1)-ECS-15 Mins
PAODP	ODP	T2025_02	T2025	TD				Nursing - (1:1) RN-15 Mins
PAODP	ODP	T2025_03	T2025	TD	UN			Nursing (1:2) RN
PAODP	ODP	T2025_04	T2025	TD	UN	U1		Nursing (1:2) RN - ECS
PAODP	ODP	T2025_05	T2025	TD	U1			Nursing - (1:1) RN-15 Mins - ECS
PAODP	ODP	T2025_06	T2025	TE				Nursing - (1:1) LPN-15 Mins
PAODP	ODP	T2025_07	T2025	TE	UN			Nursing (1:2) LPN
PAODP	ODP	T2025_08	T2025	TE	UN	U1		Nursing (1:2) LPN - ECS
PAODP	ODP	T2025_09	T2025	TE	U1			Nursing - (1:1) LPN-15 Mins - ECS
PAODP	ODP	T2025_10	T2025	GN				Speech/Language Therapy-15 Mins
PAODP	ODP	T2025_11	T2025	GN	U2			Speech/Language Therapy - 15 Mins - AAW
PAODP	ODP	T2025_12	T2025	GN	U1			Speech/Language Therapy-15 Mins - ECS
PAODP	ODP	T2025_13	T2025	GO				Occupational Therapy-15 Mins
PAODP	ODP	T2025_14	T2025	GO	U1			Occupational Therapy-15 Mins - ECS
PAODP	ODP	T2025_18	T2025	GP				Physical Therapy-15 Mins
PAODP	ODP	T2025_19	T2025	GP	U1			Physical Therapy-15 Mins - ECS
PAODP	ODP	W1724	W1724					Companion Basic (1:3)
PAODP	ODP	W1724_02	W1724	U1				Companion Basic (1:3) - ECS
PAODP	ODP	W1725	W1725					Companion Level 1 (1:2)
PAODP	ODP	W1725_02	W1725	U1				Companion Level 1 (1:2) - ECS
PAODP	ODP	W1726	W1726					Companion Level 2 (1:1)
PAODP	ODP	W1726_02	W1726	U1				Companion Level 2 (1:1) - ECS
PAODP	ODP	W1726_03	W1726	U4				Companion Level 2 (1:1) – No Benefit Allowance
PAODP	ODP	W1726_04	W1726	U4	U1			Companion Level 2 (1:1) – No Benefit Allowance - ECS
PAODP	ODP	W7058_01	W7058					IHCS Basic (1:3)
PAODP	ODP	W7058_02	W7058	U1				IHCS Basic (1:3) - ECS
PAODP	ODP	W7059_01	W7059					IHCS Level 1 (1:2)

PAODP	ODP	W7059_02	W7059	U1				IHCS Level 1 (1:2) - ECS
PAODP	ODP	W7060_01	W7060					IHCS Level 2 (1:1)
PAODP	ODP	W7060_02	W7060	U1				IHCS Level 2 (1:1) - ECS
PAODP	ODP	W7060_03	W7060	U4				IHCS Level 2 (1:1) - No Benefit Allowance
PAODP	ODP	W7060_04	W7060	U4	U1			IHCS Level 2 (1:1) - No Benefit Allowance - ECS
PAODP	ODP	W7061_01	W7061					IHCS Level 2 (1:1) Enhanced
PAODP	ODP	W7061_02	W7061	U1				IHCS Level 2 (1:1) Enhanced - ECS
PAODP	ODP	W7061_03	W7061	TE				IHCS Level 2 (1:1) Enhanced - LPN
PAODP	ODP	W7061_04	W7061	TE	U1			IHCS Level 2 (1:1) Enhanced - LPN - ECS
PAODP	ODP	W7061_05	W7061	TE	U4			IHCS Level 2 (1:1) Enhanced - LPN - No Benefit Allowance
PAODP	ODP	W7061_06	W7061	TD				IHCS Level 2 (1:1) Enhanced - RN
PAODP	ODP	W7061_07	W7061	TD	U1			IHCS Level 2 (1:1) Enhanced - RN - ECS
PAODP	ODP	W7061_08	W7061	TD	U4			IHCS Level 2 (1:1) Enhanced - RN - No Benefit Allowance
PAODP	ODP	W7061_09	W7061	U4				IHCS Level 2 (1:1) Enhanced - No Benefit Allowance
PAODP	ODP	W7061_10	W7061	U4	U1			IHCS Level 2 (1:1) Enhanced - No Benefit Allowance - ECS
PAODP	ODP	W7061_11	W7061	TE	U4	U1		IHCS Level 2 (1:1) Enhanced - LPN - No Benefit Allowance - ECS
PAODP	ODP	W7061_12	W7061	TD	U4	U1		IHCS Level 2 (1:1) Enhanced - RN - No Benefit Allowance - ECS
PAODP	ODP	W7068_01	W7068					IHCS Level 3 (2:1)
PAODP	ODP	W7068_02	W7068	U1				IHCS Level 3 (2:1) - ECS
PAODP	ODP	W7068_03	W7068	U4				IHCS Level 3 (2:1) - No Benefit Allowance
PAODP	ODP	W7068_04	W7068	U4	U1			IHCS Level 3 (2:1) - No Benefit Allowance - ECS
PAODP	ODP	W7069_01	W7069					IHCS Level 3 (2:1) Enhanced
PAODP	ODP	W7069_02	W7069	U1				IHCS Level 3 (2:1) Enhanced - ECS
PAODP	ODP	W7069_03	W7069	TE				IHCS Level 3 (2:1) Enhanced - LPN

PAODP	ODP	W7069_04	W7069	TE	U1			IHCS Level 3 (2:1) Enhanced - LPN - ECS
PAODP	ODP	W7069_05	W7069	TE	U4			IHCS Level 3 (2:1) Enhanced - LPN - No Benefit Allowance
PAODP	ODP	W7069_06	W7069	TD				IHCS Level 3 (2:1) Enhanced - RN
PAODP	ODP	W7069_07	W7069	TD	U1			IHCS Level 3 (2:1) Enhanced - RN - ECS
PAODP	ODP	W7069_08	W7069	TD	U4			IHCS Level 3 (2:1) Enhanced - RN - No Benefit Allowance
PAODP	ODP	W7069_09	W7069	U4				IHCS Level 3 (2:1) Enhanced - No Benefit Allowance
PAODP	ODP	W7069_10	W7069	U4	U1			IHCS Level 3 (2:1) Enhanced - No Benefit Allowance - ECS
PAODP	ODP	W7069_11	W7069	TE	U4	U1		IHCS Level 3 (2:1) Enhanced - LPN - No Benefit Allowance - ECS
PAODP	ODP	W7069_12	W7069	TD	U4	U1		IHCS Level 3 (2:1) Enhanced - RN - No Benefit Allowance - ECS
PAODP	ODP	W7201	W7201					Specialized Skill Development (1:1)
PAODP	ODP	W7204	W7204					Specialized Skill Development (1:2)
PAODP	ODP	W7205	W7205					Specialized Skill Development (1:3)
PAODP	ODP	W7213	W7213					Respite - Agency Managed In Home
PAODP	ODP	W7283_01	W7283					Homemaker-1 Hour
PAODP	ODP	W7283_02	W7283	U4				Homemaker - Permanent - 1 Hour - No Benefit Allowance
PAODP	ODP	W7283_03	W7283	UA				Homemaker - Temporary - 1 Hour
PAODP	ODP	W7283_04	W7283	UA	U4			Homemaker - Temporary - 1 Hour - No Benefit Allowance
PAODP	ODP	W8095_01	W8095	U4				Respite-Unlic Level 4 (2:1) Enh-No Benefit Allowance-15 mins
PAODP	ODP	W8095_02	W8095					Respite Unlicensed Level 4 (2:1) Enhanced-15 Mins
PAODP	ODP	W8095_03	W8095	U1				Respite – Unlicensed Level 4 (2:1) Enhanced) – ECS – 15 mins
PAODP	ODP	W8095_04	W8095	U4	U1			Respite–Unlic Level 4 (2:1) Enh-No Benefit Allow–ECS–15 mins

PAODP	ODP	W8095_05	W8095	TD	U1			Respite Unlicensed Level 4 (2:1) RN ECS-15 Mins
PAODP	ODP	W8095_06	W8095	TD	U4	U1		Respite Unlicensed Level 4 (2:1) RN-No Benefit Allowance-ECS-15 Mins
PAODP	ODP	W8095_07	W8095	TD	U4			Respite Unlicensed Level 4 (2:1) RN-No Benefit Allowance-15 Mins
PAODP	ODP	W8095_08	W8095	TD				Respite Unlicensed Level 4 (2:1) RN-15 Mins
PAODP	ODP	W8095_09	W8095	TE	U1			Respite Unlicensed Level 4 (2:1) LPN-ECS-15 Mins
PAODP	ODP	W8095_10	W8095	TE	U4	U1		Respite Unlic Level 4 (2:1) LPN-No Benefit Allowance-ECS-15 Mins
PAODP	ODP	W8095_11	W8095	TE	U4			Respite Unlic Level 4 (2:1) LPN-No Benefit Allowance-15 Mins
PAODP	ODP	W8095_12	W8095	TE				Respite Unlicensed Level 4 (2:1) LPN-15 Mins
PAODP	ODP	W8096_01	W8096					Respite -15 mins Basic (1:4)
PAODP	ODP	W8096_02	W8096	U1				Respite -15 mins Basic (1:4) - ECS
PAODP	ODP	W9596	W9596					Respite - Agency Managed Out of Home - 15 Mins
PAODP	ODP	W9795_01	W9795					Respite Unlicensed Basic (1:4)-Day
PAODP	ODP	W9795_02	W9795	U1				Respite Unlicensed Basic (1:4)-ECS-Day
PAODP	ODP	W9796_01	W9796					Respite Unlicensed Level 1 (1:3)-Day
PAODP	ODP	W9796_02	W9796	U1				Respite Unlicensed Level 1 (1:3)-ECS-Day
PAODP	ODP	W9797_01	W9797					Respite Unlicensed Level 2 (1:2)-Day
PAODP	ODP	W9797_02	W9797	U1				Respite Unlicensed Level 2 (1:2)-ECS-Day
PAODP	ODP	W9798_01	W9798					Respite Unlicensed Level 3 (1:1)-Day
PAODP	ODP	W9798_02	W9798	U1				Respite Unlicensed Level 3 (1:1)-ECS-Day
PAODP	ODP	W9798_03	W9798	U4				Respite Unlicensed Level 3 (1:1)-No Benefit Allowance-Day
PAODP	ODP	W9798_04	W9798	U4	U1			Respite Unlicensed Level 3 (1:1)-No Benefit Allowance-ECS-Day
PAODP	ODP	W9799_01	W9799					Respite Unlicensed Level 3 (1:1) Enhanced-Day

PAODP	ODP	W9799_02	W9799	U1				Respite Unlicensed Level 3 (1:1) Enhanced-ECS-Day
PAODP	ODP	W9799_03	W9799	U4				Respite Unlic Level 3 (1:1) Enhanced-No Benefit Allowance-Day
PAODP	ODP	W9799_04	W9799	U4	U1			Respite Unlic Level 3 (1:1) Enhanced-No Benefit Allowance-ECS-Day
PAODP	ODP	W9799_05	W9799	TD	U1			Respite Unlicensed Level 3 (1:1) - Enhanced - RN - ECS - Day
PAODP	ODP	W9799_06	W9799	TD	U4	U1		Respite Unlic Level 3 (1:1) Enh-RN-No Benefit Allowance-ECS-Day
PAODP	ODP	W9799_07	W9799	TD	U4			Respite Unlicensed Level 3 (1:1) -Enh-RN-No Benefit Allowance-Day
PAODP	ODP	W9799_08	W9799	TD				Respite Unlicensed Level 3 (1:1) - Enhanced - RN - Day
PAODP	ODP	W9799_09	W9799	TE	U1			Respite Unlicensed Level 3 (1:1) - Enhanced - LPN - ECS - Day
PAODP	ODP	W9799_10	W9799	TE	U4	U1		Respite Unlic Level 3 (1:1) Enh-LPN-No Benefit Allowance-ECS-Day
PAODP	ODP	W9799_11	W9799	TE	U4			Respite Unlicensed Level 3 (1:1) Enh-LPN-No Benefit Allowance-Day
PAODP	ODP	W9799_12	W9799	TE				Respite Unlicensed Level 3 (1:1) - Enhanced - LPN - Day
PAODP	ODP	W9800_01	W9800					Respite Unlicensed Level 4 (2:1)-Day
PAODP	ODP	W9800_02	W9800	U1				Respite Unlicensed Level 4 (2:1) ECS-Day
PAODP	ODP	W9800_03	W9800	U4				Respite Unlicensed Level 4 (2:1) No Benefit Allowance-Day
PAODP	ODP	W9800_04	W9800	U4	U1			Respite Unlicensed Level 4 (2:1) No Benefit Allowance-ECS-Day
PAODP	ODP	W9801_01	W9801					Respite Unlicensed Level 4 (2:1) Enhanced-Day
PAODP	ODP	W9801_02	W9801	U1				Respite Unlicensed Level 4 (2:1) Enhanced - ECS - Day
PAODP	ODP	W9801_03	W9801	U4				Respite Unlic Level 4 (2:1) Enhanced-No Benefit Allowance-Day
PAODP	ODP	W9801_04	W9801	U4	U1			Respite Unlic Level 4 (2:1) Enhanced-No Benefit Allowance-ECS-Day

PAODP	ODP	W9801_05	W9801	TD	U1			Respite Unlicensed Level 4 (2:1) Enhanced - RN - ECS - Day
PAODP	ODP	W9801_06	W9801	TD	U4	U1		Respite Unlic Level 4 (2:1) Enh - RN-No Benefit Allowance-ECS-Day
PAODP	ODP	W9801_07	W9801	TD	U4			Respite Unlic Level 4 (2:1) Enh – RN - No Benefit Allowance - Day
PAODP	ODP	W9801_08	W9801	TD				Respite Unlicensed Level 4 (2:1) Enhanced - RN - Day
PAODP	ODP	W9801_09	W9801	TE	U1			Respite Unlicensed Level 4 (2:1) - Enhanced - LPN - ECS - Day
PAODP	ODP	W9801_10	W9801	TE	U4	U1		Respite Unlic Level 4 (2:1) Enh-LPN-No Benefit Allowance-ECS-Day
PAODP	ODP	W9801_11	W9801	TE	U4			Respite Unlic Level 4 (2:1) - Enh - LPN-No Benefit Allowance-Day
PAODP	ODP	W9801_12	W9801	TE				Respite Unlicensed Level 4 (2:1) - Enhanced - LPN - Day
PAODP	ODP	W9860_01	W9860					Respite Unlicensed Level 1 (1:3)-15 Mins
PAODP	ODP	W9860_02	W9860	U1				Respite Unlicensed Level 1 (1:3)-ECS-15 Mins
PAODP	ODP	W9861_01	W9861					Respite Unlicensed Level 2 (1:2)-15 Mins
PAODP	ODP	W9861_02	W9861	U1				Respite Unlicensed Level 2 (1:2)-ECS-15 Mins
PAODP	ODP	W9862_01	W9862					Respite Unlicensed Level 3 (1:1)-15 Mins
PAODP	ODP	W9862_02	W9862	U1				Respite Unlicensed Level 3 (1:1)-ECS-15 Mins
PAODP	ODP	W9862_03	W9862	U4				Respite Unlicensed Level 3 (1:1)-No Benefit Allowance-15 Mins
PAODP	ODP	W9862_04	W9862	U4	U1			Respite Unlicensed Level 3 (1:1)-No Benefit Allowance-ECS-15 Mins
PAODP	ODP	W9863_01	W9863					Respite Unlicensed Level 3 (1:1) Enhanced-15 Mins
PAODP	ODP	W9863_02	W9863	U1				Respite Unlicensed Level 3 (1:1) Enhanced-ECS-15 Mins
PAODP	ODP	W9863_03	W9863	U4				Respite Unlic Level 3 (1:1) Enhanced-No Benefit Allowance-15 Mins

PAODP	ODP	W9863_04	W9863	U4	U1			Respite Unlic Level 3 (1:1) Enh-No Benefit Allowance-ECS-15 Mins
PAODP	ODP	W9863_05	W9863	TD	U1			Respite Unlicensed Level 3 (1:1) Enhanced RN-ECS-15 Mins
PAODP	ODP	W9863_06	W9863	TD	U4	U1		Respite Unlic Level 3(1:1)Enh-RN-No Benefit Allowance-ECS-15 Mins
PAODP	ODP	W9863_07	W9863	TD	U4			Respite Unlic Level 3 (1:1) Enh-RN-No Benefit Allowance-15 Mins
PAODP	ODP	W9863_08	W9863	TD				Respite Unlicensed Level 3 (1:1) Enhanced – RN - 15 Mins
PAODP	ODP	W9863_09	W9863	TE	U1			Respite Unlicensed Level 3 (1:1) Enhanced - LPN -ECS -15 Mins
PAODP	ODP	W9863_10	W9863	TE	U4	U1		Respite Unlic Level 3(1:1)Enh-LPN-No Benefit Allow-ECS-15 Mins
PAODP	ODP	W9863_11	W9863	TE	U4			Respite Unlic Level 3(1:1)Enh-LPN-No Benefit Allowance-15 Mins
PAODP	ODP	W9863_12	W9863	TE				Respite Unlicensed Level 3 (1:1) Enhanced-LPN-15 Mins
PAODP	ODP	W9864_01	W9864	U4				Respite Unlicensed Level 4 (2:1)-No Benefit Allowance-15 Mins
PAODP	ODP	W9864_02	W9864	U4	U1			Respite Unlic Level 4 (2:1)-No Benefit Allowance-ECS-15 Mins
PAODP	ODP	W9864_03	W9864					Respite Unlicensed Level 4 (2:1)-15 Mins
PAODP	ODP	W9864_04	W9864	U1				Respite Unlicensed Level 4 (2:1)-ECS-15 Mins

EVV COMPLIANCE LUNCH & LEARN

April 2, 2024

PHA
PENNSYLVANIA
HOMECARE ASSOCIATION

AGENDA

Background

Who this applies to

Why EVV

How It Works

Manual Edits

EVV Compliance Thresholds

Improving EVV Compliance

Tips, Tricks, and Best Practices!

Background

Electronic Visit Verification (EVV): A technological solution used to electronically verify that personal care providers and home health care providers delivered or rendered services as billed. EVV systems enable real-time confirmation of when a visit begins and ends, reducing the opportunity for fraudulent activities.

EVV systems must verify the:

- Type of service performed;
- Individual receiving the service;
- Date of service;
- Location of service delivery;
- Individual providing the service; and
- Time the service begins and ends

Section 12006(a) of the **21st Century Cures Act** (the Cures Act) requires states to implement EVV for all Medicaid PCS (personal care services) and HHCS (home health care services) requiring an in-home visit by a provider.

- States must have implemented EVV for PCS by January 1, 2020 and for HHCS by January 1, 2023, unless granted a one-year Good Faith Effort (GFE) exemption.

PHA
PENNSYLVANIA
HOMECARE ASSOCIATION

Who This Applies To

1. **Personal Care Services (PCS):** Services supporting Activities of Daily Living (ADLs) or services supporting both ADLs and Instrumental Activities of Daily Living (IADLs) provided under sections 1905(a)(24), 1915(c), 1915(i), 1915(j), 1915(k), or Section 1115.

   For a list of PA service codes that are considered “personal care services”, click here: EVV-PCS (pa.gov)

2. **Home Health Care Services (HHCS):** Nursing services and/or home health aide services delivered in the home provided under 1905(a)(7) of the Social Security Act or a waiver. At the state’s option, HHCS may also include physical therapy, occupational therapy, and speech pathology and audiology services.

   For a list of PA service codes that are considered “home health care services”, click here: EVV-HHCS (pa.gov)

Why EVV?

Why Payers Care About EVV?

1. **Improved Outcomes:** Care delivered to a recipient when they need it improves outcomes and supports continued independence in their home and community setting, reducing the need for more costly facility care.

2. **Reduced Cost:** Billing is more accurate with consistent capture of time in and out. Fraud and abuse is minimized.

3. **Enhanced Operational Efficiency:** Billing processes are streamlined, allowing faster claims processing, reducing administrative burden for and improving the utilization of resources within the plan.

4. **Regulatory Compliance:** The 21st Century Cures Act mandates the use of EVV. Payers must comply to avoid fines and safeguard their reputation.

5. **Long Term Sustainability:** With growing PCS and HHCS industries, it is important that plans have access to real time data. This data helps drive efficiencies, administrative oversight, and innovation. In an age where data is king, EVV rules.

PHA
PENNSYLVANIA
HOMECARE ASSOCIATION

Why EVV?

Why Providers Use EVV?

1. **Improved Outcomes:** Care delivered to a recipient when they need it improves outcomes and supports continued independence in their home and community setting, reducing the need for more costly facility care.

2. **Improved Reputation:** EVV lets providers be PROACTIVE when there are staffing issues instead of reactive, earning the respect and trust of customers.

3. **Reduced Cost through Operational Efficiency:** Reduces manual paper processes and creates automation from time capture to billing to payroll processes.

4. **Reduced Take Backs:** A well run EVV operation reduces the risk of takebacks, as you are capturing accurate claim documentation without the risk of filing misses.

5. **Regulatory Compliance:** The 21st Century Cures Act mandates the use of EVV. Providers must comply to avoid fines and safeguard their reputation.

PHA PENNSYLVANIA HOMECARE ASSOCIATION

How It Works

EVV requires workers to clock in when they are present with a member through:

1. A landline phone call (IVR/telephony),
2. A FOB device, OR
3. A submission of a GPS enabled location through a smart phone app

Best Compliance with #3: GPS Location Capture

PHA
PENNSYLVANIA
HOMECARE ASSOCIATION

TIP

Important Compliance Tip:

IVR or telephony use MUST be from a landline telephone.

Clocking in/out via IVR (calling an 800 number) from a cell phone, whether it is the customers or the employees, will result in takebacks during an audit.

Q: Can a caregiver clock in and clock out using a client's cell phone?
A: A participant's cell phone can be used under the following conditions:

- The participant has given consent to use their electronic device.
- The visit is captured via by FOB or GPS location (NOT telephony).

Q: Can I just use the phone number the MCO provided in the care plan and trust it is approved for EVV?
A: No, it is the agency's responsibility to validate that the MCO provided phone number is a landline.

Q: How do I confirm if the phone numbers programmed in my EVV system are a cell phone or landline?
A: PHA recommends using a free phone validator such as: www.phonevalidator.com to perform entity audits for compliance.

PHA
PENNSYLVANIA
HOMECARE ASSOCIATION

Manual Edits

If an EVV visit is missing information or the EVV visit information was entered incorrectly and requires any type of edit or correction, where a provider has to manipulate data in any way after the service is delivered, this is deemed a manual edit.

"Providers must be able to produce hard copy documentation of manual corrections or edits made due to missing or incorrect date elements for auditing purposes upon request. Hard copy documentation is a paper copy." MAB2022081001.pdf (pa.gov) August 10, 2022

Lack of appropriate documentation for Manual Edits is the #1 cause of MCO directed provider takebacks, as recently reported in a survey of Pennsylvania Providers

PHA PENNSYLVANIA HOMECARE ASSOCIATION

Manual Edits in CHC

Documentation Requirements for Manual Edits in CHC

	AmeriHealth Caritas/ Keystone First	PA Health & Wellness	UPMC
Provider Name	X	X	X
DCW Printed Name	X	X	X
Participant Name	X	X	X
Date of Service	X	X	X
Location of Services	X	X	X
Start Time	X	X	X
End Time	X	X	X
Total Hours Worked	X	X	X
Services Provided (Scope/Tasks)	X	X	X
Employee Signature & Date	X	X	X
Participant Signature & Date	X	X	
Agency Signature, Title & Date	X		
Last 4 digits of DCW SSN	X		
Participant Medicaid ID	X		
Provider EIN	X		

PHA
PENNSYLVANIA
HOMECARE ASSOCIATION

Manual Edits in HC

Documentation Requirements for Manual Edits in Physical HealthChoices Program

- No changes to existing documentation requirements, as dictated by licensure, CMS, and payers.

- Consider EVV requirements to be “in addition” to existing documentation requirements

- Note: **Highmark Wholecare** partnered with NetSmart for EVV. Providers are currently required at the time of clock out to capture patient and employee electronic signature when using NetSmart. This is in addition to GPS location.

  NetSmart and Highmark declined to change this policy at this time when approached by PHA. PHA will continue conversations if this presents provider hardship.

PHA PENNSYLVANIA HOMECARE ASSOCIATION

EVV Compliance

EVV Compliance is measured as the % of visits that do not have a manual edit.

Providers must achieve:

50% compliance beginning January 1, 2023

85% compliance beginning January 1, 2025

PHA
PENNSYLVANIA
HOMECARE ASSOCIATION

Calculating EVV Compliance

$$\text{EVV Compliance} = \left[1 - \frac{\text{Total Visits with Manual Edits}}{\text{Total Visits}}\right] * 100$$

Example: 2 out of 10 visits are NOT EVV compliant (manual edits).

1 – [2/10] = .80 *100 = 80% Compliant

Note: HHAeXchange offers 5 standard EVV (Exception) reports to all clients. Those reports are:

Exception By Caregivers (recommended)
Exception By Reason
Exception Detail Report
Exceptions Statistics
Exception Summary by Provider

Service Verification

"Service Verification" positions are growing in number to support:

- Caregiver training
- Care Coordinator/Scheduler training
- Monitoring of EVV dashboards
- EVV compliance tracking
- Client and caregiver satisfaction
- Value Based Payment management and development
- Collaboration and support for the following processes:
  - Billing
  - Scheduling
  - Payroll
  - Accounting
  - Quality/compliance

PHA PENNSYLVANIA HOMECARE ASSOCIATION

EVV Innovation

Don’t Fight it… Use it!

Use it to drive value for your patients and your organization….

- Capture more data, the right data, to enhances your value to payers, such as:
  - Key information influencing social determinants of health
  - Client Satisfaction
  - Changes in Condition (preventative healthcare)
  - Employee Training Needs

- Set yourself apart… while many agencies are struggling to achieve high compliance scores, set yourself apart with stellar EVV performance!

- Incentivize your workforce. Tie EVV compliance to enhanced pay rates, raise eligibility, free give away opportunities, points for gamification, or other incentives. Some providers can offset this cost with VBP from MCO payers.

PHA
PENNSYLVANIA
HOMECARE ASSOCIATION

PHA
PENNSYLVANIA
HOMECARE ASSOCIATION

Improving EVV Compliance

1. **Education and Training**
   - Train caregivers and internal teams on EVV
2. **System Integration/Automation**
   - Ensure seamless data exchange between EVV and other systems
   - Use technology to gamify EVV and improve compliance (ex: Caribou Rewards)
   - Use technology to more easily connect with caregivers on scheduling changes to improve compliance (ex: Care Connect)
   - Use technology to hold internal teams accountable to Manual Edit capture
3. **System Settings**
   - Make sure your system settings are not impacting your compliance
4. **Regular Monitoring**
   - Monitor EVV data regularly to identify discrepancies – address timely!
5. **State-Specific Requirements**
   - Understand your state-specific EVV requirements
6. **Collaborate with Stakeholders**
   - As in today's session!

PHA PENNSYLVANIA HOMECARE ASSOCIATION

Tips, Tricks and Best Practices

Tip	Description
Turn on "Automatic Splitting" for overnight shifts	This feature found in many EVV systems allows a caregiver to clock in and out one time only, even if the shift crosses two calendar days. Ex: Shift scheduled from 11PM – 7AM. Without Automatic Splitting, the direct care professional would need to clock out at midnight and clock back in immediately. With Automatic Splitting, the direct care professional clocks in at 11PM and out at 7AM only.
Turn on "Offline Option"	If internet or phone service is unavailable, many EVV systems have an offline option to allow the visit information to be captured despite the lack of service. However, this is a setting in the EVV system and frequently you have to request that this option be turned on. Make sure this setting is "ON" by contacting your EVV provider.
Lengthen the "tolerance range" for the scheduled time that a caregiver can clock in and out	In EVV systems, providers have the ability to set a tolerance range for clock ins/outs so that your system can escalate to your team when a caregiver is late for a shift or staying longer at a shift. If a caregiver clocks in and out outside of that tolerance range, it could flag or error the visit. Lengthening the clock in and out time, for example from 15 minutes to 30 minutes, could have a significant impact on your EVV Compliance score.

PHA PENNSYLVANIA HOMECARE ASSOCIATION

Tips, Tricks and Best Practices

Tip	Description
Mobile GPS Visit Verification Tolerance Range	Higher thresholds for GPS distance from client home result in less manual edits. Maximum set by EVV mandate is 1,320 ft or 0.25 miles.
Single Clock in/out for Consecutive Shifts	The scenario: Same client, same employee, two consecutive shifts with different billing rates. Caregiver ONLY has to clock in and out at the beginning of the first shift and end of the second shift if this setting is turned on. Talk to your EVV vendor about enabling this functionality.
Link Temp Members with Plan Members!	Don't negatively impact your EVV % by manually moving visit data in your HHAeXchange system. Example: If you had to create a Temp Member due to a missing authorization issue in the system, don't manually move the data to the Plan Member once it drops in HHAeXchange. Use their linking feature to assign that data to the Plan Member for EVV compliant visits. This works with redeterminations as well!
Consider allowing "unscheduled visits" for recipients with frequent schedule changes	If your EVV vendor does not allow you to link EVV attempts to scheduled shifts, consider allowing "unscheduled visits" where the worker can clock in and out without having a predetermined schedule. This requires the worker having a customer ID to identify who they are clocking in for. The agency may need to add bill rate, but the EVV capture will be assigned.

PHA PENNSYLVANIA HOMECARE ASSOCIATION

Tips, Tricks and Best Practices

Tip	Description
Rounding Rules: Let the system round for you!	Don't let rounding rules impact your compliance score. The systems are designed to do shift rounding for you! Rounding is typically done based on the total duration of a shift. For example: If the shift is 57 minutes long, it would round up to 60 minutes. Do not adjust shift times to accommodate authorization/utilization on a per day basis. MCOs have expressed flexibility in utilization management to allow for "reasonable" rounding scenarios. Providers must ensure that weekly or monthly utilization is not overutilized, but minor unit discrepancies on a per day basis are generally allowable. Providers should monitor utilization on a regular basis to ensure overutilization by the expiration of an authorization period does NOT occur. NOTE: ODP programs do not allow rounding up in any scenario. In that case, a shift that is 57 minutes would round DOWN to 45 minutes.

PHA Working For You!

When a participant requests a visit start somewhere other than the home, this is considered a **community-based visit.**

Currently in Pennsylvania:

1. This is an acceptable visit scenario… However,
2. It results in non-compliant EVV visit due to the GPS location not matching what is set as an acceptable GPS location

ADVOCACY: PHA is beginning conversations with MCOs and DHS to discuss the possibility of allowing EVV compliant "community-based" visits, if marked as such on a visit. This would likely require additional documentation to satisfy EVV needs, but may be a good option to improve compliance for agencies supporting populations that frequently begin and end care in a community setting.

Annual Conference

REIMAGINING HOMECARE

PHA

2024 ANNUAL CONFERENCE

MAY 15-17 | KALAHARI RESORTS | POCONO MOUNTAINS

As the healthcare landscape evolves, staying at the forefront of industry trends, standards and advancements is crucial for ensuring the success and quality of home care in Pennsylvania.

Join PHA as we reimagine home care during the 2024 Annual Conference, May 15-17, at Kalahari Resorts!

PHA
PENNSYLVANIA
HOMECARE ASSOCIATION


PHA
PENNSYLVANIA
HOMECARE ASSOCIATION

Thank you to all members who attended our Electronic Visit Verification (EVV) Lunch & Learn on April 2!

PHA CEO, Mia Haney, led the conversation on best practices to improve your EVV compliance. During the session we covered how to tackle common pitfalls, optimize your system, and track EVV compliance effectively. If you missed it, check out the Session Handout.

As promised, we are sharing answers to attendee questions submitted via Teams Chat!

What is telephony?

Telephony is a term used to describe Interactive Voice Response (IVR) or clocking in/out from a landline telephone number.

Where do we find the sample Community HealthChoices timesheet for AmeriHealth Caritas?

See the sample timesheet here. AmeriHealth Caritas/Keystone First Providers are not required to use this timesheet, but if they select another format, it must include the following fields (guidance announced in late 2023):

- Agency Name
- TIN and Provider ID
- Direct Care Worker's Name
- Direct Care Worker's last 4 digits of SSN
- Participant's Name
- Participant's Medicaid ID #
- Location of Service
- Date
- Start and End Time
- Total Hours Worked
- Services Provided Based on POC
- Participant's Signature and Date
- Provider's Signature, Agency Role, and Date
- Direct Care Worker's Signature and Date

See the PowerPoint presentation from the EVV Lunch & Learn for manual edit requirements by payor.

Do we still secure a physical timesheet even if there is still EVV record? I thought that because of EVV the timesheet would only be required when the caregiver missed the EVV.

If the EVV clock in and out has captured type, scope, amount, frequency, and duration of the shift, then a paper timesheet is not necessarily required. Tasks may be used to capture scope. However, if tasks are not utilized, the provider must have documentation of scope in another format to meet those claims documentation

PHA reserves the right to modify/change responses to these questions based on receipt of additional information or instruction from an oversight entity. Changes will be published in PHA's weekly "Connections" e-newsletter.

requirements. If a caregiver has failed to clock in or out, requiring a manual edit, then manual edit guidelines apply for documentation capture.

Does UPMC require customer and employee signature for manual edit documentation?
Signatures are required for the employee only with UPMC. See this guidance document which references this question.

Can we use DocuSign or a PDF filler? Are scanned, faxed, or emailed images of paper timesheets allowable?
PHA is working with the MCOs to get clarity on electronic signature options as well as acceptability of scanned paper timesheets. We will provide further updates as we receive them.

Can we have the documentation requirements for Manual Edits from all MCOs the same?
PHA is happy to discuss this with greater membership and consider adding it to our regulatory priorities.

How do we stay compliant if caregivers are telling us that other home care agencies allow caregivers to clock in/out using participant's cell phone, if we enforce landline, they threaten to transfer.
This is an unfortunate situation. We want our provider community to be engaged in activities that promote compliance and enhance accountability. Providers who are not EVV compliant and do not have satisfactory documentation for manual edits may face significant takebacks in an audit. Also, a provider's reputation with a plan is jeopardized if they do not meet baseline compliance requirements. We encourage all providers to focus on compliance and dedicate resources to fraud waste and abuse prevention in the system.

When a caregiver arrives late and the (OLTL) rounding rule is applied, resulting in a 15-minute reduction from the shift (which is automatically removed in HHA Ex), should we categorize these 15 minutes as a missed visit?
No. This would not be a missed visit.

Are there any discussions to implement exceptions to EVV for family caregivers?
Not that PHA is aware of.

How can we determine the duty codes if there is no care plan? Service coordinators are not putting in care plans.
PHA has experienced that agencies self-create a Care Plan for the participant to guide caregivers on appropriate duties that fall within the service definition of Personal Assistance Services and are the preference of the participant.

Where do we find our EVV % as a company as a whole?
If you do not use HHAeXchange, you can find your EVV compliance in the DHS Aggregator Portal, Sandata system. If you use HHAeXchange, navigate to the following reports to review compliance:

- Exception By Caregivers
- Exception By Reason
- Exception Detail Report
- Exceptions Statistics
- Exception Summary by Provider

PHA reserves the right to modify/change responses to these questions based on receipt of additional information or instruction from an oversight entity. Changes will be published in PHA's weekly "Connections" e-newsletter.

Where do you get the FOBs?
Contact your EVV vendor to see if they offer a FOB option. HHAeXchange does offer the option for FOBs. Note, FOBs may be associated with additional fees for the agency.

What do we do if a caregiver forgot to clock in/out and also failed to obtain a timesheet for the missed EVV? We are requiring our caregivers to clock in/ out but human error occurs.
In this scenario, you do not have documentation to justify the claim. This visit is not billable.

Some consumers receive services at a secondary location such as a family member's residence or out in the community. How does EVV work for this scenario? Is it acceptable for a consumer to request services be rendered somewhere other than their home and it be EVV compliant?
Yes, these examples are acceptable. In many EVV vendor software programs, providers can program multiple locations as acceptable for EVV compliance. As a best practice, providers should maintain documentation of why these locations were approved and subsequently programmed by the agency and maintain documentation that the Service Coordinator was made aware.

Do we know if Highmark Wholecare plans are changing to HHA Exchange or if any of the payors plan on changing to Sandata?
Not that PHA has been made aware of.

HHA Exchange and cell companies have outages. Does anyone know how MCOs calculate outages into our provider EVV compliance rates?
When available, providers should enable "offline mode" in these circumstances to avoid manual edits.

When will MCO start enforcing the compliance rate of 85%?
The 85% compliance threshold begins January 1, 2025.

What if your compliance is 100%?
Congratulations! We want to hear your best practices. Contact PHA to share your success tips!

Why doesn't offline mode work for me?
First, you must make sure "offline mode" is enabled for your system. This is an administrative setting. Speak with your EVV vendor to ensure it is turned on for your organization. For some phones that are still trying to connect to service in an area where service is questionable, you must put the phone in airplane mode to force the offline mode to work.

We are really struggling to get answers from HHA. Is there any way to get in touch with them besides just creating tickets with them? We've found that sometimes our tickets are being closed without a resolution.
Please use PHA's Support Form. We meet bi-weekly with HHAeXchange to escalate tickets and discuss system enhancements that would benefit all Pennsylvania providers.

PHA reserves the right to modify/change responses to these questions based on receipt of additional information or instruction from an oversight entity. Changes will be published in PHA's weekly "Connections" e-newsletter.

Do we still need to require our caregivers to have a participant signed timesheet even if there is an EVV? I thought that signed timesheet is only needed if there is a missed EVV.
The agency must maintain sufficient documentation to justify the billing claim. Documentation must include type, scope, amount, frequency, and duration of care. If the EVV capture fails to obtain this justification, additional documentation would need to be obtained. For example, if tasks are not used in EVV, the provider would need to maintain documentation of scope of services in another manner.

Many of our manual edits are due to back-to-back shifts. When you have one caregiver relieving another caregiver, there could be an overlap as the workers signing off is providing a report to the worker signing in to ensure seamless continuity of care. This results in manual edits frequently.
You cannot bill for two staff at the same time if it is not authorized on a care plan. The time spent reviewing patient information then is payable, not billable. Training with the workers on clocking in and out and reporting payable, not billable time in a manner that does not create a manual edit is advisable.

Where specifically do we turn on in HHA to capture the GPS even if no signal?
This is called "offline mode." It is most often in administrative settings. You can submit an EVV Vendor support ticket to have this changed in administrative settings if you are unable to change the setting yourself (HHAeXchange requires a support ticket for this change).

Where can we turn on automatic splitting on HHA Exchange?
You can submit an EVV Vendor support ticket to have this changed in administrative settings.

What do we do when HHA doesn't have the authorization in or when you email them to correct a patient's address or phone number and they never correct it. This will affect the EVV.
If there is no authorization, enter a Temporary Member, add the correct address as an approved GPS location (documenting with the MCO the correct address) and have the staff clock in and out. When the authorization appears in HHAeXchange, use the linking feature to link the visits to the member. This will result in a transfer of the EVV data to the member for EVV compliance purposes.

What happens if the patient is unable to sign?
MCOs have asked that you contact your Supports Coordinator for direction in this scenario.

We have an unusual situation with a current consumer. We provide dual staffing, 24/7, for this case. There is always a CNA and LPN present. It is billed under one code covering both the aide and nurse. This is through Consolidated Waiver/ODP. To be paid, we were told by ODP, that we had to "manually adjust" each punch in/out to the specific hour. Our staff is using EVV appropriately, (HHA Exchange), however, because we have to adjust, we are not considered to be within the compliance percentages. To provide you with an example… First shift is 6am to 2pm. If our nurse or aide clocks in at 5:58am, we must adjust to 6am and document a note stating, "2:1 Systems Limitation." If we do not have this, we cannot get paid. It is some kind of issue with the system because of the dual staffing.
"*For 2:1 service specifically, the system is unable to determine which care worker visit to use when calculating units if the aggregator contains overlapping time for 3 or more care workers. This scenario will typically occur during shift changes. To resolve this issue, the provider should manually adjust the third care worker's EVV visit to a time that does not overlap with the care worker's time whose shift is ending. Due to this system limitation, a manual edit for this scenario is acceptable by DHS." – DHS website*

PHA reserves the right to modify/change responses to these questions based on receipt of additional information or instruction from an oversight entity. Changes will be published in PHA's weekly "Connections" e-newsletter.

The above language suggests that you should ONLY have to do a manual edit if there is a shift change where the 2 caregivers on the first shift overlap clock in and out times with 1 or more caregivers on the second shift. If this occurs, you should only need to adjust the caregiver on shift 2's clock in time to make sure it doesn't overlap with the clock out from the "shift 1" caregivers.

Sometimes there will be an overlap in shifts. Ex: 1st shift person clocks out on time, but system rounds so it matches the clock in time and then 2nd shift clock in overlaps. We make a manual adjustment so there is no overlap, does a timesheet have to be signed?
Any time you have a manual edit, manual edit documentation guidelines apply.

Can PHA find the window of clock in and out from State, OLTL and MCOs?
There is no required clock in and out window related to scheduled time in and out. This is at the discretion of the provider.

Is the window for clocking in and out 7.5 minutes?
No. 7.5 minutes is the billing rounding rule for some program offices in Pennsylvania. Rounding and clock in/out thresholds are separate considerations.

Guidance for UPMC Community HealthChoices Personal Assistance Services Providers Regarding Record Keeping and Electronic Visit Verification Requirements

Personal assistance services (PAS) are a home- and community-based services benefit that are covered through the Community HealthChoices Long-Term Services and Supports (LTSS) program. PAS primarily include hands-on assistance for participants, as specified in a person-centered service plan (PCSP), to enable a participant to more fully integrate into their community and ensure their health, welfare, and safety. PAS are intended to help participants complete activities of daily living (ADLs) and instrumental activities of daily living (IADLs) that the participant would perform on their own if they did not have a disability.

> **Activities of daily living:** These include eating, drinking, ambulating, transferring in to and out of a bed or chair, toileting, bladder and bowel management, personal hygiene, self-administering medication, and proper turning and positioning in a bed or chair.
>
> **Instrumental activities of daily living:** These include the following activities when done on behalf of a participant: laundry, shopping, securing and using transportation, using a telephone, making and keeping appointments, caring for personal possessions, writing correspondence, using a prosthetic device, and housekeeping.

See Application for 1915(c) HCBS Waiver: PA.0386.R04.07 - Jan 01, 2022 (as of Jan 01, 2022) (the "Waiver") and 55 Pa. Code § 52.3 for more information. These definitions should be regarded as general guidance for scope of services, tasks, and duties encompassed by PAS; however, the examples are not exhaustive. As the Waiver indicates, "this service will be provided to meet the participant's needs, as determined by an assessment, in accordance with Department requirements and as outlined in the participant's service plan."

For each participant, UPMC CHC develops a person-centered service plan (PCSP) that addresses how the participant's health needs will be managed under their Community HealthChoices plan. The PCSP includes an LTSS service plan, which is designed to "identify and address how LTSS needs will be met and how services will be provided in accordance with the Person-Centered Service Planning (PCSP)." See the 2022 Community Healthchoices Agreement for more information.

PCSPs document the type, scope, amount, duration, and frequency of services needed by the participant. These plans are furnished to the participant and, can be shared directly with the PAS provider through the UPMC Health Plan Provider OnLine website in order for the PAS provider to develop a plan of care to meet the daily needs of the participant. In addition, the elements of the scope of work—the tasks that are identified in the PCSP for completion with and for the participant—are outlined in the Service Authorization through HHAeXchange. PAS providers must provide services in accordance with this scope of work.

Documentation Requirements for PAS Providers

PAS providers must complete and maintain documentation that records all services provided to a participant, and those services must be in accordance with the type, scope, amount, duration, and frequency found in the PCSP and the details of the Service Authorization. Specifically, provider records should

note all ADL/IADL tasks performed during the PAS encounter and demonstrate how each service was related to needs identified on the PCSP. Additional guidance can be found in 55 Pa. Code § 52.14 (Ongoing responsibilities of providers), § 52.15 (Provider records), and § 52.43 (Audit requirements). (Please note that the responsibilities listed in those regulations are not exhaustive.) Providers must complete documentation as contemporaneously with service delivery as possible.

Electronic Visit Verification Requirements for PAS Providers

Under Section 12006(a) of the 21st Century Cures Act (Cures Act) and Pennsylvania DHS Medical Assistance Guidance, PAS providers are required to implement Electronic Visit Verification (EVV) for all PAS services. In order to fulfill the EVV requirement, the following data must be captured and provided to UPMC Health Plan via its EVV vendor, HHAeXchange:

- Type of service performed
- Participant receiving the service
- Individual providing the service
- Date of the service
- Location of service delivery
- Time the service begins and ends

See the UPMC Health Plan Provider Manual, UPMC Community HealthChoices (Medical Assistance) – Chapter N, for further guidance on EVV.

The minimum threshold for use of EVV is electronic verification of 50 percent of all PAS encounters. Any use of EVV below this threshold is grounds for imposition of a Compliance Plan and may be grounds for termination of a PAS provider's participating provider agreement with UPMC CHC. See OLTL Bulletin 07-20-04 for more information.

The EVV requirement **is separate from and in addition to the record-keeping requirements described above.** Compliance with the EVV requirements does not abrogate a PAS provider's responsibility to keep records of all ADL/IADL tasks performed during a PAS encounter and how each service relates to needs identified on the PCSP.

Additional Requirements for PAS Providers

Finally, 28 Pa. Code § 611.57 ("Consumer protections") states that the following information must be provided by PAS providers to consumers: "A listing of the available home care services that will be provided to the consumer by the direct care worker and the identity of the direct care worker who will provide the services." This participant-facing documentation is independent of either the provider's record keeping or EVV requirements.

Frequently Asked Questions:

Aren't type, scope, amount, duration, and frequency included in the EVV encounter? Why do I need to keep separate records of task details?

The six required EVV data elements (see above) do not include all required details of the service delivery. EVV only accounts for the type (PAS or Respite and with the applicable CPT code), amount (based on the overall units of the shift between the clock in/clock out), duration (based on the elapsed time between clock in/clock out), and the frequency (based on the appropriate interval for service delivery per the PCSP and POC).

Scope (i.e., tasks, duties, ADLs, IADLs) is not part of the EVV requirements but it is a requirement based on both Pennsylvania Code (see above) and your participating provider agreement with UPMC CHC. This requirement helps ensure that participants are receiving the right care, in the right way, at the right time, every time.

How much scope detail should the direct care worker record?

The direct care worker should provide as much scope detail as possible, generally adhering to the ADL and IADL tasks noted in the definitions above and in the PCSP. All tasks for a date of service should be

recorded. Keep in mind that tasks identified on the PCSP and plan of care should be recorded if they are performed during a visit, even if they are not specified in the CMS and Pa. Code service definition.

Remember, only tasks truly completed during the encounter date of service should be recorded.

What if the provider's EVV system does not record scope of work (i.e., tasks, duties, ADLs, IADLs)?

If the provider is not recording tasks (ADLs/IADLs) in a digital system, the direct care worker should produce a document—digital or paper—that includes the scope of work performed during the visit and the direct care worker's signature.

My tasks are recorded digitally but the data is not integrated with (transferred into) HHAeXchange. What should I do?

The electronic scope detail (tasks, duties, ADLs, IADLs) should be retained according to the timeline specified in your participating provider agreement. It should be made available during an audit or a documentation request by Quality Monitoring.

If there is a missing EVV clock in OR clock out, does the provider need to have a reference document with a direct care worker sign-off that indicates the time of the clock in or out?

Yes. It does not have to be a physical copy—it could be a digital document if the provider has the technology for electronic signature attestation—but it does need to be a reference document (not necessarily a complete time sheet) for auditing purposes.

If there is both a missing EVV clock in AND clock out, what documentation should be recorded?

The provider would need a full time sheet (digital or paper) with the direct care worker's signature. Again, it could be a digital document if the provider has the capacity to record all applicable timesheet details with a direct care worker's electronic signature/attestation. It should include all the task details that were not otherwise recorded in the digital system.

If the EVV encounter was performed, do we need a direct care worker's signature on documentation?

If the EVV system captures the required scope information, a direct care worker's signature is not needed on documentation. However, if the scope of work—all the tasks performed during an encounter shift—is separately recorded in the provider's preferred system, those records would require the direct care worker's signature.

If we need to correct a minor EVV error—such as a geofence adjustment because of a participant address mismatch or a direct care worker's clock out in the community—how would we address the manual edit documentation?

The provider administrator should note the circumstances in the linked HHAeXchange note or their system of record. No direct care worker signature is required.

Can we substitute an administrator's signature for a direct care worker's signature in any of the above scenarios? What if the direct care worker no longer works for our agency?

No. The direct care worker signature is required regardless of the circumstances.

Does manual documentation require a participant's signature?

No. For agency-model services (that is, services provided by a direct care worker employed by an agency and not directly by the participant), the participant is not expected to sign the provider's time sheets or other forms of manual encounter documentation. However, the provider may choose to require a participant's signature for these circumstances based on their business practices.

Is there a recommended time frame for manual documentation completion?

Manual documents should be completed immediately, on the date of service. The provider should train the employed direct care worker to

immediately document missed clock in and clock out when identified, and to record scope (tasks, duties, ADLs, IADLs) upon completion of the task or upon the close of the encounter/shift. This should be acknowledged within a provider's internal policies.

Do I need to have a record-keeping policy/procedure and an EVV policy/procedure for my organization?

Yes, and the direct care worker should be trained on record keeping and EVV to ensure successful utilization.

As indicated in OLTL Bulletin 07-20-04, "Providers are to establish policy on documentation required to meet auditing requirements and standards, as well as organizational needs."

UPMC CHC will regularly monitor and review provider EVV policies. At minimum, policies should set clear guidelines on EVV requirements, the effective use of the provider's EVV solution of choice, and contingency planning in the event that a visit (or a portion of a visit) was not captured using EVV or requires an edit and/or correction, etc. All stakeholders—administrators, direct care workers, participants, and Support Team members—should be trained on a provider's EVV process respective of their roles.

Direct care workers should always be prepared for circumstances in which there could be manual entry circumstance for the encounter.

What happens if the GPS coordinates are in the community when the shift starts/ends but that is where the participant wants to start?

If a visit (encounter) begins or ends in the community in an atypical location (a location that is not identified as the primary residence in the managed care organization [MCO] system of record) the encounter is regarded as a noncompliant manual exception under the DHS PCS EVV Bulletin, Cures Act, and the UPMC Health Plan Provider Manual, UPMC Community HealthChoices (Medical Assistance)—Chapter N.

In these circumstances, the GPS location of the start/end location recorded on the caregiver's smartphone EVV app will not align with the customary service delivery location, or the telephone modality will be unavailable.

In best practice, the direct care worker should clock in and clock out in the community where visits begin and end using an EVV solution if/when available but notate manual exceptions per the above.

Additionally, it is allowable to revert to recording the missing EVV visit/encounter details in an alternative format (i.e., paper or a digital document) that should be signed by the attending caregiver. However, please note that this will be regarded as a manual exception, not a compliant EVV encounter.

Can a secondary service location be added to support EVV encounter recording?

Yes. A secondary service address can be added if the participant customarily receives PAS in a non-primary location (for example, if a participant receives ongoing agency PAS at their daughter's home twice a week).

Providers can request the addition of this address for the purposes of EVV compliance tracking by contacting their Network representative via CHCProviders@upmc.edu. (Participants should contact their service coordinator with all requests.)

All secondary address additions must be reviewed by the participant's service coordinator and approved in the PCSP before they are entered into the HHAeXchange system. Normal GPS geofence restrictions apply.

Can additional landlines be added to support EVV encounter recording?

Yes. Additional landlines can be approved for participants who receive services at locations other than their home. Like additional locations, additional landlines must be reviewed and approved per the above guidelines.

What if the participant only has a cell phone and the direct care worker does not have a cell phone?

Using a participant's cell phone is not acceptable for telephonic verification unless there is a way to capture location, such as a fixed visit verification device.

Telephonic verification must include validation through a GPS or location system.

EVV policies for providers incorporating a landline telephone modality should include a process for verifying the participant's phone type, ideally during new participant intake and annually.

Providers are advised to closely monitor landline telephone use, ensuring that Interactive Voice Response (IVR) call-in/call-outs associated with visits are initiated from a landline at the participant's registered service locations.

Direct care workers should be advised to provide notification of any changes that impact EVV capture.

Visits not recorded using EVV tools and entered as manual visits are regarded as noncompliant manual exceptions with the EVV for Personal Care Services, (PCS) Bulletin (#07-20-04), Cures Act, and the UPMC Health Plan Provider Manual (Chapter N).

Can my organization use fixed object devices to track EVV?

Yes. Fixed object devices (FOBs) are an allowable alternative to EVV tools. All FOBs must be permanently affixed at the primary service location.

For providers using only the free HHAeXchange system, FOBs can be requested by contacting the UPMC Health Plan Network team at CHCProviders@upmc.edu. Providers are required to complete a short survey to verify whether an FOB is the best fit for each circumstance.

How does UPMC CHC monitor for EVV compliance?

The UPMC Provider Monitoring team refers providers to the waiver citation regarding acceptable EVV methodology: "The methods used to capture visits include mobile phone applications, telephonic entry via a landline telephone, and fixed verification devices."

The Provider Monitoring team must validate a PAS visit via compliant means to ensure the location of the visit.

Noncompliant manual exceptions to EVV are factored into the aggregate EVV Compliance percentage.

For example, if a provider completes 100 visits per quarter and 25 of the 100 visits were noncompliant manual exceptions, the provider is considered to be 75 percent EVV compliant.

UPMC Health Plan monitors EVV compliance on a quarterly basis and will request Compliance Plans for providers that fail to meet a 50 percent EVV compliance threshold for all reported encounters, effective Jan. 1, 2023.

Often, situations with GPS coordinates outside the home are identified by the Monitoring and Audit teams. These teams take into consideration a participant's address history (GPS coordinates possibly tie to prior address, causing a mismatch of the caregiver and participant pins), the marked tasks/duties for the PAS visit, and manual edits in provider's participant record.

CHC EVV RCRD KP GD PAS PRVDR 23PV3480053 (MG) 3/2/23 PDF

PENNSYLVANIA HOMECARE ASSOCIATION

AmeriHealth Caritas/Keystone First Manual Edit Signature Capture Requirements

Type of Signature	Allowable?	Description of Signature type
Original Paper Signature	Allowable	Wet signature completed with a pen, pencil or other writing device on traditional paper that includes the individual's personally identifiable signature, including first and last name.
Scanned Paper Signature	Allowable	A scan or image of a paper document that had the original wet signature of the individual's first and last name in their own handwriting using a pen, pencil or other writing device.
Digitized Signatures	Allowable	The signer is asked to sign their name on a digital input device. The signature is recorded and stored with the document. For a higher level of identity validation, software may be used to compare the signature with a pre-existing sample. This is a form of biometrics. A common example of this is the use of electronic signature pads for credit card transactions in retail establishments.
Check box / Click on/ Click to Sign	Not Allowable	The signer of the document is asked to check off a box that's labeled "I accept," "Yes," "I agree," etc. or click a corresponding button. Generally he/she is given the option to make either a "Yes" or "No" choice. Sometimes the signer may be asked to type the words "I Agree" in a text box to ensure that there is no misunderstanding. Upon selecting the (usually) affirmative box, the signer is allowed to proceed with the action of the system. A common example of this is the installation of a software package on a computer. Particularly with commercial software, the installer is asked to agree to terms and conditions before the software is actually installed on the system. Failing to click on the "I Agree" button or check the "Yes" box aborts the software installation process. Despite the lack of any real validation of the installer's or user's identity, many people have been successfully prosecuted for software piracy based on this eSignature. There is little or no validation of the signer's identification in this type of eSignature. Generally it should only be used for low-risk or low-value transactions.

Personal Identification Number (PIN) or Password	Not allowable	The signer is asked to provide identifying information (userID, Social Security Number, etc.) and a shared secret (something that both parties know) such as a PIN or password. Once the information is entered, the system authenticates the signer by checking that the shared secret is indeed the one that was established for the claimed identity. Generally there needs to be a pre-existing relationship between the entities. The process for validating a user and subsequently issuing a shared secret can vary widely and may be as strong or as weak as deemed necessary for the transaction. For example, a customer may establish an account with an online retailer simply by entering some basic information (name, address, phone number, email account) and supplying their own choice of userID and password. This is sufficient to enter the site, browse the online catalog and even put items into a shopping cart. However, when it comes time for checkout, a higher level of authentication is required in the form of verifiable and valid credit card in the user's name and with the appropriate billing address, etc. Once this higher level of identity has been established, subsequent transactions of the sort may rely only on the userID and password and stored information. An example of such a system being used within the Commonwealth is the online filing of state income tax returns. Here there is a pre-existing relationship between the user and the Commonwealth. The userID is the user's Social Security Number and the validating information or shared secret is information off of the user's previous year's state income tax return or the user's PA Drivers License or Identification Card number. As noted above, the validation of the user's identity can vary widely and the process should be tailored to the risk/value of the transaction.
Digital Signatures (PKI)	Not allowable	A digital signature (not a *digitized* signature) makes use of public key infrastructure (PKI). A trusted (third party) certification authority validates the identity of a user and issues a two-piece digital key. One is the private key and is held by the user. The other is a public key and is made available to the world. The two keys are mathematically linked to each other and can be used to encrypt and to sign documents. Without going too in depth into the details, a document encrypted with one of the two keys (generally the public key) can only be decrypted with the other one of the pair. A document signed by one of the keys (generally the private one) can have the signature validated by the other key of the pair. This type of eSignature provides a high level of security and validation of a document, depending on the rigor applied in the registration process. It is correspondingly costly. Also the key pairs must be preserved for the lifetime of the document; without them the signature cannot be validated and if the document is encrypted, it cannot be decrypted. Generally this type of signature is reserved for high risk/high value transactions such as high value bank transfers or corporate orders.

Biometrics	Not allowable	Personal characteristics (fingerprints, iris or retinal patterns, DNA, voice, handwriting) can provide a very high level of identity validation when used as or as a part of an eSignature process. These are not widely used at this point in time, however, examples include the comparison of a digitized signature with a previous sample (as mentioned above) or the recording of a signer's voice as he/she makes a required statement.
Hardware Tokens	Not allowable	While not necessarily an eSignature in itself, hardware tokens such as smart cards, single use PIN generators (e.g., RSA SecureID) can be used to augment an eSignature process. A smart card, for example, can be used to hold the user's private key in a digital signature solution or a user's biometric characteristics. A PIN generator can provide a higher level of security for a shared secret eSignature.

Last Update: 7/25/2024

Avoiding Unnecessary Manual Edits With EVV: Key Tips For Compliance

August 16, 2024

As Pennsylvania prepares to move to an 85% threshold for EVV compliance on January 1, 2025, PHA is committed to helping you stay prepared. If you missed our review in last month's *Quick Hits*, here are some critical setting changes HHAeXchange users should consider to avoid unnecessary manual edits:

- Disable "Visit Confirmation Rounding"
- Disable "Auto-Round Overlapping Shifts"
- Enable "Automatic Splitting"
- Enable "Offline Option"
- Lengthen "Tolerance Range" for scheduled time a caregiver can clock in and out
- Set higher GPS Distance Thresholds (regulatory allowable is up to 0.25 miles or 1,320 ft)
- Enable "Single Clock In/Out for Consecutive Shifts" to allow caregivers to clock in at the start of the first shift and out at the end of the second shift, even with different billing rates

Use the HHAeXchange ticketing system to understand what the above requests mean to your operations. If you agree to the change implications, you can request to change to your current settings.

Join PHA on September 5 at the Best Western Premier or online in Harrisburg for our revamped EVV Compliance Collaborative. This event puts a new spin on our usual EVV Check-In, featuring peer education sessions on key compliance topics and an Enhanced Ticketing Table, where you can receive personalized support from HHAeXchange and MCO representatives. Register today!

PRINTER'S NO. 3220

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 2372 Session of 2024

INTRODUCED BY BENHAM, ORTITAY, PROBST, HOHENSTEIN, McNEILL, HARKINS, SANCHEZ, WAXMAN, KHAN, BRIGGS, ABNEY, BOROWSKI, DEASY, HILL-EVANS, DELLOSO, PISCIOTTANO, KRAJEWSKI, GREEN, CERRATO, DALEY, SHUSTERMAN, SALISBURY, DONAHUE, MADDEN, CEPEDA-FREYTIZ, FRANKEL, POWELL, MERSKI AND COOK, JUNE 3, 2024

REFERRED TO COMMITTEE ON APPROPRIATIONS, JUNE 3, 2024

AN ACT

Amending the act of April 9, 1929 (P.L.343, No.176), entitled "An act relating to the finances of the State government; providing for cancer control, prevention and research, for ambulatory surgical center data collection, for the Joint Underwriting Association, for entertainment business financial management firms, for private dam financial assurance and for reinstatement of item vetoes; providing for the settlement, assessment, collection, and lien of taxes, bonus, and all other accounts due the Commonwealth, the collection and recovery of fees and other money or property due or belonging to the Commonwealth, or any agency thereof, including escheated property and the proceeds of its sale, the custody and disbursement or other disposition of funds and securities belonging to or in the possession of the Commonwealth, and the settlement of claims against the Commonwealth, the resettlement of accounts and appeals to the courts, refunds of moneys erroneously paid to the Commonwealth, auditing the accounts of the Commonwealth and all agencies thereof, of all public officers collecting moneys payable to the Commonwealth, or any agency thereof, and all receipts of appropriations from the Commonwealth, authorizing the Commonwealth to issue tax anticipation notes to defray current expenses, implementing the provisions of section 7(a) of Article VIII of the Constitution of Pennsylvania authorizing and restricting the incurring of certain debt and imposing penalties; affecting every department, board, commission, and officer of the State government, every political subdivision of the State, and certain officers of such subdivisions, every person, association, and corporation required to pay, assess, or

collect taxes, or to make returns or reports under the laws imposing taxes for State purposes, or to pay license fees or other moneys to the Commonwealth, or any agency thereof, every State depository and every debtor or creditor of the Commonwealth," in human services, providing for personal assistance services rate; and, in general budget implementation, further providing for Department of Human Services.

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. Article XVI-T of the act of April 9, 1929 (P.L.343, No.176), known as The Fiscal Code, is amended by adding a section to read:

Section 1607-T. Personal assistance services rate.

(a) Community HealthChoices.--Effective January 1, 2025, a provider who receives funding through Community HealthChoices through the existing Office of Long-Term Living (OLTL) Home and Community Based Waiver Services Fee Schedule Rate for Procedure Codes W1793 - PAS (Agency) and W1792 - PAS (Consumer) Services shall spend no less than 80% of the funds received on salary and benefits of a personal assistance worker.

(b) Enhanced provider rate.--The Department of Human Services shall establish an enhanced rate for a provider that invests no less than 90% of funds received from the Commonwealth on the wages and benefits of an agency-directed personal assistance worker. Notice of the enhanced rate shall be transmitted to the Legislative Reference Bureau for publication in the next available issue of the Pennsylvania Bulletin.

(c) Evaluation of rate.--

(1) No later than December 31, 2027, and every three years thereafter, the Department of Human Services shall review the current rate paid to personal assistance workers and make recommendations on any proposed changes to the current rate. In the department's review, the department

shall, at a minimum:

(i) Identify key cost components for each service based on the service.

(ii) Obtain input from the Medicaid Rate Workgroup.

(iii) Collect and analyze Pennsylvania-specific wage data, including inflation and the Consumer Price Index.

(iv) Review and analyze updated assumptions.

(v) Model the fee ranges for each service and solicit feedback on the proposed fee ranges.

(2) The following shall apply:

(i) The Governor shall consider any proposed changes to the rate under this subsection in the annual budget development and implementation process.

(ii) The General Assembly shall consider any proposed changes to the rate under this subsection in the annual budget development and implementation process.

Section 2. Section 1729-E(a) of the act is amended by adding a paragraph to read:

Section 1729-E. Department of Human Services.

(a) Appropriations.--The following shall apply to appropriations for the Department of Human Services:

* * *

(9) From money appropriated for Long-Term Living (OLTL) Home and Community Based Waiver Services:

(i) Sufficient funds are included for a 16% increase, effective January 1, 2025, to the existing Office of Long-Term Living (OLTL) Home and Community Based Waiver Services Fee Schedule Rate for Procedure Code W1792 - PAS (Consumer) Services. This increase shall be used to provide a wage increase for direct care

workers providing consumer-directed personal assistance services.

(ii) Sufficient funds are included for a 10% increase, effective January 1, 2025, to the existing Office of Long-Term Living (OLTL) Home and Community Based Waiver Services Fee Schedule Rate for Procedure Code W1793 - PAS (Agency) Services. This increase shall be used to provide a wage increase for direct care workers providing agency-directed personal assistance services.

* * *

Section 3. This act shall take effect in 60 days.

Pennsylvania Homecare Association

The Honorable Stephen Kinsey
Majority Chairman
Human Services Committee
Pennsylvania House of Representatives
317 Irvis Office Building
Harrisburg, PA 17120-2201

The Honorable Doyle Heffley
Minority Chairman
Human Services Committee
Pennsylvania House of Representatives
218 Ryan Office Building
Harrisburg, PA 17120- 2122

May 9, 2024

Dear Chairmen Kinsey and Heffley,

On behalf of the Pennsylvania Homecare Association (PHA), I am writing in response to a recent House Co-Sponsorship Memorandum introduced by Reps. Jessica Benham and Jason Ortitay, "Agency Accountability and Livable Wages for Pennsylvania's Home Care Workers". PHA has nearly 700 members providing home health, homecare, and hospice services across the Commonwealth. Our members reflect the diverse landscape of home and community-based service providers credentialed by the State of Pennsylvania to deliver services to the most vulnerable Pennsylvanians.

We were encouraged to see an increase in state funding for rates under Personal Assistance Services (PAS) in PA's Medical Assistance Community HealthChoices (CHC) programs in the proposal. Additionally, we wholeheartedly support a market-based analysis of rates every three years to ensure rates are more regularly adjusted for inflation going forward.

That said, PHA has serious concerns about the requirement that at least 80 percent of the total funding be spent on workers compensation, with annual reporting requirements to document the use of public funds. This language mirrors the final "Ensuring Access to Medicaid Services" rule that was recently released by the Centers for Medicare & Medicaid Services (CMS). Despite concerns from providers and Medicaid agencies about burdensome reporting requirements, state expense for administrative oversight, disparate impacts on small and rural providers, and lack of actuarial studies to support the 80/20 data recommendation, CMS finalized the rule with the problematic provisions still in place. Separately creating a state-mandated 80/20 provision is not only duplicative, but it also exacerbates workforce challenges in homecare services rather than alleviating them.

In a national and regional context, Pennsylvania's Medicaid fee-for-service reimbursement rates for personal assistance services (PAS) are notably low, averaging $20.63, the lowest rate of our surrounding states with the exception of West Virginia. This rate has seen minimal increases over the past decade, failing to keep pace with inflation. Moreover, this rate covers all care aspects, including wages, overtime, administration, background checks, quality, nursing supervision, innovation, technology, and essential resources like PPE.

Similarly, we oppose the provision allowing "mission-driven non-profit" home-care agencies an enhanced rate for allocating 90 percent of their total rate to the workforce. Enhanced rates should be value-based and tied directly to quality and overall cost of care reductions, rather than arbitrary percentages that are not actuarily sound. Our industry focus should be on innovation, training, career pathways and investments in quality of care, rather than simply pay rates.

600 N. 12th Street, Suite 200 • Lemoyne, PA 17043
Toll-Free (800) 382-1211 • Tel (717) 975-9448 • Fax (717) 975-9456
www.pahomecare.org

PHA has been a vocal advocate for pay rate increases, especially to address the critical shortage in attracting and retaining workers. This reflects our commitment to supporting Pennsylvanians and acknowledging the vital role of direct care workers.

The Co-Sponsorship Memorandum unjustly portrayed home care agencies as solely profit-driven entities, which is inaccurate, home-based care providers are deeply committed to ensuring access to high-quality care for all Pennsylvanians in need and enhancing professional standards. PHA and our members have spearheaded efforts for homecare licensing, more stringent training requirements, and enhanced regulatory standards. Our dedication to quality care is steadfast. We support quality metrics, higher reimbursement rates and wages for DCWs, and transparency in the system.

We urge all stakeholders to collaborate for the sustainable future of home-based care and prioritize rates that support quality services over arbitrary requirements. It is imperative for Pennsylvania to establish a framework that effectively supports aging individuals and ensures high-quality care for all in need.

Sincerely,

Mia Haney, CEO
Pennsylvania Homecare Association

The Honorable Jordan Harris
Majority Chairman
Appropriations Committee
Pennsylvania House of Representatives
512E Main Capitol Building
Harrisburg, PA 17120-2186

The Honorable Seth Grove
Minority Chairman
Appropriations Committee
Pennsylvania House of Representatives
245 Main Capitol Building
Harrisburg, PA 17120- 2196

June 7, 2024

Dear Chairmen Harris and Grove:

On behalf of the undersigned associations, we write to share feedback on House Bill 2372, "Agency Accountability and Livable Wages for Pennsylvania's Home Care Workers," sponsored by Reps. Jessica Benham and Jason Ortitay. The Pennsylvania Homecare Association (PHA), the Pennsylvania Association of Home and Community-Based Services, and the Rehabilitation & Community Providers Association (RCPA) collectively represent hundreds of thousands of participants and caregivers in Pennsylvania's Medicaid Home and Community-Based Services (HCBS) program.

We fully support the proposed increases in state funding for personal assistance services (PAS). However, we advocate for the following clarifications:

1. **We request that any rate changes be made to the Office of Long-Term Living fee schedule and all applicable programs.** This ensures that the changes impact all LTSS workforce, including those providing critical brain injury supports and rehabilitation services. Current verbiage excludes these programs, which are smaller than Community HealthChoices, but just as critical.
2. **We support a 16% wage increase for direct care workers across all models of care in the LTSS space.** Creating disparities by assigning different rate increases to agency and consumer-directed models at this critical juncture in the workforce crisis is counterproductive, and creates unnecessary conflict within the industry (current verbiage contains a 10% for agency model and 16% for consumer-directed model). Increases to rates specifically address the significant changes in compensation needed to be competitive in the current marketplace. Agencies, consumer-directed care, and rehabilitation all face the same reality; their workforce can make more money at the local gas station, retail store, or restaurant. A 16% increase in all models is a recognition from the legislature that inflationary impacts must be addressed, and this workforce secured, in order to protect Pennsylvania's most vulnerable population. It also can be viewed as a positive step towards leveling rates with contiguous states, following more than a decade of under-funding across both models of care. Our current reimbursement rates lag bordering states by $4.50/hour or more.
3. **We support language that requires the Department of Human Services to adopt a rate review and rate setting process that occurs at a minimum of every three years**, including obtaining input from a Medicaid Rate Work Group comprised of stakeholders across all models of care.

We appreciate the acknowledgment of the importance of continued funding support for health-sustaining services that enable individuals across Pennsylvania to thrive in their homes and communities, which are both the preferred and more cost-effective settings. **However, we have significant concerns regarding the requirement that at least 80% of the total funding be allocated to worker compensation, along with the accompanying annual reporting requirements to document the use of public funds.** This requirement reflects the language found in the recently released "Ensuring Access to Medicaid Services" rule by the Centers for Medicare & Medicaid Services (CMS).

During an extensive review and public comment period for the CMS rule, numerous concerns were raised by providers and Medicaid agencies. These concerns included the burdensome nature of the reporting

requirements, the administrative oversight costs, the disparate impact on small and rural providers, and the lack of actuarial studies supporting the 80/20 funding allocation recommendation. Consequently, CMS delayed the implementation of this mandate until 2030 to ensure proper implementation and to avoid unintended consequences, such as a decline in access to care.

For Pennsylvania to implement a similar provision in a more expedited manner is not only duplicative but also undermines the efforts made by CMS to ensure that this federal rule is promulgated successfully and without causing undue hardship for states. **If these rules are to be implemented, the timeline should follow the federal guidelines.**

In addition, we oppose the provision allowing "mission-driven nonprofit" agencies to receive enhanced rates if they allocate 90% of their total rate to the workforce. We would suggest that all providers of Medicaid services are “mission-driven” regardless of their tax status. Any enhanced rates should be value-based and directly tied to quality and cost reductions, rather than arbitrary percentages. Our focus should be on investments in innovation, training, career pathways, and quality of care, which are critical to achieving the best outcomes for both the workforce and the individuals receiving care.

Our collective organizations believe that increased funding for personal assistance services and residential habilitation is the priority. We would welcome the opportunity to make changes to this bill that would eliminate restrictive provisions which divert attention from our true imperative and pressing need; reimbursement to support competitive wages.

We urge all stakeholders to collaborate on creating a sustainable future for home-based care, prioritizing rates that support quality services over arbitrary requirements. Pennsylvania must establish a framework that effectively supports aging individuals and ensures high-quality care for all in need.

Sincerely,

Mia Haney, CEO
Pennsylvania Homecare Association

Richard S. Edley, PhD, President/CEO
Rehabilitation and Community Providers Association

Fady Sahhar, President/CEO
ProVantaCare

Carl Berry, President
PA Association of Home and Community
Based Service Providers

CC:

The Honorable Kim L. Ward
Pennsylvania State Senate

The Honorable Joe Pittman
Pennsylvania State Senate

The Honorable Jay Costa
Pennsylvania State Senate

The Honorable Joanna McClinton
Pennsylvania House of Representatives

The Honorable Matthew D. Bradford
Pennsylvania House of Representatives

The Honorable Bryan Cutler
Pennsylvania House of Representatives

The Honorable Jason Kavulich
Secretary
Department of Aging
Commonwealth of Pennsylvania
555 Walnut Street
Harrisburg, PA 17101

June 21, 2024

Via Electronic Mail

Dear Secretary Kavulich,

As the Pennsylvania Department of Aging (PDA) works to improve the network of care, housing, and infrastructure needed to support Pennsylvania's older adults, particularly as baby boomers continue to transition into retirement, we urge you to remain cognizant of the delicate ecosystem that makes up the network of supports our commonwealth's seniors rely on. While ensuring our state's older adults have critical access to protective services should be a priority, at the current moment, lack of funding and state investment in the industry is one of the largest threats to our state's seniors. Ensuring access to care through meaningful investment and addressing an ongoing workforce crisis must be the main focus.

The below-signed associations and interested parties appreciate the opportunity to comment on the proposed legislation to reform the Older Adult Protective Service Act (OAPSA) and request that the PDA reconvene a stakeholder group to discuss this in more detail. As currently drafted, we must oppose this legislation. The comments below reflect some of our current concerns as well as the nuance that providers and the Department previously negotiated following the introduction of Senate Bill 819 (R-2019). We look forward to a robust discussion with the Department and administration before further action on the proposed legislation.

Immunity

The proposed bill does not include immunity language for facilities that make good faith efforts to comply with the bill section, which outlines the hiring or retention of applicants or employees with criminal histories, including provisional hiring of those individuals. Stakeholders have advocated for language that protects the facility's liability in attempting to hire/retain employees with a criminal history. An example of this language is:

> "A facility that employs an individual shall not be held civilly liable for any action directly related to doing so in good faith compliance with subsection 702-A of this act."

Including language to protect providers that do hire applicants affected by the justice system is needed. Additionally, there is also a **lack of civil provider protections from applicants who are awarded a waiver by the department but are ultimately not hired by the employer**.

Availability of Background Checks

The current version **does not include any parameters/responsibilities for the department to meet in order to ensure adequate access to background check processing sites**. Providers advocated for these parameters to be included to ensure that obtaining a background check is not an additional barrier to employment. Among others, requirements may include:

- Ability to schedule appointments within 10 days.
- Nonstandard business hours of operation.
- At least one location in each PA County.
- Waiving background requirements if parameters were not met.

With the lack of availability of these sites, particularly in rural areas, there will undoubtedly be delays in hiring, not just for direct care but all aging services workers.

The proposed language would also **require providers** to bear the cost of these additional background checks. Costs have increased significantly over the past few years to $25.25 per Federal Bureau of Investigation (FBI) background check, plus $22.00 per criminal history record. Imposing these added costs, in addition to initial costs of onboarding and training, in the midst of a workforce crisis, for providers who are already underfunded for the care they provide further exemplifies the department's lack of understanding regarding the impact major reforms to OAPSA would have on the aging services community. While providers may elect to cover those costs, they should not be required to do so.

Background check requirements

Current law only requires federal checks on individuals who have not lived in PA for the prior two consecutive years. The proposed bill states:

> The following individuals shall submit to the criminal history information inquiry required under subsection (a):
>
> (1) An applicant.
>
> (2) An administrator who has or may have direct contact with a recipient.
>
> (3) An operator who has or may have direct contact with a recipient.

The drafted bill requires ***applicants*** to submit check prior to employment commencing. It is unclear whether current employees are "grandfathered" into the act.

"Operator" is not defined and it is unclear who that would include.

Requiring both FBI and State background checks, even for applicants, still poses a barrier for aging services providers to hire, especially when considering other prerequisites to working in long-term care, including license/certification, tuberculosis (TB) testing, etc., and the

concerns with the availability of testing sites discussed above.

Provisional hiring

The bill allows for facilities to provisionally hire an applicant who has submitted Pennsylvania State Police (PSP) and FBI background checks if the facility has no knowledge about the applicant that would disqualify the applicant from employment and the applicant swears or affirms in writing that the applicant is not disqualified from employment under this act for **a single period of 45 days.** Stakeholders **previously advocated for a provisional hiring period of 90 days**. Given the availability of background check facilities and the potential for delays or appeals, extending the provisional hiring period would be appropriate.

Mandatory reporter protections

Stakeholders advocated that language be included to protect mandatory reporters from liability for additional reporting requirements that the department may require in addition to the required reporting outlined in the bill. Sample language would be:

> "If an area agency on aging does not advise any additional reporting, a mandatory reporter shall be deemed in compliance with this chapter and relevant licensure regulations."

Additionally, the current draft states that a mandatory reporter must make an *immediate* oral report within 24 hours. The language is confusing and should require reporters to make an oral report to the Department within 24 hours.

Imprecise Definitions

To ensure consistency in applicability and capture adequately those persons, entities, and facilities who deliver care, we recommend the following changes to Section 103-A. Definitions.

- **We recommend the following change to the definition of subsection 8 within the definition of "Facility."**

  (8) Any other public or private organization, entity, person, or part of an organization that uses Medicaid funds and is paid, in part, to provide care and support to care-dependent individuals in the older adult's place of residence or preferred community-based setting.

- **We recommend the following change to the definition of "Employee" section (iii):**
  (iii) Any person who is employed or who enters into a contractual relationship to provide care to an older adult for monetary consideration in the older adult's place of residence or preferred community-based setting.

- **We recommend the following change to the definition of "Mandated Reporters":**

  Add "(6) caregivers"

It is with these initial concerns in mind that we must oppose this legislation as currently drafted. We ask that you consider the funding and workforce crises that have culminated into an access to care crisis as you consider reforms to OAPSA. Again, all of our organizations welcome the opportunity to participate in stakeholder discussion to ensure this legislation achieves its primary goal of protecting vulnerable older adults from abuse, neglect, and exploitation while still avoiding unnecessary delays in hiring and liability risks for providers.

Again, we welcome the opportunity to participate in stakeholder discussions to ensure this legislation achieves its primary goal of protecting vulnerable elderly adults from abuse, neglect, and exploitation without exacerbating workforce challenges.

CC:

The Honorable Valerie A. Arkoosh
Department of Human Services

The Honorable Matt Bradford
Pennsylvania House of Representatives

The Honorable Kim L. Ward
Pennsylvania State Senate

The Honorable Bryan Cutler
Pennsylvania House of Representatives

The Honorable Joe Pittman
Pennsylvania State Senate

The Honorable Maureen Madden
Pennsylvania House of Representatives

The Honorable Jay Costa
Pennsylvania State Senate

The Honorable Steven Mentzer
Pennsylvania House of Representatives

The Honorable Joanna McClinton
Pennsylvania House of Representatives

Pennsylvania Homecare Association

The Honorable Maureen Madden
Majority Chair
House Aging and Adult Services Committee
Pennsylvania House of Representatives
301 Irvis Office Building
Harrisburg, PA 17120-2115

The Honorable Steven Mentzer
Minority Chair
House Aging and Adult Services Committee
Pennsylvania House of Representatives
41B East Wing
Harrisburg, PA 17120-2097

Dear Chairpersons Madden and Mentzer,

I am writing on behalf of the Pennsylvania Homecare Association (PHA), representing over 700 home health, hospice, and homecare members across the Commonwealth. Our member agencies employ thousands of direct care workers and home health personnel who provide essential care to hundreds of thousands of Pennsylvanians, enabling our aging and disabled populations to remain in their homes and communities. We wish to share our feedback regarding the proposed OAPSA omnibus rewrite.

The Older Adult Protective Services Act (OAPSA) is crucial to PHA, our members, and the constituencies they serve. PHA wholeheartedly supports the primary goal of this legislation—protecting vulnerable elderly adults from abuse, neglect, and exploitation. However, we have concerns about the practical implications of the legislation as currently drafted. PHA advocates for enhanced protections for seniors, including a comprehensive overhaul of the financial protection provisions of OAPSA.

However, we oppose this bill as written and urge you to consider the consequences for the home health care and long-term care industry, specifically:

Provider/Stakeholder Input Must Be Considered to Protect Access to Care

PHA would happily participate in discussions on how to revise OAPSA to best meet the needs of the long-term care community.

Over the past several years, significant provider effort resulted in revisions to formerly proposed bills that we would welcome revisiting to be able to ensure the safety of the most vulnerable in our Commonwealth. This proposal does not address key concerns that were previously discussed at length with revision recommendations being overlooked in this current proposal. This language addressed those provisions that were overly burdensome and those that put workforce availability at risk, which in turn creates access to care issues across the long-term care continuum in the Commonwealth. Should the Department like to revisit those revision recommendations, PHA would be willing to engage in this effort.

Additional and Costly Background Checks Delay and Deter Hiring During Severe Workforce Shortage

The legislation proposes that all applicants be subject to both the state police background check and the FBI background check, the latter to be administered by the Pennsylvania Department of Aging (PDA).

This move to subject *all applicants* to the federal background check is new and problematic for the following reasons:

1. PDA, is unlikely to be able to handle the higher volume of federal background checks. Currently they are only using federal checks on individuals that have not lived in PA for the prior two consecutive years. The home health care industry alone represents 292,577 jobs in Pennsylvania. Compounded by high turnover rates that will result in multiple criminal record reviews for the same individual who is changing employers, it is unlikely PDA will be capable of keeping pace with this increased workload without considerable investment from the Department.

2. The cost of these additional background checks will be borne by facilities. The cost has increased significantly over the past few years to $25.25 per FBI background check, plus $22.00 per criminal history record. Facilities having to now bear this cost for *all applicants* plus the proposed training requirements, which would result in additional wages, means that providers will have to make cuts in other places. Additionally, the Department must consider that reimbursement rates for set by the state for public assistance programs, such as Home and Community Based Services, will now need to reflect these additional costs in their rate setting methodologies, increasing budgetary costs that are not directly reflected in this proposed legislation. For providers such as those who offer Office of Long Term Living Personal Assistance Services, reimbursement rates of just over $20/hour mean that increases to hiring costs will mean cuts to other areas of the program, potentially impacting quality of care or workforce benefits.

3. Medicaid beneficiaries receiving personal assistance services who choose to hire their own caregivers and direct their own care without an agency would also be required to the new background check requirements at the expense of the Commonwealth.

4. FBI fingerprint locations already are limited, especially in rural areas, and many have wait times for applicants to secure appointments, which will result in delays to hiring and thus access to care limitations. Applicants often end up spending significant time and money traveling to far locations for fingerprinting. This exacerbates an already precarious workforce crisis, especially for caregiving and nursing positions and places undue burden on this workforce.

Department of Aging as an Employment Clearing House Diminishes a Workforce Already in Crisis

This legislation proposes that the Department of Aging takes the responsibility of acting as a clearinghouse for both the Pennsylvania State Police criminal history report as well as the FBI fingerprinting and background checks for all applicants for employment, which in the long-term care industry will be thousands of individuals monthly. Currently, the Department only acts as an intermediary for FBI checks for a limited population of applicants – only individuals who have not lived in the state of Pennsylvania for the two years immediately preceding their application for employment.

PHA has serious concerns that the Department will create lengthy delays in the hiring process for Pennsylvania's critical home healthcare workforce. The proposed legislation requires that the Department make a determination with 30 days, a timeframe within which an applicant could find employment outside of the industry. Policy should dictate that we push people towards this profession,

not away from it. Furthermore, for the critical Direct Care Workforce, 30 days without employment hinders their ability to feed their families, pay rent and provide basic essentials for everyday life. While 30 days may seem satisfactory to a government entity, we assure you, this is unacceptable in real world applications.

The Department's increase in workload to act as a criminal record clearing house will be exponential compared to what they process today. The impacts of any delay to hiring, let alone delays that are weeks long (as that is the current wait time for FBI fingerprint processing) could be crippling to care delivery in Pennsylvania.

Lack of Employer Transparency in Hiring Decisions and Waiver Process

While we appreciate the Department's recognition that the legislation must reflect a due process option for individuals who have been deemed ineligible for employment, we must point out the lack of transparency for the employer who would no longer be a part of the deliberation surrounding the criminal conviction, and thus no longer responsible for the hiring decisions, or termination decision if provisionally hired.

In discussions with the Department regarding previous iterations of OAPSA, Department staff have repeatedly told providers that they would receive a notice stating only whether an applicant could be hired or not. They are not able to disclose what is on a criminal history check that was submitted to them, leaving the would-be-employer with only a portion of the information to make a hiring decision. Confounding the issue, OAPSA bills that had been previously introduced did not provide immunity for providers who hired someone with a waiver without knowing the full history of who they were hiring, leaving them in a difficult position whether to hire or not.

Furthermore, without this information, employers are less likely to take advantage of the waiver process as they would not be aware of why the applicant was denied employment in the first place. Applicants would likely be offput by the lengthy time to 1. Receive an employment determination, 2. Apply for a waiver and 3. Await department decisioning on a waiver application, deteriorating the workforce. In many home care programs, employees are family members or close friends to the patient. The department will see a volume of waiver applications from these models of care that are likely unprecedented. Determinations could result in a family member unable to care for their aging or ill loved one. Without a fair, timely and transparent waiver process, the industry could be left with a dwindling workforce that cannot meet the demand of Pennsylvania's aging population.

Excessive Conviction List Limits Workforce Availability

The list of convictions, which is much longer than those included in the original OAPSA statute, must be revisited to ensure that the prohibitions do not prevent employment for individuals that are otherwise qualified. For instance, there is a prohibition on employment for five years for anyone convicted of check fraud. This seems obvious to prevent the employment of someone who may be more likely to steal an older adult's money. However, many applicants for caregiving are low-income, single mothers who are working multiple jobs to make ends meet. There is a very real possibility that these individuals might have to choose to write a check for rent that they know will bounce and buy groceries or go without food for their families.

A thorough review of the list of criminal convictions contained in the legislation is necessary to make sure that the bill serves its intended purpose.

Grandfathering of Current Workforce

PHA would also like to address the issue of "grandfathering" for current employees. The homecare industry is unique in that placement of employees is not simply about filling open positions. Our agencies work to place care workers in the homes of individuals where the worker is essentially "part of the family." For those employees who have been providing care to a consumer for several years, PHA respectfully recommends that the care worker be grandfathered under this legislation.

Provisional Hire Policies Diminish Workforce Hiring, Deter Workforce from the Industry, and Disparately Impact Rural Providers

Current language includes a provisional hiring period of 45 days, which conflicts with currently established Department of Health provisional hiring periods of 30 or 90 days, depending on whether an individual has lived in the Commonwealth in the 2 years prior to hire. Contradictory regulations confuse providers and hinder the use of provisional hiring. Without effective provisional hiring, the workforce time to hire will increase dramatically, adding a waiting window for 1. a criminal history check, 2. An FBI fingerprint check (which has to occur at a live site with available appointment times) and 3. a Department issued "eligibility for hire" designation following the review of #s 1. and 2.

PHA estimates this will delay hiring by 4 – 12 weeks, disparately impacting rural providers where fingerprinting locations and available appointments are scarce. This will also deter individuals from entering the home based care industry, as they can get hired more quickly in other industries.

Immunity for the Provider Community

First and foremost, the legislation, as currently drafted, does not contain any language that addresses immunity from civil liability for providers. The following is current law:

"§ 10225.503. Grounds for denying employment.

> (c) Immunity.--An administrator or a facility shall not be held civilly liable for any action directly related to good faith compliance with this section."

"§ 10225.707. Immunity.
An administrator or a facility shall not be held civilly liable for any action directly related to good faith compliance with this chapter."

The homecare provider community is unaware of the policy determination behind the repeal of these sections from the OAPSA bill. Our providers already face the difficult task of appropriately placing care workers and home health workers with clients. With a workforce shortage already taking a toll on the home health industry, a provider who acts in good faith to their detriment based on a decision rendered by the Department of Aging should not be punished. Accordingly, we respectfully request that you replace the immunity language that is currently removed from OAPSA in your legislation.

Improved Data Transparency

As previously advocated for, improved transparency of data regarding older adult protective services and the needs of the Commonwealth would better inform revisions to OAPSA and help secure stakeholder consensus for provisions of the act and their applicability. We continue to advocate for this data transparency.

Conclusion

Historically, PHA has been an active partner in providing feedback and thought leadership on various proposals pertaining to OAPSA, which have included cumbersome hurdles to hiring practices for all long-term care providers. While PHA recognizes the need for concrete guidance on hiring practices, we caution that elements of the current proposal will create new, less-desirable challenges.

In summary, it is crucial to balance the need for thorough background checks and employment restrictions with the realities of workforce shortages and the practical challenges faced by providers. Overly stringent regulations may hinder the ability to provide quality care and meet the growing demand for services.

We welcome the opportunity to participate in stakeholder discussions to ensure this legislation achieves its primary goal of protecting vulnerable elderly adults from abuse, neglect, and exploitation without exacerbating workforce challenges.

Sincerely,

Mia Haney
Chief Executive Officer

Alexandra McMahon
Director of Government Relations

PRIOR PRINTER'S NO. 132 PRINTER'S NO. 951

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 155 Session of 2023

INTRODUCED BY SANCHEZ, MADDEN, GUENST, HANBIDGE, STURLA, FRANKEL, HILL-EVANS, DELLOSO, HOWARD, BURGOS, D. WILLIAMS, CERRATO, VENKAT, SCHLOSSBERG, McNEILL, MULLINS, BENHAM, T. DAVIS, WEBSTER, SOLOMON, RADER, BRENNAN, ROZZI, HARKINS, N. NELSON, SHUSTERMAN, OTTEN, CONKLIN, BENNINGHOFF, KHAN AND MALAGARI, MARCH 8, 2023

AS REPORTED FROM COMMITTEE ON HEALTH, HOUSE OF REPRESENTATIVES, AS AMENDED, APRIL 21, 2023

AN ACT

Amending the act of July 19, 1979 (P.L.130, No.48), entitled "An act relating to health care; prescribing the powers and duties of the Department of Health; establishing and providing the powers and duties of the State Health Coordinating Council, health systems agencies and Health Care Policy Board in the Department of Health, and State Health Facility Hearing Board in the Department of Justice; providing for certification of need of health care providers and prescribing penalties," in licensing of health care facilities, further providing for consumer protections; and abrogating a regulation.

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. Section 806.3(b)(7) of the act of July 19, 1979 (P.L.130, No.48), known as the Health Care Facilities Act, is amended to read:

Section 806.3. Consumer protections.

* * *

(b) Information to be provided.--Each consumer or the consumer's legal representative or responsible family member

shall receive an information packet from the home care agency or home care registry prior to the commencement of services which includes the following in a form that is able to be easily understood and read:

* * *

(7) Documentation from the home care agency or a home care registry that demonstrates personal face-to-face interviews with all employees from a home care agency or independent contractors referred by the home care registry and documentation of at least two satisfactory reference checks prior to referral to the consumer. The face-to-face requirement of this paragraph may be fulfilled through the use of two-way video ~~or other~~ remote technology. <--

* * *

Section 2. The provisions of 28 Pa. Code § 611.51(a)(1) are abrogated to the extent of any inconsistency with this act.

Section 3. This act shall take effect immediately.

ALLOW VIRTUAL INTERVIEWS IN HOMECARE HIRING

BACKGROUND

Current regulations at 28 Pa. Code §611.51(a)(1) require providers to conduct "face-to-face" interviews prior to hiring direct care workers (DCWs).

However, between 2020 and 2022, a COVID-19 waiver enabled homecare agencies to conduct remote video interviews with DCWs, resulting in efficient hiring practices with no adverse effects on consumers.

CALL TO ACTION

Support House Bill 155. Allow homecare providers across Pennsylvania to conduct remote 'face-to-face' interviews.

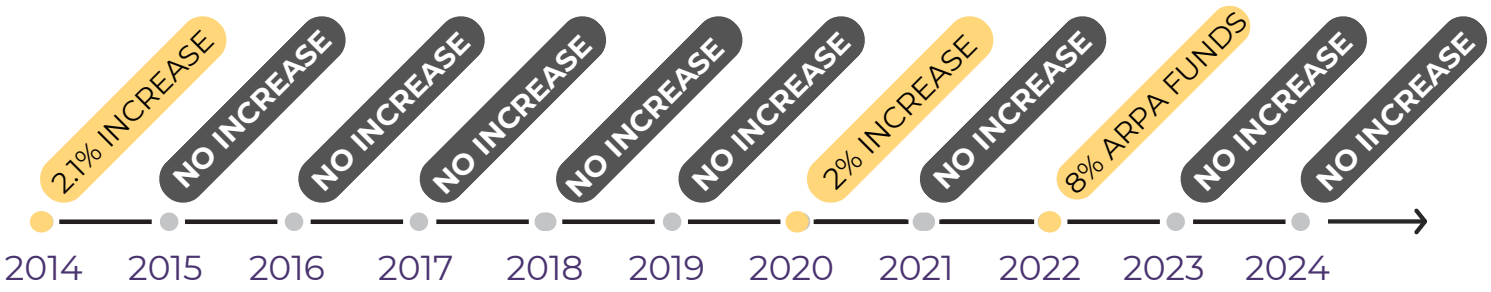
Virtual interviews are easier to schedule and conduct, eliminating transportation costs and obstacles to hiring for the direct care workforce.

This will help to ensure that individuals in need have timely access to a quality workforce.

OUR POSITION

- Homecare agencies in Pennsylvania face severe workforce shortages, requiring efficient recruitment and onboarding support for quality caregivers.
- Pennsylvania's Department of Labor predicts a demand for 65,000+ DCWs in the near future to address workforce shortages.
- Many DCWs rely on public transportation or hold multiple jobs, posing challenges for scheduling in-person interviews.
- The interview phase is part of a multi-step onboarding process, allowing providers ample opportunity to implement recruitment and retention best practices.
- Flexibility ensures Pennsylvania avoids unnecessary barriers to critical care access for vulnerable citizens.
- Several agencies obtained permanent exceptions to the PA Department of Health's rule interpretation; supporting this change extends flexibility to all providers.

Support Rate Increases for Direct Care Workers



BACKGROUND

The need for in-home personal assistance services has surged in recent years. Aging adults and adults with disabilities prefer to be cared for in the comfort of their homes, where they experience better health outcomes. Notably, home care is also cost-effective, with institutional care costing 117% more.

PA faces a significant workforce shortage, ranking fifth in the nation for the need for Direct Care Workers (DCWs). By 2035, the state is projected to require 65,370 more DCWs. This shortage has critical implications for access to care and quality of care across the Commonwealth, particularly for the more than 130,000 Medicaid home care recipients currently relying on these services.

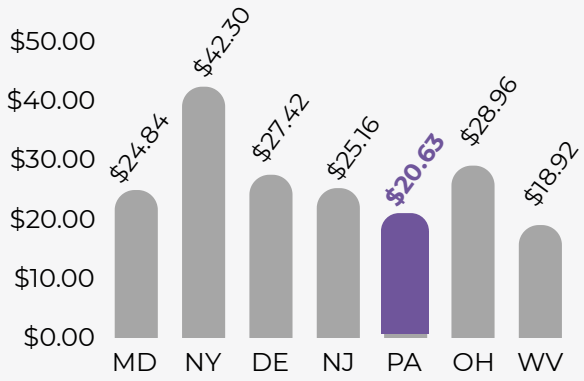
CALL TO ACTION

- **Support a 10% increase** for Personal Assistance Services in the Office of Long Term Living (OLTL) programs; a $212M annual impact in state funding.
- Support language that requires the Office of Long-Term Living to **review rates at least every three years** consistent with other PA programs.

	Current Rate	Proposed Rate
Region 1 (Pitt)	$ 19.32	$ 21.25
Region 2	$ 21.48	$ 23.63
Region 3	$ 20.20	$ 22.22
Region 4 (Phila)	$ 21.52	$ 23.67

OUR POSITION

- Pennsylvania Direct Care Workers (DCWs) earn $13.94/hour[1]. However, employer taxes and regulatory mandates consume reimbursement, hindering:
  - Fair DCW compensation commensurate with the important work they perform
  - Sufficient investment in quality and innovation
- Reimbursement rates have not kept pace with inflation and increased cost of care.
- Pennsylvania's critical underfunding of this program exacerbates the workforce crisis in comparison to neighboring states:



- PA has varying Medicaid program rates due to disparities in rate review and study practices. Consequently, OLTL programs are left significantly underfunded.

1 https://www.bls.gov/oes/current/oes_pa.htm#39-0000

January 18, 2024

The Honorable Josh Shapiro
Governor
Commonwealth of Pennsylvania
508 Main Capitol Building
Harrisburg, PA 17120
Via Electronic Mail

Dear Governor Shapiro:

On behalf of the Pennsylvania Homecare Association (PHA), a statewide association representing nearly 700 homecare, home health, hospice, and supporting organizational members, I write in advance of your 2024-25 Executive Budget address to urge you to include an increase in funding for programs and services that will enhance the quality of life for vulnerable populations, as previously discussed with members of your administration.

PHA represents nursing, therapy, non-medical personal assistance services (PAS), and end-of-life care in hundreds of thousands of individual's homes across the Commonwealth. Many of the services are provided through Pennsylvania's Medical Assistance program and require an investment of state funds. Without the necessary funding, home-based care providers cannot compete in the marketplace for qualified employees because they cannot offer competitive wages. Unlike providers who provide care to non-Medicaid recipients, Medicaid-enrolled providers are unable to pass costs through to their consumers and patients. Recent increases have not kept pace with inflation, nor do they reflect the actual cost of delivering high quality care.

In Pennsylvania the average Medicaid fee-for-service reimbursement rate for personal assistance services is $20.63 per hour, which is significantly less than nearly all the bordering states. While some neighboring states have a moderately higher average cost of living per U.S. News and World Report, it is especially notable that Ohio recently increased rates while ranking below Pennsylvania in average cost of living. Additionally, Pennsylvania ranks fifth among all the states in population of adults 65 years or older, with the population of adults over 85 years of age with more acute needs growing at more than 10 times the general population.

Medicaid Fee – for – Service Rates for Personal Assistance Services

State	Hourly Rate	Average Cost of Living Per Year [1]
Pennsylvania	$20.63	$40,066
New York	$42.30	$49,623
New Jersey	$25.16	$49,511
Maryland	$47.00	$48,235
Ohio	$28.96	$35,932
Delaware	$27.42	$44,389
West Virginia	$18.92	$34,861

[1] Examining The Cost Of Living By State In 2024

Private Duty Nursing Medicaid Fee – for – Service Rates

State	Hourly Rate Registered Nurse (RN)	Hourly Rate Licensed Practical Nurse (LPN)
Pennsylvania	$66.20	$44.08
New Jersey	$63.00	$51.00
Maryland	$71.27	$46.18
Connecticut	$59.17	$50.06
Delaware	$63.66	$57.04
Virginia	NOVA: $81.62 Rest of State: $71.29	NOVA: $71.29 Rest of State: $52.40

The reality is direct care workers, nurses, and home health aides providing care to the most vulnerable communities are not being paid competitive wages that reflect the valuable work that they do. Retaining workers in a field with an average turnover rate of 40 to 60 percent each year is an impossibility with the current level of state support. If home health care agencies are going to attract and retain a highly qualified workforce, Pennsylvania's Medical Assistance programs must be funded appropriately.

We commend you for your allocation of state funds to offset expiring federal ARPA funds during the current 2023-24 fiscal year, and we hope that commitment to retain previous increases is included in your upcoming proposal. Further, we recognize the recently-announced grant funding available through the Department of Labor and Industry to bolster programs that support the direct care workforce. That said, more must be done.

Over a decade of chronic underfunding as a result of largely stagnant Medicaid rates for personal assistance services has placed a severe strain on homecare agencies across the Commonwealth – additional funding is needed now. By directing additional funding to the Community HealthChoices waiver, pediatric home health aide services, pediatric shift nursing services, and adult shift nursing services, you will help to incentivize individuals to join and remain in the caregiving workforce, which will protect access to high quality home-based care for thousands of Pennsylvanians every day.

The challenges facing Pennsylvania’s health care continuum and broader economic health are worsening with an increased demand for health care and long-term care services predicted in the coming years. The burden placed on family caregivers has already had downstream impacts on the state’s broader workforce and economy, and the outlook remains negative without significant investment in supporting a stable, sustainable homecare workforce.

I urge you to prioritize individuals who rely on home-based care as a lifeline as well as caregivers providing that critical care in this year’s budget. Pennsylvania’s economic viability depends upon it.

Sincerely,

Mia Haney

Mia Haney
Interim CEO
PA Homecare Association

cc: The Honorable Uri Monson
Governor’s Office of Budget

The Honorable Kim L. Ward
Pennsylvania State Senate

The Honorable Joe Pittman
Pennsylvania State Senate

The Honorable Jay Costa
Pennsylvania State Senate

The Honorable Joanna McClinton
Pennsylvania House of Representatives

The Honorable Matthew D. Bradford
Pennsylvania House of Representatives

The Honorable Bryan Cutler
Pennsylvania House of Representatives

Pennsylvania Homecare Association

The Honorable Scott Martin
Majority Chair
Senate Appropriations Committee
281 Main Capitol
Harrisburg, PA 17120

The Honorable Vincent Hughes
Minority Chair
Senate Appropriations Committee
545 Main Capitol
Harrisburg, PA 17120

The Honorable Jordan Harris
Majority Chair
House Appropriations Committee
512E Main Capitol Building
Harrisburg, PA 17120

The Honorable Seth Grove
Minority Chair
House Appropriations Committee
245 Main Capitol Building
Harrisburg, PA 17120

June 27, 2024

Re: Fiscal Code Rate Considerations for Home Health Care Services within the Department of Human Services

Dear Chairmen:

The Pennsylvania Homecare Association (PHA) is a statewide membership association with approximately 700 home health, homecare and hospice members across Pennsylvania. On behalf of our members, we offer the following comments regarding increased reimbursement rates that **support compensation for Direct Care Workers, Nurses and Home Health Aides across the Commonwealth.**

Personal Assistance Services (PAS) - Office of Long-Term Living

1. **Current reimbursement rates are insufficient to support this critical Direct Care Workforce:** Since the last Department commissioned rate study in 2010, several factors necessitate a re-evaluation and adjustment of the current rates. The primary drivers for this request include:

    - **Increases in Minimum Wage**: *A rising minimum wage will significantly impact labor costs across both models of Personal Assistance Services: Consumer-directed and Agency Model care.* Increases to minimum wages apply equally to both models. Ensuring competitive compensation is crucial to attract and retain a qualified workforce.
    - **Inflationary Effects**: General inflation has increased the cost of goods and services, impacting operational costs for providers.
    - **Workforce Compensation**: Adequate compensation for Direct Care Workers is essential to secure a stable and skilled workforce capable of delivering quality care to vulnerable patients.

2. **Support 10% rate adjustment for PAS in both consumer-directed and agency models:**
Recent legislation (HB2372) was proposed to increase PAS rates disproportionately for the agency model by 10% and the consumer-directed model by 16%.

PHA is writing to advocate for an equitable adjustment in reimbursement rates of 10% for both models of Personal Assistance Services (PAS).

By aligning both models to the same % increase, we equally prioritize all workers in these programs.

3. **Historically both the consumer-direct and agency models of care have received equal % rate adjustments, setting precedent and aligning with third party rate setting methodologies:** The state has a long history of proportionally increasing PAS rates regardless of the existing two models of care: consumer-directed or agency model. We ask that that practice of giving the same % increase to both models continue. The current rate setting methodology was established through a study conducted by Mercer and commissioned by the Department of Public Welfare. This methodology identified differences in reimbursement between consumer-directed services and the agency model. This study took into account the varying requirements and administrative burdens associated with each model. While both service models fundamentally provide similar care, the agency model incurs significantly higher administrative responsibilities, compliance requirements, quality assurance, and oversight, justifying the current rate differential.

Reimbursement increases that are inequitable, or that only recognize one model of care, would fail to recognize the inherent regulatory differences between the models. This approach would be inequitable, break historic precedent, disregard previously commissioned rate setting methodologies, and would further destabilize this workforce population that is already in crisis.

As the budget is discussed, the rates that should be increased proportionally are the following HCPCS codes found at this OLTL HCBS fee schedule:

- W1793 (agency PAS)
- W1792 (consumer-directed PAS)
- W1792 TU (consumer-directed PAS overtime)
- T1005 Respite (agency Respite)
- S5150 (consumer-directed Respite)

Adult and Pediatric Shift Nursing & Home Health Aides Services - Office of Long Term Living and Office of Medical Assistance Programs

We also urge our legislative leaders to increase funding for the pediatric and adult shift nursing programs. Nurses and home health aides working in this program provide life sustaining care to more than 13,000 medically complex children, adults, and seniors in the Commonwealth. Because of years of inadequate reimbursement rates, children are spending much more time in the hospital (in some cases over 800 days) because the industry does not have the nurses needed to bring these individuals home. This negatively impacts the patient and their families, causing financial distress to them and to Pennsylvania. We ask that you support these programs by:

1. **Increasing the pediatric shift nursing rates by $5 per hour**
2. **Increase the pediatric home health aide rate delivered in conjunction with nursing by 10%.**
3. **Standardize the shift nursing rate under OLTL to $55 per hour.**

We urge you as appropriators to take this request into account as the details of the budget are finalized. The sustainability of home and community-based services depends on adequate funding and support. By addressing these financial challenges, we can continue to provide essential services to our most vulnerable populations and ensure that they receive the care they deserve.

Thank you for your attention to this matter. Should you require any additional information or wish to discuss this further, please do not hesitate to contact me

Sincerely,

Mia Haney, CEO
Pennsylvania Homecare Association
MHaney@pahomcare.org

CC:

The Honorable Kim L. Ward
Pennsylvania State Senate

The Honorable Jay Costa
Pennsylvania State Senate

The Honorable Matthew D. Bradford
Pennsylvania House of Representatives

The Honorable Joe Pittman
Pennsylvania State Senate

The Honorable Joanna McClinton
Pennsylvania House of Representatives

The Honorable Bryan Cutler
Pennsylvania House of Representatives

Pennsylvania Homecare Association

Deputy Secretary, Juliet Marsala
Department of Human Services
Office of Long–Term Living
555 Walnut Street, Forum Place 6th Floor
Harrisburg, PA 17101

Amy Korzenowski, LHSE, Principal
Mercer
akorzenowski@mercer.com

Dear Deputy Secretary Marsala and Ms. Korzenowski:

I am writing on behalf of the Pennsylvania Homecare Association (PHA), representing over 700 home health, hospice, and homecare members across the Commonwealth. Our member agencies employ thousands of direct care workers and home health personnel who provide essential care to hundreds of thousands of Pennsylvanians, enabling our aging and disabled populations to remain in their homes and communities.

The rate study Mercer is conducting on behalf of the Office of Long Term Living is of significant interest to our membership. **We commend OLTL for initiating this rate study which has the ability to inform future rate setting methodologies and reimbursement.** The need for this study and subsequent rate adjustments has grown significantly over the 10+ years since this was last conducted and the workforce challenges that our providers face are at an all–time high. We hope that OLTL policymakers, along with our Governor's office, will consider ongoing rate reviews in the future of no less than every three years for OLTL programs, akin to other similar HCBS programs in Pennsylvania.

PHA and its membership recognizes that the current rate study is being conducted in an expedited manner to meet forecasting and budgeting needs. However, our membership is concerned that these condensed time frames could jeopardize the quality of the data provided *OR* result in an incomplete depiction of the true cost of care. In an effort to address this concern, **our membership has collectively gathered the below information to help inform data capture, collection and analysis related to this rate study, particularly for the provision of Personal Assistance Services.**

We welcome engagement from Mercer as they further conduct this analysis and would be happy to provide additional feedback and input throughout the process.

Considerations/Recommendations

1. **QuestionPro Provider Survey:**
    a. **Provider Education**: Implement training how–to guides and webinars to educate providers on the Provider Survey to be released via QuestionPro. This will ensure the information provided is accurate and comprehensive.
    b. **Confidentiality Commitments**: Ensure that Mercer/OLTL includes a privacy notice or confidentiality agreement for providers completing the Question Pro survey. Many organizations will not submit information without such commitments from the state.

2. **Market Analysis**:
    a. **Multi-Industry Approach:** Conduct a thorough market analysis of industries competing for the same workforce, including retail stores, gas stations, and other customer service industries.
    b. **Regional (State by State) Rate Comparison**: Analyze rates in regional area or neighboring states and consider their rate–setting methodologies to ensure a comprehensive and competitive approach for Pennsylvania. This will ensure that caregivers in Pennsylvania that live near the state border do not secure work in other states due to higher pay wages.
3. **Addressing Current and Future Demand**: Given that the prior rate study was conducted over a decade ago, it is crucial to account for current and projected demands for HCBS services in this rate study. Rates must support a workforce poised to meet the growing needs of Pennsylvania's expanding aging population, reflecting these well–documented trends.
4. **21st Century Cures Act Compliance**: While initial intentions were that the Electronic Visit Verification requirement of the 21st Century Cures Act would not financially impact providers, providers across the nation argue otherwise. The costs of EVV software and the administrative investment costs for the management of the service verification process have resulted in many organizations increasing FTE headcounts significantly to 1. ensure compliance, 2. combat fraud waste and abuse, and 3. prevent audits or takebacks from unintended misuse of the system.
5. **CMS Final Rule Consideration:** Given the historic precedent of infrequent rate studies, this study should include recommendations for consideration of the 80/20 provision of the recently released CMS final rule that is scheduled to be implemented in 2030. The impact of this provision to the provider community is significant and should be accounted for in this rate study.
6. **State Policy Goals**: Align the rate–setting process with state policy goals, such as promoting community–based care over institutional care, improving patient outcomes, and driving improvements in quality of care. Eliminating non-required or non-regulatory functions from the rate study consideration jeopardizes future enhancements and improvements in care delivery. It also does not account for the preventative nature of HCBS spending compared to more costly institutional interventions.
7. **Attracting Qualified Staff**: Ensure rates are sufficient to attract and retain qualified staff capable of providing high–quality care. The workforce crisis continues to escalate across the nation, but especially in Pennsylvania where the volume of the aging population is among the highest in the country.
8. **Inflation and Cost Adjustments**: Adjust rates to account for inflation and increases in the costs of goods and services both historically and into the future.
9. **Stakeholder Feedback**: Gather robust input from stakeholders, including feedback from recipients and their families, regarding access to and quality of care.
10. **Equitable Access**: Ensure rates support equitable access to care across different communities, including underserved areas.
11. **Cultural Competence**: Set rates that allow providers to offer culturally competent care to diverse populations, especially those where English is a second language.

Direct Costs for Agencies

Categories	Area of Cost	Regulatory Body
Direct Wages	Direct care hours	FLSA
	Training hours	FLSA, OLTL, DOH
	Travel time	FLSA
	Show up time (employee arrives, customer not home)	FLSA
	Sick time	City of Philadelphia
	Paid time off	*Agency policies to remain competitive*
	Overtime	FLSA
	Employment orientation	FLSA
	Deeming competence in direct care	DOH
Insurance and Taxes	Workers Compensation Costs	OLTL
	Payroll Related Taxes (Social Security, Medicare)	SSA
	Unemployment Insurance	DOL
Onboarding Expenses	PPE (gloves, masks, hand sanitizer, gowns)	DOH
	TB testing (up to an including chest x–ray) on hire and ongoing	DOH/CDC
	Hepatitis B vaccination	OSHA
	Scrubs/Uniforms	*Agency policies to remain competitive*
	Background Checks (criminal $22, FBI Dept of Aging $25.25, FBI CPS $25.25, Child abuse $13)	OAPSA, CPSL, DOH, OLTL
	Social Security Number Verification	OLTL
	Training for mandated reporters (if any likelihood of child in the home)	CPSL
	Initial and monthly Medicaid, Medicare Fraud Checks	OLTL
	Department regulated ID Badges	DOH
Perks and Benefits	401k administration and matching	*Agency policies to remain competitive*
	health insurance	ACA
	ancillary benefits, including dental, vision, STD, etc	*Agency policies to remain competitive*
	Appreciation Bonuses, Sign–on Bonuses, and Performance Bonuses	*Agency policies to remain competitive*

General and Administrative Agency Costs

Quality	Trainers	OLTL, DOH
	Training equipment	OLTL, DOH
	Patient Health Outcome Innovation and Initiatives	OLTL
	Coordination with SCE and Case Management entities	OLTL
	Quality Management Plan administration and oversight	OLTL
	Supervisory team, often including nursing staff, performing start of care visits, delivering and reviewing	DOH, OLTL

	consumer protections, for oversight of care, workforce training and support and advisement for improved patient outcomes	
Insurance	Commercial General Liability Insurance Costs	OLTL
	Professional Liability Insurance	OLTL
Compliance	TB Maintenance Program (annual TB risk assessment)	CDC/DOH
	Incident Reporting	DOH, OAPSA, APS, CPS, OLTL, MCOs
	HIPAA (including staff training)	OLTL, HIPAA
	Americans with Disabilities Act	ADA
	OSHA, including administration of annual OSHA Reporting, including ongoing data capture of workplace injuries	OSHA
	QMET	OLTL
	DOH	DOH
	Cost of annual licensure	DOH
Workforce	English Proficiency/ESL services and supports	OLTL
	Oversight of DCW for provisional hiring	OLTL, DOH
	Marketing/Advertising	Standard business expenses
	Workforce Development Initiatives	DHS
Operations	Brick/mortar office space (required for licensure)	DOH
	Office equipment (printer, fax, software licenses, etc)	Standard business operating expenses
	Office Expenses	DOH, Standard business expenses
	Accounting support (financial solvency, tax returns, balance sheets and other requirements for validation, audits for audited financials as required in Medicaid revalidation)	OLTL, DHS
	Payroll support	FLSA
	Medicaid revalidation support	ACA
	Billing and Accounts Receivable	OLTL
	Scheduling and Case Management Support	OLTL, DOH
	Service Verification Support (EVV verification)	OLTL, 21st Century Cures Act
	Provider Monitoring/Oversight	OLTL, QMET, BPI, BFO, OIG
	Talent Acquisition/Workforce Development	Standard business operating expenses
	Human Resources Support	Standard business operating expenses
	Administrative Salaries	Standard business operating expenses
	Training and Professional Development	Standard business operating expenses
	Travel (including mileage for supervisory staff) and	Standard business

	Transportation	operating expenses
	Technology Support to support integrations with the state aggregator, clearing houses, etc	21st Century Cures Act, DHS
Technology	Computers	21st Century Cures Act, DHS
	Electronic Visit Verification Software, maintenance	21st Century Cures Act, DHS
	Record Retention firms (ex: Iron Mountain)	OLTL, DOH, DOL, HIPAA, etc
	Satisfaction/Complaint Survey (NPS, eNPS, etc)	OLTL
	Phone Systems	Standard business operating expenses
	Fax	Standard business operating expenses
	Websites	Standard business operating expenses
	Texting technology for mass communication with DCWs	Standard business operating expenses
	Cybersecurity measures	HIPAA
Miscellaneous	Dues for professional associations, subscriptions to industry publications	Standard business operating expenses
	Accreditation	Standard business operating expense
	Legal Fees	Standard business operating expenses
	Consulting Services	Standard business operating expenses

Historically, PHA has been an active partner in providing feedback and thought leadership to enhance the Department of Human Services program. We welcome the opportunity to participate in stakeholder discussions to ensure this rate study achieves its primary goal of protecting the important population receiving these services and securing a quality and sufficient workforce to meet growing demands.

Sincerely,

Mia Haney
Chief Executive Officer

Alexandra McMahon
Director of Government Relations

2024 COMMUNITY HEALTHCHOICES AGREEMENT

Table of Contents

APPENDICES

1	Community HealthChoices RFP
2	Proposal
3a	Explanation of Capitation Payments
3b	Medical Loss Ratio (MLR) Reporting and Remittance Requirements
3c	Capitation Rates
3d	Overview of Methodologies for Rate Setting
3e	Participant Enrollment Mix Adjustment
3f	Peer Group 13 Risk Pool
3g	COVID-19 Vaccine Non-Risk Arrangement
4	Community HealthChoices Revenue Sharing
5	In Lieu of Services (ILOS)

AGREEMENT EXHIBITS

A	Covered Services List
B	Standard Terms and Conditions for Services
B(1)	DHS Addendum to Standard Contract Terms and Conditions
C	Managed Long-Term Services and Supports Regulatory Compliance Guidelines
D	Drug Services
E	Prior Authorization Guidelines for CHC-MCOs
F	Quality Management and Utilization Management Program Requirements
G	Complaint, Grievance, and Fair Hearing Processes
H	Coordination with BH-MCOs
I	Guidelines for CHC-MCO Advertising, Sponsorships, and Outreach
J	Participant CHC-MCO Selection and Assignment
K	CHC-MCO Participant Coverage Document
L	Participant Rights and Responsibilities
M	Participant Handbook
N	Provider Directory
O	CHC Audit Clause
P	Required Contract Terms for Administrative Subcontractors
Q	Reporting Suspected Fraud, Waste, and Abuse
R	Behavioral Health Mixed Services Protocol
S	Provider Manual
T	Provider Network Composition/Service Access
U	Provider Agreements
V	Requirements for Provider Terminations

W External Quality Review
W(1) Critical Incident Reporting and Management and Provider Preventable Conditions/Preventable Serious Adverse Events Reporting
W(2) Healthcare Effectiveness Data and Information Set (HEDIS®) and Consumer Assessment of Healthcare Providers and Systems (CAHPS®)
X Encounter Data Submission Requirements and Sanction Applications
Y Guideline for Sanctioning Regarding Fraud, Waste, and Abuse
Z Person-Centered Service Planning
AA Managed Care Definitions for Participant Communications
BB CHC Waiver Assurance Performance Measure Requirements and Sanctions
CC Financial Management Services (FMS)
DD(1) CHC-MCO Pay for Performance
DD(2) Nursing Facility Quality Incentive Program
EE Opioid Use Disorder Centers of Excellence
FF Requirements for Non-Commonwealth Hosted Applications/Services

AGREEMENT ACRONYMS

For the purpose of this Agreement, the acronyms set forth shall apply.

ACA — Affordable Care Act.
ADA — Americans with Disabilities Act.
ADL — Activities of Daily Living.
APS — Adult Protective Services.
BH — Behavioral Health.
BHA — Bureau of Hearings and Appeals.
BH-MCO — Behavioral Health Managed Care Organization.
BLE — Benefit Limit Exception.
BPI — Bureau of Program Integrity.
CAHPS — Consumer Assessment of Healthcare Providers and Systems.
CAO — County Assistance Office.
CBO—Community Based Organization.
CDC — Centers for Disease Control and Prevention.
CHC — Community HealthChoices.
CHC-MCO — Community HealthChoices MCO.
CHS — Contract Health Services.
CLIA — Clinical Laboratory Improvement Amendment.
CMN — Certificate of Medical Necessity.
CMS — Centers for Medicare & Medicaid Services.
COB — Coordination of Benefits.
CRNP — Certified Registered Nurse Practitioner.
DD — Developmental Disabilities
DEA — Drug Enforcement Agency.
DESI —Drug Efficacy Study Implementation.
DME — Durable Medical Equipment.
DOH — Department of Health of the Commonwealth of Pennsylvania.
D-SNP — Dual Eligible Special Needs Plan.
DHS — Department of Human Services of the Commonwealth of Pennsylvania.
DRG — Diagnosis Related Group.
DUR — Drug Utilization Review.
eCIS — Client Information System.
ED — Emergency Department.
EOB — Explanation of Benefits.
EQR — External Quality Review.
EQRO — External Quality Review Organization.
EVV — Electronic Visit Verification.
EVS — Eligibility Verification System.
ERISA — Employees Retirement Income Security Act of 1974.
FDA — Food and Drug Administration.
FFS — Fee-for-Service.
FMS — Financial Management Services.

FQHC — Federally Qualified Health Center.
FTP — File Transfer Protocol.
HBP — Healthy Beginnings Plus.
HCAC — Healthcare-Acquired Condition.
HCBS — Home- and Community-Based Services.
HEDIS — Healthcare Effectiveness Data and Information Set.
HIPAA — Health Insurance Portability and Accountability Act.
HIPP — Health Insurance Premium Payment.
HMO — Health Maintenance Organization.
IADL — Instrumental Activities of Daily Living.
ICN – Internal Control Number.
ID — Intellectual Disability.
IEB — Independent Enrollment Broker.
IHS — Indian Health Service.
IRM — Information Resource Management.
IRO — Independent Review Organization.
LEP —Limited English Proficiency.
I/T/U — Indian Tribe, Tribal Organization, or Urban Indian Organization.
LTC — Long-Term Care.
LTSS — Long-Term Services and Supports.
JCAHO — Joint Commission for the Accreditation of Healthcare Organizations.
LIFE—Living Independence for the Elderly.
MA — Medical Assistance.
MAAC — Medical Assistance Advisory Committee.
MATP — Medical Assistance Transportation Program.
MCO — Managed Care Organization.
MIPPA — Medicare Improvements for Patients and Providers Act of 2008.
MIS — Management Information System.
MMIS — Medicaid Management Information System.
MPI — Master Provider Index.
NCPDP — National Council for Prescription Drug Programs.
NCQA — National Committee for Quality Assurance.
NF — Nursing Facility.
NFCE — Nursing Facility Clinically Eligible.
NFI — Nursing Facility Ineligible.
NHT — Nursing Home Transition.
NPDB — National Practitioner Data Bank.
NPI — National Provider Identifier.
NPPES — National Provider Plan and
Enumeration System.
OAPS — Older Adult Protective Services.
OBRA — Omnibus Budget Reconciliation Act.
OIP — Other Insurance Paid.
OLTL — Office of Long-Term Living.
OMAP — Office of Medical Assistance Programs.
ORC — Other Related Conditions.

OTC — Over-the-Counter.
OUD-COE — Opioid Use Disorder Centers of Excellence
OVR — Department of Labor & Industry, Office of Vocational Rehabilitation of the Commonwealth of Pennsylvania.
P&T — Pharmacy & Therapeutics.
P4P — Pay for Performance
PAC — Participant Advisory Committee.
PARP — Prior Authorization Review Panel.
PASRR — Preadmission Screening and Resident Review
PBM — Pharmacy Benefit Manager.
PCP — Primary Care Practitioner.
PCSP — Person-Centered Service Plan.
PCPT — Person-Centered Planning Team.
PDA — Pennsylvania Department of Aging.
PDL — Preferred Drug List.
PH — Physical Health.
PID — Pennsylvania Insurance Department.
PMPM — Per-Member, Per-Month.
POSNet — Pennsylvania Open Systems Network.
PPC — Provider Preventable Condition.
QA — Quality Assurance.
QARI — Quality Assurance Reform Initiative.
QM — Quality Management.
QMC — Quality Management Committee.
QM/QI — Quality Management/Quality Improvement.
RBC — Risk Based Capital.
RHC — Rural Health Clinic.
RN — Registered Nurse.
SAP — Statutory Accounting Principles.
SDOH—Social Determinants of Health.
SMI — Serious Mental Illness.
SSA — Social Security Act.
SSADMF — Social Security Administration's Death Master File
SSI — Supplemental Security Income.
SUD — Substance Use Disorder.
TANF — Temporary Assistance for Needy Families.
TPL — Third Party Liability.
TPR — Third Party Resources.
TTY — Text Telephone Typewriter.
UM — Utilization Management.
URCAP — Utilization Review Criteria Assessment Process.
US DHHS — United States Department of Health and Human Services.
VBP — Value-Based Purchasing
WIC — Women, Infants and Children.

SECTION I: INCORPORATION OF DOCUMENTS

A. Operative Documents

This Agreement is comprised of the following documents, which are listed in the order of precedence in the event of a conflict between documents:

1. This document consisting of its Recitals and Sections I-XVI and Appendices 3-5 and Exhibits A – FF.
2. RFP Number 12-15 attached as Appendix 1.
3. The CHC-MCO's Proposal, attached as Appendix 2.

B. Approval of CHC-MCO Policies, Procedures, and Processes

The CHC-MCO must submit for Department review and approval any type of change to Department previously approved CHC-MCO policies, processes and procedures prior to the implementation of the change. Unless otherwise required by law, the CHC-MCO must continue to operate in accordance with the existing approved policy, process, or procedure until the Department has approved the change.

SECTION II: DEFINITIONS

Abuse — Any practices that are inconsistent with sound fiscal, business, or medical practices and result in unnecessary costs to the MA Program or in reimbursement for services that are not Medically Necessary or that fail to meet professionally recognized standards or Agreement obligations and the requirements of Federal or State statutes and regulations for healthcare in a managed care setting, committed by the CHC-MCO, a subcontractor, Provider, or Participant, among others.

ACCESS Card — An identification card issued by the Department to each MA Participant.

Act 150 Program — A state-funded program under the Attendant Care Services Act (62 P.S. §§ 3051 – 3058), which provides certain personal assistance services to eligible adults.

Activities of Daily Living (ADLs) — Basic personal everyday activities that include bathing, dressing, transferring (e.g., from bed to chair), toileting, mobility, and eating.

Actuarially Sound Capitation Rate — Actuarially sound Capitation rates are projected to provide reasonable, appropriate and attainable costs that are required under the terms of the contract and for the operation of the Primary Contractor for the time period and the population covered under the terms of the contracts, and

such Capitation rates are developed in accordance with the requirement in 42 C.F.R. §438.4(b).

Adjudicated Claim — A Claim that has been processed to payment or denial.

Advanced Healthcare Directive — A healthcare power of attorney, living will, or a written combination of a healthcare power of attorney and living will.

Affiliate — An individual, corporation, partnership, joint venture, trust, unincorporated organization or association, or other similar organization ("Person") controlling, controlled by, or under common control with the CHC-MCO or its parent(s), whether such control be direct or indirect. Without limitation, all officers, or persons, holding five percent (5%) or more of the outstanding ownership interests of the CHC-MCO or its parent(s), directors, or subsidiaries of the CHC-MCO or of the parent(s) are Affiliates. For purposes of this definition, "control" means the possession, directly or indirectly, of the power (whether or not exercised) to direct or cause the direction of the management or policies of a person, whether through the ownership of voting securities, other ownership interests, or by contract or otherwise, including but not limited to the power to elect a majority of the directors of a corporation or trustees of a trust.

Behavioral Health Managed Care Organization (BH-MCO) — An entity, operated by county government or licensed by the Commonwealth as a risk-bearing HMO, which manages the purchase and provision of Behavioral Health Services under an Agreement with the Department.

Behavioral Health Services — Mental health and substance use disorder services.

Beneficiary — A person determined eligible to receive services in the MA Program.

Capitation Payment — A payment the Department pays per month to the CHC-MCO for each Participant to provide coverage of all Covered Services, whether or not the Participant receives services during the period covered by the payment.

Centers for Medicare & Medicaid Services (CMS) — The federal agency within the US DHHS responsible for oversight of the Medicare and Medicaid Programs.

Certificate of Authority — A document issued jointly by the Pennsylvania Departments of Health and Insurance authorizing a corporation to establish, maintain, and operate an HMO in Pennsylvania.

Certified Nurse Midwife — A licensed registered nurse licensed to practice

midwifery in the Commonwealth.

Certified Registered Nurse Practitioner (CRNP) — A registered nurse licensed in the Commonwealth who is certified in a particular clinical specialty area and who, while functioning in the expanded role as a professional nurse, performs acts of medical diagnosis or prescription of medical therapeutic or corrective measures in collaboration with and under the direction of a physician licensed to practice medicine in the Commonwealth.

Claim — A bill from a Provider that is assigned a unique identifier (i.e., Claim reference number). A Claim does not include an Encounter form for which no payment is made or only a nominal payment is made.

Clean Claim — A Claim that can be processed without obtaining additional information from the Provider or from a third party, including a Claim with errors originating in the CHC-MCO's Claims system. Claims under investigation for Fraud or Abuse or under review to determine if they are Medically Necessary are not Clean Claims.

Client Information System (eCIS) — The Department's database of Beneficiaries, including Participants, containing demographic and eligibility information for all Participants.

Clinical Eligibility Determination — A determination of an individual's clinical eligibility for LTSS.

Cloud Computing Service — Any computing service that is procured through and hosted by or within a third-party vendor, licensor, contractor, or supplier (Service Organizations) or its subcontractor(s) (Subservice Organization(s)) managed infrastructure regardless of deployment model (public, private, or hybrid) or type such as, but not limited to, software-as-a-service (SaaS) for web-based applications, infrastructure-as-a-service (IaaS) for Internet-based access to storage and computing power, and platform-as-a-service (PaaS) that gives developers the tools to build and host Web applications. Solutions deployed through traditional hosting methods and without the use of NIST Cloud capabilities (i.e., rapid elasticity, resource pooling, measured service, broad network access, and on demand self-service) are also included.

Commonwealth — The Commonwealth of Pennsylvania

Community-Based Organizations (CBOs) — Community-Based Organizations (CBOs) are nonprofit organizations that work at a local level to improve life for residents and normally focus on building equality across society in many areas, including but not limited to access to social services. These organizations must also be registered as a 501(c)(3) nonprofit corporation in Pennsylvania. A health care provider is not considered a CBO.

Complaint — A dispute or objection regarding a particular Provider or the coverage operations, or management of a CHC-MCO, which has not been resolved by the CHC-MCO and has been filed with the CHC-MCO or with PID's Bureau of Managed Care (BMC), including but not limited to:

- a denial because the requested service or item is not a Covered Service; which does not include BLE;
- the failure of the CHC-MCO to provide a service or item in a timely manner, as defined by the Department;
- the failure of the CHC-MCO to decide a Complaint or Grievance within the specified time frames;
- a denial of payment by the CHC-MCO after a service has been delivered because the service or item was provided without authorization by a provider not enrolled in the MA Program;
- a denial of payment by the CHC-MCO after a service or item has been delivered because the service or item provided is not a Covered Service for the Participant; or
- a denial of a Participant's request to dispute a financial liability, including cost sharing, copayments, premiums, deductibles, coinsurance, and other Participant financial liabilities.

The term does not include a Grievance.

Comprehensive Medical and Service Record — A record kept by the CHC-MCO and available to the Participant and relevant Providers that contains, at a minimum, documentation of care and services rendered to the Participant by Providers.

Comprehensive Needs Assessment (Assessment)– An evaluation, utilizing a Department approved tool, of the Participant's physical health; the Participant's behavioral health; and the Participant's social, psychosocial, environmental, caregiver, LTSS, and other needs and the Participant's preferences, goals, housing, and informal supports.

Concurrent Review — A review conducted by the CHC-MCO during a course of treatment to determine whether the amount, duration, and scope of the prescribed service continues to be Medically Necessary or whether any service, a different service, or lesser level of service is Medically Necessary.

Consumer Assessment of Healthcare Providers and Systems (CAHPS) — A comprehensive and evolving family of survey instruments to evaluate Participant experience and quality of care on various aspects of services.

County Assistance Office (CAO) — The county offices of the Department that determine eligibility for all benefit programs, including MA, on the local level.

Covered Drug — A brand name drug, a generic drug, or an OTC drug which:

- Is approved by the FDA;
- Is distributed by a manufacturer that entered into a Federal Drug Rebate Program Agreement with the CMS;
- May be dispensed only upon prescription in the MA Program;
- Has been prescribed or ordered by a licensed prescriber within the scope of the prescriber's practice.

The term includes biological products and insulin.

Covered Services — Services which the CHC-MCO is required to offer to Participants as specified in Exhibit A, Covered Services List.

Critical Incident — An occurrence of an event that jeopardizes the participant's health or welfare.

Cultural Competency — The ability of individuals, as reflected in personal and organizational responsiveness, to understand the social, linguistic, moral, intellectual, and behavioral characteristics of a community or population, and translate this understanding systematically to enhance the effectiveness of healthcare delivery to diverse populations.

Daily 834 Eligibility File — An electronic file in a HIPAA compliant 834 format using data from eCIS that is transmitted to the CHC-MCO daily on state business days by the Department's MMIS contractor.

Day — A calendar day unless specified otherwise.

Deliverables — Documents, records, and reports required to be furnished to the Department for review and approval pursuant to the terms of this Agreement.

Denied Claim — An Adjudicated Claim that does not result in a payment obligation to a Provider.

Department — The Department of Human Services of the Commonwealth of Pennsylvania.

Direct Care Worker — A person employed for compensation by a provider or Participant who provides personal assistance services or respite services.

Disability Competency — The demonstration that an entity or individual has the capacity to understand the diverse nature of disabilities and the impact that different disabilities can have on a Participant, access to services, and experience of care.

Disease Management — An integrated treatment approach that includes the collaboration and coordination of patient care delivery systems and that focuses on measurably improving clinical outcomes for a particular medical condition through the use of appropriate clinical resources such as preventive care, treatment guidelines, patient counseling, education, and outpatient care; and that includes evaluation of the appropriateness of the scope, setting, and level of care in relation to clinical outcomes and cost of a particular condition.

Disenrollment — The process by which a Participant's ability to receive services from a CHC-MCO is terminated.

Drug Efficacy Study Implementation (DESI) — Drug products that have been classified as less-than-effective by the FDA.

Dual Eligible — A Beneficiary who is enrolled in Medicare.

Dual Eligible Special Needs Plan (D-SNP) — A Medicare Advantage Plan that primarily or exclusively enrolls individuals who are enrolled in both Medicare and MA.

Eligibility Period — A period of time during which an individual is eligible to receive MA benefits, indicated by the eligibility start and end dates in eCIS, and a blank eligibility end date signifies an open-ended Eligibility Period.

Eligibility Verification System (EVS) — An automated system available to Providers and other specified organizations for automated verification of MA eligibility, CHC-MCO Enrollment, PCP assignment, TPR, and scope of benefits.

Emergency Back-up Plan – The steps to be taken to meet the Participant's medical and non-medical needs during an emergency. Emergency back-up plans address power outages, weather events, travel restrictions, and other events, including failure of individualized back-up plans during emergency events. Federal and state emergency management agencies (FEMA/PEMA) provide guidance on emergency planning.

Emergency Medical Condition — A medical condition manifesting itself by acute symptoms of sufficient severity, including severe pain, such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in: (a) placing the health of the individual or, in respect to a pregnant woman, the health of the woman or her unborn child, in serious jeopardy, (b) serious impairment to bodily functions, or (c) serious dysfunction of any bodily organ or part.

Emergency Participant Issue — A problem of a CHC-MCO Participant, including problems related to whether an individual is a Participant, the resolution of which should occur immediately or before the beginning of the next

day in order to prevent a denial or significant delay in care to the Participant that could precipitate an Emergency Medical Condition or need for urgent care.

Emergency Services — Covered inpatient and outpatient services that: (a) are furnished by a Provider, and (b) are needed to evaluate or stabilize an Emergency Medical Condition.

Encounter — Any Covered Service provided to a Participant, regardless of whether it has an associated Claim.

Encounter Data — A record of any Covered Service provided to a Participant and includes Encounters reimbursed through Capitation, FFS, or other methods of payment regardless of whether payment is due or made.

Enrollment — The process by which a Participant is enrolled in a CHC-MCO.

Enrollment Date — Date that a Beneficiary becomes eligible for CHC.

Enterprise Incident Management (EIM) system — Under CHC, EIM is a comprehensive, web-based incident reporting system that provides the capability to record and review incidents for HCBS LTSS program participants.

Expanded Service — A Medically Necessary service provided to a Participant which is covered under Title XIX of the SSA, 42 U.S.C. §§ 1396 et seq., but not included in the Commonwealth's Medicaid State Plan.

External Quality Review — An annual independent, external review by an EQRO of the quality of services furnished by a CHC-MCO including the evaluation of quality outcomes, timeliness, and access to services.

External Quality Review Organization (EQRO) — An independent organization that meets the competence and independence requirements set forth in 42 C.F.R. § 438.354, and performs EQR or other EQR-related activities as set forth in 42 C.F.R. § 438.358, or both.

Extranet – An Intranet site that can be accessed by authorized internal and external users to enable information exchange securely over the Internet.

Family Planning Services — Diagnosis, treatment, drugs, supplies, and related counseling which are provided to individuals of child-bearing age to enable the individuals to determine freely the number and spacing of their children.

Federally Qualified Health Center (FQHC) — An individual health center site location that is receiving, or meets all of the requirements to receive (FQHC "look alike"), grant funds under Sections 329, 330, 340, or 340A of the Public Health

Services (PHS) Act; or that does not currently meet all of the FQHC requirements under the PHS Act, but does meet all applicable requirements for Medical Assistance (MA) providers as set forth in Chapter 1101 of the MA regulations (including licensure and certification standards under Pennsylvania Law), and receives a temporary waiver from the Secretary of the U.S. Department of Health and Human Services allowing the health center to act as a FQHC.

Fee-for-Service (FFS) — Payment to Providers on a per-service basis for healthcare services provided to Beneficiaries.

Formulary — A Department-approved list of Medicaid covered drugs and products not included on the Statewide Preferred Drug List (PDL) and determined by the CHC-MCO's P&T Committee to have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, and cost for the CHC-MCO Participants. MCOs may also refer to this list as the supplemental formulary or supplemental PDL.

Fraud — Any type of intentional deception or misrepresentation, including any act that constitutes fraud under applicable Federal or State law, made by an entity or person with the knowledge that the deception could result in some unauthorized benefit to the entity or person, or some other person in a managed care setting, committed by any entity, including the CHC-MCO, a subcontractor, a Provider, or a Participant.

Grievance — A request to an MA Managed Care Plan by a Participant or a health care provider (with the written consent of the Participant), or a Participant's authorized representative to have an MA Managed Care Plan reconsider a decision solely concerning the medical necessity, appropriateness, health care setting, level of care or effectiveness of a health care service. If the MA Managed Care Plan is unable to resolve the matter, a grievance may be filed regarding the decision that:

(1) disapproves full or partial payment for a requested health care service;
(2) approves the provision of a requested health care service for a lesser scope or duration than requested; or
(3) disapproves payment for the provision of a requested health care service but approves payment for the provision of an alternative health care service
(4) reduces, suspends, or terminates a previously authorized service.

The term does not include a complaint.

Healthcare-Acquired Condition (HCAC) — A condition occurring in any inpatient hospital setting, identified as a hospital-acquired condition by the US DHHS Secretary under § 1886(d)(4)(D)(iv) of the SSA, other than Deep Vein Thrombosis/Pulmonary Embolism as related to total knee replacement or hip

replacement surgery in pediatric and obstetric patients.

Healthcare-Associated Infection — A localized or systemic condition that results from an adverse reaction to the presence of an infectious agent or its toxins that:

- occurs in a patient in a healthcare setting;
- was not present or incubating at the time of admission, unless the infection was related to a previous admission to the same setting; and
- if occurring in a hospital setting, meets the criteria for a specific infection site as defined by the CDC in its National Healthcare Safety Network.

Healthcare Effectiveness Data and Information Set (HEDIS®) — The set of managed care performance measures maintained by the NCQA.

Health Information Organization (HIO) — An entity that governs the exchange of health-related information among organizations according to nationally recognized standards.

Health Maintenance Organization (HMO) — A Commonwealth-licensed risk-bearing entity which combines delivery and financing of healthcare and which provides basic health services to enrolled Participants for fixed, prepaid fees.

Home- and Community-Based Services (HCBS) — A range of services and supports provided to individuals in their homes and communities, including assistance with ADLs and IADLs, which promote the ability for older adults and adults with disabilities to live independently to the greatest degree and remain in their homes for the longest time as is possible.

Hospice — A coordinated program of home and inpatient care that provides non-curative medical and support services for persons certified by a physician to be terminally ill with a life expectancy of six or fewer (6) months, including palliative and supportive care to Participants and their families.

Implementation Date — The date on which an CHC-MCO began in a particular zone.

In Lieu of Services (ILOS) — ILOS is defined as a service or setting that is provided to a Participant as a substitute for a State Plan Service or Setting in accordance with 42 CFR § 438.3(e)(2). This includes services and settings defined in 1905(a), 1915(i), or 1915(k) of the Social Security Act, or a waiver under section 1915(c) of the Social Security Act. An ILOS can be used as an immediate or longer-term substitute for a State Plan Service or Setting, or when the ILOS can be expected to reduce or prevent the future need to utilize a State Plan Service or Setting.

Independent Enrollment Entity (IEB) — An independent and conflict-free entity that is responsible for providing information about CHC and the CHC-MCOs and otherwise assist the individual to choose a CHC-MCO and enrollment services to Potential Participants and Participants.

Independent Review Organization (IRO) — An entity approved by the Pennsylvania Insurance Department that conducts independent reviews of grievances.

Individualized Back-Up Plan — An individualized plan that is developed as part of the PCSP, which identifies the strategies to be taken in the event that authorized services are not able to be delivered to a Participant, which, depending on the Participant's preferences and choice, may include but are not limited to the use of family and friends of the Participant's choice, or agency staff, or both.

Information Resource Management (IRM) — A program planned, developed, implemented, and managed by DHS's Bureau of Information Systems, the purpose of which is to provide coordinated, effective, and efficient employment of information resources in support of DHS business goals and objectives.

Instrumental Activities of Daily Living (IADLs) — Activities related to independent living, including preparing meals, managing money, shopping for groceries or personal items, performing housework, and communication.

Internal Control Number (ICN) — The unique number assigned by the Department's MMIS to identify an individual Claim or Encounter.

Limited English Proficiency (LEP) — An individual's limited ability to read, write, speak, or understand English because English is not the individual's primary language.

Linguistic Competency — The demonstration that an entity or individual has the capacity to communicate effectively and convey information in a manner that is easily understood by diverse audiences including persons with LEP, persons who have low literacy skills or are not literate, and persons with disabilities who require communication accommodations.

Living Independence for the Elderly (LIFE) — A comprehensive service delivery and financing program model in certain geographic areas of the Commonwealth (which is known nationally as the Program of All-Inclusive Care for the Elderly) that provides comprehensive healthcare services under dual capitation agreements with Medicare and the MA Program to individuals age 55 and over who are NFCE.

Lock-In — The restriction of a Participant who is involved in fraudulent activities

or who is identified as abusing MA services to one or more specific Providers to obtain all of his or her services in an attempt to appropriately manage care.

Long-Term Services and Supports (LTSS) — Services and supports provided to a Participant who has functional limitations or chronic illnesses that have a primary purpose of supporting the ability of the Participant to live or work in the setting of his or her choice, which may include the individual's home or worksite, a provider-owned or -controlled residential setting, a NF, or other institutional setting.

Market Share — The percentage of Participants enrolled with a particular CHC-MCO when compared to the total number of Participants enrolled in all the CHC-MCOs within a CHC zone.

Marketing — Any communication from the CHC-MCO, or any of its agents or independent contractors, with a potential Participant who is not enrolled in the CHC-MCO, that can reasonably be interpreted as intended to influence that individual to enroll in the CHC-MCO or to disenroll from or not enroll in another CHC-MCO.

Marketing Materials – Any materials that are produced in any medium by or on behalf of the CHC-MCO that can reasonably be interpreted as intended to be Marketing.

Master Provider Index (MPI) — A component of the Department's MMIS, which is a central repository of Provider profiles and demographic information that registers and identifies Providers uniquely within the Department.

Medical Assistance (MA) — The Medical Assistance Program authorized by Title XIX of the SSA, 42 U.S.C. §§ 1396 et seq., and regulations promulgated thereunder, and 62 P.S. §§ 441.1 et seq. and regulations at 55 Pa. Code Chapters 1101 et seq.

Medical Assistance Transportation Program (MATP) — A non-emergency medical transportation service provided to eligible persons who need to make trips to or from any MA service for the purpose of receiving treatment, medical evaluation, or purchasing prescription drugs or medical equipment.

Medically Necessary (also referred to as Medical Necessity) — Compensable under the MA Program and meeting any one of the following standards:

- Will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.

- Will assist a Participant to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Participant and those functional capacities that are appropriate for Participants of the same age.
- Will provide the opportunity for a Participant receiving LTSS to have access to the benefits of community living, to achieve person-centered goals, and live and work in the setting of his or her choice.

Medicare — The federal health insurance program administered by CMS pursuant to 42 U.S.C. §§ 1395 et seq., covering almost all Americans sixty-five (65) years of age and older and certain individuals under sixty-five (65) who have disabilities or chronic kidney disease.

MIPPA Agreement — An agreement required under the Medicare Improvements for Patients and Providers Act of 2008, Pub. Law 110–275, between a D-SNP and the Department which documents each entity's roles and responsibilities with regard to Dual Eligibles and describes the D-SNP's responsibility to integrate and coordinate Medicare and MA benefits.

MMIS Provider ID — A thirteen (13)-digit number consisting of a combination of the nine (9)-digit base MPI Provider Number and a four (4)-digit service location.

Monthly 834 Eligibility File — An electronic file in a HIPAA-compliant 834 format using data from eCIS that is transmitted to the CHC-MCO on a monthly basis by the Department's MMIS contractor.

Network — All contracted or employed Providers with the CHC-MCO who are providing Covered Services.

Network Provider — An MA-enrolled Provider that has a written Network Provider Agreement and, participates in the CHC-MCO's Network to serve Participants.

Net Worth (Equity) — The residual interest in the assets of an entity that remains after deducting its liabilities.

Non-Participating Provider — A Health Care Provider not enrolled in the Pennsylvania Medicaid Program.

Nursing Facility (NF) — A general, county, or hospital-based nursing facility, which is licensed by DOH and enrolled in the MA Program.

Nursing Facility Clinically Eligible (NFCE) — Having clinical needs that require the level of care provided in a NF.

Nursing Facility Ineligible (NFI) — Having clinical needs that do not require

the level of care provided in a NF.

Ongoing Medication — A medication that has been previously dispensed to a Participant for the treatment of an illness that is chronic in nature or for an illness for which the medication is required for a length of time to complete a course of treatment, until the medication is no longer considered necessary by the prescriber, and that has been used by the Participant without a gap in treatment.

OPTIONS Program — The Pennsylvania Department of Aging's state-funded program of HCBS for eligible consumers who are 60 years of age and older to assist them in maintaining independence in the community.

Other Related Condition (ORC) — A physical disability such as cerebral palsy, epilepsy, spina bifida or similar condition which occurs before the age of twenty-two (22), is likely to continue indefinitely, and results in three (3) or more substantial functional limitations in the following areas: self-care, receptive and expressive language, learning, mobility, self-direction, and capacity for independent living.

Out-of-Area Covered Services — Covered Services provided to a Participant under one (1) or more of the following circumstances:

- The Participant has An Emergency Medical Condition that occurs while outside the CHC zone.
- The health of the Participant would be endangered if the Participant returned to the CHC zone for needed services.
- The Participant is attending a college or university in a state other than the Commonwealth or a zone other than his or her zone of residence or who is travelling outside of the CHC zone but remains a resident of the Commonwealth and the CHC zone and requires Covered Services, as identified in his or her PCSP or otherwise.
- The Provider is located outside the CHC zone, but regularly provides Covered Services to Participants at the request of the CHC-MCO.
- The needed Covered Services are not available in the CHC zone.

Out-of-Network Provider — A Provider that does not have a signed Network Provider Agreement with the CHC-MCO and does not participate in the CHC MCO's network but provides services to a CHC-MCO participant.

Out-of-Plan Services — Services which are non-capitated and are not the responsibility of the CHC-MCO as Covered Services.

Participant — A Beneficiary who is enrolled with the CHC-MCO.

Participant Self-Directed Service — A Covered Service that the Department specifies may be directed by a Participant or their designated representative

as a common-law employer.

Participant-Direction — The opportunity for a Participant to exercise choice and control in identifying, accessing, and managing LTSS and other supports in accordance with his or her needs and personal preferences.

Participant Record — A record contained on the Daily 834 Eligibility File or Monthly 834 Eligibility File that contains information on MA eligibility, managed care coverage, and the category of assistance, which establish the Covered Services for which a Participant is eligible.

Penalty Period — A Period of ineligibility for the payment of LTSS, including NF and HCBS, due to a transfer of assets for less than fair market value or excess home equity.

Pennsylvania Open Systems Network (POSNet) — A peer-to-peer network based on open systems products and protocols that was previously used for the transfer of information between the Department and MCOs and has been replaced by IRM Standards.

Performance Improvement Project — A project in which a CHC-MCO assesses its organization and makes changes to meet its goals through assessment, systematic gathering of information, and making improvements in care or services.

Person-Centered Planning Team (PCPT) — A team of individuals that participates in Person-Centered Service Planning with and provides person-centered coordinated services to a Participant.

Person-Centered Service Plan (PCSP) — A written description of Participant-specific healthcare, LTSS, and wellness goals to be achieved, and the amount, duration, frequency, and scope of the Covered Services to be provided to a Participant in order to achieve such goals, which is based on the comprehensive assessment of the Participant's healthcare, LTSS, and wellness needs and preferences.

Person-Centered Service Planning — The process of developing an individualized PCSP based on an assessment of needs and preferences of the Participant.

Personal Assistance Services — As set forth in the “Section 1915(c) Home and Community-Based Services Waiver” for Community HealthChoices, services aimed at assisting the participant to complete ADLs and IADLs that would be performed independently if the participant had no disability.

Physician Incentive Plan — A compensation arrangement between a CHC-

MCO and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services furnished to Participants.

Plan Transfer — The process by which a Participant changes CHC-MCOs.

Post-Stabilization Services — Medically Necessary Covered Services as defined in 42 C.F.R. § 438.114.

Potential Participant — An individual who has applied to enroll in CHC.

Preadmission Screening and Resident Review (PASRR) — A Federally mandated process that applies to all individuals seeking admission to a NF enrolled in the MA Program, regardless of payment source (private pay, private insurance, or MA), and is completed prior to admission and no later than the day of admission, to determine whether an individual who has a mental illness, ID, or an ORC requires NF services and also requires specialized services to treat the co-occurring conditions, based on the criteria established by CMS.

Primary Care — Healthcare services and laboratory services customarily furnished by or through a general practitioner, family physician, internal medicine physician, or obstetrician/gynecologist acting within the scope of practice.

Primary Care Practitioner (PCP) — A specific physician, physician group, or CRNP acting within the scope of his or her practice, who is responsible for supervising, prescribing, and providing Primary Care services; locating, coordinating, and monitoring other medical care and rehabilitative services; and maintaining continuity of care on behalf of a Participant.

Primary Care Practitioner Site — The location or office of a PCP where Participant care is delivered.

Prior Authorization — A determination made by the CHC-MCO to approve or deny payment for a Provider's request to provide a service or course of treatment of a specific duration and scope to a Participant prior to the Provider's initiation or continuation of the requested service.

Provider — An individual or entity that is engaged in the delivery of medical or professional services, or ordering or referring for those services, and is legally authorized to do so by the Commonwealth or State in which it delivers the services, including a licensed hospital or healthcare facility, medical equipment supplier, or person who is licensed, certified, or otherwise regulated to provide healthcare services under the laws of the Commonwealth or states in which the entity or person provides services, including a physician, podiatrist, optometrist, psychologist, physical therapist, CRNP, RN, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, physician’s assistant,

chiropractor, dentist, dental hygienist, pharmacist, and an individual accredited or certified to provide behavioral health services.

Provider Agreement — A Department-approved written agreement between the CHC-MCO and a Provider to provide medical or professional services to Participants to fulfill the requirements of this Agreement.

Provider Appeal — A written request from a Provider for reversal of a determination by the CHC-MCO of:

- A Provider credentialing denial;
- A Claim denial; or
- A Provider Agreement termination.

Provider Dispute — A written communication to a CHC-MCO, made by a Provider, expressing dissatisfaction with a CHC-MCO decision that directly impacts the Provider, excluding decisions concerning Medical Necessity.

Provider-Preventable Condition — A condition that meets the definition of an HCAC or other condition as defined in 42 C.F.R. § 447.26(b).

Provider Reimbursement (and) Operations Management Information System electronic (PROMISe™) — The Department's Medicaid Management Information System (MMIS) that supports the FFS and managed care delivery programs, or its successor system.

Quality Management/Quality Improvement (QM/QI) — An ongoing, objective, and systematic process of monitoring, evaluating, and improving the quality, appropriateness, and effectiveness of care.

Readily Accessible — Electronic information and services which comply with modern accessibility standards such as section 508 guidelines, section 504 of the Rehabilitation Act, and W3C's Web Content Accessibility Guidelines (WCAG) 2.0 AA and successor versions.

Recipient Restriction Program — The program to Lock-In Participants for a period of time.

Rejected Claim — A non-claim that has erroneously been assigned a unique identifier and is removed from the claims processing system prior to adjudication.

Related Party — An entity that is an Affiliate of the CHC-MCO or a CHC-MCO subcontractor and (1) performs some of the CHC-MCO or subcontracting CHC-MCO's management functions under contract or delegation; or (2) furnishes services to Participants under a written agreement; or (3) leases real property or

sells materials to the CHC-MCO or CHC-MCO's subcontractor at a cost of more than $2,500.00 during any year of this Agreement.

Restraint — A Restraint can be physical or chemical.

- A physical restraint is any apparatus, appliance, device, or garment applied to or adjacent to a Participant's body, which restricts or diminishes the Participant's level of independence or freedom.
- A chemical restraint is a psychopharmacologic drug that is used for discipline or convenience and not required to treat medical symptoms.
- A device used to provide support for functional body position or proper balance or a device used for medical treatment, such as sand bags to limit movement after medical treatment, a wheelchair belt used for body positioning and support, or a helmet to prevent injury during seizure activity is not a restraint.

Retrospective Review — A review conducted by the CHC-MCO to determine whether services were delivered as authorized and consistent with the CHC-MCO's payment policies and procedures.

Routine Care — Care for conditions that generally do not need immediate attention and minor episodic illnesses that are not deemed urgent. Examples of routine care include immunizations, screenings, and physical exams.

Seclusion — The involuntary confinement of an individual alone in a room or an area from which the individual is physically prevented from having contact with others or leaving.

Services My Way — The Budget Authority model of service, which provides Participants with a range of opportunities for Participant Self-Direction under which Participants have the opportunity to hire and manage staff that perform personal assistance type services, manage a flexible spending plan, and purchase allowable goods and services through their spending plan.

Sexual Abuse of a Participant — Intentionally, knowingly, or recklessly causing or attempting to cause the rape of, involuntary deviate sexual intercourse with, sexual assault of, statutory sexual assault of, aggravated indecent assault of, indecent assault of, or incest with a Participant.

Social Determinants of Health (SDOH) — Conditions in the environments in which people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes which can lead to inequities and risks.

Start Date — The first date on which the CHC-MCO is operationally responsible and financially liable for the provision of Covered Services to a Participant.

Statewide Preferred Drug List (Statewide PDL) – A list of drugs and products that are grouped into therapeutic classes. The Department's Pharmacy and Therapeutics (P&T) Committee recommends therapeutic classes to include on the Statewide PDL, preferred or non-preferred status for the drugs in each class, and corresponding prior authorization guidelines for each class. The committee's recommendations are approved by the secretary of the Department of Human Services (DHS) prior to implementation. The Statewide PDL applies to beneficiaries who receive their pharmacy benefits through the FFS and managed care delivery systems.

Step Therapy — A type of Prior Authorization requirement intended as a cost savings that begins drug therapy with the most cost-effective drug therapy, and progresses to other more costly therapies determined to be Medically Necessary.

Stop-Loss Protection — Coverage designed to limit the amount of financial loss experienced by a Provider.

Subcapitation — A fixed per capita amount that is paid by the CHC-MCO to a Network Provider for each Participant identified as being in its capitation group, whether or not the Participant receives medical services.

Subcontract — A contract between the CHC-MCO and an individual or entity to perform part or all of the CHC-MCO's responsibilities under this Agreement, excluding Provider Agreements.

Sustained Improvement — Improvement in performance documented through continued measurement of quality indicators after the performance project/study/quality initiative is completed.

Substantial Financial Risk — Financial risk set at greater than twenty-five percent (25%) of potential payments for Covered Services, regardless of the frequency of assessment (i.e., collection) or distribution of payments. The term "potential payments" means the maximum anticipated total payments that a physician or physician group could receive if the use or cost of referral services were significantly low.

Third Party Liability — The financial responsibility for all or part of a Participant's healthcare or LTSS expenses of an individual, entity, or program (e.g., Medicare) other than the CHC-MCO.

Third Party Resource — An individual, entity, or program that is liable to pay all or part of the medical or service cost of injury, disease, or disability of a Participant. Examples of TPR include government insurance programs such as Medicare or CHAMPUS; private health insurance companies or carriers; liability

or casualty insurance; and court-ordered medical support.

Urgent Medical Condition — An illness, injury, or severe condition which under reasonable standards of medical practice should be diagnosed and treated within a twenty-four (24) hour period and, if left untreated, could rapidly become a crisis or Emergency Medical Condition. The term also includes situations where a Participant's discharge from a hospital will be delayed until services are approved or a Participant's ability to avoid hospitalization depends upon prompt approval of services.

Utilization Management — An objective and systematic process for planning, organizing, directing, and coordinating healthcare resources to provide Medically Necessary, timely, and quality healthcare services in the most cost-effective manner.

Utilization Review Guidelines — Detailed standards, decision algorithms, models, or informational tools that describe the factors used to make Medical Necessity determinations for services, including but not limited to level of care, place of service, scope of service, and duration of service.

Value-Added Service — A service that is not a Covered Service that the CHC-MCO offers to encourage Participant Enrollment, encourage healthy lifestyles, or otherwise support CHC program objectives.

Value-Based Payments (VBP) Arrangements — Agreements between the MCO and providers, which specify how providers are paid for services rendered. VBP arrangements link provider payments to the value of services provided and to relevant quality measures that are indicative of health outcomes.

Value-Based Purchasing Models — VBP Models define a way to organize and deliver care, and may incorporate one or more VBP Payment Strategies as ways to pay providers.

Value-Based Purchasing Payment Strategies — Refers to the mechanism that MCOs use to pay providers (such as performance-based contracting, shared savings, shared risk, population-based payment).

Vital Documents — Documents which contain information that is critical for obtaining or understanding CHC-MCO benefits and services, such as provider directories, Participant handbooks, denial, complaint and grievance notices, and other documents identified by the Department as critical to obtaining services.

SECTION III: RELATIONSHIP OF PARTIES

A. Term of Agreement

The term of this Agreement will commence on January 1, 2018, and will have an initial term of five (5) years, provided that no court order, administrative decision, or action by the Federal or State government is outstanding which prevents the commencement of the Agreement.

The Department has the option to extend this Agreement for an additional two (2) year period upon the same terms and conditions. DHS will notify the CHC-MCO of its election to exercise the renewal option in writing at least one hundred twenty (120) days prior to the expiration of the then-current term provided, however, that the Department's right to exercise any such renewal option shall not expire unless and until the CHC-MCO has given the Department written notice of the Department's failure to timely exercise its renewal option and has provided a ten (10) day opportunity from the Department's receipt of the notice to cure the failure. If the Department exercises its option to renew, it will promptly commence rate discussions with the CHC-MCO.

If the Department has exercised its option to extend and the CHC-MCO and the Department are unable to agree upon terms for the extension, this Agreement will continue on the same terms and conditions for a period of one hundred twenty (120) days after the expiration of the Initial Term unless this Agreement has been terminated in accordance with Exhibit B, Standard Terms and Conditions for Services.

B. Nature of Agreement

The CHC-MCO must provide for all Covered Services and related services to Participants through Providers in accordance with this Agreement in the following zones: the Southwest Zone, Southeast Zone, Lehigh Capital Zone, Northwest Zone, and Northeast Zone. The Department may impose remediation for any CHC-MCO non-compliance with CHC program requirements contained within this Agreement.

SECTION IV: APPLICABLE STATUTES AND REGULATIONS

A. Certification, Licensing and Accreditation

1. Providers

The CHC-MCO must require its Network Providers to comply with all certification and licensing laws and regulations applicable to the profession or

entity. All ordering, referring, prescribing, or rendering providers within an MCO's network must be MA enrolled. The CHC-MCO may not employ or enter into a relationship with a Provider that is precluded from participation in the MA Program or other Federally funded healthcare program in any State. The CHC-MCO must screen all Providers at the time of hire or contracting and thereafter, on an ongoing monthly basis, to determine if they have been excluded from participation in any federally funded healthcare programs.

The CHC-MCO must use the streamlined credentialing process that the Department develops, in conjunction with that of the CHC-MCO.

2. National Accreditation

The CHC-MCO must be accredited by NCQA and obtain accreditation within the accreditation body's specified timelines. A CHC-MCO applying for accreditation must select an accreditation option and notify the accrediting body of the accreditation option chosen. Accreditation obtained under the NCQA Full Accreditation Survey (First Survey), or the LTSS Distinction for Health Plans options will be accepted by the Department. The Department will accept the use of the NCQA Corporate Survey process, to the extent deemed allowable by NCQA, in the NCQA accreditation of the CHC-MCO, however, the CHC-MCO must obtain accreditation in a manner that allows the plan to submit their HEDIS results to NCQA for the CHC-MCO Participant population only.

If the CHC-MCO is accredited as of the Start Date, the CHC-MCO shall maintain accreditation throughout the term of this Agreement. If the CHC-MCO is not accredited as of the Start Date, the CHC-MCO shall obtain the First Survey accreditation and the LTSS Distinction for Health Plans no later than the end of the second full calendar year of operation and shall maintain accreditation for the term of this Agreement.

The Department will confirm the CHC-MCO's accreditation on an annual basis and will consider failure to obtain accreditation and failure to maintain accreditation a material breach of this Agreement. A CHC-MCO with provisional accreditation status must submit a corrective action plan to the Department within thirty (30) days of receipt of notification from the accreditation body and may be subject to termination of this Agreement.

The CHC-MCO must submit the final hard copy Accreditation Report for each accreditation cycle within ten (10) days of receipt of the report. The CHC-MCO must submit to the Department updates of accreditation status, based on annual HEDIS scores, within ten (10) days of receipt. The Department will post the accreditation status on the Department's website.

B. Specific to the Medical Assistance Program

The CHC-MCO must enroll to participate in the MA Program, arrange for the provision of Medically Necessary Covered Services to its Participants, and comply with all Federal and State laws generally and specifically governing participation in the MA Program. The CHC-MCO must provide services in the manner prescribed by 42 U.S.C. § 300e(b), and warrants that the organization and operation of the CHC-MCO is in compliance with 42 U.S.C. § 300e(c). The CHC-MCO must comply with all applicable rules, regulations, and Bulletins promulgated under such laws, including but not limited to, 42 U.S.C. §§ 1396 et seq.; 62 P.S. §§ 101 et. seq.; 42 C.F.R. Parts 431 through 481 and 45 C.F.R Parts 74, 80, and 84, and the Department regulations except as specified in Exhibit C, Managed Long Term Services and Supports Regulatory Compliance Guidelines.

A Participant who is an Indian, as defined in 42 CFR § 438.14(a), and who is eligible to receive or has received an item or service furnished by an I/T/U HCP or through referral under contract health services as defined in 42 CFR § 447.51 is exempt from any premiums or other cost sharing imposed by the Department.

C. Specific to Medicare

The CHC-MCO must operate a CMS-approved D-SNP as provided in this Agreement in each zone.

The D-SNP must enter into a MIPPA Agreement with the Department. The MIPPA Agreement will address the eight (8) required elements set forth in CMS Medicare Managed Care Manual, Chapter 16b, § 40.5.1 (Rev. Nov. 28, 1014), Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c16b.pdf, and will include additional requirements to ensure the greatest possible coordination between the CHC-MCO and the D-SNP, including but not limited to the following:

1. The goal of the CHC-MCO and its companion D-SNP is to provide a coordinated experience from the perspective of Dual Eligible Participants who enroll in both. This includes but is not limited to an integrated assessment and care coordination process that spans all MA and Medicare services, including behavioral health services.
2. Administrative integration is expected to evolve over the life of CHC. The CHC-MCO will cooperate fully with the Department and CMS in their ongoing efforts to streamline administration of the two programs, which may include, but is not limited to, coordinated readiness reviews, monitoring, enrollment, Participant materials and appeals processes.

D. General Statutes and Regulations

1. The CHC-MCO must comply with Titles VI and VII of the Civil Rights Act of 1964, 42 U.S.C. §§ 2000d et seq. and 2000e et seq.; Title IX of the Education Amendments of 1972, 20 U.S.C. §§ 1681 et seq.; Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. § 794; the Age Discrimination in Employment Act of 1975, 42 U.S.C. §§ 6101 et seq.; the Americans with Disabilities Act, 42 U.S.C. §§ 12101 et seq.; Section 1557 of the Patient Protection and Affordable Care Act (ACA), [42 C.F.R. 438.3(f)(1); 42 C.F.R. 438.100(d)]; the Health Insurance Portability and Accountability Act of 1996 (HIPAA) 42 U.S.C. §§ 1320d-1320d-9; the Pennsylvania Human Relations Act of 1955, 71 P.S. §§ 941 et seq.; Article XXI of the Insurance Company Law of 1921, 40 P.S. §§ 991.2102 et seq.; and the Drug and Alcohol Use and Dependency Coverage Law (Act 106 of 1989), 40 P.S. §§ 908-1 et seq.

2. The CHC-MCO must comply with all applicable regulations and policies of DOH and PID.

   The CHC-MCO must comply with applicable Federal and State laws that pertain to Participant rights and protections.

3. The CHC-MCO and its subcontractors must respect the conscience rights of providers, and comply with the state law prohibiting discrimination on the basis of a refusal or willingness to provide healthcare services on moral or religious grounds as set forth in 40 P.S. § 901.2121(e)(3) and § 991.2171; 43 P.S. § 955.2 and 18 Pa. C.S. § 3213(d).

   If the CHC-MCO elects not to provide, pay for, or provide coverage of a counseling or referral service because of an objection on moral or religious grounds, the CHC-MCO must furnish information, to the Department, about the services not covered in accordance with the provisions of 42 C.F.R. § 438.102(b):

   - With its Proposal in response to the RFP
   - Whenever it adopts the policy during the term of the Agreement.

   The CHC-MCO must provide this information to the IEB for Enrollment purposes and to Participants no less than thirty (30) days prior to the effective date of the policy.

4. Nothing in this Agreement shall be construed to permit or require the Department to pay for any services or items which are not or cease to be compensable under the statutes, rules, and regulations governing the MA Program at the time such services are provided.

E. Limitation on the Department's Obligations

The obligations of the Department under this Agreement are limited and subject to

the availability of funds.

F. Statutes, Regulations, Policies, and Procedures

The CHC-MCO must comply with future changes in Federal and State statutes and regulations, and Department requirements and procedures related to changes in the MA Program, including any changes to 1915(b) or (c) Waivers and changes to MIPPA Agreements.

The Department will issue CHC Operations (CHC OPS) Memos via the Pennsylvania HealthChoices Extranet https://pagov.sharepoint.com/sites/DHS-HC-Extranetto provide clarifications to requirements pertaining to CHC and copies of required templates referenced in the Agreement. The CHC-MCOs must routinely check the Pennsylvania HealthChoices Extranet site.

Unauthorized Programs and Activities

Should any part of the scope of work under this Agreement relate to a state program that is no longer authorized by law (e.g., which has been vacated by a court of law, or for which CMS has withdrawn federal authority, or which is the subject of a legislative repeal), CHC-MCOs must do no work on that part after the effective date of the loss of program authority. The state must adjust capitation rates to remove costs that are specific to any program or activity that is no longer authorized by law. If a CHC-MCO works on a program or activity no longer authorized by law after the date the legal authority for the work ends, the CHC-MCO will not be paid for that work. If the state paid a CHC-MCO in advance to work on a no-longer-authorized program or activity and under the terms of this Agreement the work was to be performed after the date the legal authority ended, the payment for that work should be returned to the state. However, if a CHC-MCO worked on a program or activity prior to the date legal authority ended for that program or activity, and the state included the cost of performing that work in its payments to the MCO, the MCO may keep the payment for that work even if the payment was made after the date the program or activity lost legal authority.

SECTION V: PROGRAM REQUIREMENTS

The Department may impose remediation for any CHC-MCO non-compliance with the CHC program requirements contained in this section.

A. Covered Services

The CHC-MCO must provide Medically Necessary PH services and LTSS in accordance with the requirements of this Agreement. The CHC-MCO must require that Medical Necessity determinations of Covered Services be documented in writing and that they be based on medical information provided by a Participant, the Participant's family or caretaker and PCP, as well as other Providers,

programs, or agencies that have evaluated the Participant. A determination of Medical Necessity must be made by qualified and trained Providers with clinical expertise comparable to the prescribing Provider.

The MCO may but is not required to impose copayments, but only for those services, items, and pharmacy services that have a copayment in the MA FFS delivery system and subject to the exemptions in the MA FFS delivery system. If the MCO imposes copayments, the amount of the copayments may not exceed the amounts imposed in the MA FFS delivery system. If the CHC-MCO is found to have overcharged Participants for copayments, they will be required to return the amount of the overcharge to the Participant. Network Providers and other Providers that may render services under the Agreement may not deny a covered service because a Participant is unable to pay the copayment amount, but the Provider may continue to attempt to collect the copayment amount.

1. Amount, Duration, and Scope

At a minimum, the CHC-MCO must provide the Covered Services in Exhibit A, Covered Services List, in the amount, duration, and scope available in the MA FFS Program and in the approved 1915(c) waiver for CHC. The CHC-MCO must provide services that are sufficient in amount, duration, and scope to reasonably be expected to achieve the purpose for which the services are furnished. If services are added to the MA Program or the CHC Program, or if Covered Services are expanded or eliminated, the CHC-MCO must implement such changes on the same day as the Department, unless the CHC-MCO is notified by the Department of an alternative implementation date.

The CHC-MCO shall not arbitrarily deny or reduce the amount, duration, or scope of a Covered Service based on a Participant's diagnosis, disability, or type of illness/condition.

2. Home- and Community-Based Services

The CHC-MCO must provide Home and Community Based LTSS as Covered Services for Participants determined to be NFCE. The CHC-MCO must make HCBS LTSS services available seven (7) days per week, twenty-four (24) hours per day at any hour of the day and for any number or combination of hours, as dictated by Participants' needs and outlined in their approved PCSPs.

For Participants who were living in the community at the time of implementation of CHC in the zone and who chose to remain in the community, the CHC-MCO must support that choice and support the Participants in the community.

3. Program Exceptions

The CHC-MCO must establish a program exception process, reviewed and approved by the Department, whereby a Provider or Participant may request coverage, under extraordinary circumstances, for items or services that are of a type covered by the MA program but are not currently listed on the MA Program Fee Schedule. The CHC-MCO must use the program exception process to accept requests to exceed limits for items or services that are on the Fee Schedule if the limits are not based in statute or regulation. These requests are recognized by the Department as a Program Exception as described in 55 Pa. Code § 1150.63.

4. Expanded Services and Value-Added Services

The CHC-MCO may provide Expanded Services or Value-Added Services with prior written approval by the Department. Best practice approaches to delivering Covered Services are not Expanded Services or Value-Added Services.

If it provides Expanded Services or Value-Added Services, the CHC-MCO must offer the services to all Participants for whom the services are appropriate and must provide them at no cost to the Department. These services must be made available by appropriate Network Providers. The CHC-MCO may generally not condition these services on specific Participant performance; however, the Department may grant exceptions in limited circumstances if the CHC-MCO demonstrates the benefit of such condition for the Participant. Once an Expanded Service or Value-Added Service is approved, the CHC-MCO must continue to offer the service unless the CHC-MCO is notified, in writing, by the Department to discontinue the service or the Department approves a request from the CHC-MCO to discontinue the service. The CHC-MCO must send written notice to Participants and affected Providers at least thirty (30) days prior to the effective date of the change and must simultaneously amend all written materials describing its Expanded Service or Value-Added Services.

The CHC-MCO is permitted and encouraged to offer LTSS Services as Expanded Services to Participants who are not NFCE.

The CHC-MCO may provide individually tailored supportive items or services in addition to Covered Services where such services are determined by the CHC-MCO through the PCSP process to be appropriate for supporting a Participant in remaining in his or her home- or community-based setting. The CHC-MCO must report these individually tailored service or item authorizations to the Department but does not need prior approval from the Department.

The CHC-MCO may cover services or settings for Participants that are in lieu of those covered under the state plan if the Department determines that the

alternative service or setting is a medically appropriate and cost-effective substitute for the covered service or setting under the state plan.

The CHC-MCO may also cover services or settings for Participants that are in lieu of those covered under the state plan if:

- the Participant is not required by the CHC-MCO to use the alternative service or setting
- the in lieu of service (ILOS) is annually authorized and approved by the Department, utilizing the template developed by the Department in Appendix 5
- the approved ILOS are authorized and identified in the CHC-MCO contract; and
- the approved ILOS are offered to Participants at the option of the CHC-MCO.

The Department may determine that certain in lieu of services, which are medically necessary and cost-effective alternatives to State Plan services or settings, may be provided by the CHC-MCO. CHC-MCOs are not required to provide in lieu of services but have the option to provide these approved services. Appendix 5 contains the required process/instructions for obtaining Department approval and a list of approved ILOS.

5. Referrals

The CHC-MCO must establish and maintain a referral process to effectively utilize and manage the care of its Participants. The CHC-MCO may require a referral for any medical services that cannot be provided by the PCP, except where specifically provided otherwise in this Agreement.

The CHC-MCO must allow an Out-of-Network I/T/U HCP to refer a Participant who is an Indian to a CHC-MCO Network Provider as defined in 42 CFR § 438.14(a).

6. Self-Referral/Direct Access

A Participant may self-refer for vision, dental care, obstetrical and gynecological (OB/GYN) services, provided the Participant obtains the services within Network. A Participant may access chiropractic services in accordance with the process set forth in Medical Assistance Bulletin 15-07-01, and physical therapy services in accordance with the Physical Therapy Act (63 P.S. §§ 1301 et seq.) The CHC-MCO may request Department approval to allow other Covered Services to be directly available without referral.

The CHC-MCO may not use either the referral process or Prior Authorization

to manage the utilization of Family Planning Services. The CHC-MCO may not restrict the right of a Participant to choose a Provider for Family Planning Services and must make such services available without regard to marital status, age, sex, sexual orientation, gender identity, or parenthood. Participants may access, at a minimum, health education and counseling necessary to make an informed choice about contraceptive methods, pregnancy testing and counseling, basic contraceptive supplies such as oral birth control pills, diaphragms, foams, creams, jellies, condoms (male and female), Norplant, injectables, intrauterine devices, and family planning procedures. The CHC-MCO must pay for Out-of-Network Family Planning Services.

The CHC-MCO must permit Participants to select a Network Provider, including Certified Nurse Midwives, to obtain OB/GYN Services without prior approval from a PCP, including selecting a Network Provider to provide an annual well-woman gynecological visit, primary and preventive gynecology care, including PAP smears and referrals for diagnostic testing related to maternity and gynecological care, and follow-up care.

In situations where a newly enrolled Participant is pregnant and already receiving care from an Out-of-Network OB/GYN specialist at the time of Enrollment, the Participant may continue to receive services from that specialist throughout the pregnancy and postpartum care related to the delivery.

7. Drug Services

The CHC-MCO must provide coverage of prescription and OTC medicines for Participants who are not otherwise eligible for a Medicare Part D prescription drug plan. The CHC-MCO must provide pharmacy services for all other Participants. The CHC-MCO must coordinate pharmacy services with Medicare Part D, and other third party pharmacy coverage so that the Participant receives the pharmacy services outlined in the Participant's PCSP. The CHC-MCO must offer assistance to Dual Eligible Participants in selecting a Medicare Part D plan, including advising on the benefit of enrolling in a Medicare Part D plan with a zero co-pay and assisting the Participant with obtaining health insurance counseling through Pennsylvania Medicare Education and Decision Insight (PA MEDI).

The CHC-MCO must also comply with the requirements described in Exhibit D, Drug Services.

8. Emergency Services

The CHC-MCO is responsible for ensuring the coordination of Emergency Services including those categorized as mental health or drug and alcohol

services, except for ED evaluations for voluntary and involuntary commitments pursuant to 50 P.S. §§ 7101 et seq.

The CHC-MCO must comply with the provisions of 42 U.S.C. § 1396u-2(b)(2), 40 P.S. § 991.2102 and § 991.2116, and 28 Pa. Code § 9.672 pertaining to coverage and payment of Medically Necessary Emergency Services.

The CHC-MCO may not:

- Limit what constitutes an Emergency Medical Condition based on lists of diagnoses or symptoms.
- Refuse to cover Emergency Services based on the ED, hospital, or fiscal agent not notifying the Participant's PCP or CHC-MCO of the Participant's screening and treatment within ten (10) calendar days of presentation for Emergency Services.
- Hold a Participant who has an Emergency Medical Condition liable for payment of subsequent screening and treatment needed to diagnose the specific condition or stabilize the Participant.
- Deny claims for emergency services provided to Participants by a Provider that is a licensed emergency medical services agency solely because the Participant did not require transportation or refused transportation.

The CHC-MCO may not require Prior Authorization of Emergency Services. A Provider may initiate necessary intervention to stabilize an Emergency Medical Condition without seeking or receiving Prior Authorization. The treating Provider determines when a Participant is sufficiently stabilized for transfer or discharge, and that determination is binding on the CHC-MCO.

The CHC-MCO must limit the amount paid to Out-of-Network Providers of Emergency Services to no more than the amount that would have been paid for such services under the Department's FFS Program.

The CHC-MCO may not deny payment for Emergency Services when:

- A Participant has an Emergency Medical Condition, including cases in which the absence of immediate medical attention would not have placed the health of the individual or, with respect to a pregnant woman, the health of the woman or her unborn child, in serious jeopardy, serious impairment to bodily functions, or serious dysfunction of any bodily organ or part; or
- A representative of the CHC-MCO instructs the Participant to seek Emergency Services.

The CHC-MCO may not apply case management protocols when they would

interfere with Emergency Services. In the case of a pregnant woman who is having contractions, the CHC-MCO may not use case management protocols unless adequate time exists to effect a safe transfer before delivery or the transfer would not pose a threat to the health and safety of the Participant or the unborn child. When a transfer occurs, the CHC-MCO must have and maintain documentation that its case management protocols did not interfere with the transferring hospital's obligation to:

- Restrict transfer until the Participant is stabilized;
- Effect an appropriate transfer or provide medical treatment within its capacity to minimize the risk of transfer;
- Require a supervised transfer;
- Provide the Participant with the opportunity to make an informed decision to consent to or refuse transfer, along with documentation of the associated risks and benefits; and
- Not divert the Participant being transported by emergency vehicle on the basis of insurance coverage.

A CHC-MCO may:

- Track, trend, and profile ED utilization;
- Retrospectively review and, where appropriate, deny payment for inappropriate ED use;
- Use appropriate methods to encourage Participants to use PCPs rather than EDs for symptoms that do not qualify as an Emergency Medical Condition; and
- Use a Participant Lock-In methodology for Participants with a history of significant inappropriate ED usage as referenced in Section V.X.1., Recipient Restriction Program.

The CHC-MCO must have a process to have PCPs promptly see Participants who presented to an ED but did not require or receive services for those symptoms prompting the ED visit.

9. Post-Stabilization Services

The CHC-MCO must cover Post-Stabilization Services.

The CHC-MCO must limit charges to a Participant for Post-Stabilization Services to an amount no greater than what the CHC-MCO would charge the Participant if he or she had obtained the services through the Network.

The CHC-MCO must cover Post-Stabilization Services without authorization, and regardless of whether the Participant obtains the services within or outside of its Network if any of the following situations exists:

a. The Post-Stabilization Services were administered to maintain the Participant's stabilized condition within one (1) hour of the Provider's request to the CHC-MCO for pre-approval of Post-Stabilization Services.

b. The Post-Stabilization Services were not pre-approved by the CHC-MCO because the CHC-MCO did not respond to the Provider's request for pre-approval of the Post-Stabilization Services within one (1) hour of the request.

c. The Post-Stabilization Services were not pre-approved by the CHC-MCO because the Provider could not reach the CHC-MCO to request pre-approval.

d. The CHC-MCO and the treating physician could not reach an agreement concerning the Participant's care and a CHC-MCO physician is not available for consultation. In this situation, the CHC-MCO must give the treating physician the opportunity to consult with a CHC-MCO physician, and the treating physician may continue with the care of the Participant until a CHC-MCO physician is reached or one of the criteria applicable to termination of a CHC-MCO's financial responsibility described below is met.

The CHC-MCO's financial responsibility for Post-Stabilization Services that the CHC-MCO has not pre-approved ends when:

a. A Network physician with privileges at the treating hospital assumes responsibility for the Participant's care;

b. A Network physician assumes responsibility for the Participant's care through transfer;

c. The CHC-MCO and the treating physician reach an agreement concerning the Participant's care; or

d. The Participant is discharged.

10. Examinations to Determine Abuse or Neglect

a. The CHC-MCO must provide Participants under evaluation as possible victims of abuse or neglect and who present for physical examinations for determination of abuse or neglect, with such services.

b. The CHC-MCO must inform Network Providers they are mandatory reporters and must require all Network Providers to know the procedures for reporting suspected abuse and neglect. This requirement must be included in all applicable Provider Agreements. The CHC-MCO must have

a sufficient number of Network Providers qualified to conduct the specialty evaluations necessary for investigating alleged physical and sexual abuse.

c. Should a Network PCP determine that a mental health assessment is needed, the PCP must inform the Participant or the APS or OAPS representative on how to access mental health services and coordinate access to these services, when necessary.

11. Hospice Services

The CHC-MCO must provide Hospice and use certified Hospice Providers in accordance with 42 C.F.R. Part 418, Subpart G. The CHC-MCO must coordinate with Hospice Providers for Dual Eligible Participants who are receiving Hospice through their Medicare coverage. Hospice provided to Participants by Medicare-approved Hospice Providers is directly reimbursed by Medicare.

12. Organ Transplants

The CHC-MCO must pay for transplants to the extent that the MA FFS Program pays for such transplants. When Medically Necessary, the MA FFS program currently covers the following transplants: kidney, heart, heart/lung, lung, liver, pancreas, pancreas/kidney, intestinal, corneal, stem cell, bone marrow, or peripheral stem cell.

13. Transportation

The CHC-MCO must provide all Participants with Medically Necessary emergency ambulance transportation and Medically Necessary non-emergency ambulance transportation. The CHC-MCO must provide all NFCE Participants with non-medical transportation. The CHC-MCO may provide non-medical transportation to other Participants at its own discretion and own cost. Non-medical transportation includes transportation to community activities, grocery shopping, religious services, Adult Daily Living centers, employment and volunteering, and other activities or LTSS services as specified in the Participant's PCSP.

a. The CHC-MCO must pay rates for ambulance services that are not less than the amounts listed in PA's MA fee schedule. If the MA fee schedule rates are increased to comply with Act 15 of 2023, and if the change is such that an actuarial analysis determines that a rate change is appropriate, the Department will adjust capitation rates to account for this change.

b. Effective January 1, 2021, the CHC-MCOs must pay rates to the ambulance service owned and operated by the City of Pittsburgh that are at least 105 percent of the Medicare Fee Schedule, Urban Base Rate for the following list

of services. Effective January 1, 2023, the CHC-MCOs must pay rates to the ambulance service owned and operated the City of Philadelphia that are at least 105 percent of the Medicare Fee Schedule, Urban Base Rate for the following list of services.

- Basic Life Support, non-emergency transport - (A0428)
- Basic Life Support, emergency transport - (A0429)
- Advanced Life Support, Level 1 - (A0426 & A0427)
- Advanced Life Support, Level 2 - (A0433)

If the payment rates required in Section V.A.13.a are higher than any or all of the payment rates required by this Section, then the CHC-MCO must apply Section V.A.13.a in place of the requirements in this Section for any or all of the ground ambulance services listed above. For all other services provided by the ground ambulance service owned and operated by the City of Pittsburgh and the City of Philadelphia not specifically listed in this Section, the CHC-MCO must apply Section V.A.13.a requirements above.

c. The requirements in subsections 13.a., and 13.b. above apply to any Subcontractor of the CHC-MCO, as required by Section V.X.2.

The CHC-MCO must provide non-emergency medical transportation for NF residents. The CHC-MCO must also provide any specialized non-emergency medical transportation for Participants, including transportation for Participants who are stretcher-bound.

All other non-emergency transportation for Participants to and from Medicare-covered services and Covered Services must be arranged through the MATP vendor.

The Medical Assistance Transportation Program (MATP) is responsible for the following:

- Non-emergency transportation to a medical service that is covered by Medicare or CHC. This includes transportation for urgent care appointments. Participants whose service is paid by Medicare can receive MATP service as long as the service is performed by a Network Provider and all other eligibility requirements are met.

- Transportation to another county, as Medically Necessary, to get medical care as well as advice on locating a train, bus, and route information.

- Reimbursement for mileage, parking, and tolls with valid receipts, if the Participant used own car or someone else's car to get to the Provider.

When requested, the CHC-MCO must arrange non-emergency medical transportation for urgent appointments for its Participants through the MATP. Some Participants may qualify for non-emergency medical transportation through programs such as Shared Ride. Because MATP is the payor of last resort, for Participants who require CHC-MCO assistance in coordinating non-emergency medical transportation the CHC-MCO must coordinate access to transportation through all available programs and not just the MATP program.

MATP agencies have been instructed to contact the CHC-MCO for verification that a Participant's request is for transportation to a Covered Service. The CHC-MCO should jointly undertake activities with MATP agencies such as sharing Provider Network information, developing informational brochures, and establishing procedures which enhance transportation services for Participants.

The CHC-MCO must arrange and coordinate transportation with the MATP providers so Participants receive the MATP services outlined in their PCSP.

14. Healthy Beginnings Plus Program

The CHC-MCO must provide services that meet or exceed HBP standards in effect as defined in 55 Pa. Code Chapter 1140 (relating to Healthy Beginnings Plus Program) and current or future guidance provided in MA Bulletins. The CHC-MCO must also continue the coordinated services relating to pregnancy included in the HBP Program by utilizing enrolled HBP Providers or developing comparable resources. The CHC-MCO must submit any such comparable programs to the Department for review and approval.

The CHC-MCO's prenatal program must have the majority of its pregnant Participants seen face-to-face in a community setting. Majority is defined as greater than fifty percent (50%) of unique pregnant women that have an initial care management assessment as reported. This will be accomplished by relationships within the CHC-MCO's Network, CHC-MCO employees, or delegated vendor relationship.

The HBP Program requires that pregnant women be adequately screened for substance use disorders and referred to treatment for positive screenings.

15. Nursing Facility Services

The CHC-MCO is responsible for payment for Medically Necessary NF services, including bed hold days up to fifteen (15) days per hospitalization if the NF satisfies the occupancy percentage requirements and up to thirty (30) Therapeutic Leave Days per year if a Participant is admitted to a NF or resides in a NF at the time of Enrollment.

The CHC-MCO must, in coordination with the Department, monitor for

completion of all NF-related processes, including but not limited to: PASRR process, specialized service delivery, Participant's rights, patient pay liability, personal care accounts, or other identified processes. CHC-MCOs must cover all Program required and necessary specialized services for CHC-enrolled Participants as mandated in the Federal PASRR regulations. In accordance with those regulations, which control, CHC-MCOs are required to provide supportive services to individuals residing in nursing facilities who have been determined to have a condition that meets program criteria for Mental Health, ID/DD, and ORC (Physical, Sensory, or Neurological disability), for which they require specialized services. These services are ancillary to the services a nursing facility generally provides. For individuals with Mental Health conditions, the CHC-MCOs in coordination with the BH-MCO, must at a minimum provide specialized services for partial psychiatric hospitalization, psychiatric outpatient clinic, mobile mental health treatment, crisis intervention services, targeted mental health case management and resource coordination, peer support services, and outpatient drug and alcohol services. For individuals with ID/DD, the CHC-MCOs must at a minimum provide assistive technology, behavioral support, communication specialist, companion services, housing transition and tenancy sustaining services, in-home and community support, supports coordination, support in a medical environment, and transportation. For individuals with an Other Related Condition, the CHC-MCOs must at a minimum provide specialized services for service coordination/advocacy, community integration, peer counseling/support groups, training, and transportation needed to access specialized services. BH-MCOs are responsible for payment of behavioral health specialized services. CHC-MCOs must ensure that their staff is adequately educated on the PASRR process and specialized services.

16. Participant Self-Directed Services

CHC-MCOs must offer and educate Participants who are eligible for HCBS the opportunity to self-direct Personal Assistance Services as the first option over the traditional agency model, through one of the following models. CHC-MCOs must discuss what this model entails and provide educational materials to Participants on the self-directed model of care. CHC-MCOs must document the rationale given if a Participant decides to opt out of the self-directed model.

a. Vendor/Fiscal Employer Agent

- Participants may elect the Participant-Directed Employer Authority model, in which the Participant employs his or her own personal assistance and/or respite provider, who can be a family member, a friend, a neighbor, or any other qualified personal assistance worker as determined by the Department. Participants in this model may elect to also receive some of

their services through an agency or both; or

- Participants may elect the Budget Authority model called Services My Way, in which the PCSP is converted to a budget and the Participant develops a spending plan to purchase needed goods and services. Participants in this model may elect to receive personal assistance and/or respite services through an agency or to employ their own personal assistance providers, or both.

Under the Participant-Directed Employer Authority model and Budget Authority model an FMS vendor processes timesheets, makes payments, and manages all required tax withholdings, including Federal Insurance Contributions Act (FICA) taxes, for personal assistance workers employed by Participants under either self-directed model. A full FMS description can be found in Exhibit CC, Financial Management Services (FMS).

b. Agency with Choice

- Upon Federal approval, Participants may elect the Participant-Directed Agency with Choice (AWC) model, in which the participant selects his or her own personal assistance service and/or respite worker, who can be a family member, a friend, a neighbor, or any other qualified personal assistance worker as determined by the Department. The Participant is supported by an agency that provides administrative functions to the DCWs recruited by the Participant. The Participant directs the DCWs and is considered their managing employer. The Participant, as the managing employer, is responsible for, selecting and dismissing DCWs, directing the responsibilities of their DCWs, scheduling, and arranging for back-up services (with assistance from the Agency as requested), and any individualized training.

  The CHC-MCO may use only the AWC entity procured by the Department and must establish agreements and cooperate with the Commonwealth-procured AWC entity in order that necessary AWC services are provided to Participants. The CHC-MCO is responsible for paying the AWC provider:

- Reimbursement for payments the AWC FMS provider makes on behalf of the Participant-employer for workers' training, required pre-service orientation and wages.

- A per-member per-month fee to perform the tasks outlined in the AWC FMS service description

CHC-MCOs must at a minimum exceed baseline counts per CHC-MCO as of September 2023 as determined by Department data for the number of

Participants receiving services in the self-directed model of care in each of the CHC Zones.

CHC-MCOs must develop and implement strategies to increase education on the use of participant self-directed services. The Department will monitor the CHC-MCOs progress towards an increase in the use of Participant self-directed services through ad hoc and operations reports. The Department may establish a pay for performance program designed to provide incentives to support consumer direction as the first option over traditional agency model in subsequent years.

17. Health and Wellness Education and Outreach for Participants and Caregivers

The CHC-MCO must provide health and wellness opportunities for Participants, such as providing classes, support groups, and workshops, disseminating educational materials and resources, and providing website, email, or mobile application communications on topics including but not limited to heart attack and stroke prevention, asthma, living with chronic conditions, back care, stress management, healthy eating and weight management, oral hygiene, and osteoporosis. The CHC-MCO may also include annual or other preventive care reminders and caregiver resources. The CHC-MCO is also encouraged to identify regional community health education opportunities, improve outreach and communication with Participants and community-based organizations, and actively promote healthy lifestyles as well as disease prevention and health promotion.

18. Settings for HCBS

The CHC-MCO must provide services in the least restrictive, most integrated setting. The CHC-MCO shall only provide HCBS in settings that comply with 42 C.F.R. § 441.301. NFCE Participants who are residing in Personal Care Homes as of the Implementation Date will be permitted to remain in those settings while in CHC. Settings cannot be located on the grounds of a NF, Intermediate Care Facility, Institution for Mental Disease, or a Hospital, unless it meets the standards for the heightened scrutiny process established under 42 C.F.R. § 441.301(c)(5) and is included in the PCSP.

The CHC-MCO must work in collaboration with the Department to assess settings for compliance, which includes, but is not limited to, the following:

a. The CHC-MCO must identify a point person to participate in Department activities related to settings compliance with 42 C.F.R. § 441.301.

b. The CHC-MCO must comply with Department decisions on provider disenrollment in accordance with Exhibit V, CHC-MCO Requirements for Provider Terminations.

CHC-MCOs must also submit within ten (10) business days of identification any possible instances of non-compliance they identify in a format determined by the Department. The CHC-MCO remains obligated to comply with the regulations and may not provide services in a non-compliant setting.

19. Service Delivery Innovation

The CHC-MCO must promote innovation in the CHC service delivery system, including innovation pursued by the CHC-MCO on its own initiative, as well as collaborative efforts with the Department, CMS and local partners. Initial required target areas for CHC-MCO innovation are as follows.

a. Housing innovation that includes but is not limited to:

   i. Pre-tenancy and tenancy supports that help Participants at risk of homelessness or institutionalization obtain and maintain homes in the community, including but not limited to: outreach to and engagement of Participants, housing search assistance, assistance and applying for housing and benefits, assistance with SSI eligibility processes, advocacy and negotiation with landlords and other tenants, moving assistance, eviction prevention, motivational interviewing, and incorporating social determinants of health into the person-centered planning process.

   ii. Participation in local and statewide housing collaboratives, including implementing a Landlord Risk Mitigation program with the Self Determination Housing of PA (SDHP) to address housing barriers, for individuals transitioning from a nursing facility or at risk of a nursing facility placement and cooperating with other local and state housing agencies and social services organizations on housing initiatives.

b. Employment innovation that supports a Participant's ability and efforts to seek, find, and maintain competitive integrated employment or self-employment.

c. Workforce innovation that improves the recruitment, retention, and skills of direct care workers, which may include but are not limited to direct or enhanced payment and other incentives to Providers, Participant-Directed employers, and direct care workers for education, training, and other initiatives designed to enable direct care workers to

become a more functional member of the PCPT. Such initiatives may include but not be limited to:

- Labor/management partnerships or employee/employer partnerships;
- Training programs that exceed DOH and DHS requirements for direct-care worker qualifications, including programs to address complex needs of Participants;
- Pre-service orientation;
- Promotion of direct-care worker organizations and associations;
- Professional support, certifications, and career-ladder opportunities;
- Care team integration that engages front line workers;
- Marketing for the purposes of education and increased awareness of Participant-directed services options.

d. Technology innovation that supports a Participant's ability and efforts to lead a healthy and independent life in the community, which may include but not be limited to home monitoring and telemedicine applications.

e. CHC-MCOs must contract with at least one Health Information Organization that is capable of connecting to the PA Patient and Provider Network (or "P3N"). CHC-MCOs must work with the Department and Health Information Organizations (HIOs) to establish a resource and referral tool.

The CHC-MCO must participate in initiatives in these target innovation areas when requested by the Department. In addition, the CHC-MCO must submit a report to the Department annually that outlines the CHC-MCO's efforts in each of the four areas, lessons learned, and plans for the following year. The CHC-MCO must submit its first report by a date specified by the Department, and submit each subsequent report annually thereafter.

20. Exceptional Durable Medical Equipment

The CHC-MCO must provide Exceptional DME to NF residents. The CHC-MCO must have a process to provide a separate payment for Exceptional DME, Ventilators, and related supplies. The CHC-MCO must also have a process for directly paying a DME vendor for Exceptional DME.

The Department separately includes Exceptional DME from standard DME in developing the capitation rates. In the event of an Exceptional DME purchase, the equipment will belong to the Participant. The CHC-MCO will pay the DME vendor directly for Exceptional DME. The amount of the additional payment authorized is based upon the necessary, reasonable, and prudent cost of the Exceptional DME.

A Ventilator Authorization allows exceptional payments under specific terms to a NF, in addition to the NF's per diem rate, for NF services that are provided for the use of certain ventilator supplies. The amount of the additional payment authorized is based upon the necessary, reasonable, and prudent cost of the Ventilators and related supplies specified in the agreement with the NF.

The CHC-MCO must provide, in accordance with then-existing Department policies and procedures, an Exceptional DME or Ventilator payment where the Exceptional DME or Ventilator is Medically Necessary, and it must be specially adapted for the Participant or designated by the Department. The Department will publish an annual list of Exceptional DME by notice in the *Pennsylvania Bulletin.*

21. Dental Benefit Limit Exceptions (BLEs)

The CHC-MCO has the option to impose the same benefit limits or lesser benefit limits as the Department. For dental services that are covered in a Participant's benefit package only with an approved BLE, the CHC-MCO must use the same criteria as the Department or may use criteria that are less restrictive for its review of a BLE request.

The CHC-MCO must establish and maintain written policies and procedures for its dental BLE process. The CHC-MCO must receive advance written approval from the Department of these policies and procedures. The policies and procedures must comply with guidance issued by the Department. The CHC-MCO's submission of revised policies and procedures for review and approval by the Department shall not act to void any existing policies and procedures which have been prior approved by the Department for operation in a CHC Zone. Unless otherwise required by law, the CHC-MCO may continue to operate under such existing policies and procedures until such time as the Department approves the new or revised version thereof. The Department may periodically request ad hoc information related to CHC-MCO operations surrounding these dental BLE requests.

If the CHC-MCO imposes benefit limits, the CHC-MCO must issue notices to its Participants and notify network providers at least thirty (30) days in advance of the changes. The Participant notices must receive advance Department approval prior to being sent to Participants.

The time frames for notices of decisions for prior authorization set forth at Section V.B.2 and V.B.3. apply to requests for BLEs. If the CHC-MCO denies a BLE request, the CHC-MCO must issue a written denial notice, using the appropriate template available in docuShare.

If the Participant is currently receiving a service or item that is subject to a

benefit limit and the request for a BLE is denied, and the Participant files a complaint, grievance or request for a Fair Hearing that is postmarked or hand-delivered within 10 days of the date of the notice, the CHC-MCO must continue to provide the service until a decision is made.

Participants with approved BLE's are in a course of treatment. As such, the requirements for Continuity of Care for Course of Treatment Services Not Requiring Prior Authorization for Adults Age 21 and Older and Children Under the Age of 21, set forth in MA Bulletin 99-03-13, Attachment D, apply. CHC-MCOs are required to honor all approved BLE requests issued by the Fee-for-Service (FFS) program, another CHC-MCO, or a PH-MCO. The FFS delivery system and PH-MCOs will also honor all approved BLE requests issued by CHC-MCOs.

22. Complex Care Unit

The CHC-MCO must develop, train, and maintain a Complex Care Unit for complex case management and hard to place cases within its organizational structure that will be responsible to provide support and case management services to Participants with complex care needs. The purpose of the Complex Care Unit is to ensure that all Participants with complex circumstances, such as traumatic brain injury or ventilator dependence, are able to receive all necessary services and supports in a timely manner. The Complex Care Unit must also assist each Participant with a complex condition with access to services and information relevant to their special condition or circumstance. The Complex Care Unit must proactively identify and outreach to both NFCE and NFI Participants with special needs to provide these services and information. These services will include all those needed by a Participant with a complex condition to address their condition or circumstance.

B. Prior Authorization of Services

1. General Prior Authorization Requirements

The CHC-MCO may require Prior Authorization for services that require Prior Authorization in the FFS Program. If the CHC-MCO wishes to require Prior Authorization, the CHC-MCO must establish and maintain written policies and procedures which must have advance written approval from the Department. In addition, the CHC-MCO must submit a list and scope of services for referral and Prior Authorization for Department review and prior written approval as outlined in Exhibit E, Prior Authorization Guidelines for CHC-MCOs, and Exhibit F, Quality Management and Utilization Management Program Requirements.

The Department will use its best efforts to review and provide feedback to the

CHC-MCO on requests for written approval, corrective action plans, or denials, within sixty (60) days from the date the Department receives the request for review. For minor updates to existing approved Prior Authorization plans, the Department will use its best efforts to review updates within forty-five (45) days from the date the Department receives the request.

The Department may subject Prior Authorization Denials issued under unapproved Prior Authorization policies to Retrospective Review and reversal and may impose sanctions and require corrective action plans in the event that the CHC-MCO improperly implements a Prior Authorization policy or procedure or implements such policy or procedure without Department approval.

When the CHC-MCO makes a decision to deny, in whole or in part, a request for a service or item, the CHC-MCO must issue a written notice of denial using the appropriate notice templates provided by the Department. In addition, the CHC-MCO must make the notice available in accessible formats for individuals with visual impairments and for persons with LEP. If the CHC-MCO receives a request from the Participant, prior to the end of the required period of advance notice, for a translated and/or accessible version of the notice of denial, the required period of advance notice will begin anew as of the date that CHC-MCO mails the translated and/or accessible notice of denial to the Participant.

The CHC-MCO may not require Prior Authorization of Medicare services for Dual Eligible Participants. If coverage of the service is denied by Medicare, the CHC-MCO may require Prior Authorization if such authorization is required under the CHC-MCO's approved Prior Authorization policies and procedures. If the CHC-MCO does not require Prior Authorization of the services, the CHC-MCO will approve the service. Service Coordinators are required to work with the Participant's Medicare plan to obtain expeditious decision-making and communication of decisions.

2. Time Frames for Notice of Decisions

a. The CHC-MCO must process each request for Prior Authorization and notify the Participant of the decision as expeditiously as the Participant's health condition requires, or at least orally, within two (2) business days of receiving the request, unless additional information is needed. If no additional information is needed, the CHC-MCO must mail written notice of the decision to the Participant, the Participant's PCP, and the prescribing Provider within two (2) business days after the decision is made. The CHC-MCO may make notification of coverage approvals via electronic notices as permitted under 28 Pa. Code § 9.753(b). The two (2) business day decision timeframe for physical health services requests begins on the date the prescribing provider submits the request. The two (2) business day notification timeframe for HCBS requests begins on the date that the updated PCSP is

finalized as a result of the assessment and signed by the Participant, or when an assessment is not necessary, on the date the request is made by the Participant or Participant's representative, which may include the Participant's Provider, or the Participant's Service Coordinator. If additional information is needed to make a decision, the CHC-MCO must request such information from the appropriate Provider within two (2) business days of receiving the request and allow fourteen (14) days for the Provider to submit the additional information. If the CHC-MCO requests additional information, the CHC-MCO must notify the Participant on the date the additional information is requested, using the template provided by the Department, Request for Additional Information Letter. Timeframes specific to home/vehicle modifications, pest eradication, or assistive technology decisions are addressed in Section V.B.3.

b. If the requested information is provided within fourteen (14) days, the CHC-MCO must make the decision to approve or deny the service, and notify the Participant orally, within two (2) business days of receipt of the additional information. The CHC-MCO must mail written notice of the decision to the Participant, the Participant's PCP, and the prescribing Provider within two (2) business days after the decision is made.

c. If the requested information is not received within fourteen (14) days, the CHC-MCO must make the decision to approve or deny the service based upon the available information and notify the Participant orally within two (2) business days after the additional information was to have been received. The CHC-MCO must mail written notice of the decision to the Participant, the Participant's PCP, and the prescribing Provider within two (2) business days after the decision is made.

d. In all cases, the CHC-MCO must make the decision to approve or deny a covered service or item and the Participant must receive written notification of the decision no later than twenty-one (21) calendar days from the date the CHC-MCO received the request, or the service or item is automatically approved. To satisfy the twenty-one (21) day time period, the CHC-MCO may mail written notice to the Participant, the Participant's PCP, and the prescribing Provider on or before the eighteenth (18th) day from the date the request is received. If the notice is not mailed by the eighteenth (18th) day after the request is received, the CHC-MCO must hand deliver the notice to the Participant by the twenty-first (21st) day, or the request is automatically approved.

e. If the Participant is currently receiving a requested service and the CHC-MCO decides to deny the Prior Authorization request, the CHC-MCO must mail the written notice of denial at least ten (10) days prior to the effective date of the denial of authorization for continued services. If probable Participant fraud has been verified, the period of advance notice is

shortened to five (5) days. The CHC-MCO is not required to provide advance notice when it has factual information of the following:

- confirmation of a Participant's death.
- receipt of a clear written statement signed by a Participant that she or he no longer wishes the requested service or gives information that requires termination or reduction of services and indicates that she or he understands that termination will be the result of supplying that information. The Participant's signature on the PCSP alone does not constitute the "clear written statement" that is required under this provision.
- the Participant has been admitted to an institution where she or he is ineligible under CHC for further services.
- the Participant's whereabouts are unknown and the post office returns mail directed to him or her indicating no forwarding address.
- the CHC-MCO established the fact that the Participant has been accepted for MA by another State.
- a change in the level of medical care is prescribed by the Participant's physician.
- the notice involves an adverse determination with regard to preadmission screening requirements of section 1919(e)(7) of the Act (relating to nursing facility admission of individuals with mental illness or intellectual disabilities).
- the transfer or discharge from a facility will occur in an expedited fashion.

3. Time Frames for Notice of Decision for HCBS Waiver Home or Vehicle Modifications, Pest Eradication, or Assistive Technology Requests

The CHC-MCO must evaluate and mail a decision for each home/vehicle modification, pest eradication, or assistive technology request within sixty (60) business days of the date of request. The date of the request is deemed as when the Participant or Participant's representative requests the service or item, or the date the need for these services are identified during an assessment or nursing home transition process. During the sixty-day time frame the CHC-MCO must obtain all information pertinent to rendering a decision and mail the Participant the notice of decision by sixty (60) business days. Requests for additional information must be mailed within fifteen (15) business days of receiving the request and must allow thirty (30) business days for the additional information to be provided. Upon receipt of the additional information the CHC-MCO must make a determination as expeditiously as the Participant's health condition requires and send the Participant notification of the decision. If the service is approved, the CHC-MCO must initiate the process necessary to complete the task within seven (7) business days of authorization by inclusion on the Participant's PCSP. If by sixty (60) business days the CHC-MCO has not been

provided the information necessary to render a decision a denial notice shall be mailed. If the service is denied due to missing information and that information is later received, the request should be reopened as a new request and the process should continue when feasible.

During the sixty (60) business days, the CHC-MCO must obtain all information pertinent to rendering a decision as detailed in the CHC 1915(c) waiver.

Service Coordinators must clearly communicate the process to the Participant, including the information needed within sixty (60) business days and that when feasible the request may be reopened if the needed documentation is received after the denial notice is issued.

In cases where the item or service requested is not a covered service, the CHC-MCO must make a determination within two (2) business days of receipt of the request and mail a denial notice within two (2) business days of the decision.

4. Prior Authorization of Pharmacy Services

The CHC-MCO must comply with the requirements of Exhibit D, Drug Services, specific to Prior Authorization of Drug Services.

C. Continuity of Care

The CHC-MCO must provide continuity of care to Participants upon transition into CHC as follows:

1. NF Residents

A Participant who was already residing in a NF on the CHC Implementation Date must receive NF services from the same NF until the earliest date any of the following:

a. The Participant's stay in the NF ends.
b. The Participant is disenrolled from CHC.
c. The NF is no longer enrolled in the MA Program.

If a Participant appeals a decision to transfer or discharge the Participant from the NF, the continuity of care period will continue until the Participant's appeal is adjudicated by BHA.

A change in CHC-MCO, a temporary hospitalization, or therapeutic leave does not interfere with or terminate this continuity of care period as long as the Participant remains a resident of the NF.

The CHC-MCO in which the Participant is enrolled must enter into an agreement or payment arrangement with the Participant's NF to make

payments for the Participant's NF services during the continuity of care period, regardless of whether the NF is in the CHC-MCO Network. The Department is requiring the extended continuity of care provision described above to avoid unnecessary disruptions in continuity of care for NF residents and to promote their quality of care and quality of life. To meet this requirement the Department expects CHC-MCOs to pay all NFs at the FFS level unless the parties otherwise agree to another payment arrangement. The CHC-MCO may require Out-of-Network NFs to meet the same requirements as Network NFs, with the exception that a CHC-MCO may not require Out-of-Network Providers to undergo full credentialing.

Participants who do not qualify for the continuity of care period in this section, will receive the continuity of care described in Sections C. 3.

2. All Participants

For all Participants, the CHC-MCO must comply with continuity of care requirements for continuation of physical health Providers, services, and any ongoing course of treatment outlined in MA Bulletin 99-03-13, Continuity of Care for Recipients Transferring Between and Among Fee-for-Service and Managed Care Organizations. To ensure continuity of services for Participants receiving LTSS, CHC-MCOs must obtain the transitioning Participants' current PCSP or obtain an electronic record that includes all of the information contained in the current PCSP. CHC-MCOs must contact the providers identified in the service plan from the transferring Fee-for-Service program or CHC-MCO to confirm continuation of service authorization and payment. The term contact means the CHC-MCO provides an authorization of service that includes the type, scope, amount, duration, and frequency of services to be provided. The CHC-MCO must initiate contact within two business days of the date the CHC-MCO receives the PCSP or electronic record. LTSS identified on the Participants PCSP must remain in place until a reassessment is completed.

3. Other Care or Service Plan Transition

For a Participant who is receiving home- and community-based services other than through an HCBS Waiver on the Participant's Start Date, the CHC-MCO must coordinate the Participant's transition into CHC with entities that are providing care or Service Coordination to the Participant at the time of their CHC Enrollment. Entities might include but are not limited to the Act 150 program, the OPTIONS program or OMAP's Special Needs Unit. If a Participant becomes financially ineligible for CHC, their service coordinator shall provide them with information for the Act 150 Program.

D. Choice of Provider

The CHC-MCO must provide Participants with choice of Providers within its Network. The CHC-MCO may not attempt to steer Participants to Affiliates who are Providers or interfere with the Participants' choice of Network Providers. Participants may choose a Provider from within the Network at any time, even during a continuity of care period.

E. Comprehensive Needs Assessments and Reassessments

The CHC MCOs must screen each new Participant who is not NFCE for need within ninety (90) days of the Start Date. This requirement is separate from the assessment of those with LTSS or other special health needs.

The CHC-MCO must conduct a Comprehensive Needs Assessment (Assessment) of every Participant who is determined NFCE. If the Participant has not been determined NFCE, then the CHC-MCO must conduct an Assessment of a Participant when the Participant requests an Assessment or self-identifies as needing LTSS or if either the CHC-MCO or the IEB identifies that the Participant has unmet needs, service gaps, or a need for Service Coordination.

The CHC MCO must complete an in-person Assessment in accordance with the timeframes noted below.

- For NFCE Participants who are not receiving LTSS on their Enrollment Date, no later than five (5) business days from the Start Date.
- For Dual Eligible Participants identified by the IEB as having a need for immediate services, no later than five (5) business days from the Start Date.
- For Participants who are identified as having unmet needs, service gaps, or a need for Service Coordination, no later than fifteen (15) business days from the date the CHC-MCO is aware of the unmet needs, service gaps, or need for Service Coordination.
- When requested by a Participant or a Participant's designee or family member, no later than fifteen (15) days from the request.

The CHC-MCO must conduct a Comprehensive Needs Reassessment (Reassessment) of NFCE Participants at least annually (at least once every 365 days) following the most recent prior Assessment or Reassessment unless a trigger event occurs. CHC-MCOs may conduct a Reassessment prior to the one-year mark of the last Assessment for Participants who are transitioning to them from another CHC-MCO. If a trigger event occurs, the CHC-MCO must complete a Reassessment as expeditiously as possible in accordance with the circumstances and as clinically indicated by the Participant's health status and needs, but in no case more than fourteen (14) days after the occurrence of the following trigger events:

- A significant healthcare event to include but not be limited to a hospital admission, a transition between healthcare settings, or a hospital discharge.
- A change in functional status.
- A change in caregiver or informal support status if the change impacts one or more areas of health or functional status.
- A change in the home setting or environment if the change impacts one or more areas of health or functional status.
- A change in diagnosis that is not temporary or episodic and that impacts one or more area of health status or functioning.
- As requested by the Participant or designee, caregiver, Provider, or the PCPT or PCPT Participant, or the Department.

In addition to the trigger events listed above, if the CHC-MCO identifies that a Participant has not been receiving services to assist with activities of daily living, as indicated on the service plan, for five (5) consecutive scheduled days of service or more, and the suspension of services was not pre-planned, the CHC-MCO must communicate with the Participant to determine the reason for the service suspension within 24 hours of identifying the issue. If a Participant receives an alternative HCBS in this five (5) day span during which activities of daily living are addressed, outreach by the CHC-MCO is not required. If, after communicating, the CHC-MCO determined that the Participant's health status or needs have changed, then the CHC-MCO must conduct a Reassessment within fourteen (14) days of identifying the issue. Unless one of the trigger events listed in this section occur, or the Participant has transitioned from another CHC-MCO, the Reassessment cannot be conducted more than sixty (60) days prior to the one-year mark of the last Assessment date.

CHC-MCOs should utilize the Minimum Data Set (MDS) to evaluate if a Participant requires a Reassessment while in a nursing facility. For Participants who have been in a nursing facility for more than six (6) months, the MCO should conduct an appropriate assessment, including the Inter RAI for Participants who will be receiving HCBS in the community, to determine the Participant's HCBS needs in order to develop a new PCSP upon discharge to community living.

Through the Assessment and Reassessment, the CHC-MCO must assess a Participant's physical health, behavioral health, social, psychosocial, environmental, caregiver, back-up supports, emergency preparedness needs, LTSS, and other needs as well as preferences, goals, housing, and informal supports. The Assessment and Reassessment processes developed by the CHC-MCO must capture the following:

- Need for traditional comprehensive care management of chronic conditions and Disease Management.
- Functional limitations, including cognitive limitations, in performing ADLs and IADLs and level of supports required by the Participant.

- Ability to manage and direct services and finances independently.
- Level of supervision required.
- Supports for unpaid caregivers.
- Identification of risks to the Participant's health and safety.
- Environmental challenges to independence and safety concerns.
- Availability of able and willing informal supports.
- Diagnoses and ongoing treatments.
- Medications.
- Use of adaptive devices.
- Preferences for community engagement.
- Employment and educational goals.

If, after conducting the Assessment, the CHC-MCO determines that a Participant who has not been determined NFCE has a need for LTSS, the CHC-MCO shall refer the Participant for a clinical eligibility determination. The CHC-MCO must abide by the clinical eligibility determination entity's decision as to the need for NF services.

The Department will designate a tool to be used for Assessments and Reassessments. The CHC-MCO is permitted to gather additional information not included in the designated tool to supplement, but not supplant, the Department-designated tool.

F. Person-Centered Planning Team Approach Required

The CHC-MCO must develop a PCPT policy for PCSP development and implementation for Participants who require LTSS. The PCPT approach must comply with the PCPT requirements of 42 C.F.R. § 441.301(c)(1) through (3) and of this Agreement. The CHC-MCO must include the PCPT approach as part of the service planning and Service Coordination processes for Participants who require LTSS. The CHC-MCO may include the PCPT approach as part of the overall care coordination approach for Participants who do not require LTSS. The CHC-MCO PCPT approach must be person-centered and must consider all goals and requirements of CHC. The CHC-MCO must annually submit and obtain Department approval of its PCPT policy prior to the expiration date of the previously approved policy.

G. Person-Centered Service Plans

The CHC-MCO must develop and implement a written, holistic PCSP for each Participant who requires LTSS. The CHC-MCO must comply with the PCSP requirements specified in 42 C.F.R. § 438.208(c)(3) and § 441.301(b) and (c) in developing the PCSP. The developer of the PCSP must be trained in person-centered planning using a person-centered process. Refer to Exhibit Z Person-Centered Service Planning for additional information on PCSP requirements.

The PCSP must address how the Participant's physical, cognitive, and behavioral health needs will be managed, including how Medicare coverage (if the Participant is Dual Eligible) will be coordinated and how the Participant's LTSS services will be coordinated. The holistic PCSP at a minimum, must include the following:

1. Care Management Plan

A Care Management Plan to identify and address how the Participant's physical, cognitive, and behavioral healthcare needs will be care managed, including:

- Active chronic problems, current non-chronic problems, cognitive needs, and problems that were previously controlled or classified as maintenance care but have been exacerbated by disease progression or other intervening conditions.
- Current medications.
- All services authorized and the scope, amount, duration and frequency of the services authorized, including any services that were authorized by the CHC-MCO since the last PCSP was finalized that need to be authorized moving forward.
- A schedule of preventive service needs or requirements.
- Disease Management action steps.
- Known needed physical and behavioral healthcare and services.
- All designated points of contact and the Participant's authorizations of who may request and receive information about the Participant's services.
- How the Service Coordinator will assist the Participant in accessing Services identified in the PCSP.
- How the Service Coordinator will address and offer assistance with barriers to compliance with the physical or behavioral health treatment plans.
- How the CHC-MCO will coordinate with the Participant's Medicare, Veterans, BH-MCO, and other health insurers and other supports.

2. LTSS Service Plan

A LTSS Service Plan to identify and address how LTSS needs will be met and how services will be provided in accordance with the PCSP. The LTSS Service Plan must include the following:

- All LTSS services necessary to support the Participant in living as independently as possible and remaining as engaged in his or her community as possible.
- For the needs identified in the Assessment, the interventions to address each need or preference, reasonable long-term and short-term goals, the measurable outcomes to be achieved by the interventions, the anticipated timelines in which to achieve the desired outcomes, and the staff responsible for conducting the interventions

and monitoring the outcomes.

- Potential problems that can be anticipated, including the risks and how these risks can be minimized to foster the Participant's maximum functioning level of well-being.
- Participant decisions around self-directed care and whether the Participant is participating in Participant-Direction.
- Communications plan.
- The scope, amount, duration and frequency that specific services will be provided.
- Whether and, if so, how technology and telehealth will be used.
- Participant choice of Providers.
- Participant preferences for how often they would like to engage with their Service Coordinator (Participants must not be steered toward minimal quarterly contacts).
- Participant communication preferences including how they would like to be identified, addressed and preferred method of communication.
- Participant identified goals.
- Health related education needs and a plan to ensure understanding of health needs and treatment plan.
- Individualized Back-Up Plan that is verified by the service coordinator.
- Individuals and organizations identified to be included as part of the PCPT.
- The person(s) and Providers responsible for specific interventions or services.
- Participant's available, willing, and able informal support network and services.
- Participant's need for and plan to access community resources, non-covered services, and other supports, including any reasonable accommodations.
- How to accommodate preferences for leisure activities, hobbies, and community engagement.
- Any other needs or preferences of the Participant.
- Participant's goals for the least restrictive setting possible, if he or she is being discharged or transitioned from an inpatient setting.
- How the CHC-MCO will coordinate with the Participant's Medicare, Veterans Benefits, BH-MCO, other health coverage insurers, and other supports.
- Participant's employment and educational goals.
- Emergency back-up plan that is verified by the Service Coordinator, safe and realistic.
- A plan for regularly scheduled follow up communications with the Participant.
- Barriers to the Participant meeting defined goals.
- Measures to prevent future falls which must include at a minimum offering exercise therapy or referral to exercise for participants who have a history of falls or who have been assessed as a fall risk.

The PCSP must specify the need for referrals and the need for assistance from the Service Coordinator in obtaining referrals. To the extent that the PCP is part of the PCSP development or PCTP process, the PCSP must also articulate referrals that the Service Coordinator will enter in the appropriate systems. CHC-MCOs are required to utilize the PCSP checklist template developed by the Department.

If requested, the MCO must share minimum necessary service plan information with providers, consistent with HIPAA rules and regulations. If sufficient justification is demonstrated by a provider, that information may include the following:

• Total number of authorized units per week (i.e., amount);
• Service provision dates (i.e., service begin and end dates);
• Preferred schedule (i.e., duration and frequency);
• List of tasks detailing participant needs (i.e., ADLs/IADLs);
• Service coordinator name, phone, and email address;
• Off hours service coordination contact number;• Special conditions and instructions;
• Unique circumstances (e.g., allergies, smoking, pets, children under 18 years of age, etc.)

When new services are authorized or services are increased via inclusion on a Participant's PCSP, the new service or increased service level must commence within seven (7) business days of the approval, unless the Participant requests a longer timeframe for the services to start.

If a Participant requests a voluntary reduction or termination of services authorized on their PCSP, the CHC-MCO must obtain a clear written statement signed by the Participant attesting to the fact that they no longer wish to receive the service as previously authorized.

The PCSP must consider both In and Out-of-Network Covered Services to support the individual in the environment of his or her choice as well as caregivers' support needs.

PCSPs must be developed and implemented no more than thirty (30) calendar days from the date the Assessment or Reassessment is completed.

PCSPs must be developed by the Service Coordinator, the Participant, the Participant's representative, as appropriate, and the Participant's PCPT. Participants may appeal part or all of their Service Plan as provided in Exhibit G, Complaint, Grievance and DHS Fair Hearing Processes.

H. Care Management Plans

The CHC-MCO must make care management plans available to all Participants. Additionally, the CHC-MCO must develop and implement a written care plan for Participants who do not require LTSS but who have unmet needs, service gaps, or a need for Service Coordination. The care management plan must address how the Participant's physical, cognitive, and BH needs will be care managed, including how Medicare coverage (if the Participant is Dual Eligible) will be coordinated. The CHC-MCO must include in care management plans for Participants who do not require LTSS, at a minimum, the following:

- Active chronic problems, current non-chronic problems, cognitive needs, and problems that were previously controlled or classified as maintenance care but have been exacerbated by disease progression or other intervening conditions.
- Most recent, up to date, medications list.
- Current PCP and specialty providers.
- Potential future LTSS needs based on reasonably anticipated disease progression.
- All services authorized and the scope, amount, duration and frequency of the services authorized, including any services that were authorized by the CHC-MCO since the last care management plan was finalized that need to be authorized moving forward.
- A schedule of preventive service needs or requirements.
- Disease Management action steps.
- Known needed physical and behavioral healthcare and services.
- All designated points of contact and the Participant's authorizations of who may request and receive information about the Participant's services.
- How the care manager will assist the Participant in accessing services identified in the care management plan.
- How the CHC-MCO will coordinate with the Participant's Medicare, Veterans Benefits, BH-MCO, Lottery-funded Services and other healthcare insurance providers.

I. Department Review of Changes in PCSPs

The Department may review, question, and request revisions to PCSPs. The CHC-MCO must provide the Department with monthly aggregate reports on PCSP changes in a format specified by the Department. Additional PCSP requirements can be found in Exhibit Z.

J. Service Coordination

Service Coordinators must assist Participants who need LTSS in obtaining the services that they need. Service Coordinators lead the PCSP process and oversee the implementation of PCSPs. The CHC-MCO must annually submit and obtain Department approval of its Service Coordination staffing plan, including a staff-to-Participant ratio that is consistent with the ratio in its proposal,

after-hours and emergency staffing, Service Coordinator to Participant communications and contact plans, including the required frequency of in-person Service Coordinator contact, Service Coordinator caseloads, and how Service Coordinators share and receive real-time information about Participants and Participant encounters. The CHC-MCO must provide each Participant with a choice of available Service Coordinators employed by the CHC-MCO or Service Coordination entity contracted with the CHC-MCO. Service coordinators must meet with LTSS Participant's at least once every three (3) months by phone or in-person to assure that a Participant's LTSS are meeting their needs. At least two (2) of these visits must be in-person every year. Service Coordinators must allow for more frequent contacts based on Participant's preferences. Service Coordinators must not steer Participants toward minimal quarterly contacts. For Participants residing in a nursing facility that do not have direct telephone access the remote contact can be with the nursing facility staff that oversees the Participants care plan.

Service Coordinators must identify, coordinate, and assist Participants in gaining access to needed LTSS services and other Covered Services, as well as noncovered medical, social, housing, educational, and other services and supports. Service Coordination includes the primary functions of providing information to Participants and facilitating access to, locating, coordinating, and monitoring needed services and supports for Participants. Service Coordinators are also responsible for: informing Participants about available LTSS, required needs assessments, the PCSP process, service alternatives, service delivery options (including opportunities for Participant-Direction), roles, rights (including complaint, grievance, and DHS Fair Hearing rights), Participant's risks and responsibilities; assisting with fair hearing requests when needed and requested; and protecting a Participant's health, welfare, and safety on an ongoing basis.

Service Coordinators must also collect additional necessary information, including, at a minimum, Participant preferences, strengths, and goals to inform the development of the PCSP; conduct the Reassessment annually or more frequently as needed in accordance with Department requirements; assist the Participant and his or her PCPT in identifying and choosing willing and qualified Providers; coordinate efforts and prompt the Participant to complete activities necessary to maintain LTSS eligibility; explore coverage of services to address Participant-identified needs through other sources, including services provided under Medicare or private insurance and other community resources; and actively coordinate with other individuals and entities essential in the physical and behavioral care delivery for the Participant to provide for seamless coordination between physical, behavioral, and support services.

The CHC-MCO must oversee pre-tenancy and transition services for housing, which prepare and support the Participant's move to housing in an integrated setting. These services include assistance to obtain and retain housing,

activities to foster independence, and assistance in developing community resources to support successful tenancy and maintain residency in the community.

The CHC-MCO must develop, submit for DHS approval, and implement a plan to monitor the performance of Service Coordinators. The maximum caseload ratio for Service Coordinators serving HCBS Participants is 1:65 effective January 1, 2024, and will decrease to 1:60 effective July 1, 2024. The maximum caseload ratio for Service Coordinators serving Participants in nursing facilities is 1:225.

Service Coordinators must respond to Participant outreach within two (2) business days, or sooner when an imminent risk to a participant's health and safety is involved.

The CHC-MCO must assist Service Coordination entities with data sharing that supports quality of services for Participants.

The CHC-MCO must provide Service Coordination as an administrative function through appropriately qualified staff or contracts with Service Coordination entities.

All Service Coordinators assigned to nursing homes must have a PPD test for tuberculosis prior to providing services to Participants in nursing homes. See Exhibit B(1)R for additional information on PPD testing requirements.

The CHC-MCO must cooperate with the Department's Disability Advocacy Program, which aids Participants in applying for SSI or Social Security Disability benefits, by sharing Participant-specific information and performing coordination activities as requested by the Department, on a case-by-case basis.

For Participants not already receiving Service Coordination, the CHC-MCO must coordinate with the Participant's Medicare, Veterans, BH-MCO, other health insurers and other supports, including but not limited to the Act 150 program, the OPTIONS program or OMAP's Special Needs Unit, to assist the Participant in accessing all necessary services and supports.

K. Service Coordinator and Service Coordinator Supervisor Qualification Requirements

The CHC-MCO must provide Service Coordinators and Service Coordinator supervisors that have the following qualifications:

- Service Coordinators must: (1) be a Registered Nurse (RN); or (2) have a Bachelor's degree in Social Work, Psychology, or other related fields; or (3) have at least three (3) or more years of experience in a social service or a

healthcare related setting. Service Coordinators hired prior to the CHC zone Implementation Date must have the qualifications and standards proposed by the CHC-MCOs and approved by the Department.

- Service Coordinator supervisors must either: (1) be a RN; or (2) have a Master's degree in Social Work or in a human services or healthcare field and three (3) years of relevant experience with a commitment to obtain either a Pennsylvania Social Work or mental health professional license within one year of hire. Service Coordinator supervisors hired prior to the CHC zone Implementation Date (who do not have a license) must either: 1) obtain a license within one Year of the Implementation Date in the applicable CHC zone, or 2) have the qualifications and standards proposed by the CHC-MCOs and approved by the Department.

L. Nursing Home Transition

CHC-MCOs must provide NHT activities to Participants residing in NFs who express a desire to move back to their homes or other community-based settings. The CHC-MCO must provide NHT as an administrative function through appropriately qualified staff or contracts with nursing home transition entities.

Participants interested in transitioning to a community setting must be referred for NHT services. CHC-MCOs and the NHT provider are responsible to talk to the Participant and their support network about NHT, HCBS, community supports, and their options. If the Participant expresses a choice to move forward with the transition, the CHC-MCOs NHT provider must refer the Participant to the IEB to complete a Medical Assistance HCBS application. If the Participant is found to be ineligible for HCBS for any reason, a denial notice with appeals rights will be issued by the IEB. If a Participant is found eligible for HCBS services, but the CHC-MCO assesses the Participant and determines it would not be a safe discharge from the nursing facility, the CHC-MCO must issue a notice of denial of HCBS services with appeal rights.

M. CHC-MCO and BH-MCO Coordination

To enhance the treatment of Participants who need both Covered Services and BH Services, the CHC-MCO must develop and implement written agreements with each BH-MCO in the CHC zone regarding the interaction and coordination of services provided to Participants. This agreement must include the provisions specified in Exhibit H, coordination with Behavioral Health Managed Care Organizations. The CHC-MCO must submit any newly executed agreements for Department review and prior approval at least thirty (30) days prior to the implementation and make the agreements available to the Department upon request. The CHC-MCO is encouraged to develop uniform coordination agreements with the BH-MCOs to promote consistency in the delivery and administration of services.

The CHC-MCO must work in collaboration with the BH-MCOs through participation in joint initiatives to improve overall health outcomes of its Participants and in those activities that are required by the Department, including:

a. Information exchanges, including BH utilization data provided by the Department to control avoidable hospital admissions, readmissions and emergency department usage for Participants with SMI or SUDs or both.

b. Specific coordination mechanisms to assess and, where appropriate, reduce the use of psychotropic medications prescribed for Participants.

c. The CHC-MCO must, and the Department will require BH-MCOs to, submit to independent binding arbitration in the event of a dispute between the CHC-MCO and a BH-MCO concerning their respective obligations. The Agreement of the CHC-MCO and a BH-MCO to an arbitration process must be included in the written Agreement between the CHC-MCO and the BH-MCO.

d. The CHC-MCO must comply with the requirements specified in Exhibit D, Drug Services.

N. CHC-MCO Responsibility for Reportable Conditions

The CHC-MCO must work with DOH State and District Office Epidemiologists in partnership with the designated county or municipal health department staffs to appropriately report reportable conditions in accordance with 28 Pa. Code §§ 27.1 et seq. The CHC-MCO must designate a single contact person responsible for this requirement.

O. Participant Enrollment, Disenrollment, Outreach, and Communications

1. General

The CHC-MCO is prohibited from restricting Participants from changing CHC-MCOs. A Participant has the right to change his or her CHC-MCO at any time.

The CHC-MCO is prohibited from offering or exchanging financial payments, incentives, or commissions, to another CHC-MCO not receiving a CHC Agreement or choosing not to continue in CHC for the exchange of information on the other MCO's Participants. This includes offering incentives to a terminating CHC-MCO to recommend that its Participants join the CHC-MCO offering the incentives.

2. CHC-MCO Outreach Materials

The CHC-MCO must develop outreach materials such as pamphlets and brochures to be used by the IEB to assist Potential Participants and Participants in choosing a CHC-MCO and PCP. The CHC-MCO must develop such materials in the form and content required by the Department. The Department must approve such materials in writing prior to their use. The Department's review will be conducted within thirty (30) calendar days and approval will not be unreasonably withheld.

The CHC-MCO must develop outreach materials, including the Participant Handbook, and other Participant materials which are accessible, easily understood, written at not more than a sixth (6^{th}) grade reading level and comply with the other requirements in 42 C.F.R. § 438.10 pertaining to information requirements.

The CHC-MCO is prohibited from distributing, directly or through an agent or independent contractor, outreach materials without advance written approval of the Department. In addition, the CHC-MCO must comply with the following:

a. The CHC-MCO may not seek to influence an individual's Enrollment with the CHC-MCO in conjunction with the sale of any other insurance.

b. The CHC-MCO must comply with the Enrollment procedures established by the Department so that an individual is provided with accurate oral and written information sufficient to make an informed decision on Enrollment.

c. The CHC-MCO may not directly or indirectly conduct door-to-door, telephone, email, or texting marketing activities.

d. The CHC-MCO must develop and provide outreach plans, procedures and materials that are accurate and do not mislead, confuse, or defraud either the Participant or the Department and must comply with Exhibit I, Guidelines for CHC-MCO Advertising, Sponsorships, and Outreach.

3. CHC-MCO Outreach Activities

a. The CHC-MCO is prohibited from engaging in Marketing activities associated with Enrollment into the CHC-MCO, except as provided below. Marketing is any interaction with a potential Participant who is not enrolled in the CHC-MCO, that can reasonably be interpreted as intended to:
    1. Influence a potential Participant to enroll in the CHC-MCO,
    2. Persuade a potential Participant to change enrollment from another managed care organization in CHC to the CHC-MCO contacting the potential Participant, or
    3. Dissuade a potential Participant from enrolling with another managed care organization in CHC and enrolling with the CHC-

MCO contacting the potential Participant.

The CHC-MCO is prohibited from subcontracting with an outside entity to engage in outreach activities associated with any form of Enrollment to Potential Participants. The CHC-MCO must not engage in outreach activities associated with Enrollments at the following locations and activities:

- CAOs
- Providers' offices
- Malls, Commercial, or retail establishments
- Hospitals
- NFs
- Adult Day Centers
- Senior Centers
- Check cashing establishments
- Door-to-door visitations
- Telemarketing
- Direct Mail
- Community Centers
- Churches
- Emails
- Texting

b. The CHC-MCO may market its approved, companion D-SNP product to Dual Eligible Participants.

c. The CHC-MCO, either individually or as a joint effort with other CHC-MCOs in the zone, may use commonly accepted media methods for the advertisement of quality initiatives, educational outreach, and health-related materials and activities.

The CHC-MCO may not include, in administrative costs reported to the Department, the cost of advertisements in mass media, including but not limited to television, radio, billboards, the Internet and printed media for purposes other than noted above unless specific prior approval is provided by the Department. The CHC-MCO must obtain from the Department advance written approval of any advertising placed in mass media.

d. The CHC-MCO may participate in or sponsor health fairs or community events. The Department may set limits on contributions and payments made to non-profit groups in connection with health fairs or community events and requires advance written approval for contributions and payments of Two Thousand Dollars ($2,000.00) or more. The Department will consider participation or sponsorship when the CHC-MCO submits a

written request thirty (30) days in advance of the event or fair, thus allowing the Department reasonable time to review the request and provide timely advance written approval. All contributions and payments are subject to audit by the Department and its designees.

e. The CHC-MCO may offer items of little or no intrinsic value such as trinkets with promotional CHC-MCO logos at approved health fairs or other approved community events. The CHC-MCO must make such items available to the general public; such items may not exceed Five Dollars ($5.00) in retail value and must not be connected in any way to Enrollment activity. All such items are subject to advance written approval by the Department.

f. As permitted by Section V.A.4, Expanded Services and Value-Added Services, the CHC-MCO may offer Participants Expanded or Value-Added Services and is permitted to feature such Services in approved outreach materials.

g. The CHC-MCO may offer Participants consumer incentives only if they are directly related to improving health outcomes. The CHC-MCO may not use an incentive to influence a Participant to receive any item or service from a Provider, practitioner, or supplier. In addition, the incentive cannot exceed the total cost of the service being provided. The CHC-MCO must receive advance written approval from the Department prior to offering a Participant incentive. CHC-MCOs must comply with any managed care ops memos related to Participant incentives.

h. Unless approved by the Department, CHC-MCOs are not permitted to directly provide products of value unless they are health-related and are prescribed by a licensed Provider. CHC-MCOs may not offer Participants coupons for products of value.

i. Except where review and approval are specifically required, the Department may review any and all other outreach activities and advertising materials and procedures used by the CHC-MCO, including all outreach activities, advertising materials, and corporate initiatives that are likely to reach MA Beneficiaries. In addition to any other sanctions, the Department may impose monetary penalties or restrict Enrollment if the Department determines the CHC-MCO used unapproved outreach materials or engaged in unapproved outreach practices. The Department may suspend all outreach activities and the completion of applications for new Participants. Such suspensions may be imposed for a period of up to sixty (60) days from notification by the Department to the CHC-MCO citing the violation.

j. The CHC-MCO may not under any conditions use the Department's eligibility system to identify and market to individuals participating in the

LIFE Program or enrolled in another CHC-MCO. The CHC-MCO may not share or sell Participant lists for any purpose, with the limited exception of sharing Participant information with Affiliates or subcontractors under Department-approved arrangements to fulfill the requirements of this Agreement.

k. The CHC-MCO must submit a plan for advertising, sponsorship, and outreach procedures to the Department for advance written approval in accordance with Exhibit I, Guidelines for CHC-MCO Advertising, Sponsorships, and Outreach.

l. The CHC-MCO must conduct and participate in Department Provider and Participant outreach efforts.

m. The CHC-MCO shall include the following statement or a substantially similar statement in all marketing materials in boldface type: “Your managed care plan may not cover all your health care expenses. Read your participant handbook carefully to determine which health care services are covered.”

4. Limited English Proficiency Requirements

Beginning at Enrollment, the CHC-MCO must seek to identify Participants who speak a language other than English as their primary language and who have a limited ability to read, write, speak, or understand English. The CHC-MCO must identify and communicate using spoken and written language preferences identified by the IEB and CHC-MCO during their contacts with the Participant.

The CHC-MCO must provide, at no cost to Participants, oral interpretation and written translation services in the requested language, including American sign language, to meet the needs of Participants. Oral interpretation requirements apply to all non-English languages, not just those that are identified as prevalent. The CHC-MCO must notify Participants that oral interpretation for any language and written translation in prevalent languages, are available upon request at no cost to the Participant. The CHC-MCO must require Network Providers to offer interpretation services and prohibit Network Providers from requiring that a Participant’s family member be used for interpretation. Interpretation services must also include all services dictated by federal requirements. If a Network Provider is unable or unwilling to provide these services, the CHC-MCO must provide interpretation services.

The CHC-MCO must make all Vital Documents disseminated to English speaking Participants available in the prevalent languages designated by the Department. The CHC-MCO must include appropriate instructions in all materials about how to access or receive assistance to access materials in a

prevalent and other language.

Vital Documents must be readily accessible and in an electronic form which can be electronically retained and printed. The CHC-MCO must post Vital Documents on its website and a location that is prominent and Readily Accessible and inform Participants that the information is available in paper form without charge upon request. The CHC-MCO must provide paper forms upon request within five (5) business days.

5. Alternative Format Requirements

The CHC-MCO must provide alternative methods of communication for Participants who have neurocognitive impairments or who are visually or hearing impaired or both, including Braille, audio tapes, large print, compact disc, DVD, computer diskette, special support services, and electronic communication. The CHC-MCO must, upon request from the Participant, make all written materials disseminated to Participants accessible to visually impaired Participants at no cost to the Participant. The CHC-MCO must provide TTY/Videophone and/or Pennsylvania Telecommunication Relay Service for communicating with Participants who are deaf or hearing impaired, upon request.

The CHC-MCO must include appropriate instructions in all materials about how to access or receive assistance to access materials in an alternative format. The CHC-MCO must include in all written material taglines as well as large print, explaining the availability of written translation or oral interpretation to understand the information provided and the toll-free and TTY/TDD telephone number of the CHC-MCO's call center. Large print means printed in a font size no smaller than eighteen (18) points.

6. Enrollment Procedures

The CHC-MCO must have in effect written Enrollment policies and procedures for newly enrolled Participants. The CHC-MCO must also provide written policies and procedures for coordinating Enrollment information with the Department's IEB. The CHC-MCO must receive advance written approval from the Department regarding these policies and procedures.

The CHC-MCO must enroll any Potential Participant who selects or is assigned to the CHC-MCO in accordance with the Enrollment and Disenrollment dating rules that are determined and provided by the Department on the Pennsylvania HealthChoices Extranet and Exhibit J, Participant CHC-MCO Selection and Assignment, regardless of the individual’s race, color, creed, religion, age, sex, national origin, ancestry, marital status, sexual orientation, gender identity, income status, program participation, Grievance status, MA category status, health status, pre-existing

condition, physical or mental disability or anticipated need for healthcare. CHC-MCOs must offer assistance to Participants enrolled in their Plan with completing all paperwork necessary for the Participant to maintain MA eligibility.

The Department will disenroll a Participant from the CHC-MCO when a change in residence places the Participant outside the CHC zone, as indicated on the individual county file maintained by the Department's Office of Income Maintenance.

7. Enrollment of Newborns

Newborns will not be enrolled in CHC. Newborns will be auto-assigned to the HealthChoices PH-MCO aligned with the mother's CHC-MCO if available in the Zone where they reside.

8. Transitioning Participants Between CHC-MCOs

Service Coordinators will assist Participants in facilitating a seamless transition between CHC-MCOs. The CHC-MCO must follow the Department's established processes as outlined in Exhibit K, CHC-MCO Participant Coverage Document.

The CHC-MCO must provide an electronic or hard paper copy of a Participant's existing Comprehensive Medical and Service Record, including PCSPs, and notification if the Participant has had more than three critical incidents within a 12-month period and when there is a substantiated incident related to abuse, neglect, exploitation or abandonment, to the CHC-MCO to which a Participant transfers. The CHC-MCO must expeditiously transfer the information as soon as they are made aware of the transfer, electronically, if possible, not to exceed five (5) business days after notification of the transfer.

9. Transitioning Participants Between the CHC-MCO and LIFE

The Service Coordinator will assist Participants eligible for LIFE who voluntarily choose to transition between the CHC-MCO and LIFE, where available, in order to facilitate a seamless transition. All transitions to the LIFE program will be effective on the date specified by the Department.

10. Change in Participant Status

The CHC-MCO must report the following to the Department's MMIS on the Weekly Enrollment/Disenrollment/Alert file: pregnancy (not in eCIS), death (not on eCIS),and returned mail alerts in accordance with Section VIII.C.5, Alerts.

The CHC-MCO must report HCBS Participant status changes to the

appropriate CAO using the PA 1768 Form within ten (10) business days of the change becoming known. The CHC-MCO must report status changes for all other Participants using the CAO Notification Form within ten (10) business days of the change becoming known. These changes include phone number, address, experiencing homelessness, pregnancy, death, and family addition/deletion. The CHC-MCO also must provide a detailed explanation on the CAO Notification form of how the information was verified.

11. Participant Files

a. Monthly File

The Department will provide a Monthly 834 Eligibility File to the CHC-MCO on the next to the last Saturday of each month. The file contains the MA Eligibility Period, CHC-MCO coverage, BH-MCO coverage, and Participant demographic information. It will contain only the most current record for each CHC Participant where the Participant is both MA and CHC eligible at some point in the following month. The CHC-MCO must reconcile this Participant file against its internal Participant information.

If discrepancies are found, the CHC-MCO must first check eCIS and subsequent Daily 834 files to see if the discrepancy has been resolved prior to reaching out to the Department. If the MCO cannot resolve the discrepancy, the MCO must notify the Department within thirty (30) business days of receipt of the Monthly 834 file with the discrepancy.

Participants not included on the Monthly 834 Eligibility File with a specification of prospective coverage will not be the responsibility of the CHC-MCO unless a subsequent Daily 834 Membership File indicates otherwise.

b. Daily File

The Department will provide a Daily 834 Eligibility File to the CHC-MCO that contains one record for each action taken in eCIS for each Participant where data for that Participant has changed that day. The file will contain add, termination, and change records, but will not contain BH-related information. The file will contain demographic changes, eligibility changes, Enrollment changes, Participants enrolled through the automatic assignment process, and TPL information. The CHC-MCO must process this file within twenty-four (24) hours of receipt.

The CHC-MCO must reconcile this file against its internal Participant data and notify the Department of any discrepancies within thirty (30) business days.

12. Enrollment and Disenrollment Updates

a. Weekly Enrollment/Disenrollment/Alert Reconciliation File

The Department will provide a weekly file with information on Participants enrolled or disenrolled in CHC and the dispositions of Alerts previously submitted by the CHC-MCO. The CHC-MCO must use this file to reconcile Alerts submitted to the Department.

b. Disenrollment Effective Dates

Participant disenrollments will become effective on the date specified by the Department. The CHC-MCO must have written policies and procedures for complying with the disenrollment decisions by the Department. These policies and procedures must be approved by the Department.

13. Involuntary Disenrollment

The Department will involuntarily disenroll Participants from CHC when it determines the Participant is no longer eligible for CHC. The CHC-MCO may not request disenrollment of a Participant for any reason.

The CHC-MCO must aid the disenrolled Participant in transitioning to other resources to provide for continuity of care.

14. New Participant Orientation

The CHC-MCO must provide an orientation to a new Participant within thirty (30) days of the new Participant's start date with the CHC-MCO. For new Participant's receiving LTSS, the CHC-MCO must conduct the orientation face-to-face (the orientation may be part of the service coordination visit). For purposes of New Participant Orientation, a Participant would be considered new to the CHC-MCO if they were not enrolled with the CHC-MCO 365 days prior to the current enrollment. The CHC-MCO must have a written orientation plan or program for new Participants that includes:

- Educational and preventive care programs that include an emphasis on health promotion, wellness and healthy lifestyles and practices,
- The proper use of the CHC-MCO identification card and the ACCESS Card,
- The role of the PCP,
- The Assessment process,
- Access to behavioral health services, transportation, home modifications, etc.,
- What to do in an emergency or urgent medical situation,
- How to report abuse, neglect, and exploitation,
- How to utilize services in other circumstances,

- How to request information from the CHC-MCO,
- How to register a Complaint, file a Grievance or request a DHS Fair Hearing,
- Notice that balance billing is prohibited and what to do in the event a Provider balance bills,
- What Expanded Services or Value-Added Services the CHC-MCO has been approved to provide and how long these are required to be available to Participants who qualify to receive them,
- Assistance in coordinating Medicare services that are available to the Participant,
- The benefit of enrolling in a Medicare Part D plan with a zero copay.

For participant's receiving LTSS, the orientation must also include the following topics:

- The role of the Service Coordinator,
- The role of the PCPT,
- PCSPs and the service planning process,
- Participant Self-Directed models (for Participants receiving HCBS),
- Individual back-up plan,
- Emergency Preparedness,
- Employment Services,
- The role of Service Coordination Unit and how to contact it directly, if necessary.

The CHC-MCO must obtain the Department's advance written approval of the orientation plan or program.

The CHC-MCO is prohibited from contacting a Potential Participant who is identified on the Daily Participant Enrollment File with an automatic assignment indicator (either an "A" auto-assigned or "M" Participant assigned) until five (5) business days before the Enrollment Date, unless otherwise requested by the Department.

15. CHC-MCO Identification Cards

The CHC-MCO must issue its own identification card to Participants. The CHC-MCO must issue an identification card(s) to Participants enrolled in the aligned D-SNP for both the CHC-MCO and the D-SNP.

The Department also issues an identification card, called an ACCESS Card, to each Recipient, which the Participant is required to use when accessing services. Providers must use this card to verify the Participant's most current eligibility in the EVS system.

16. Participant Handbook

The CHC-MCO must provide a Participant handbook with information on

Participant rights and protections as outlined in this Agreement and Exhibit L, Participant Rights and Responsibilities, and how to access services, in the appropriate language or alternative format to Participants within five (5) business days of a Participant's Start Date. As directed by the Department, the CHC-MCO must use the Participant handbook template developed by the Department to create a Participant handbook that complies with this section and Exhibit M, Participant handbook.

The CHC-MCO may provide the Participant handbook in formats other than hard copy. The CHC-MCO will provide Participants with the handbook in one of the following manners:

- A printed copy of the information mailed to the Participant's mailing address;
- By email after obtaining the Participant's agreement to receive the information by email;
- By posting on the CHC-MCO's website and advising the Participant in paper or electronic form that the information is available on the Internet and including the applicable Internet address, provided that Participants with disabilities who cannot access this information online are provided auxiliary aids and services upon request at no cost; or
- By any other method that can reasonably be expected to result in the enrollee receiving that information.

The CHC-MCO must inform Participants what formats are available and how to access each format. The CHC-MCO must annually review the Participant handbook and document that it reviewed the Participant handbook for accuracy and that all necessary modifications were made. The CHC-MCO must notify all Participants on an annual basis of any changes made, and the formats and methods available to access the handbook. Upon request, the CHC-MCO must provide a hard copy of the Participant handbook to the Participant.

a. Participant Handbook Requirements

The Participant handbook must be accessible, easily understood, and written at no higher than a sixth (6^{th}) grade reading level and must include, at a minimum, the information outlined in Exhibit M, Participant Handbook. The CHC-MCO must include a reference and a link to the handbook for the aligned D-SNP so that Participants enrolled in both plans may easily reference the D-SNP handbook.

Additionally, the CHC-MCO must (i) use a font and format are Readily Accessible, (ii) place the information on its CHC-MCO website where it is prominent and available, and (iii) provide that information in an electronic form that can be electronically retained and printed.

b. Department Approval

CHC-MCOs must submit the Participant handbook to the Department for advance written approval prior to distribution to Participants. The CHC-MCO must make any modifications to the Participant Handbook if required for Department approval.

17. Provider Directory

The CHC-MCO must maintain a single directory for all types of Network Providers.

The CHC-MCO must utilize a web-based Provider directory. The web-based Provider directory must be available in a machine-readable file and format as specified in 42 C.F.R. § 438.10. The web-based Provider directory must be updated no less than thirty (30) days after the CHC-MCO receives updated information from the Provider. The CHC-MCO must establish a process to address the accuracy of electronically posted content, including a method to monitor and update changes in Provider information. The CHC-MCO must perform at least monthly reviews and revisions of the web-based Provider directory, subject to random monitoring by the Department.

The CHC-MCO must provide the IEB with an updated electronic version of its Provider directory on at least a weekly basis. The file must include information regarding terminations, additions, PCPs and specialists not accepting new assignments, and other information determined by the Department to be necessary. The CHC-MCO must utilize the file layout and format specified by the Department. The file must include the information specified in Exhibit N, Provider Directory, but not be limited to:

- Correct MMIS Provider ID
- All Providers in the CHC-MCO's Network
- Locations where the PCP will see Participants and if evening or weekend hours are available
- Wheelchair accessibility of Provider sites
- List of non-English language(s) spoken by Providers.

The CHC-MCO must notify its Participants annually of their right to request and obtain a hard copy of the Provider directory and where the online directory may be found. Upon request, the CHC-MCO must provide Participants with a hard copy of its Provider directory in the prevalent languages specified by the Department and in alternative formats. The CHC-MCO must review the Provider directory information and make any necessary updates at least monthly. Upon request from a Participant, the CHC-MCO must print the most recent electronic version from its Provider file and mail it to the Participant.

The CHC-MCO must submit the Provider directory to the Department for advance written approval before distribution to its Participants. Unless the CHC-MCO makes significant format or substantive changes, the CHC-MCO is not required to submit changes to the Department for approval.

The CHC-MCO must reference and include a link to the Provider directory for the aligned D-SNP in the Provider directory so that Participants enrolled in both plans may easily reference the D-SNP directory.

18. Participant Advisory Committee

The CHC-MCO must establish and maintain a PAC for each zone in which it operates. The PAC must include Participants, Network Providers and direct care worker representatives to advise on the experiences and needs of Participants. The CHC-MCO must include Participants who are representative of the population being served as well as family caregivers as members of the PAC. Provider representation must include PH, BH, dental health and LTSS. The CHC-MCO must provide the Department annually with the membership (including designation) of the PAC. The PAC membership must be composed of at least fifty percent (50%) Participants, with twenty-five percent (25%) of the total membership receiving LTSS, ten percent (10%) of which must be nursing facility residents or a representative of a nursing facility resident. In addition to the individual diversity, the CHC-MCO should seek geographic diversity, including both rural and urban representation.

The CHC-MCO must schedule PAC meetings no less than quarterly with in-person meetings, and will reimburse travel expenses for Participants, caregivers, and their family members. The CHC-MCO will provide necessary reasonable accommodations to allow for in-person access to the PAC. PAC communications and meetings must be accessible to Participants with LEP.

The CHC-MCO must provide the Department with advance notification of the date, time, and location of all PAC meetings.

As part of the PAC meetings the CHC-MCOs must detail health education and outreach activities including coordination of health education materials, activities, and programs with public health entities, particularly as they relate to public health priorities and population-based interventions. Population-based interventions include those that are relevant to the populations being served and that take into consideration the ability of these populations to understand and act upon health information.

The CHC-MCO must provide the Department with a written description of all planned health education activities and targeted implementation dates on an annual basis.

The CHC-MCO must also work with the Department to provide its PAC members with an effective means to consult with each other and, when appropriate, coordinate efforts and resources for the benefit of the entire CHC population in the zone and/or populations with LTSS needs. The CHC-MCO must report out any updates or proposed changes, the number and nature of complaints, and any quality improvement strategies or implementations and invite PAC members to raise questions and concerns about topics affecting their quality of life and their experience with the CHC-MCO. The CHC-MCO must provide minutes of the PAC meeting to the Department and post them on the CHC-MCO website.

P. Participant Services

1. General

The CHC-MCO's Participant services functions must be operational, at a minimum, during regular business hours (9:00 a.m. to 5:00 p.m., Monday through Friday), plus one (1) evening per week (5:00 p.m. to 8:00 p.m.) or one (1) weekend per month to address non-emergency problems encountered by Participants. The CHC-MCO must have arrangements to receive, identify, and resolve in a timely manner Emergency Participant Issues on a twenty-four (24) hour-per-day, seven (7) day-per-week basis. The CHC-MCO's Participant services functions include, but are not limited to, the following:

- Explaining the operation of the CHC-MCO and assisting Participants in PCP selection.
- Assisting Participants with making appointments and obtaining services, including interpreter services, as needed.
- Assisting with transportation for Participants through the MATP as required in Section V.A.13., Transportation.
- Receiving, identifying, and resolving Emergency Participant Issues.

The CHC-MCO is prohibited from using unlicensed Participant services staff to provide health-related advice to Participants requesting clinical information. The CHC-MCO must require that all such inquiries be addressed by clinical personnel acting within the scope of their licensure to practice a health-related profession.

The CHC-MCO must forward all telephone calls received by the Participant Service area in which the caller requests his or her Service Coordinator to the Participant's Service Coordinator.

2. CHC-MCO Internal Participant Dedicated Hotline

The CHC-MCO must maintain and staff a twenty-four (24) hour-per-day,

seven (7) day-per-week dedicated toll-free telephone hotline to respond to Participants' inquiries, issues and problems regarding services. The CHC-MCO's internal Participant hotline staff must ask the callers whether they are satisfied with the response given to their call. The CHC-MCO must document all calls. If the caller is not satisfied, the CHC-MCO must refer the call to the appropriate individual within the CHC-MCO for follow-up and resolution within forty-eight (48) hours of the call.

The CHC-MCO is not permitted to utilize electronic call answering methods as a substitute for staff persons. The CHC-MCO must have a dedicated hotline that meets the following performance standards:

- Provides for a dedicated toll-free telephone line for Participants.
- Provides for necessary translation and interpreter assistance for LEP Participants.
- Includes a function specific to connecting Participants with their Service Coordinator.
- Requires representatives to document calls and forward call notes to the Participant's Service Coordinator.
- Be staffed by individuals fully trained by the CHC-MCO in the following areas before allowing staff to assist Participants by handling phone calls:

  – Cultural, Linguistic, and Disability Competency.
  – Addressing the needs of covered populations.
  – The availability of contact information for, and the functions of, the Service Coordinator.
  – Requirements for accessibility.
  – Coordination with BH-MCOs.
  – How to identify and handle any emergency.
  – When to transfer callers to the Nurse Hotline.
  – Covered Services and the availability of protective and social services within the community.
  – Medicare coverage and addressing questions relating to the CHC-MCO's companion D-SNP plan.
  – Medical and non-medical transportation.

- Be staffed with adequate service representatives so that the abandonment rate is less than or equal to five percent (5%) of the total calls.
- Be staffed with adequate service representatives so that at least eighty-five percent (85%) of all calls are answered within thirty (30) seconds.
- Provide for TTY/Videophone and/or Pennsylvania Telecommunication Relay Service availability for Participants who are deaf or hard of hearing.

The CHC-MCO must provide the Department with the capability to monitor the CHC-MCO's Participant services and internal Participant dedicated hotline from each of the CHC-MCO's offices. The Department will only monitor calls from Participants, or their representatives, and will cease monitoring activity

as soon as it becomes apparent that the call is not related to a Participant.

All criteria above also apply to the Service Coordination functionality of the Participant Hotline.

3. Nurse Hotline

The CHC-MCO must maintain and staff a twenty-four (24) hour-per-day, seven (7) day-per-week dedicated toll-free telephone Nurse Hotline to respond to Participants' urgent health matters.

4. Informational Materials

The CHC-MCO must distribute Participant newsletters at least three (3) times per year to each Participant household. The CHC-MCO may provide Participant newsletters in formats other than hard copy, but must provide a hard copy to a Participant who asks for one. The CHC-MCO must include information about common procedures in its Participant newsletter and information provided by the Department related to Department initiatives, and make the same information available on its website in an effort to increase Participant health literacy. The CHC-MCO will also provide information about its aligned D-SNP, including the services covered, the enhanced Service Coordination available to Participants enrolled in both, and how to request enrollment. The CHC-MCO must obtain advance written approval from the Department of all Participant newsletters. The CHC-MCO must notify all Participants of the availability and methods to access each Participant newsletter.

The CHC-MCO must obtain advance written approval from the Department to use Participant or CHC-related information on electronic websites and bulletin boards which are accessible to the public or to the CHC-MCO's Participants.

Q. Additional Addressee

The CHC-MCO must comply with HIPAA and State law requirements and have administrative mechanisms for sending copies of information, notices and other written materials to a Participant's legal guardian, agent under power of attorney, or other designated third party, as per the request and signed consent of the Participant. The CHC-MCO must develop plans to process such individual requests and for obtaining the necessary releases signed by the Participant to protect the Participant's confidentiality rights.

R. Complaint, Grievance, and Fair Hearing Processes

The CHC-MCO must develop, implement, and maintain a Complaint and Grievance process that provides for resolution of Participants' Complaints and Grievances and the processing of requests for DHS Fair Hearings as outlined in Exhibit G, Complaint, Grievance, and Fair Hearing Processes. The CHC-MCO must use templates provided by the Department to inform Participants regarding decisions and the process.

The CHC-MCO must have written policies and procedures approved by the Department, for resolving Participant Complaints and for processing Grievances and DHS Fair Hearing requests, that meet the requirements established by the Department and the provisions of 40 P.S. §991.2101 et seq. (known as Act 68), 28 Pa. Code Chapter 9, 31 Pa. Code CHs. 154 and 301, and 42 C.F.R. §431.200 et seq. The CHC-MCO must also comply with 55 Pa. Code Chapter 275 regarding DHS Fair Hearing Requests and 42 C.F.R. §438.406(b).

The CHC-MCO's submission of new or revised policies and procedures for review and approval by the Department shall not act to void any existing policies and procedures which have been prior approved by the Department. Unless otherwise required by law, the CHC-MCO may continue to operate under such existing policies and procedures until such time as the Department approves the new or revised version.

The CHC-MCO must abide by the final decision of the PID when a Participant has filed an external appeal of a second level Complaint decision.

In accordance with 28 Pa. Code § 9.707(j), when a Participant files an external appeal of a Grievance decision, the CHC-MCO must abide by the decision of the Independent Review Organization (IRO), which was assigned to conduct the independent external review.

The CHC-MCO must abide by the final decision of BHA for those cases when a Participant has requested a DHS Fair Hearing, unless requesting reconsideration by the Secretary of the Department.

S. OLTL and other DHS Hotlines

The CHC-MCO will cooperate with OLTL and other Department Hotlines, which are intended to address clinically-related systems issues encountered by Participants and their advocates or Providers.

T. Provider Dispute Resolution Process

The CHC-MCO must develop, implement, and maintain a Provider Dispute Resolution Process, which provides for informal resolution of Provider Disputes at the lowest level and a formal process for Provider Appeals. The CHC-MCO and

the Provider must handle the resolution of all issues regarding the interpretation of Provider Agreements and shall not involve the Department; therefore, Provider disputes and appeals are not within the jurisdiction of the Department's BHA.

Prior to implementation, the CHC-MCO must submit to the Department its policies and procedures for resolution of Provider Disputes and Provider Appeals for approval.

The CHC-MCO's Provider Disputes and Provider Appeals policies and procedures must include, at a minimum:

- Informal and formal processes for settlement of Provider Disputes.
- Acceptance and usage of this Agreement's definition of Provider Appeals and Provider Disputes.
- Time frames for submission and resolution of Provider Disputes and Provider Appeals.
- Processes to provide equitability for all Providers.
- Establishment of a CHC-MCO Committee to process formal Provider Appeals, which must provide:

  – At least one-fourth (1/4th) of the membership of the Committee must be composed of Providers/peers.
  – Committee members who have the authority, training, and expertise to address and resolve Provider Dispute/Provider Appeal issues.
  – Access to data necessary to assist Committee members in making decisions.
  – Documentation of meetings and decisions of the Committee.

U. Certification of Authority and County Operational Authority

The CHC-MCO must maintain a Certificate of Authority to operate as an HMO in Pennsylvania and must provide to the Department a copy of its Certificate of Authority upon request.

The CHC-MCO must also maintain operating authority in each county within the zone and must provide to the Department a copy of the PID correspondence granting operating authority in each county upon request.

V. Executive Management

The CHC-MCO must include in its Executive Management structure:

- A full-time Administrator with authority over the entire operation of the CHC-MCO.

- A full-time CHC Program Manager to oversee the operation of this

Agreement, if different from the Administrator.

- A full-time Medical Director who is a current Pennsylvania-licensed physician. The Medical Director must be actively involved in all major clinical program components of the CHC-MCO and directly participate in the oversight of the QM Department and UM Department. The Medical Director and his or her staff/consultant physicians must devote sufficient time to the CHC-MCO to provide timely medical decisions, including after-hours consultation, as needed.

- A full-time Pharmacy Director who is a current Pennsylvania-licensed pharmacist. The Pharmacy Director must oversee the pharmacy management and serve on the CHC-MCO P&T Committee.

- A full-time Director of Quality Management who is a Pennsylvania-licensed RN, physician or physician's assistant or is a Certified Professional in Healthcare Quality by the National Association for Healthcare or Quality Certified in Healthcare Quality and Management by the American Board of Quality Assurance and Utilization Review Providers. The Director of Quality Management must be located in Pennsylvania and have experience in quality management and quality improvement. Sufficient local staffing under this position must be in place to meet QM Requirements. The primary functions of the Director of Quality Management position are:

    - Evaluate individual and systemic quality of care
    - Integrate quality throughout the organization
    - Implement process improvement
    - Resolve, track, and trend quality of care complaints
    - Develop and maintain a credentialed Provider network

- A full-time Director of LTSS who is responsible for and oversees all LTSS. The Director of LTSS must have at least five (5) years of experience administering managed long-term care programs. On a case-by-case basis, equivalent experience in administering long-term care programs and services, including HCBS, or in managed care may be substituted, subject to the prior approval of the Department.

- A full-time Chief Financial Officer (CFO) to oversee the budget and accounting systems implemented by the CHC-MCO. The CFO is responsible for providing accurate and timely financial reports. The CFO shall devote sufficient time and resources to responsibilities under this Agreement.

- A full-time Information Systems Coordinator, who is responsible for the oversight of all information systems issues with the Department. The Information Systems Coordinator must have a good working knowledge of the CHC-MCO's entire program and operation, as well as the technical expertise

to answer questions related to the operation of the information system.

- A full-time Special Investigations Unit (SIU) Director who serves as the Department's primary contact for program integrity functions. The SIU Director oversees staff responsible for fraud, waste and abuse activities.

- A Dental Director who is a current Pennsylvania-licensed Doctor of Dental Medicine or Doctor of Dental Surgery. The Dental Director must be actively involved in all program components related to dental services including, but not limited to, dental provider recruitment strategy, assessment of dental network adequacy, providing oversight and strategic direction in the quality of dental services provided, actively engaged in the development and implementation of quality initiatives, and monitor the performance of the dental benefit manger if dental benefits are subcontracted. The Dental Director must be available a minimum of thirty (30) hours per week. They can be shared across Medicaid products for purposes of satisfying this requirement but must be specific to work in Pennsylvania.

Aside from the CFO and Dental Director, these full-time positions must be solely dedicated to CHC. The CHC-MCO must report immediately any changes to Executive Management structure to the Department. Resumes for all Executive Management positions must be submitted to the Department.

W. Other Administrative Components

The CHC-MCO must provide for each of the administrative functions listed below:

- A Quality Management/Quality Improvement Coordinator who is a Pennsylvania-licensed physician, RN, or physician's assistant with past experience or education in QM systems. At the CHC-MCO's request, the Department may consider other advanced degrees relevant to QM in lieu of professional licensure. The QM/QI Coordinator is responsible for overseeing reporting and outcome measurement and HEDIS data collection, serving as point person between the Department and the Department's EQR contractor.

- A BH Coordinator who is a behavioral health professional and is located in Pennsylvania. The Behavioral Health Coordinator shall monitor the CHC-MCO for adherence to BH requirements in this Agreement. The primary functions of the BH Coordinator are:
  - Coordinate Participant care needs with BH Providers.
  - Develop processes to coordinate behavioral healthcare between PCPs and BH Providers.
  - Participate in the identification of best practices for BH in a primary care setting.
  - Coordinate behavioral care with medically necessary services.

- Be knowledgeable of the BH Managed Care Agreement requirements and coordinate with the BH-MCO to effectuate the requirements.

- A Director of Network Management who coordinates all communications and contractual relationships between the CHC-MCO and its subcontractors and Providers. The Director of Network Management must be located in Pennsylvania and is responsible for providing Providers with prompt resolution of their problems or inquiries and appropriate education about participation in CHC and maintaining a sufficient Network. Individual Provider representatives will report directly to the Director of Network Management.

- A UM Coordinator who is a Pennsylvania-licensed physician, RN or physician's assistant with past experience or education in UM systems. At the CHC-MCO's request, the Department may consider other advanced degrees relevant to UM in lieu of professional licensure.

- A Director of Service Coordination who oversees all Service Coordination functions of the CHC plan and who shall have the qualifications of a Service Coordinator and a minimum of five (5) years of management/supervisory experience in the healthcare field. The Director of Service Coordination is responsible for all Service Coordination functions, whether the CHC-MCO provides all Service Coordinator functions in house or contracts with outside entities to meet Service Coordination requirements.

- A Direct Care Worker (DCW) Workforce Coordinator who oversees DCW recruitment and retention.

- A Government Liaison who serves as the Department's primary point of contact with the CHC-MCO for day-to-day management of contractual and operational issues. The CHC-MCO must have a designated back-up trained to be able to handle urgent or time-sensitive issues when the Government Liaison is not available.

- A Participant Services Manager who oversees staff to coordinate communications with Participants and enables Participants to receive prompt resolution of their issues, problems or inquiries.

- A Provider Services Manager who oversees staff to coordinate communications between the CHC-MCO and its Network Providers. There must be sufficient staff in CHC-MCO Provider Services, or equivalent department that addresses this function, staff to promptly resolve Provider Disputes, problems or inquiries. Staff must also be adequately trained to understand Cultural, Linguistic, and Disability competencies.

- A Provider Claims Educator who is located in Pennsylvania and facilitates the exchange of information between the Grievances, Claims processing,

and Provider relations systems. The primary functions of the Provider Claims Educator are to:

- Educate contracted and non-contracted Providers (e.g., HCBS Providers and Participant-Directed Services Providers) regarding appropriate Claims submission requirements, coding updates, electronic Claims transactions and electronic fund transfer, and available CHC-MCO resources such as Provider manuals, website, fee schedules, etc.
- Interface with the CHC-MCO's call center to compile, analyze, and disseminate information from Provider calls.
- Identify trends and guide the development and implementation of strategies to improve Provider satisfaction.
- Communicate frequently (i.e., telephonic and on-site) with Providers to provide for the effective exchange of information and to gain feedback regarding the extent to which Providers are informed about appropriate claims submission practices.

- A Complaint, Grievance and DHS Fair Hearing Coordinator whose qualifications demonstrate the ability to assist Participants throughout the Complaint, Grievance and DHS Fair Hearing processes.

- A Claims Administrator who oversees staff to provide for the timely and accurate processing of Claims, Encounter forms and other information necessary for meeting Agreement requirements and the efficient management of the CHC-MCO.

- A Contract Compliance Officer who monitors the CHC-MCO's compliance with all the requirements of the Agreement.

The CHC-MCO must ensure all staff have appropriate training, education, experience, and orientation to fulfill the requirements of their position and maintain documentation of completion. The CHC-MCO must update job descriptions for each of the positions if responsibilities for these positions change.

The CHC-MCO's staffing should represent the racial, ethnic, and cultural diversity of the Participants being served by CHC and comply with all requirements of Exhibit B, Standard Terms and Conditions for Services. The Cultural Competency may be reflected by the CHC-MCO's pursuit to:

- Identify and value differences.

- Acknowledge the interactive dynamics of cultural differences.

- Continually expand cultural knowledge and resources with regard to the populations served.

- Recruit racial and ethnic minority staff in proportion to the populations served.

- Collaborate with the community regarding service provisions and delivery.

- Commit to cross-cultural training of staff and the development of policies to provide relevant, effective programs for the diversity of people served.

The CHC-MCO must have in place sufficient administrative staff and organizational components to comply with the requirements of this Agreement and include in its organizational structure the components outlined in this Agreement. The CHC-MCO must staff these functions with qualified persons in numbers appropriate to the CHC-MCO's size of Enrollment. The Department will determine whether or not the CHC-MCO is in compliance.

The CHC-MCO may contract with a third party to perform one (1) or more of its functions, subject to the subcontractor conditions described in Section XII, Subcontractual Relationships. The CHC-MCO is required to keep the Department informed at all times of the management individuals whose duties include each of the responsibilities outlined in this section.

X. Administration

The CHC-MCO must have an administrative office within the CHC zone. In its discretion, the Department may grant exceptions if the CHC-MCO has administrative offices elsewhere in Pennsylvania and the CHC-MCO is in compliance with all standards set forth by the DOH and PID.

The CHC-MCO must submit for review by the Department its organizational structure listing the function of each executive as well as administrative staff members. Staff positions outlined in this Agreement must be approved and maintained in accordance with the Department's requirements. The CHC-MCO key personnel must be available to the Department upon request.

1. Recipient Restriction Program

BPI manages a Centralized Recipient Restriction (Lock-in) Program for the MA FFS and the managed care delivery systems. The Department is solely responsible for restricting Participants.

The CHC-MCO will maintain a Recipient Restriction (Lock-in) Program to interface with the Department’s Recipient Restriction (Lock-in) Program, and will provide for appropriate professional resources to manage the CHC-MCO program and to cooperate with the Department in all procedures necessary to restrict Participants. In accordance with 42 CFR § 431.54(e), the restrictions do not apply to emergency services furnished to the Participant. The CHC-

MCO must obtain approval from the Department prior to implementing a Lock-in, including approval of written policies and procedures and correspondence to Participants. The CHC-MCO's process must include:

- Designating a Recipient Restriction Coordinator within the CHC-MCO to manage processes.
- Identifying Participants who are overutilizing or misutilizing medical services, receiving unnecessary services or may be defrauding the MA program.
- Offering a voluntary restriction to a participant to protect his/her medical card from alleged misuse. A voluntary restriction can end at any time.
- Evaluating the degree of abuse including review of pharmacy, medical and inpatient claims/encounter history, diagnoses and other documentation, as applicable.
- Proposing whether the Participant should be restricted to obtaining services from a single, designated Provider for a period of five (5) years.
- Forwarding case information and supporting documentation to BPI at the address below or via secure electronic method for review to determine appropriateness of restriction and to approve the action.
- Forwarding case information to BPI for allegations of participant fraud.
- Upon BPI approval, sending notification via mail to the Participant of the proposed Lock-in, including reason(s), effective date and length of Lock-in, name of designated Provider(s), option to change Provider(s) and appeal rights, with a copy to BPI.
- Sending notification of the Participant's Lock-in to the designated Provider(s) and the CAO.
- Enforcing Restrictions (Lock-ins) through appropriate notifications and edits in the claims payment system.
- Preparing and presenting the case at a DHS Fair Hearing to support Lock-in action.
- Monitoring subsequent utilization to ensure compliance.
- Changing the selected Provider per the Participant, Department or Provider's request, within thirty (30) days from the date of the request, with prompt notification within five (5) business days to BPI through the Intranet Provider change process.
- Continuing a Participant Lock-in from the previous delivery system as a Participant enrolls in an MCO, with written notification to BPI.
- Reviewing the Participant's services prior to the end of the Lock-in period to determine if the Lock-in should be removed or maintained, with notification of the results of the review to BPI, Participant, Provider(s) and CAO.
- Submitting a participant's claim data to BPI, upon request, within ten (10) business days.
- Performing necessary administrative activities to maintain accurate records.
- Educating Participants and Providers about the Lock-in program, including

explanations in handbooks and printed materials.

MA Participants may appeal a Lock-in by requesting a DHS Fair Hearing, but may not file a Complaint or Grievance with the CHC-MCO. A request for a DHS Fair Hearing must be in writing, signed by the Participant and sent to:

Department of Human Services Office of Administration
Bureau of Program Integrity
Division of Program and Provider Compliance Recipient Restriction
P.O. Box 2675
Harrisburg, Pennsylvania 17105-2675
Phone number: (717) 772-4627

2. Contracts and Subcontracts

The CHC-MCO may rely on subcontractors to perform or arrange for the performance of services to be provided to Participants. Notwithstanding its use of subcontractor(s), the CHC-MCO is responsible for compliance with this Agreement, including:

a. The provision of and/or arrangement for the services under this Agreement.

b. The evaluation of a prospective subcontractor's ability to perform the activities to be delegated.

c. The payment of claim payment liabilities owed to Providers for services rendered to Participants under this Agreement, for which a subcontractor is the primary obligor, provided that the Provider has exhausted its remedies against the subcontractor; and provided further that such Provider would not be required to continue to pursue its remedies against the subcontractor in the event the subcontractor becomes insolvent, in which case the Provider may seek payment of such Claims from the CHC-MCO. For the purposes of this section, the term "insolvent" shall mean:

   i. The adjudication by a court of competent jurisdiction or administrative tribunal of a party as bankrupt or otherwise approving a petition seeking reorganization, readjustment, arrangement, composition, or similar relief under the applicable bankruptcy laws or any other similar, applicable Federal or State statute or regulation; or

   ii. The appointment by such a court or tribunal having competent jurisdiction of a receiver or receivers, or trustee, or liquidator or liquidators of a party or of all or any substantial part of its property upon the application of any creditor or other party entitled to so apply in any insolvency or bankruptcy proceeding or other creditor's suit; and

d. The oversight and accountability for any functions and responsibilities delegated to a subcontractor.

The above notwithstanding, if the CHC-MCO makes payments to a subcontractor over the course of a year that exceed one-half of the amount of the Department's payments to the CHC-MCO, the CHC-MCO is responsible for any obligation by the subcontractor to a Provider that is overdue by at least sixty (60) days.

The CHC-MCO shall require that all subcontractors and Network Providers comply with all applicable CHC requirements. The CHC-MCO shall require Subcontractors to comply with all applicable Medicaid rules, regulations, and guidance including the requirement that the subcontractor and Network Providers agree to the audit and inspection authority of the Pennsylvania Office of Attorney General Medicaid Fraud Control Section pursuant to 42 CFR §438.230(3).

The CHC-MCO must make all Subcontracts available to the Department within five (5) days of a request by the Department. All Subcontracts must be in writing and must include, at a minimum, the provisions contained in Exhibit P, Required Contract Terms for Administrative Subcontractors.

In accordance with Exhibit B, Standard Terms and Conditions, the CHC-MCO must submit for prior approval Subcontracts to perform part or all of the selected CHC-MCO's responsibilities under this Agreement. This provision includes, but is not limited to, contracts for vision services, dental services, Claims processing, Participant services, and pharmacy services.

3. Records Retention

The CHC-MCO will comply with program standards regarding records retention, which are set forth in federal and state law and regulations, Exhibit B, Standard Terms and Conditions for Services, and Exhibit O, CHC Audit Clause, except that, for purposes of this Agreement, all records must be retained for a period of ten (10) years beyond expiration or termination of the Agreement, unless otherwise authorized by the Department.

Upon thirty (30) day notice from the Department, the CHC-MCO must provide copies of all records to the Department at the CHC-MCO's site or other location determined by the Department, if requested. This thirty (30) day notice requirement does not apply to records requested by federal or state government agencies for purposes of audits or investigations.

The specific timeframes for providing records requested by federal or state government agencies will be designated by the requesting agency. The

retention requirements in this section do not apply to Department-generated Remittance Advices.

4. Fraud, Waste, and Abuse

The CHC-MCO must develop and implement administrative and management arrangements and procedures and a mandatory written compliance plan to prevent, detect, and correct Fraud, Waste, and Abuse that contains the elements described in 42 CFR §438.608(a)(1)(i-vii) and CMS publication "Guidelines for Constructing a Compliance Program for Medicaid Managed Care Organizations and Prepaid Health Plans" found at:
https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/FraudAbuseforProfs/Downloads/mccomplan.pdf
and that includes the following:

- Written policies, procedures, and standards of conduct that articulate the CHC-MCO's commitment to comply with all applicable requirements and standards under the Agreement, and all applicable Federal and State requirements.
- The designation of a compliance officer and a compliance committee that reports directly to the Chief Executive Officer and the board of directors and is responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements of this Agreement.
- The establishment of a Regulatory Compliance Committee on the Board of Directors and at the senior management level charged with overseeing the organization's compliance program and its compliance with the requirements under this Agreement.
- Effective training and education for the compliance officer, senior management and CHC-MCO employees on the applicable Federal and State requirements and applicable standards and requirements under the Agreement.
- Effective lines of communication between the compliance officer and CHC-MCO employees.
- Enforcement of standards through well publicized disciplinary guidelines.
- The establishment and implementation of procedures and a system with dedicated staff for routine internal monitoring and auditing of compliance risks, for prompt response to compliance issues as they are raised, for investigation of potential compliance problems as identified in the course of self-evaluation and audits, for correction of such problems promptly and thoroughly (or coordination of suspected criminal acts with law enforcement agencies) to reduce the potential for recurrence, and for ongoing compliance with the requirements under the Agreement.
- Procedures for systematic confirmation of services actually provided.
- Policies and procedures for reporting all Fraud, Waste, and Abuse to the Department and applicable law enforcement agencies.

- Policies and procedures for Fraud, Waste, and Abuse prevention, detection and investigation.
- A policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including, but not limited to, reporting potential issues, investigating issues, conducting self-evaluations, audits and remedial actions, and reporting to appropriate officials.
- A policy and procedure for monitoring provider preclusion through databases identified by the Department.

a. Fraud, Waste and Abuse Unit

The CHC-MCO must establish a Fraud, Waste and Abuse Unit comprised of experienced Fraud, Waste and Abuse reviewers. This Unit must have the primary purpose of preventing, detecting, reducing, investigating, referring, and reporting suspected Fraud, Waste and Abuse that may be committed by Network Providers, Subcontractors, Participants, caregivers, employees, or other third parties. If the CHC-MCO has multiple lines of business, the Fraud, Waste and Abuse Unit must devote sufficient time and resources to the CHC Fraud, Waste and Abuse activities. The Department will determine whether or not the CHC-MCO is in compliance with these requirements in accordance with 42 CFR 438.608(a)(7).

b. Written Policies

The CHC-MCO must create and maintain written policies and procedures for the prevention, detection, investigation, reporting and referral of suspected Fraud, Waste and Abuse, including any and all fraud and abuse policies delineated under state and or federal mandate.

c. Access to Provider Records

The CHC-MCO's Fraud, Waste and Abuse policies and procedures must provide and certify that the CHC-MCO's Fraud, Waste and Abuse unit, as well as the entire Department, and the Pennsylvania Office of Attorney General Medicaid Fraud Control Section, has timely access to records of Network Providers, Subcontractors, and the CHC-MCOs.

d. Audit Protocol

The CHC-MCO must inform all Network Providers of the Pennsylvania MA Provider Self Audit Protocol which allows Providers to voluntarily disclose overpayments or improper payments of MA funds. This includes, but is not limited to, inclusion in the Provider handbook. The CHC-MCO must provide written documentation that this action has been completed.

The protocol is available on the Department's website at https://www.dhs.pa.gov/about/Fraud-And-Abuse/Pages/MA-Provider-Self-Audit-Protocol.aspx

e. Procedure for Identifying Fraud, Waste and Abuse

The CHC-MCO's policies and procedures must also contain the following:

i. A description of the methodology and standard operating procedures used to identify and investigate Fraud, Waste and Abuse.

ii. An active method for verifying directly with Participants whether services billed by providers were received, as required by 42 CFR § 438.608(a)(5). Active verification requires the CHC-MCO to directly engage with consumers and develop a process to track both methods of verification and the results of verification attempts.

iii. A process to recover overpayments or otherwise sanction Providers as required by 42 CFR §§438.608(a)(5) and 438.608(d)(1)(i-iv).

iv. Provisions for payment suspension to a network provider for which the State determines that there is a credible allegation of fraud as required in 42 CFR §§455.23 and 438.608(a)(8).

v. Policies and procedures to initiate a prepayment review of a network provider's services where a review indicates billings are inconsistent with MA regulations or MCO policies, are unnecessary, are inappropriate to the members' health needs or contrary to customary standards of practice.

vi. A description of specific controls in place for Fraud, Waste and Abuse detection, including an explanation of the technology used to identify aberrant billing patterns, edits, post-processing review of Claims, and record reviews.

f. Fraud, Waste, and Abuse Referral

The CHC-MCO must establish and implement a policy on the referral of a suspected Provider or Direct Care Worker of Fraud, Waste and Abuse to the Department and also referral of suspected fraud to the Pennsylvania Office of Attorney General, Medicaid Fraud Control Section as required in 42 C.F.R. §438.608(a)(7). A standardized referral process is outlined in Exhibit Q, Reporting Suspected Fraud, Waste, and Abuse to the

Department and the Pennsylvania Office of Attorney General Medicaid Fraud Control Section.

If a CHC-MCO fails to promptly report a case of suspected fraud or abuse before the suspected fraud or abuse is identified by the Commonwealth of Pennsylvania, its designees, the United States or private parties acting on behalf of the United States, any portion of the fraud or abuse recovered by the Commonwealth of Pennsylvania or designee shall be retained by the Commonwealth of Pennsylvania or its designees.

g. Education Plan

The CHC-MCO must create and disseminate written materials for the purpose of educating its employees, Providers, subcontractors and subcontractors' employees about healthcare Fraud laws, the CHC-MCO's policies and procedures for preventing and detecting Fraud, Waste, and Abuse and the rights of individuals to act as whistleblowers. The CHC-MCO must provide written policies to all employees and to any contractor or agent that provides detailed information about the False Claims Act and other Federal and State laws described in 42 U.S.C. § 1396a(a)(68) and 62 P.S. §1401, et. seq., including information about rights of employees to be protected as whistleblowers.

h. Referral to Senior Management

The CHC-MCO must develop a certification process that demonstrates the policies and procedures under section 4.b above were reviewed and approved by the CHC-MCO's senior management on an annual basis.

i. Prior Department Approval

The Fraud, Waste and Abuse policies and procedures must be submitted to the Department for prior approval, and the Department may, upon review of these policies and procedures, require that specified changes be made within a designated time in order for the CHC-MCO to remain in compliance with the terms of the Agreement. To the extent that changes to the Fraud, Waste and Abuse unit are made, or the policies or procedures are altered, updated policies and procedures must be submitted promptly to the Department. The Department may also require new or updated policies and procedures during the course of the Agreement period.

j. Duty to Cooperate with Oversight Agencies

CHC-MCO employees must cooperate fully with oversight agencies responsible for Fraud, Waste and Abuse detection, investigation, and prosecution activities. Such agencies include, but are not limited to, the Department, Governor's Office of the Budget, Pennsylvania Office of Attorney General Medicaid Fraud Control Section, Pennsylvania Department of the Auditor General, Pennsylvania Treasury Department, Pennsylvania Office of Inspector General, US DHHS Office of Inspector General, CMS, United States Attorney's Office/Justice Department and the Federal Bureau of Investigations.

Such cooperation must include providing access to all necessary case information, computer files, and appropriate staff as well as the results of associated internal investigations and audits. In addition, such cooperation will include participating in periodic Fraud, Waste and Abuse training sessions, meetings, and joint reviews of Providers, subcontractors, caregivers, or Participants.

k. Hotline Information

The CHC-MCO must distribute the Department's toll-free MA Provider Compliance Hotline telephone number and accompanying explanatory statement to its Participants and Providers through its Participant Handbook and Provider handbooks. The explanatory statement needs to include at a minimum the following information:

i. *Recipient Fraud*: Someone who receives cash assistance, Supplemental Nutritional Assistance Program (SNAP) benefits, Heating/Energy Assistance (LIHEAP), child care, medical assistance, or other public benefits AND that person is not reporting income, not reporting ownership of resources or property, not reporting who lives in the household, allowing another person to use his or her ACCESS/MCO card, forging or altering prescriptions, selling prescriptions/medications, trafficking SNAP benefits or taking advantage of the system in any way.

ii. *Provider Fraud*: Billing for services not rendered, billing separately for services in lieu of an available combination code; misrepresentation of the service/supplies rendered (billing brand named for generic drugs; upcoding to more expensive service than was rendered; billing for more time or units of service than provided, billing incorrect provider or service location); altering claims, submission of any false data on claims, such as date of service, provider or prescriber of service, duplicate billing for the same

service; billing for services provided by unlicensed or unqualified persons; billing for used items as new.

I. Duty to Notify

i. Department's Responsibility

The Department will provide the CHC-MCO with prompt notice via electronic transmission or access to Medicheck listings or upon request if a Network Provider is subsequently suspended or terminated from participation in the MA or Medicare Programs. Upon notification from the Department, the CHC-MCO must immediately act to terminate the Provider from its Network. A CHC-MCO's termination must coincide with the MA effective date of termination for loss of licensures and criminal convictions.

The CHC-MCO is required to check the Social Security Administration's Death Master File (SSADMF), and National Plan and Provider Enumeration System (NPPES) at the time of initial enrollment and re-enrollment as well as providers, owners, agents, and managing employees against the U.S. Department of Health and Human Services-Office of Inspector General's (HHS-OIG) List of Excluded Individuals and Entities (LEIE), the Excluded Party List System (EPLS) on the System for Award Management (SAM), and the PA Medicheck list on a monthly basis as required in 42 CFR. §455.436.

ii. CHC-MCO's Responsibility

The CHC-MCO may not knowingly have a Relationship with the following:

- Individuals, entities or subcontractors with a disclosure of any relationship prohibited by 42 C.F.R. § 438.610(b).
- An individual who is an Affiliate, as defined in the Federal Acquisition Regulation, as covered by 48 C.F.R. § 2.101.

"Relationship," for purposes of this section, is defined as follows:

- A director, officer, or partner of the CHC-MCO.
- A person with beneficial ownership of five percent (5%) or more of the CHC-MCO's equity.
- A person with an employment, consulting or other arrangement for the provision of items and services that are significant and material to the CHC-MCO's obligations under this Agreement.
- A Subcontractor as governed by 42 C.F.R. § 438.230.

The CHC-MCO must notify the Department within 24 hours, in writing, if a Network Provider or Subcontractor is suspended, terminated, or voluntarily withdraws from participation in the MA program as a result of suspected or confirmed Fraud, Waste, or Abuse. The CHC-MCO must also immediately notify the Department, in writing, if it terminates or suspends an employee as a result of suspected or confirmed Fraud, Waste, or Abuse. The CHC-MCO must inform the Department, in writing, of the specific underlying conduct that led to the suspension, termination including for cause and/or best interest, or voluntary withdrawal.

The CHC-MCO must also notify the Department if it recovers overpayments or improper payments related to Fraud, Waste, or Abuse of MA funds from non-administrative overpayments, or improper payments made to Network Providers, or otherwise takes an adverse action against a Network Provider, such as restricting the Participants or services of a PCP.

m. Sanctions

The Department may impose sanctions or take other actions as specified in Section VIII.I if the CHC-MCO fails to report the information required in Section V.X.4.I or the Department determines that a CHC-MCO, Network Provider, employee, caregiver or subcontractor has committed Fraud, Waste, or Abuse as defined in this Agreement or has otherwise violated applicable law.

n. Subcontracts and Provider Agreements

i. The CHC-MCO must require all Network Providers and all subcontractors to take actions as are necessary to permit the CHC-MCO to comply with the Fraud, Waste, and Abuse requirements in this Agreement.

ii. To the extent that the CHC-MCO delegates oversight responsibilities to a third party (such as a Pharmacy Benefit Manager), the CHC-MCO must require that such third party complies with the applicable provisions of this Agreement relating to Fraud, Waste and Abuse.

iii. The CHC-MCO will require, via its Provider Agreement, that Network Providers comply with MA regulations and any enforcement actions initiated by the Department under its regulations, including termination and restitution actions.

iv. The CHC-MCO must suspend payment to a Network Provider when the Department determines there is a credible allegation of fraud against that Network Provider, unless the Department determines there is good cause for not suspending such payments pending the investigation.

v. The CHC-MCO shall require its Subcontractors to comply with the requirements set forth at 42 CFR §438.230(c)(3).

vi. The CHC-MCO subcontractor agreement must specifically state that the subcontractor will grant the Department, CMS, the Pennsylvania Office of Attorney General Medicaid Fraud Control Section, HHS OIG, the Comptroller General, or their designees, access to audit, evaluate, and inspect books, records, etc., which pertain to the delivery of or payment for Medicaid services. Subcontractors must make books, records, premises, equipment, staff, etc. all available for an audit at any time. The right to inspect extends for ten (10) years after termination of contract, or conclusion of an audit, whichever is later.

o. Provider Reviews and Overpayment Recovery

- The CHC-MCO shall audit, review and investigate Providers/Participants/caregivers within its Network through prepayment and retrospective payment reviews. The CHC-MCO shall cost avoid or recover any overpayments directly from its Network Providers for audits, reviews or investigations conducted solely by the CHC-MCO or through Network Provider self-audits.

    - The CHC-MCO must notify BPI in writing when it plans to recover and when it has recovered overpayments or improper payments related to Fraud, Abuse or Waste of Medical Assistance services.
    - The CHC-MCO will void Encounters for those claims involving full recovery of the payment and adjust Encounters for partial recoveries.
    - The CHC-MCO must report all voids and adjustments to Encounters to the Department.

- The Department may audit, review and investigate MA Providers/Participants/caregivers in and out of the CHC-MCO network.
    - The CHC-MCO will coordinate audits, reviews or investigations

of MA Providers with the Department to avoid duplication of effort.

- The CHC-MCO must provide information to BPI as requested including, but not limited to, the CHC-MCO's claims history, policies/procedures, provider contracts and fee schedules, provider/participant/caregiver review history and current status, complaints, barriers to reviewing the subject provider/member/caregiver and payment methodology.
- The CHC-MCO must provide this information within fifteen (15) calendar days of the Department's request. The CHC-MCO must respond to urgent requests within two (2) business days.
- The CHC-MCO may not initiate or continue a review, project, or recovery, of a MA Provider/Participant/caregiver after the Department advises the CHC-MCO of its intention to open a review or investigation by the Department, its designee, or another Federal or State agency, without written Departmental authorization to proceed.
  The CHC-MCO will not notify Providers/Participants/caregivers of the Department's intention to initiate a review.
- The Department will inform the CHC-MCO and the subject Provider(s) of its request for records, and the preliminary and final review findings related to BPI's review.
- The Department may utilize statistically valid random sampling in the selection of claims/encounters for review and may apply extrapolation methodology in determining the recover amount in any restitution demand.
- The CHC-MCO must submit an annual report of overpayment recoveries as required in 42 C.F.R. § 438.608(d)(3).
- The CHC-MCO must recover overpayments identified by the Department from its Network Provider after the CHC-MCO receives the final results of the Department review.
- Overpayment recoveries resulting from audits, reviews or investigations initiated by or on behalf of the Department, that are not part of a mutually agreed upon joint investigation, will be recouped from the CHC-MCO.
- The Department will deduct the restitution demanded from a future payment to the CHC-MCO after forty five (45) days from the mail date of the Department's notice of final findings.
- The CHC-MCO must submit a corrective action plan to the Department, upon request, to resolve any Network Provider's regulatory violations identified through the Department's, its vendor's, or other designee's audit, review or investigation.

- The Department may require the CHC-MCO to suspend payment to a MA Provider or to initiate a pre-payment review as a result of law enforcement reviews and activities or the Department's audits, reviews or investigations as required in 42 CFR §§438.608(a)(8)

and 455.23.

- The CHC-MCO will monitor claims to a provider during a payment suspension, and report on a monthly basis, in writing, to BPI the amount of funds withheld to the provider during the payment suspension. If the provider is subsequently convicted, these funds will be adjusted from the capitated payments.
- The Department may agree to joint reviews, audits or investigations with the CHC-MCO or any CMS contractor. Any recoveries as a result of an agreed upon joint audit, review or investigation shall be shared equally between the CHC-MCO and Department after payment to any CMS contractor. DHS's, its contractor's or other designee's request for vetting of a provider and/or the MCO's provision of information related to a provider review, audit or investigation does not constitute a mutually agreed upon joint review.
- The Department may periodically monitor and evaluate the CHC-MCO's audits, reviews and investigations of MA Providers/Participants/caregivers within the CHC-MCO's network.

5. Electronic Visit Verification

The CHC-MCO must have a fully operational EVV system for in-home personal care and home health services that complies with the requirements of 42 U.S.C. § 1396b(l). The EVV system must verify and record electronically (for example, through a telephone or computer-based system) at least the following: the type of service performed, the individual receiving the service, the individual providing the service, the date of the service, the location of the service, and the time the service begins and ends. In addition to capturing the elements outlined above, the EVV system must meet the technical specifications outlined in the DHS EVV Addendum and be able to interface with the DHS EVV Aggregator.

Providers may choose to use their own EVV vendor/system so long as the system meets all of the necessary requirements. Providers using an alternate EVV system in the CHC program will need to establish an interface with the CHC-MCOs.

The CHC-MCOs must follow all EVV requirements outlined by the Department. The CHC-MCOs are responsible for monitoring provider compliance requirements outlined in the corresponding bulletins and must implement corrective action plans when providers do not meet the compliance requirements.

CHC-MCOs are required to validate that visit data submissions support claims submissions as part of the adjudication process. All encounter claims submitted for services subjected to EVV requirements must have

corresponding visit data submitted to the DHS Aggregator.

The implementation of EVV must not negatively impact the provision of services. Neither CHC-MCOs nor Providers may limit the locations for EVV as long as the locations are allowable by the program. The Department's policies and procedures regarding the provision of services remain the same and service delivery should continue as it did before the implementation of these EVV requirements. EVV does not change the method and location for service delivery.

6. Management Information Systems

The CHC-MCO must have a secure, comprehensive, automated, and integrated MIS that includes a test environment and is capable of meeting the requirements listed below and throughout this Agreement. Information on Business and Technical Standards is available on the DHS website.

a. The CHC-MCO must have a minimum of the following MIS components or the capability to interface with other systems containing Participant, Provider, Claims Processing, Prior Authorization, and Reference data.

b. The CHC-MCO must have a sufficient MIS to support data reporting requirements specified in this Agreement.

c. The CHC-MCO's Participant management system must have the capability to receive, update, and maintain Participant files consistent with specifications provided by the Department. The CHC-MCO must have the capability to provide daily updates of Participant information to Subcontractors and Providers who have responsibility for processing Claims or authorizing services based on Participant information.

d. The CHC-MCO's Provider database must be maintained with detailed information on each Provider sufficient to support Provider payment and meet the Department's reporting and Encounter Data requirements.

   The CHC-MCO must be able to cross-reference its internal Provider identification number to the correct MMIS Provider ID and NPI number in the Department's MMIS for each location at which the Provider renders services for the CHC-MCO.

   The CHC-MCO must verify that each Network Provider service location is enrolled and active with MA, and that information for all service locations is maintained in its own system.

   The CHC-MCO must verify that each Network Provider's license

information is valid in the Department's MMIS and must outreach to Network Providers to stress the importance of maintaining up-to-date information in the Department's MMIS.

The CHC-MCO must require Network Providers with specific Provider types and specialties have the same Provider types and specialties in the Department's MMIS for each service location.

e. The CHC-MCO's Claims Processing system must have the capability to process Claims consistent with timeliness and accuracy requirements identified in this Agreement.

f. The CHC-MCO's Prior Authorization system must be linked with its Claims Processing component.

g. The CHC-MCO's MIS must be able to maintain its Claims history with sufficient detail to meet all Department reporting and Encounter Data requirements.

h. The CHC-MCO's credentialing system must have the capability to store and report on Provider-specific data sufficient to meet the Department's credentialing requirements and those listed in Exhibit F, Quality Management and Utilization Management Program Requirements.

i. The CHC-MCO must have sufficient telecommunication capabilities, including email, to meet the requirements of this Agreement.

j. The CHC-MCO must have the capability to electronically exchange data files with the Department and the IEB. The CHC-MCO must use a secure FTP product that is compatible with the Department's product.

k. The CHC-MCO's MIS must be bidirectionally linked to all operational systems listed in this Agreement, so that data captured in Encounter records accurately matches data in Participant, Provider, Claims, and Prior Authorization files. Encounter Data will be utilized for:

- Participant and Provider profiling,
- Claims validation,
- Fraud, Waste, and Abuse monitoring activities,
- Rate setting, and
- Any other research and reporting purposes defined by the Department.

l. The CHC-MCO must comply with the Department's Business and Technical Standards including connectivity to the Commonwealth's network for Extranet access. The CHC-MCO must also comply with any

changes made to these Standards.

The CHC-MCO must comply with the Department's Se-Government Data Exchange Standards.

Whenever possible, the Department will provide advance notice of at least sixty (60) days prior to the implementation of changes. For more complex changes, the Department will make every reasonable effort to provide additional notice.

m. The CHC-MCO must be prepared to document its ability to expand claims processing or MIS capacity should either be exceeded through the enrollment of Participants.

n. The CHC-MCO must designate appropriate staff to participate in DHS-directed development and implementation activities.

o. The CHC-MCO must have formalized System Development Life Cycle processes, procedures, controls, and governance frameworks in place for management of its MIS and affiliated infrastructure, affiliated application, technology, and infrastructure roadmaps in place that outline the current capabilities and future direction of the MIS, and procedures for when CHC-MCO and DHS representatives will be engaged to address current and future business needs and requirements.

p. Subcontractors must meet the same MIS requirements as the CHC-MCO, and the CHC-MCO will be held responsible for MIS errors or noncompliance resulting from the action of a Subcontractor. The CHC-MCO must provide its Subcontractors with the appropriate files and information to meet this requirement (e.g., the Daily 834 Eligibility File, Provider files).

q. The CHC-MCO's MIS shall be subject to review and approval during the Department's Readiness Review process.

r. The CHC-MCO must maintain the security of Commonwealth data and information including:

- Compliance with all applicable Federal and State statutes and regulations regarding security standards,
- Demonstration that specific controls are in place to safeguard MIS and Commonwealth data and information, and
- Demonstration of procedures for mitigating data breaches.

s. Prior to any major modifications to the CHC-MCO's MIS, including

upgrades and new purchases, the CHC-MCO must inform the Department in writing of the potential changes at least 180 days prior to the change. The CHC-MCO must provide a work plan detailing recovery efforts and the use of parallel system testing.

t. The CHC-MCO must be able to accept and generate HIPAA-compliant transactions as required in the ASC X12 Implementation Guides.

u. The Department will make Drug, Procedure Code, and Diagnosis Code reference files available to the CHC-MCO on a routine basis to allow it to effectively meet its obligation to provide services and record information consistent with requirements in this Agreement.

   If the CHC-MCO chooses not to use these files, it must document the use of comparable files to meet its obligation with this Agreement.

   Information about these files is available on the Pennsylvania HealthChoices Extranet.

v. The Department will supply Provider files on a routine basis to allow the CHC-MCO to effectively meet its obligation to provide services and record information consistent with requirements in this Agreement. These files include:

   - List of Active and Closed Providers (PRV414 and PRV415),
   - NPI Crosswalk (PRV430),
   - Provider Revalidation File (PRV720),
   - Special Indicators (PRV435), and
   - Network Provider File (Managed Care Affiliates, PRV640Q).

   The CHC-MCO must use the PRV414 or PRV415 files with the PRV430 on a monthly basis to reconcile its Provider database with that of the Department to confirm:

   - All participating Providers are enrolled in MA for all service locations as defined by MA enrollment rules,
   - Participating Provider license information is valid,
   - Provider Types and Specialties match, and
   - Each Provider's NPI, taxonomy, and nine-digit zip code for each service location match.

   CHC-MCOs must use the PRV640Q to reconcile Provider information previously submitted on the Network Provider file (PRV640M).

   Information about these files is available on the Pennsylvania

HealthChoices Extranet.

w. The CHC-MCO must have a disaster recovery plan in place with written policies and procedures containing information on system backup and recovery in the event of a disaster.

x. The CHC-MCO must reconcile the 820 Capitation Payment file with its internal membership information and report any discrepancies to the Department within thirty (30) days.

y. To support the CHC-MCO in meeting the requirements of this agreement, the Department will provide access to the following systems:

- The Department's MMIS
- Pennsylvania HealthChoices Extranet
- Client Information System (eCIS)
- DocuShare

Access to these systems is in addition to the various files that CHC-MCOs will receive via secure file transfer. Information on obtaining access to these resources is on the Pennsylvania HealthChoices Extranet.

7. Department Access

The CHC-MCO must provide Department staff access to appropriate on-site private office space and equipment. The CHC-MCO must grant the Department, CMS, the Pennsylvania Office of Attorney General Medicaid Fraud Control Section, HHS OIG, the Comptroller General, or their designees to audit, evaluate, and inspect books, records, etc., which pertain to the delivery of or payment for Medicaid services. Subcontractors must make books, records, premises, equipment, staff, etc. all available for an audit at any time. The right to inspect extends for ten (10) years after termination of Agreement, or conclusion of an audit, whichever is later.

In addition to other access requirements, the CHC-MCO must provide the Department with access to administrative policies and procedures pertaining to operations, including, but not limited to:

- Personnel policies and procedures.
- Procurement policies and procedures.
- Public relations and marketing policies and procedures.
- Operations policies and procedures.
- Policies and procedures developed to comply with this Agreement.

Y. Selection and Assignment of PCPs

The CHC-MCO must have a PCP selection process that includes, at a minimum, the following:

- Honors a Participant's selection of a PCP or PCP group, if permitted through the IEB.
- Honors a Dual Eligible Participant's selection of a PCP. A Dual Eligible Participant is not required to have a Network Provider as a PCP and must be permitted to designate his/her Medicare-participating PCP as his or her CHC PCP.
- For all non-dual eligible Participants, the PCP must be a Network Provider except where an Out-Of-Network PCP is permitted under DOH regulations.
- May allow selection of a PCP group. In addition, the CHC-MCO may assign a PCP group to a Participant if the Participant has not selected a PCP or a PCP group at the time of Enrollment.
- If the Participant has not selected a PCP through the IEB for reasons other than cause, the CHC-MCO must make contact with the Participant within seven (7) business days of his or her Enrollment and provide information on options for selecting a PCP, unless the CHC-MCO has information that the Participant should be immediately contacted due to a medical condition requiring immediate care.
- If a Participant does not select a PCP within fourteen (14) business days of Enrollment, the CHC-MCO must make an assignment. If the Participant is enrolled in the D-SNP aligned with the CHC-MCO, the CHC-MCO must assign the PCP who the Participant uses in the D-SNP. The CHC-MCO must consider such factors to the extent they are known, such as current Provider relationships that may be identified through Encounters, existing Service Plans, or any CHC-MCO contacts with the Participant, specific medical needs, physical disabilities of the Participant, language needs, cultural compatibility, area of residence and access to transportation. The CHC-MCO must then notify the Participant by telephone or in writing of his or her PCP's name, location and office telephone number. The CHC-MCO must make every effort to determine PCP choice and confirm this with the Participant prior to the commencement of the CHC-MCO coverage in accordance with Participant Enrollment and Disenrollment, so that new Participants do not go without a PCP for a period of time after Enrollment begins.
- The CHC-MCO must have written policies and procedures for allowing Participants to select or be assigned to a new PCP whenever requested by the Participant, when a PCP is terminated from the Network, or when a PCP change is required as part of the resolution to a Grievance or Complaint proceeding. The policies and procedures must receive advance written approval from the Department.
- In cases where a PCP has been terminated from the Network for reasons other than cause, the CHC-MCO must immediately inform Participants assigned to

that PCP in order to allow them to select another PCP prior to the PCP's termination effective date. In cases where a Participant fails to select a new PCP, re-assignment must take place prior to the PCP's termination effective date.

- Participants can request a specialist as a PCP. If the CHC-MCO denies the request, that denial is appealable.
- If a Participant uses a Pediatrician or Pediatric Specialist as a PCP, the CHC-MCO must, upon request, assist with the transition to a PCP who provides services for adults.
- The CHC-MCO must allow any Participant who is an Indian as defined in 42 CFR § 438.14(a), and who is both enrolled in the CHC-MCO and eligible to receive services from an I/T/U Health Care Provider ("I/T/U HCP") PCP participating in the CHC-MCO's network, to choose that participating I/T/U HCP as their PCP, as long as the I/T/U HCP has capacity to provide the services.

CHC-MCOs must assist medically fragile young adult Participants and or their guardians when transitioning to an adult PCP and are required to develop payment mechanisms to enable both pediatric and adult care Providers to receive payment for medically necessary services provided concurrently during the transition process.

Should the CHC-MCO choose to implement a process for the assignment of a primary dentist, the CHC-MCO must submit the process for advance written approval from the Department prior to its implementation.

Z. Selection and Assignment of Service Coordinators

The CHC-MCO must develop and maintain a process for the selection and assignment of Service Coordinators that includes, at a minimum, the following:

- The CHC-MCO must offer the Participant a choice of Service Coordinators from amongst those employed by or under contract with the CHC-MCO. During the Service Coordinator selection process, the CHC-MCO must provide the Participant with information about Service Coordinators within their coverage area, including a brief description of any special skills and work experience. If requested, the Participant must be allowed to speak to the Service Coordinators as part of the selection process.
- At the time of an Assessment that indicates a need for LTSS, the CHC-MCO must provide the Participant with information on options for selecting or changing a Service Coordinator. If the Participant has not selected a Service Coordinator within seven (7) business days of the Assessment, then the CHC-MCO must assign a Service Coordinator. The CHC-MCO shall assign the Service Coordinator immediately if the CHC-MCO has information that the Participant should be immediately contacted due to a medical condition requiring immediate care.

- When assigning a Service Coordinator the CHC-MCO may consider such factors (to the extent they are known) as current Provider relationships, prior service coordinator, the person assigned to the Participant for care management in the CHC-MCO's aligned D-SNP, specific medical needs, physical disabilities of the Participant, language needs, cultural compatibility, area of residence and access to transportation. The CHC-MCO must then notify the Participant by telephone and in writing of his or her Service Coordinator's name, location and office telephone number. The CHC-MCO must make every effort to determine Service Coordinator choice and confirm this with the Participant. The CHC-MCO may contact new Participants prior to the commencement of their CHC-MCO coverage, so that new Participants do not go without a Service Coordinator for a period of time after Enrollment begins or after Assessment.
- If a Participant requests a change in his or her selected or assigned Service Coordinator, the CHC-MCO must promptly grant the request and process the change in a timely manner.
- The CHC-MCO must have written policies and procedures for allowing Participants to select or be assigned to a new Service Coordinator whenever requested by the Participant, when a Service Coordinator is terminated from the Network or when a Service Coordinator change is required as part of the resolution to a Grievance or Complaint proceeding.
- The CHC-MCO must submit its policies and procedures for review and approval by the Department.

AA. Provider Services

The CHC-MCO must operate Provider service functions, at a minimum, during regular business hours (9:00 a.m. to 5:00 p.m., Monday through Friday). Provider services functions include, but are not limited to, the following:

- Assisting Providers with questions concerning Participant eligibility status.
- Assisting Providers with CHC-MCO Prior Authorization and referral procedures.
- Assisting Providers with PCSP and PCPT Procedures.
- Assisting Providers with Claims payment procedures and handling Provider Disputes and issues.
- Facilitating transfer of Participant medical records among Providers, as necessary.
- Providing to PCPs a monthly list of Participants who are under their care, including identification of new and deleted Participants. An explanation guide detailing use of the list must also be provided to PCPs.
- Developing a process to respond to Provider inquiries regarding current Enrollment.
- Coordinating the administration of Out-of-Plan Services.

Beginning July 1, 2024, CHC-MCOs must maintain a provider portal that complies

with 40 P.S. § 991.2153.

1. Provider Manual

The CHC-MCO must keep its Network Providers informed and up-to-date with the latest policy and procedures changes as they affect the MA Program and must develop and maintain a Provider Manual. The CHC-MCO must distribute Provider Manuals in a manner that makes them easily accessible to all Network Providers. The CHC-MCO may specifically delegate this responsibility to large Providers in its Provider Agreement. The Provider Manual must be updated annually. The Department may grant an exception to this annual requirement upon written request from the CHC-MCO provided there are no major changes to the manual.

The CHC-MCO must submit its Provider Manual and annual updates to the Department for review and prior approval.

The CHC-MCO must include the information in its Provider manual as specified in Exhibit S, Provider Manual.

2. Provider Orientation and Ongoing Education

The CHC-MCO must develop and maintain a Provider Network that is knowledgeable and experienced in treating and supporting Participants in CHC. The CHC-MCO must submit and obtain prior approval from the Department for a new Provider orientation and training work plan and an annual ongoing Provider educational plan that outlines its plans to educate and train Network Providers and its process for measuring outcomes, including the tracking of schedules and attendance. The initial Provider orientation must be completed by the CHC-MCO no later than 45 days after the provider's contract effective date. Ongoing Provider education must be completed at a minimum (each calendar year) yearly by each Provider in the MCOs network. The format for this work plan will be designated by the Department through its operations reporting requirements found on the Pennsylvania HealthChoices Extranet. The CHC-MCO must develop its work plan in conjunction with the Department and must include all topic areas identified by the Department. The CHC-MCO must also include Participants, advocates, direct care worker representatives, and family members in designing and implementation of the work plan.

At a minimum, the CHC-MCO must conduct the new Provider orientation and training, and yearly ongoing Provider education, as appropriate, in the following areas:

a. Needs screening, Assessment and Reassessment, service planning system and protocols and a description of the Provider's role in service planning and Service Coordination.

b. Service Coordination and how the Provider will fit into the PCPT approach.

c. The population being served through CHC.

d. Accessibility requirements with which Providers must comply.

e. Application of the Agreement definition of Medically Necessary.

f. Information around Alzheimer's Disease and related dementias, including information on assisting with and managing the symptoms and care needs of people with dementia throughout the course of their disease.

g. Identification and appropriate referral for mental health and drug, and alcohol and substance abuse services.

h. The diverse needs of persons with disabilities, such as persons who are deaf or hard of hearing, how to obtain sign language interpreters and how to work effectively with sign language interpreters.

i. CHC-MCO policies against discrimination to achieve competency in treating Participants without discrimination on the basis of race, color, creed, sex, religion, age, national origin, ancestry, marital status, sexual orientation, gender identity, language, MA status, income status, program participation, health status, disease or pre-existing condition, anticipated need for healthcare or physical or mental handicap.

j. Cultural, Linguistic and Disability Competency, including: the right of Participants with LEP to engage in effective communication in their language; how to obtain interpreters; and how to work effectively with interpreters.

k. Treating the populations served by the CHC-MCO, including treatment for Participants with disabilities.

l. Administrative processes that include, but are not limited to: COB, Recipient Restriction Program, and Encounter Data reporting.

m. Issues identified by Provider relations or Provider hotline staff in response to calls or complaints by Providers.

n. Issues identified through the QM process.

o. The process to submit materials to the CHC-MCO for utilization review and Prior Authorization review decisions. Submitted materials must include, but are not limited to, letters of medical necessity.

p. The Complaint, Grievance and DHS Fair Hearing and Appeals process, including, but not limited to, expectations for a Provider should a Provider represent a Participant at a Grievance hearing.

q. Performance Improvement Plans and how Providers may benefit from participation in these programs.

r. Dual eligibility for Medicare and Medicaid and coordination of services for Participants who are Dual Eligible.

s. Inform Providers of the Pennsylvania MA Provider Self Audit Protocol located at https://www.dhs.pa.gov/about/Fraud-And-Abuse/Pages/MA-Provider-Self-Audit-Protocol.aspx

The CHC-MCO may submit for review and Department prior approval an alternate Provider training and education work plan should the CHC-MCO wish to combine its activities with other CHC-MCOs operating in the CHC zone or wish to develop and implement new and innovative methods for Provider training and education. Should the Department approve an alternative work plan, the CHC-MCO must have the ability to track and report on the components included in the CHC-MCO's alternative Provider training and education work plan.

BB. Provider Network

The CHC-MCO must establish and maintain adequate Networks to serve all of the eligible CHC population in the CHC zone, including those with LEP or physical or mental disabilities. The CHC-MCO must include Providers for all Covered Services in its Network. The CHC-MCO must comply with the composition of Networks and Participant access to services set forth in Exhibit T, Provider Network Composition/Service Access.

If the CHC-MCO's Provider Network is unable to provide necessary Covered Services covered under the Agreement to a Participant, the CHC-MCO must adequately and timely cover these services out-of-network with an MA-enrolled Provider for the Participant for as long as the CHC-MCO is unable to provide them and must coordinate with that Provider with respect to payment.

1. Provider Qualifications

The CHC-MCO may only include Providers in its Network that meet the minimum qualification requirements established by the Department. The CHC-MCO must credential Providers in accordance with the credentialing framework provided by the Department.

2. Provider Agreements

The CHC-MCO must have written Provider Agreements with a sufficient number of Providers to provide Participant access to all Covered Services as set forth in Exhibit T, Provider Network Composition/Service Access.

The requirements for these Provider Agreements are set forth in Exhibit U, Provider Agreements.

Provider Agreements may not prohibit a Provider from contracting with another CHC-MCO or prohibit or penalize the CHC-MCO for contracting with other Providers.

3. Cultural Competency, Linguistic Competency, and Disability Competency

Both the CHC-MCO and Network Providers must demonstrate Cultural Competency, Linguistic Competency, and Disability Competency.

Racial, ethnic, linguistic, gender, sexual orientation, gender identity and cultural differences between Provider and Participant must not present barriers to Participants' access to and receipt of quality services. The CHC-MCO must develop and implement policies to prevent and monitor access free from such barriers. The CHC-MCO must be willing and able to make the necessary distinctions between traditional treatment methods and non-traditional treatment methods that are consistent with the Participant's racial, ethnic, linguistic or cultural background and which may be equally or more effective and appropriate for the particular Participant; and must demonstrate consistency in providing quality care across a variety of races, ethnicities, and cultures. For example, language, religious beliefs, cultural norms, social-economic conditions, diet, etc., may make one treatment method more palatable to a Participant of a particular culture than to another of a differing culture.

The CHC-MCO must also develop, implement, and monitor policies that require Network Providers to demonstrate willingness and ability to make necessary accommodations in providing services, to employ appropriate language when referring to and talking with people with disabilities, and to understand communication, transportation, scheduling, structural, and attitudinal barriers to accessing services.

4. Primary Care Practitioner Responsibilities

The CHC-MCO must have written policies and procedures for the choice and assignment of PCPs. The PCP must serve as the Participant's initial and most important point of contact regarding healthcare needs. At a minimum, the CHC-

MCO Network PCPs are responsible for:

a. Providing primary and preventive care, acting as the Participant's advocate, and providing, recommending, and arranging for services.

b. Documenting all care rendered in a complete and accurate Encounter record that meets or exceeds the DHS data specifications.

c. Maintaining continuity of each Participant's healthcare.

d. Communicating effectively with the Participant by using specialized interpretive services for Participants who are deaf and blind, and oral interpreters for those Participants with LEP when needed. Interpreter services must be free of charge to the Participant and the PCP cannot require family members to be used for interpretation.

e. Making referrals for specialty care and other Medically Necessary services, both in and out-of-plan.

f. Maintaining a current medical and other service record for the Participant, including documentation of all services provided to the Participant by the PCP, as well as any specialty or referral services.

g. Coordinating BH Services by working with BH-MCOs as specified in Exhibit H, Coordination with the BH-MCOs.

h. The CHC-MCO will retain responsibility for monitoring PCP actions for compliance with this Agreement.

5. Specialists as PCPs

The CHC-MCO must allow a Participant to select a specialist as PCP.

The CHC-MCO must adopt and maintain procedures by which a Participant may request and receive:

- A standing referral to a specialist with clinical expertise in treating the disease or condition; or

- The designation of a specialist to provide and coordinate the Participant's primary and specialty care.

When possible, the specialist must be a Provider participating in the CHC-MCO's Network. If the specialist is not a Network Provider, the CHC-MCO may require the specialist to meet the requirements of the CHC-MCO's Network Providers, including the CHC-MCO's credentialing criteria outlined in

the framework provided by the Department and QM/UM Program policies and procedures.

The CHC-MCO must provide Participants with information on the procedures to request and receive approval for a Specialist to act as a PCP.

The CHC-MCO must have adequate Network capacity of qualified specialists to act as PCPs. These physicians may be predetermined and listed in the directory but may also be determined on an as-needed basis. The CHC-MCO must establish credentialing and recredentialing policies and procedures to ensure compliance with these specifications that meet the credentialing requirements outlined in the framework provided by the Department.

The CHC-MCO must require that Providers credentialed as specialists and as PCPs meet all of the CHC-MCO's standards for credentialing PCPs and specialists, including compliance with recordkeeping standards, the Department's access and availability standards and other QM/UM Program standards. The specialist as a PCP must provide or arrange for all Primary Care, consistent with CHC-MCO preventive care guidelines, including routine preventive care, and provide those specialty medical services consistent with the Participant's assessed needs in accordance with the CHC-MCO's standards and within the scope of the specialist's specialty training and clinical expertise. In order to accommodate the full spectrum of care, the specialist as a PCP also must have admitting privileges at a hospital in the Network.

6. Related Party

A hospital, NF, or home health agency that is a Related Party to a CHC-MCO must negotiate in good faith with other CHC-MCOs regarding the provision of services to Participants. The Department may terminate this Agreement with the CHC-MCO if it determines that a Provider related to the CHC-MCO has refused to negotiate in good faith with other CHC-MCOs. The CHC-MCO must negotiate and make referrals in good faith with non-related providers.

A CHC-MCO must negotiate with and make referrals in good faith to providers that are not Related Parties.

The CHC-MCO must offer Participants a choice of Related-Party and Non-Related Party Network Providers.

7. Integration

The CHC-MCO must prohibit Network Providers from intentionally segregating or discriminating against Participants in any way on the basis of race, color, creed, sex, religion, age, national origin, ancestry, marital status, sexual orientation, gender identity, language, MA status, income status, program participation, health status, disease or pre-existing condition,

anticipated need for healthcare or physical or mental disability, except where medically indicated.

The CHC-MCO must investigate Complaints and take affirmative action when Participants experience discriminatory treatment or are segregated without a medical indication. Examples of prohibited practices include, but are not limited to, the following:

- Denying or not providing a Participant a Covered Service or availability of a facility within the CHC-MCO's Network.
- Subjecting a Participant to segregated, separate, or different treatment, including a different place or time from that provided to other Participants, public or private patients, in any manner related to the receipt of any Covered Service, except where Medically Necessary.
- The assignment of times or places for the provision of services on the basis of the race, color, creed, religion, age, sex, national origin, ancestry, marital status, sexual orientation, gender identity, income status, program participation, language, Medical Assistance status, health status, disease or pre-existing condition, anticipated need for healthcare or physical or mental disability of the participants to be served.

If the CHC-MCO knowingly executes an Agreement with a Provider with the intent of allowing or permitting the Provider to implement barriers to care (i.e., the terms of the Provider Agreement are more restrictive than this Agreement), the CHC-MCO shall be in breach of this Agreement.

The CHC-MCO must have explicit policies to provide access to complex interventions such as cardiopulmonary resuscitations, intensive care, transplantation and rehabilitation when medically indicated and must educate its Network Providers on these policies. Healthcare and treatment necessary to preserve life must be provided to all Participants who are not terminally ill or permanently unconscious, except where a competent Participant objects to such care on his or her own behalf or has objected through an executed Advanced Healthcare Directive.

8. Network Changes/Provider Terminations

a. Network Changes

i) Notification to the Department

Other than terminations outlined below in Section 8.b Provider Terminations, the CHC-MCO must notify the Department within ten (10) days of any changes to its Provider Network such as closed panels, relocations, death of a Provider, and a change in a Network Provider's circumstances that would negatively impact the ability of Participants to access services.

ii) Procedures and Work Plans
The CHC-MCO must have procedures to address changes in its Network that impact Participant access to services, in accordance with the requirements of Exhibit T, Provider Network Composition/Service Access. The Department may find the CHC-MCO in default based on its failure to address changes in Network composition that negatively affect Participant access.

iii) Timeframes for Notification to Participants
The CHC-MCO must update web-based Provider directories to reflect any changes in the Provider Network.

b. Provider Terminations

The CHC-MCO must comply with the requirements for Provider terminations as outlined in Exhibit V, CHC-MCO Requirements for Provider Terminations.

9. Other Provider Enrollment Standards

The CHC-MCO must comply with the program standards regarding Provider enrollment that are set forth in this Agreement.

The CHC-MCO must require all Network Providers to be enrolled in the Commonwealth's MA program and possess an active MMIS Provider ID for each location in which they provide services for the CHC-MCO. In addition, the CHC-MCO must be able to store and utilize the MMIS Provider ID and NPI stored in the Department's MMIS for each location.

CHC-MCOs are not required to contract with all willing Providers (excluding any willing pharmacy requirements), but must accept and respond to letters of interest from any Provider interested in joining the MCO's network.

10. Twenty-Four-Hour Coverage

The CHC-MCO must have coverage available directly or through its PCPs, who may have on-call arrangements with other qualified Providers, for urgent or emergency care on a twenty-four (24) hour-per day, seven (7) day-per-week basis. The CHC-MCO must not use answering services in lieu of the PCP emergency coverage requirements without the knowledge of the Participant. For Emergency or Urgent Medical Conditions, the CHC-MCO must have written policies and procedures on how Participants and Providers can make contact to receive instruction for treatment. If the PCP determines that emergency care is not required, 1) the PCP must see the Participant in accordance with the time frame specified in Exhibit T, Provider Network Composition/Service Access under Appointment Standards, or 2) the

Participant must be referred to an urgent care clinic which can see the Participant in accordance with the time frame specified in Exhibit T.

11. Opioid Use Disorder Centers of Excellence

The OUD-COE initiative is designed to increase capacity to care for those seeking treatment for OUD, as well as increase the overall quality of care. CHC-MCOs must comply with the Department's OUD-COE requirements specified in Exhibit EE Opioid Use Disorder Centers of Excellence.

CC. QM and UM Program Requirements

1. Overview

The CHC-MCO shall provide a Quality Assessment and Performance Improvement Program consistent with federal guidelines under Title XIX of the SSA, 42 C.F.R. Part 438, Subpart E and must comply with the Department's QM and UM Program standards and requirements set forth in Exhibit F, Quality Management and Utilization Management Program Requirements; Exhibit W, External Quality Review; and Exhibit W(2), Healthcare Effectiveness Data and Information Set (HEDIS®) and Consumer Assessment of Healthcare Providers and Systems (CAHPS®). The CHC-MCO must comply with the critical incident reporting and management, provider-preventable condition, and provider serious adverse events reporting requirements outlined in Exhibit W(1), Critical Incident Reporting and Management and Provider Preventable Conditions/Preventable Service Adverse Events Reporting.

The CHC-MCO must comply with the Quality Management/Utilization Management Reporting Requirements found on the Pennsylvania HealthChoices Extranet. The Department retains the right of advance written approval and to review on an ongoing basis all aspects of the CHC-MCO's QM and UM programs, including subsequent changes. The CHC-MCO must comply with all QM and UM program reporting requirements and must submit data in formats to be determined by the Department.

The Department, in collaboration with the CHC-MCO, will determine and prioritize QM and UM activities and initiatives based on areas of importance to the Department and CMS.

2. Quality Management and Performance Improvement

The Department's goal for CHC is to deliver quality and appropriate care that enables Participants to stay healthy, get better, manage chronic illnesses and disabilities, and maintain/improve their quality of life. The CHC-MCO shall provide quality LTSS to Participants and promote improvement in the quality and appropriateness of care provided to Participants through established

quality management and performance improvement processes. The CHC-MCO shall have a written QM/QI program that clearly defines its quality improvement structures and processes and assigns responsibility to appropriate individuals. The CHC-MCO shall have a QMC which shall include medical and LTSS staff and Providers. The role of the committee is to analyze and evaluate the results of QM/QI activities and to develop appropriate policies, actions and follow-up to provide appropriate services to Participants. The CHC-MCO must establish the QMC as a distinct unit within the organizational structure and the QMC must remain separate from other units in the organization.

The CHC-MCO must include the following in its QM program:

- A written Quality Assessment and Performance Improvement plan completed on an annual basis with quarterly updates.
- Monitoring and evaluation activities which include peer review and a QMC.
- Protection of Participant records.
- Communicate and honor Participant rights and responsibilities as outlined in this Agreement and Exhibit L, Participant Rights.
- Tracking and trending Participant and Provider issues.
- Mechanism to assess the quality and appropriateness of care furnished to Participants.
- Performance Improvement programs.
- Submission of Participant's specific data.
- Reporting on designated quality measures as outlined in the Department's reporting requirements, to identify outcomes and trends and how trends will be addressed.
- Procedures outlining how and when information will be entered into the Department's quality data reporting system.
- Mechanisms to assess the quality and appropriateness of care furnished to Participants with special health care needs as defined by the Department in its quality strategy.

3. Utilization Management

The CHC-MCO shall establish a Utilization Management structure consistent with guidance from the Department.

4. Healthcare Effectiveness Data and Information Set

The CHC-MCO must comply with the requirements for HEDIS as set forth in Exhibit W(2), Healthcare Effectiveness Data and Information Set (HEDIS®) and Consumer Assessment of Healthcare Providers and Systems (CAHPS®). The previous calendar year is the standard measurement year for HEDIS data.

5. External Quality Review

The CHC-MCO must comply with the requirements set forth in Exhibit W, External Quality Review. On at least an annual basis, the CHC-MCO will cooperate fully with any external evaluations and assessments of its performance authorized by the Department under this Agreement and conducted by the Department's contracted EQRO or other designee. Independent assessments will include, but not be limited to, any independent evaluation required or allowed by Federal or State statute or regulation. The Department may use the term PA Performance Measures in place of EQR performance measures throughout this Agreement.

6. Pay for Performance Programs

The Department conducts a Pay for Performance (P4P) Program that provides financial incentives for CHC-MCOs that meet quality goals. Information regarding MCO Pay for Performance Programs may be found in Exhibit DD(1), CHC-MCO Pay for Performance Program and Exhibit DD(2), Nursing Facility Quality Incentive Program.

7. QM/UM Program Reporting Requirements

The CHC-MCO must comply with all QM and UM program reporting requirements and time frames outlined in Exhibit F, Quality Management and Utilization Management Program Requirements. The Department will, on a periodic basis, review the required reports and make changes to the information/data and/or formats requested based on the changing needs of CHC. The CHC-MCO must comply with all requested changes to the report information and formats as deemed necessary by the Department. The Department will provide the CHC-MCO with at least sixty (60) days notice of changes to the QM/UM reporting requirements. Information regarding QM and UM reporting requirements may be found on the Pennsylvania HealthChoices Extranet.

8. Delegated Quality Management and Utilization Management Functions

The CHC-MCO may not structure compensation or payments to individuals or entities that conduct UM activities so as to provide incentives for the individual or entity to deny, limit, or discontinue Medically Necessary services to any Participant.

9. Participation in the Quality Management and Utilization Management Programs

The CHC-MCO will participate and cooperate in the work and review of the

Department's formal advisory body through participation in the MAAC and its subcommittees. Additionally, the CHC-MCO will solicit input on its QM and UM programs from the PAC.

10. Confidentiality

The CHC-MCO must have written policies and procedures for maintaining the confidentiality of data that addresses medical records, Participant information and Provider information and is in compliance with the provisions set forth in HIPAA, Section 2131 of the Insurance Company Law of 1921, 40 P.S. § 991.2131; 55 Pa. Code Chapter 105; and 45 C.F.R. Parts 160 and 164 (Standards for Privacy of Individually Identifiable Health Information).

The CHC-MCO must require its Network Provider to have mechanisms that guard against unauthorized or inadvertent disclosure of confidential information.

The CHC-MCO must obtain the Department's prior written approval to release data to third parties, except for releases for the purpose of individual care and coordination among Providers, releases authorized by the Participant or those releases required by court order, subpoena or law.

11. Department Oversight

The CHC-MCO and its subcontractor(s) and Network Providers will make available to the Department upon request, data, clinical and other records and reports for review of quality of care, access and utilization issues, including, but not limited to, activities related to EQR, HEDIS, Encounter Data validation, and other related activities.

The CHC-MCO must submit a plan, in accordance with the timeframes established by the Department, to resolve any performance or quality of care deficiencies identified through ongoing monitoring activities and any independent assessments or evaluations requested by the Department.

The CHC-MCO must obtain advance written approval from the Department before releasing or sharing data, correspondence and/or improvements from the Department regarding the CHC-MCO's internal QM and UM programs with any of the other CHC-MCOs or any external entity.

The CHC-MCO must obtain advance written approval from the Department before participating in or providing letters of support for QM or UM data studies and/or any data related external research projects related to CHC with any entity.

12. CHC-MCO Cooperation with Research and Evaluation

The CHC-MCO must cooperate fully with research and evaluation activities as requested by the Department.

DD. Mergers, Acquisitions, Mark, Insignia, Logo and Product Name

1. Mergers and Acquisitions

The CHC-MCO must notify the Department at least thirty (30) days in advance of a merger or acquisition of the CHC-MCO. The CHC-MCO must bear the cost of reprinting CHC outreach material, if a change involving content is made prior to the IEB's annual revision of materials.

2. Mark, Insignia, Logo, and Product Name Changes

The CHC-MCO must submit mark, insignia, logo, and product name changes within thirty (30) calendar days of projected implementation for the Department's review. The CHC-MCO logo must appear with the DHS CHC logo in all documents. The CHC-MCO is responsible for the cost of reprinting CHC outreach materials, if a change is made prior to the IEB's annual revision of materials.

EE. Cooperation with IEB

The CHC-MCO must cooperate with the IEB, as instructed by the Department.

FF. Employment Support

The CHC-MCO must include employment-related needs and service requirements of Participants as part of the person-centered service plan. The CHC-MCO will provide information about services available through OVR or similar resources to Participants who are not working but express an interest in work or who are working but whose employment status may be jeopardized due to their disability; and will refer the Participant to OVR or other resources in accordance with the approved CHC 1915(c) waiver, unless the Participant makes an informed choice not to be referred for this support. The CHC-MCO must cooperate with OVR or other resources.

As detailed in Pennsylvania's "Employment First" policy, the first consideration and preferred outcome of publicly-funded long-term services and supports for working-age Pennsylvanians with a disability is competitive integrated employment. Competitive integrated employment means any full or part-time work for which a person is:

1. Compensated at not less than federal minimum wage requirements or

State or local minimum wage law (whichever is higher) and not less than the customary rate paid by the employer for the same or similar work performed by people without a disability;
2. At a location where the employee interacts with people without a disability (not including supervisory personnel or people who are providing services to such employee); and
3. Presented, as appropriate, opportunities for similar benefits and advancement like those for other employees without a disability and who have similar positions.

CHC-MCOs will collect and publish data on Participant competitive-integrated employment outcomes, including, but not limited to, number and percentage of Participants, by age group and disability type, in self-employment or competitive-integrated employment as defined by the Workforce Innovation and Opportunities Act, wage rates, weekly wages earned, weekly hours worked, type or classification of job, and whether benefits are part of the compensation package.

CHC-MCOs will offer services that promote or lead to securing or maintaining competitive-integrated employment, including, but not limited to, job coaching and job finding, customized employment, Discovery (for participants with to-be-defined challenging needs), benefits counseling, and transportation. CHC-MCOs must provide the necessary employment related training, resources, and communication to their employment staff and SCs. SCs must engage Participants in ongoing education and discussions with Participants regarding employment and assist Participants with a goal of achieving competitive integrated employment with accessing all available resources.

GG. Advance Directives

The CHC-MCO must maintain written policies and procedures for advance directives (durable power of attorney, mental health, and living wills) for Participants, which shall include the following information:

a. the description of applicable State law;
b. the process for notifying the Participant of any changes in applicable State law as soon as possible, but no later than ninety (90) days after the effective date of the change;
c. any limitation the CHC-MCO has regarding implementation of advance directives as a matter of conscience;
d. the process for Participants or the Participant's representative to file a Complaint concerning noncompliance with the advance directive requirements with the CHC-MCO and DOH;
e. noncompliance with the advance directive requirements with the CHC-MCO and DOH; and

f. how to request written information on advance directive policies.

The CHC-MCO must educate staff concerning its policies and procedures on advance directives.

The CHC-MCO may not condition the provision of care or otherwise discriminate against a Participant based on whether or not the Participant has executed an advance directive.

SECTION VI: PROGRAM OUTCOMES AND DELIVERABLES

Prior to the Enrollment of Participants and a Zone Start Date for a CHC-MCO, the Department will conduct Readiness Review activities to determine the CHC-MCO's ability to provide services as required by this Agreement. The CHC-MCO must cooperate with all the Readiness Review activities, including on-site reviews conducted by the Department. As part of Readiness Review, the CHC-MCO must test successfully its claims processing system in a given zone. Test samples must include all types of payments and adjustments that are billed through the Department's MMIS claims processing system. If the Department determines the CHC-MCO has not demonstrated readiness to provide services as required by this Agreement, the Department will not permit the enrollment of Potential Participants with the CHC-MCO and may extend the time period for the Readiness Review or not operationalize this Agreement.

SECTION VII: FINANCIAL REQUIREMENTS

A. Financial Standards

1. Equity Requirements and Solvency Protection

The CHC-MCO must meet the Equity and solvency protection requirements set forth below and with all financial requirements included in this Agreement, in addition to those of the PID.

The CHC-MCO must maintain a SAP-basis Equity equal to the highest of the amounts determined by the following "Three (3) Part Test" as of the last day of each calendar quarter:

- Twenty Million Dollars ($20.00 million);
- Seven percent (7.000%) of revenue earned by the CHC-MCO during the most recent four (4) calendar quarters; or
- Seven percent (7.000%) of revenue earned by the CHC-MCO during the

current quarter multiplied by three (3).

Revenue, for the purpose of the Equity requirement calculation, is defined as the total gross Direct Business Premiums, for all Pennsylvania lines of business, reported in Schedule T, “Premiums and Other Considerations,” of the PID report.

For the purpose of this requirement, Equity amounts, as of the last day of each calendar quarter, shall be determined in accordance with statutory accounting principles as specified or accepted by the PID. The Department will accept PID determinations of Equity amounts, and in the absence of such determination, will rely on required financial statements filed by the CHC-MCO with PID to determine Equity amounts.

The CHC-MCO must provide the Department with reports as specified in Section VIII.E and F. Financial Reports and Equity.

If the CHC-MCO operates its plan through another legal entity or entities, and if that other entity or those other entities receive(s) from the CHC-MCO a total amount that is at least seventy five percent (75%) of the revenue paid by the Department to the CHC-MCO, then the CHC-MCO may request the following equity requirement as an alternative to the Three (3) Part Test set forth above, subject to the approval of the Department:

1. The CHC-MCO RBC ratio must be at least three (3.0);

2. The CHC-MCO must maintain a SAP-basis Equity no less than an amount that is the higher of:

    a. Five and one-half percent (5.5%) of revenue earned by the CHC-MCO during the most recent four (4) calendar quarters; or

    b. Five and one-half percent (5.5%) of revenue earned by the CHC-MCO during the then-current calendar quarter multiplied by 3; and

3. The other entity or other entities that operate(s) the CHC-MCO’s plan in a particular zone must maintain (individually, in the case of multiple entities) Equity no less than an amount that is the higher of:

    a. Eight and three-tenths percent (8.3%) of revenue earned by the entity during the most recent four (4) calendar quarters; or

    b. Eight and three-tenths percent (8.3%) of revenue earned by the entity during the then-current calendar quarter multiplied by three (3).

Revenue, for the purpose of this alternative equity requirement, would be premiums as noted on the most-recent audited statements.

The CHC-MCO must provide documentation of compliance that is satisfactory to the Department, and failing that, must comply with the standard Three Part Test.

2. Risk Based Capital

The RBC ratio is defined as:

- The Total Adjusted Capital figure in Column One from the page titled Five Year Historical Data in the Annual Statement for the most recent year filed most recently with the PID, divided by the Authorized Control Level Risk-based Capital figure.

The CHC-MCO must maintain a RBC ratio of two (2.0).

3. Prior Approval of Payments to Affiliates

With the exception of payment of a Claim for a medical product or service that was provided to a Participant, and that is paid in accordance with a written Provider Agreement, the CHC-MCO may not pay money or transfer any assets for any reason to an Affiliate without prior approval from the Department, if any of the following criteria apply:

a. The CHC-MCO's RBC ratio was less than two (2.0) as of December 31 of the most recent year for which the due date for filing the annual unaudited PID financial report has passed;

b. The CHC-MCO was not in compliance with the Agreement Equity and solvency protection requirement as of the last day of the most recent quarter for which the due date for filing PID financial reports has passed;

c. After the proposed transaction took place, the CHC-MCO would not be in compliance with the Agreement Equity and solvency protection requirement; or

d. Subsequent adjustments are made to the CHC-MCO's financial statement as the result of an audit, or otherwise modified, such that after the transaction took place, a final determination is made that the CHC-MCO was not in compliance with the Agreement's Equity requirements. In this event, the Department may require repayment of amounts involved in the transaction.

The Department may elect to waive the requirements of this section.

4. Change in Independent Actuary or Independent Auditor

The CHC-MCO must notify the Department within ten (10) days when its contract with an independent auditor or actuary has ended. The CHC-MCO must include in the notification, the date and reason for the change or termination and the name of the replacement auditor or actuary, if any. If the change or termination occurred as a result of a disagreement or dispute, the CHC-MCO must disclose the nature of the disagreement or dispute.

5. Modified Current Ratio

The CHC-MCO must maintain current assets, plus long-term investments that can be converted to cash within five (5) business days without incurring a penalty of more than twenty percent (20%) that equal or exceed current liabilities.

- If a penalty for conversion of long-term investments is applicable, only the value net of the penalty may be counted for the purpose of compliance with this requirement.
- The definitions of current assets and current liabilities are included in the Financial Reporting Requirements.
- Restricted assets may be included only with authorization from the Department.
- The following types of long-term investments may be counted, consistent with above requirements, so long as they are not issued by or include an interest in an Affiliate:

  – Certificates of Deposit
  – United States Treasury Notes and Bonds
  – United States Treasury Bills
  – Federal Farm Credit Funding Corporation Notes and Bonds
  – Federal Home Loan Bank Bonds
  – Federal National Mortgage Association Bonds
  – Government National Mortgage Association Bonds
  – Municipal Bonds
  – Corporate Bonds
  – Stocks
  – Mutual Funds

6. Sanctions

In addition to the Department's general sanction authority specified in Section VIII.I, Sanctions, if the CHC-MCO fails to comply with the requirements of Section VII.A, Financial Requirements, the Department may take any or all of the following actions, in accordance with 42 C.F.R. §§ 438.700; 438.702; and 438.704:

- Discuss fiscal plans with the CHC-MCO's management;
- Suspend payments or a portion of payments for Participants enrolled after the effective date of the sanction and until the Department is satisfied that the reason for the imposition of the sanction no longer exists and is not likely to recur;
- Require the CHC-MCO to submit and implement a corrective action plan;
- Suspend all new and default Enrollment of Participants into the CHC-MCO, including auto-assignments, after notification by the Federal or State government;
- Terminate this Agreement upon forty-five (45) days written notice, in accordance with Section X of this Agreement, Termination and Default.

In addition, the Department may impose sanctions described above when a CHC-MCO, either directly or through a Subcontractor, acts or fails to act as follows:

- Fails substantially to arrange for Medically Necessary services that the CHC-MCO is required to provide to a Participant under law or under its Agreement.
- Imposes on Participants premiums or charges that are in excess of the premiums or charges permitted under the MA program.
- Acts to discriminate among Participants on the basis of their health status or need for healthcare services.
- Misrepresents or falsifies information that it furnishes to CMS, the Department, Participants, Potential Participants, or Healthcare Providers.
- Fails to comply with requirements for PIPs as set forth in 42 C.F.R. §§ 422.208 and 422.210.
- Has distributed directly, or indirectly through any agent or independent contractor, marketing materials that have not been approved by the Department or that contain false or materially misleading information.

7. Payment for Disproportionate Share Hospitals and Graduate Medical Education

The Department will make direct Disproportionate Share Hospital and Graduate Medical Education Payments to hospitals.

8. Participant Liability

In accordance with 42 C.F.R. § 438.106, the CHC-MCO must provide that its Participants are not held liable for the following:

a. Debts of the CHC-MCO in the event of the CHC-MCO's insolvency.

b. Services provided to the Participant in the event that the CHC-MCO fails to receive payment from the Department for such services.

c. Services provided to the Participant in the event of a Provider with a contractual, referral or other arrangement with the CHC-MCO failing to receive payment from the Department or the CHC-MCO for such services.

d. Payments to a Provider that furnishes compensable services under a contractual, referral or other arrangement with the CHC-MCO in excess of the amount that would be owed by the Participant if the CHC-MCO had directly provided the services.

e. Balance billing for Covered Services.

If a Participant's eligibility for MA LTSS is terminated retroactively because the Participant was determined functionally ineligible as a result of the CHC-MCO failure to conduct the Participant's annual Reassessment, the CHC-MCO must continue to provide coverage for services to the Participant until the Participant's functional eligibility determination is made. The CHC-MCO may not recover payments to providers for services provided to the Participant or seek to hold the Participant financially responsible for such services.

9. Restitution for Fees Owed to the Department

The Department may require the CHC-MCO to offset against any payment amount due to a Provider from the CHC-MCO any amounts that are due to the Department from the Provider and that have not been paid by the Provider.

- The Department will notify the CHC-MCO and the Provider in writing of the amount due to the Department.
- If the Network Provider fails to make payment of the amount within 30 days of the written notice, then the Department will notify the CHC-MCO that it must offset the amount due to the Department, for the amount identified by the department, from the CHC-MCO's payments to the Network Provider and pay the Department until the amount due to the Department has been collected in full.
- The Department reserves the right to deduct any unpaid amounts due from Network Provider from future payments to the CHC-MCO after ninety (90) days from the mailing date of the written notice.

B. Department Capitation Payments

1. Payments for Covered Services

The obligation of the Department to make payments shall be limited to Capitation payments and any other payments provided by this Agreement.

2. Capitation Payments

i. The CHC-MCO shall receive capitated payments for the previous month for Covered Services as defined in Section VII.B.1, Payments for Covered Services, and in Appendix 3a, Explanation of Capitation Payments.

ii. The Department will compute Capitation payments using daily per diem rates. The Department will make a monthly payment to the CHC-MCO for each Participant enrolled in the CHC-MCO, for the first (1st) day in the month the Participant is enrolled in the CHC-MCO and for each subsequent day, through and including the last day of the month.

iii. The Department will not make a Capitation payment for a Participant Month if the Department notifies the CHC-MCO before the first (1st) of the month that the individual's MA eligibility or CHC-MCO Enrollment ends prior to the first (1st) of the month.

iv. The Department will make payments by wire transfer or electronic funds transfer unless the CHC-MCO is unable or unwilling to receive payment through wire or electronic funds transfer. If such arrangements are not in place, the Department will provide payments through the U.S. Mail.

v. Upon notice to the CHC-MCO, and for those months specified by the Department, by the fifteenth (15th) of each month, the Department will make a Capitation payment, referenced in Section VII.B.1, for each Participant for all dates of Enrollment indicated on the Department's eCIS through the last day of the current month. This payment will be limited to those days for which the Department has not previously made payment to the CHC-MCO.

vi. This paragraph vi. is applicable unless it is superseded by paragraph v. immediately above. By the fifteenth (15th) of each month, the Department will make a Capitation payment, referenced in Section VII.B.1, for each Participant for all dates of Enrollment indicated on the Department's eCIS prior to the first day of the current month. This payment will be limited to those days for which the Department has not previously made payment to the CHC-MCO.

vii. The Department will recover Capitation payments made for Participants who were later determined to be ineligible for managed care for up to twelve (12) months after the service month for which payment was made. The Department will recover Capitation payments made for deceased Participants for up to twenty-one (21) months after the service month in which the date of death occurred. See Exhibit K, CHC-MCO Participant Coverage Document.

viii. The CHC-MCO must report to the Department within sixty (60) calendar days when it has identified capitation payments or other payments in excess of amounts specified in the Agreement.

ix. Upon written notification to the CHC-MCO, the Department may delay the capitation payments made in May and/or June of each calendar year that would have otherwise been made under Section VII.B.2.v above, to payment dates in July of the same calendar year. The Department will include in the written notification the applicable payment dates for the delayed capitation payments.

3. Program Changes

Amendments, revisions, or additions to the Medicaid State Plan, the CHC 1915(b) and 1915(c) Waivers, or to Federal or State statutes and regulations, guidelines, or policies shall, insofar as they affect the scope or nature of benefits available to Participants, amend the CHC-MCO's obligations as specified herein, unless the Department notifies the CHC-MCO otherwise. The Department will inform the CHC-MCO of any changes, amendments, revisions, or additions to the Medicaid State Plan or 1915(b) and 1915(c) Waivers or changes in the Department's regulations, guidelines, or policies in a timely manner.

If the scope of Eligible Individuals or services, inclusive of limitations on those services that are the responsibility of the CHC-MCO, is changed, the Department will determine whether the change is sufficient that an actuarial analysis might conclude that a rate change is appropriate. If the Department makes such determination in the affirmative, the Department will arrange for the actuarial analysis, and the Department will determine whether a rate change is appropriate. The Department will take into account the actuarial analysis and will consider input from the CHC-MCO when making this determination. At a minimum, the Department will adjust the rates as necessary to maintain actuarial soundness. If the Department makes a change, the Department will provide the analysis used to determine the rate adjustment. If the scope of services or Eligible Individuals that are the responsibility of the CHC-MCO is changed, upon request by the CHC-MCO, the Department will provide written information on whether the rates will be adjusted and how, along with an explanation for the Department’s decision.

The Department will appropriately adjust the rates provided by Appendix 3c, Capitation Rates, to reflect changes in an Assessment, Premium Tax, or other similar tax.

The rates in Appendix 3c, Capitation Rates, will remain in effect until an Agreement is reached on new rates and their effective date**,** unless modified to reflect changes to the scope of services or consumers in the manner

described in the preceding paragraph.

C. Acceptance of Actuarially Sound Rates

By executing this Agreement, the CHC-MCO has reviewed the rates set forth in Appendix 3c, Capitation Rates, and accepts the rates for the relevant Agreement period.

D. Claims Processing Standards, Monthly Report and Sanctions

These requirements and assessments are applied separately by zone.

1. Timeliness Standards

The CHC-MCO must adjudicate Provider Claims consistent with the requirements below. These requirements apply to Claims processed both by the CHC-MCO and by any subcontractor the CHC-MCO may have contracted with to receive and process claims for it. Subcapitation payments and claims adjustments are excluded from these requirements.

The adjudication timeliness standards follow for each of four (4) categories of Claims:

a. Claims received from a hospital for inpatient admissions ("Inpatient"):

90.0% of Clean Claims must be adjudicated within thirty (30) days of receipt.

100.0% of Clean Claims must be adjudicated within forty-five (45) days of receipt.

100.0% of all Claims must be adjudicated within ninety (90) days of receipt.

b. Nursing Facility (NF) Claims:

90.0% of Clean Claims must be adjudicated within thirty (30) days of receipt.

100.0% of Clean Claims must be adjudicated within forty-five (45) days of receipt.

100.0% of all Claims must be adjudicated within ninety (90) days of receipt.

c. Home and Community Based Services (HCBS) Claims:

90.0% of Clean Claims must be adjudicated within thirty (30) days of receipt.

100.0% of Clean Claims must be adjudicated within forty-five (45) days of receipt.

100.0% of all Claims must be adjudicated within ninety (90) days of receipt.

d. Other Claims (Not Inpatient, NF, HCBS or Pharmacy):

90.0% of Clean Claims must be adjudicated within thirty (30) days of receipt.

100.0% of Clean Claims must be adjudicated within forty-five (45) days of receipt.

100.0% of all Claims must be adjudicated within ninety (90) days of receipt.

The adjudication timeliness standards do not apply to Claims submitted by Providers under investigation for Fraud, Waste or Abuse from the date of service to the date of adjudication of the Claims. The CHC-MCO, however, must provide immediate notification to the Department of providers under investigation by the CHC-MCO.

The CHC-MCO must adjudicate every Claim entered into its MIS that is not a Rejected Claim. The CHC-MCO must maintain an electronic file of Rejected Claims, including a reason or reason code for rejection. The CHC-MCO will deny a claim for services provided to an individual who was not a CHC-MCO Participant as of the date of service and notify the Provider of the denial.

The amount of time required to adjudicate a paid Claim is computed by comparing the date the Claim was received with the check date or the CHC-MCO bank notification date for electronic payment. The check date is the date printed on the check. The amount of time required to adjudicate a Denied Claim is computed by comparing the date the Claim was received with the date the denial notice was created or the transmission date of an electronic denial notice. The CHC-MCO must mail checks no later than three (3) business days from the check date. Electronic payments must also occur within three (3) business days of the bank notification date.

The CHC-MCO must record, on every Claim processed, the date the Claim

was received. A date of receipt embedded in a Claim reference number is acceptable. The CHC-MCO must have this date carried on Claims records in the Claims processing computer system. Each hardcopy Claim received by the CHC-MCO, or the electronic image thereof, must be date-stamped with the date of receipt no later than the first (1st) business day after the date of receipt. The CHC-MCO must add a date of receipt to each Claim received in the form of an electronic record or file within one (1) business day of receipt.

If responsibility to receive Claims is subcontracted, the date of initial receipt by the subcontractor determines the date of receipt applicable to these requirements.

2. Sanctions

The Department will utilize the monthly report that is due on the fifth (5th) calendar day of the fifth (5th) subsequent month after the Claim is received to determine compliance with Claims processing standards. For example, the Department shall utilize the monthly report that is due January 5th, to determine Claims processing compliance for Claims received in the previous August.

The Department will consider all Claims received during the month for which compliance is being determined and that remain non-adjudicated at the time compliance is being determined to be Clean Claims.

If a Commonwealth audit, or an audit done on the Commonwealth's behalf, determines Claims processing timeliness data that are different than data submitted by the CHC-MCO, or if the CHC-MCO has not submitted required Claims processing data, the Department will use the audit results to determine compliance.

If the Department determines that a CHC-MCO has not complied with the Claims Processing timeliness standards, the Department may separately impose sanctions to the following claims types:

a) Inpatient Claims.
b) NF Claims
c) HCBS Claims
d) Other Claims (Not Inpatient, NF, HCBS or Pharmacy)

The sanctions provided by this Section apply to all Claims, including Claims processed by any subcontractor.

The CHC-MCO will be considered in compliance with the requirement for adjudication of one hundred percent (100.0%) of all Inpatient, NF, and HCBS Claims if ninety-nine-and-one-half percent (99.5%) of all Inpatient, NF and

HCBS Claims are adjudicated within ninety (90) days of receipt. The CHC-MCO will be considered in compliance with the requirement of adjudication of one hundred percent (100.0%) of all Other Claims (not Inpatient, NF, HCBS or Pharmacy) if ninety-nine-and-one-half percent (99.5%) of all Other Claims (not Inpatient, NF, HCBS or Pharmacy) are adjudicated within ninety (90) days of receipt.

The Department will reduce the sanctions below by one-third (1/3) if the CHC-MCO has fifty thousand (50,000) to one hundred thousand (100,000) Participants and by two-thirds (2/3) if the CHC-MCO has less than fifty thousand (50,000) Participants.

CLAIMS ADJUDICATION MONTHLY SANCTIONS CHART

The Department will compute sanctions for failure to adjudicate Inpatient, NF, HCBS and Other Claims (not Inpatient, NF, HCBS, or Pharmacy) as shown in the following tables.

Percentage of Clean Claims Adjudicated within Thirty (30) Days	Sanctions
88.0 – 89.9	$2,000
80.0 – 87.9	$6,000
70.0 – 79.9	$10,000
60.0 – 69.9	$16,000
50.0 – 59.9	$20,000
Less than 50.0	$30,000
Percentage of Clean Claims Adjudicated within Forty-five (45) Days	Sanctions
98.0 – 99.5	$2,000
90.0 – 97.9	$6,000
80.0 – 89.9	$10,000
70.0 – 79.9	$16,000
60.0 – 69.9	$20,000
Less than 60.0	$30,000
Percentage of All Claims Adjudicated within Ninety (90) Days	Sanctions
98.0 – 99.5	$2,000
90.0 – 97.9	$6,000
80.0 – 89.9	$10,000
70.0 – 79.9	$16,000
60.0 – 69.9	$20,000

Less than 60.0	$30,000

E. Other Financial Requirements

1. Provider Incentive Arrangements

a. CHC-MCOs must comply with the PIP requirements included under 42 C.F.R. §§ 422.208 and 422.210, which apply to MA managed care under 42 C.F.R. § 438.3(i).

b. The CHC-MCO may operate PIPs if 1) no specific payment is made directly or indirectly to a physician or physician group as an inducement to reduce or limit Medically Necessary services furnished to a Participant; and 2) the disclosure, computation of Substantial Financial Risk, Stop-Loss Protection, and Participant survey requirements of this section are met.

c. The CHC-MCO must provide information specified in the regulations to the Department and CMS, upon request. In addition, the CHC-MCO must provide the information on its PIPs to any Participant, upon request. CHC-MCOs that have PIPs placing a physician or physician group at Substantial Financial Risk for the cost of services the physician or physician group does not furnish must require that the physician or physician group has adequate Stop-Loss Protection. CHC-MCOs that have PIPs placing a physician or physician group at Substantial Financial Risk for the cost of service the physician or physician group does not furnish must also conduct surveys of Participants and disenrollees addressing their satisfaction with the quality of services and their degree of access to the services.

d. CHC-MCOs must provide the following information concerning their PIPs to the Department:

- whether referral services are included in the PIP,
- the type of incentive arrangement used, i.e., withhold, bonus, capitation,
- a determination of the percent of payment under the contract that is based on the use of referral services to determine if Substantial Financial Risk exists,
- panel size and, if patients are pooled, pooling method used to determine if Substantial Financial Risk exists, and
- Evidence that the physician or physician group has adequate Stop-Loss Protection and the type of coverage, if this requirement applies.

Where Participant/disenrollee survey requirements exist, the CHC-MCO must provide the survey results.

e. The CHC-MCO must provide the disclosure information specified in 1.d. immediately above to the Department annually, unless the Department has notified the CHC-MCO of the suspension of this requirement.

f. CHC-MCOs shall not use any financial incentive that compensates any provider for providing less than medically necessary and appropriate care to a Participant.

2. Retroactive Eligibility Period

The CHC-MCO shall not be responsible for any payments owed to Providers for services that were rendered prior to the Participants' Start Date.

3. In-Network Services

The CHC-MCO must make timely payment for Medically Necessary, Covered Services rendered by Network Providers when:

a. Services were rendered to treat an Emergency Medical Condition;

b. Services were rendered under the terms of the Provider Agreement;

c. Services were Prior Authorized or did not require Prior Authorization;

d. The CHC-MCO denied Prior Authorization of services but the Department determined, after a hearing, that the services should have been authorized.

4. Payments for Out-of-Network Providers

The CHC-MCO must coordinate with Out-of-Network Providers to make timely payments for Medically Necessary Covered Services as otherwise provided for in this Agreement, including, but not limited to, when:

a. Services were rendered to treat an Emergency Medical Condition;

b. Services were Prior Authorized;

c. Services were not available in Network;

d. The CHC-MCO denied Prior Authorization of services but the Department determined, after a hearing, that the services

should have been authorized.

The CHC-MCO may not impose any cost on the Participant for using an Out-of-Network Provider that is greater than the cost would have been if a Network Provider furnished the services.

The CHC-MCO must allow a Participant, who is an Indian as defined in 42 CFR § 438.14(a), to obtain Covered Services from Out-of-Network I/T/U HCPs from which that Participant is otherwise eligible to receive services.

The CHC-MCO is not financially liable for:

a. Services rendered to treat a non-emergency condition in a hospital ED except to the extent required elsewhere in law, unless the services were Prior Authorized;

b. Prescriptions presented at Out-of-Network Pharmacies that were written by Non-Participating or non-network prescribers unless:

- the Non-Participating Provider or non-network Provider arrangements were approved in advance by the CHC-MCO and any Prior Authorization requirements (if applicable) were met; or
- the Non-Participating or non-network prescriber and the pharmacy are the Participant's Medicare Providers; or
- the Participant is covered by a third party carrier and the Non-Participating or non-network prescriber and the pharmacy are the Participant's third party Providers.

The CHC-MCO is responsible, in accordance with applicable law, for emergency services and urgently needed services as defined in 42 C.F.R. § 417.401 that are obtained by its Participants from Providers and suppliers outside the Network even in the absence of the CHC-MCO's prior approval.

5. Payments to FQHCs and Rural Health Centers (RHCs)

The CHC-MCO must pay all FQHCs and RHCs rates that are not less than FFS Prospective Payment System (PPS) rates, as determined by the Department. The CHC-MCO must also include in its Network every FQHC and RHC that is willing to accept FFS Prospective Payment System rates as payment in full and are located within the CHC zone. The CHC-MCO must consider the FQHC and/or RHC as both the billing and rendering provider of clinic services provided to Participants.

If a FQHC/RHC has opted-out of receiving the PPS rate from the CHC-MCOs, upon notification from the Department of the date that the FQHC/RHC has opted-out, the CHC-MCO is no longer required to make payment at the FFS

PPS rate, as noted above. Effective with the FQHC/RHC opt-out, the CHC-MCO must negotiate and pay the opted-out FQHC/RHC at rates that are no less than what the CHC-MCO pays to other providers who provide comparable services within the CHC-MCO's Provider Network.

CHC-MCOs will have 90 days from the date of the Department's notification to the CHC-MCO of a retroactive PPS rate adjustment to reprocess all applicable FQHC and/or RHC claims that were subject to the requirements of this section. The CHC-MCO must send notification to the Department no later than 10 working days after the completion of the required claims reprocessing.

1. Failure to complete the required claims reprocessing for each FQHC and RHC and to submit notification of the completion of the claims reprocessing to the Department will result in the full assessment of the 90 day claims processing sanctions in Section VII.D. In addition to the sanction amount, the Department will complete a settlement in place of the CHC-MCO's claims reprocessing for the FQHC or RHC. The amount the Department pays to the FQHC or RHC for this settlement will be an obligation of the CHC-MCO to the Department and recovered by the Department from the CHC-MCO through a reduction to a future payment.

The CHC-MCO may require that an FQHC and RHC comply with Service Coordination procedures that apply to other entities that provide similar benefits or services.

6. Payments to Nursing Facilities

The CHC-MCO shall pay all NFs at a payment rate that is not less than the facility-specific minimum payment rate established by the Department and shared with the CHC-MCO. The Department will notify the MCO of the facility-specific payment rate. Nothing in this provision should be construed to prohibit the CHC-MCO and the NF to agree to a higher payment rate or to a VBP Payment Arrangement in accordance with Section VII.E.16 that provides an alternative payment for services that is at a payment rate equal to or greater than the facility-specific minimum payment rate. An incentive payment earned under the Nursing Facility Quality Incentive Program described in Exhibit DD(2) shall be in addition to the facility-specific minimum payment rate required under this subsection.

7. Coverage for Participants in an IMD

The Department will make Capitation payments for a Participant aged twenty-one through sixty-four (21 – 64) residing in a freestanding Institution for Mental Diseases (IMD) and the Participant's condition is not related to Substance Use Disorder (SUD) based on the following criteria:

- If the stay is no more than fifteen (15) cumulative days during the period of the monthly capitation payment and the provision of inpatient psychiatric treatment in a freestanding IMD meets the requirements for in lieu of services in 42 C.F.R. 438.3 (e) (2)(i) through (iv), payment will be full capitation in which a Participant is enrolled in the CHC-MCO.

- If the stay is at least sixteen (16) cumulative days during the period of the monthly capitation payment and the provision of inpatient psychiatric treatment in a freestanding IMD meets the requirements for in lieu of services in 42 C.F.R. 438.3 (e) (2)(i) through (iv), the payment will be based as follows: per diem rate identified in Section VII.B.1 multiplied by the number of days the Participant is both enrolled in the CHC-MCO and not residing in a freestanding IMD.

8. Liability during an Active Grievance or Appeal

The CHC-MCO shall not be liable to pay Claims to Providers if the validity of the Claim is being challenged by the CHC-MCO through a Grievance or appeal, unless the CHC-MCO is obligated to pay the Claim or a portion of the Claim through a separate Agreement with the Provider.

9. Financial Responsibility for Dual Eligible Participants

The CHC-MCO must pay Medicare deductibles and coinsurance amounts relating to any Medicare-covered service for Dual Eligible Participants in accordance with Section 4714 of the Balanced Budget Act of 1997. If Medicare's payment exceeds the CHC-MCOs contracted rates for a particular Medicare service, the CHC-MCO does not make a payment. When the CHC-MCOs contracted rate exceeds the amount paid by Medicare, the CHC-MCO must pay the difference between the amount paid by Medicare and the CHC-MCO contracted rate. The CHC-MCO will not be responsible for copayments or cost-sharing for Medicare Part D prescriptions.

If no contracted CHC-MCO rate exists or if the Provider of the service is an Out-of-Network Provider, the CHC-MCO must pay deductibles and coinsurance up to the applicable MA fee schedule rate for the service.

For Medicare services that are not covered by MA or the CHC-MCO, the CHC-MCO must pay cost-sharing to the extent that the payment made under Medicare for the service and the payment made by the CHC-MCO do not exceed eighty percent (80%) of the Medicare-approved amount.

The CHC-MCO, its subcontractors and Providers are prohibited from balance

billing Participants for Medicare deductibles or coinsurance. Participants who are dually eligible for Medicare and Medicaid are allowed to continue using their Medicare PCP even if the PCP is not MA enrolled. The CHC-MCO must provide a Dual Eligible Participant access to Medicare products and services from the Medicare Provider of his or her choice. The CHC-MCO is responsible to pay any Medicare coinsurance and deductible amount, whether or not the Medicare Provider is included in the CHC-MCO's Provider Network, is a participating provider in Medicaid, and whether or not the Medicare Provider has complied with the Prior Authorization requirements of the CHC-MCO.

The Commonwealth enters into a Coordination of Benefits Agreement with Medicare. Consistent with 42 C.F.R. §438.3(t), the CHC-MCO must enter into individual Coordination of Benefits Agreements with Medicare for members dually eligible for Medicaid and Medicare and participate in the automated claims crossover process.

10. Confidentiality

The Department may elect from time to time to share with the CHC-MCO an internal Business Requirements Document or an internal Business Design Document, FFS inpatient hospital rates, cost-to-charge ratio information, and other LTSS rates. The CHC-MCO shall not use this information for any purpose other than to support the CHC-MCO's performance of its responsibilities under this Agreement and related responsibilities provided by law. The CHC-MCO may share a Business Requirements Document, a Business Design Document, or the FFS inpatient hospital rates, cost-to-charge ratio, and relative value information provided by the Department with another party, provided that the other party does not use the information for any purpose other than to support the CHC-MCO's performance of its responsibilities of this Agreement and any other related responsibilities provided by law.

11. Audits

The CHC-MCO must comply with audit requirements as specified in Exhibit O, CHC Audit Clause.

12 Restitution for Overpayments

The CHC-MCO must make full and prompt restitution to the Department, as directed by the Department, for any payments received in excess of amounts due to the CHC-MCO after such overpayment is discovered by the CHC-MCO, the Department, or third party.

13 Penalty Periods

The CHC-MCO must, in coordination with the Department, monitor the

completion of all NF and HCBS related processes, including the maintenance of a Penalty Period, if applicable.

14 Prohibited Payments

The CHC-MCO shall not pay for an item or service (other than an emergency item or service, not including items or services furnished in an emergency room of a hospital), that is furnished:

a. by, or at the medical direction or prescription of, any individual or entity during any period that the individual or entity is excluded from participation in Medicare, Medicaid, the federal Maternal and Child Health Services Block Grant program or the federal Social Services Block Grant program; or

b. by any individual or entity during any period when there is a pending investigation of a credible allegation of fraud against the individual or entity, unless the Department determines in accordance with then-applicable federal regulations there is good cause not to suspend such payments.

The CHC-MCO must not pay any amount for which funds may not be used under the federal Assisted Suicide Funding Restriction Act of 1997, including payments for items or services furnished for the purpose of causing, or for the purpose of assisting in causing, the death of any individual, such as by assisted suicide, euthanasia or mercy killing.

The CHC-MCO must not pay for any item or service for road bridges, stadiums, or any other item or service not provided for under this Agreement.

15 Payment for Personal Assistance Services

The Department requires CHC-MCOs to pay for Personal Assistance Services at no less than the HCBS MA fee schedule rate. Nothing in this provision should be construed to prohibit the CHC-MCO and the provider to agree to a higher payment rate.

16 Value-Based Purchasing (VBP)

Value-based purchasing (VBP) is the Department's initiative to transition providers to being paid for the value of the services provided, rather than simply the volume of services. VBP Payment Strategies and VBP Models are critical for improving quality of care, efficiency of services, reducing cost, and addressing Social Determinants of Health.

The Department has developed an aligned VBP framework that consists of both VBP Payment Strategies and VBP Models. VBP Payment Strategies define the mechanism by which the providers are paid by the MCO. VBP Payment Strategies are tiered by three levels of risk: low, medium, and high.

VBP Models define a way to organize and deliver care and may incorporate one or more VBP Payment Strategies as ways to pay providers. The Department is categorizing VBP Models into recommended models and required models.

CHC-MCOs, BH-MCOs, PH-MCOs, and CHIP-MCOs can form integrated VBP models. MCOs should work towards integrating VBP models, because addressing all service and supports needs will improve health outcomes.

a. VBP Payment Strategies

The MCO must enter into VBP Payment Arrangements with Providers that incorporate approved VBP Payment Strategies. The Department retains the ability to accept or reject any proposals to count toward the required VBP medical spend percentage. The approved VBP Payment Strategies are tiered as low-risk (performance based contracting), medium risk (shared savings, shared risk, bundled payments), and high risk (global payments).

Each arrangement must include quality benchmarks, financial incentives, penalties or both, without which the Department will reject the arrangement as counting towards the required VBP medical or LTSS spend percentage. MCOs can also layer additional non-financial incentives as long as financial incentives are also in the arrangement.

Approved payment strategies:

i. Performance based contracting (low-risk strategy): FFS contracts in which incentives payments and/or penalties are linked to Network Provider performance. The MCO must measure Network Providers against quality benchmarks or incremental improvement benchmarks and must include in the contract incentives or penalties or both based upon meeting these benchmarks.

ii. Shared Savings (medium-risk strategy): Supplemental payments to Network Providers if they can reduce health care spending relative to an annual cost benchmark, either for a defined Participant sub-population or the total Participant population served by a Network Provider. The cost benchmark

should be developed prospectively, based at least in part on historical claims, and be risk adjusted if needed. The supplemental payment is a percentage of the net savings generated by the Network Provider.

iii. Shared Risk (medium-risk strategy): Supplemental payments to Network Providers if they are able to reduce health care spending relative to a cost benchmark, either for a defined Participant sub-population or the total Participant population served by a Network Provider. The cost benchmark should be developed prospectively, based at least in part on historical claims, and risk adjusted if needed. The payment is a percentage of the net savings generated by the Network Provider. These arrangements also include shared losses with Network Providers if costs are higher relative to a benchmark.

iv. Bundled payments (medium-risk strategy): Bundled payments include all payments for services rendered to treat a Participant for an identified condition during a specific time period. The payments may either be made in bulk, or be paid over regular predetermined intervals. DHS may specify certain services that must be paid through bundled payments.

v. Global payment (high-risk strategy): Population-based payments that cover all services rendered by a Network Provider, hospital, or health system by the participating MCO.

i. An annual global budget is developed prospectively. These payments can either be made in bulk, delivered over regular predetermined intervals, or based on fee-for-service payments with retrospective reconciliation to the global budget. If these payments are subject to retrospective reconciliation, at least a portion of the payment must be prospective to allow Network Providers to make upfront investments in population health infrastructure.

ii Global payments should link payments to both improved physical health and behavioral health quality measures, and provide incentive to reduce potentially avoidable utilization and address social determinants of health. Global payments must also take into consideration market shift on an annual basis, to ensure that Network Providers are not simply decreasing the amount of care provided.

iii Network Providers who are paid via global payments are excluded from participating in separate bundled payment, shared savings, and shared risk arrangements with the same MCO, because this would be a duplication of payment for services rendered.

b. VBP Models:

VBP Models are divided into Recommended Models, which the Department encourages MCOs to adopt, and Required Models, which are models that MCOs must adopt if they decide to contract with participating Network Providers. MCOs may also implement VBP payment arrangements outside of the recommended models and required models.

Recommended Model:

i. Accountable Care Organization (ACO): An ACO Model integrates the financing arm with the delivery arm within the same organization, such that both are collectively responsible for the Participant. ACO models may include shared savings, shared risk, or global payments.

ii. Patient Centered Medical Home (PCMH): MCOs may include PCMH models as defined by NCQA, current existing Medicare PCMH programs, current D-SNP PCMH programs, and the HealthChoices PCMH program to have the arrangement qualify as a PCMH. Note that payments to PCMHs must be categorized as one of the VBP payment arrangements listed in Section A, and still include quality benchmarks, with incentives or penalties or both based upon meeting these benchmarks, without which the payments will not count towards the required VBP medical spend percentage.

iii. Performance-based Contracting (PBC): Fee-for-Service (FFS) contracts in which incentives payments and/or penalties are linked to Network Provider performance. The MCO must measure Network Providers against quality benchmarks or incremental improvement benchmarks, and must include in the contract incentives or penalties or both based upon meeting these benchmarks.

iv. Shared Savings: Supplemental payments to Network Providers if they can reduce health care spending relative to an annual cost benchmark, either for a defined Participant sub-population or the total Participant population served by a Network Provider. The cost benchmark should be developed prospectively, based at least in part on historical claims and be risk adjusted if needed. The supplemental payment is a percentage of the net savings generated by the Network Provider.

v. Shared Risk: Supplemental payments to Network Providers if they are able to reduce health care spending relative to a cost benchmark, either for a defined Participant sub-population or the total Participant population served by a Network Provider. The cost benchmark should be developed prospectively, based at least in part on historical claims and risk adjusted if needed. The payment is a percentage of the net savings generated by the Network Provider. These arrangements also include shared losses with Network Providers if costs are higher relative to a benchmark.

vi. Bundled Payments: Bundled payments include all payments for services rendered to treat a Participant for an identified condition during a specific time period. The payments may either be made in bulk or be paid over regular predetermined intervals. The Department of Human Services (DHS) may specify certain services that must be paid through bundled payments.

vii. Global Payment: Population-based payments that cover all services rendered by a Network Provider, hospital or health system by the participating MCO.

1) An annual global budget is developed prospectively. These payments can either be made in bulk, delivered over regular predetermined intervals or based on FFS payments with retrospective reconciliation to the global budget. If these payments are retrospective, at least a portion of the payment must be prospective to allow Network Providers to make upfront investments in population health infrastructure.
2) Global payments should link payments to both improved physical health and behavioral health quality measures, and provide incentive to reduce potentially avoidable utilization and address social determinants of health. Global payments must also take into consideration market shift on an annual basis, to ensure that Network Providers are not simply decreasing the amount of care provided.
3) Network Providers who are paid via global payments are excluded from participating in bundled payment arrangements, because this

would make the Network Provider doubly liable for the services rendered. MCOs should consider reduction of prior authorization requirements for Network Providers who are paid via global payments.

Required Models:

MCOs must participate in required VBP payment models if specified by the Department and work with the Department on the development of new models.

c. Financial Goals

The financial goals for the VBP strategies for each calendar year are based on a percentage of the CHC-MCO's expenditures to the medical portion of the risk adjusted capitation revenue without consideration of risk sharing risk pools, P4P or other revenue or revenue adjustments. These goals apply collectively to all Community HealthChoices Agreements between the CHC-MCO and the Department in all Community HealthChoices Zones. For the purpose of this requirement, Capitation revenue is gross of premiums for risk sharing or risk pool arrangements without adjustment for risk sharing or risk pool results. The CHC-MCO must achieve the following percentages through VBP arrangements:

i. Calendar year 2024 – fifteen percent (15%) of the medical portion of the capitation must be expended through VBP. The fifteen percent (15%) may be from any combination of strategies 8.a.i through 8.a.v., and twenty five percent (25%) of LTSS payments through a value-based payment arrangement. A minimum of ten percent (10%) of the total LTSS spend must be in the Medium or High Financial Risk categories.

d. Reporting

The Department will measure compliance through required reports that have been developed by the Department. By October 1st of each calendar year, the CHC-MCO must submit its proposed VBP plan to the Department in the format required by the Department that outlines and describes its plan for compliance in that calendar year. The Department will review and provide feedback on the plan to the CHC-MCO. By the last work day of every quarter, the CHC-MCO must submit a progress report.

By June 30 of the subsequent calendar year, the CHC-MCO must submit a report as directed by the Department on accomplishments from the prior year. This annual report must include a listing of the VBP arrangements by

provider; and an explanation of each arrangement; and the dollar amount spent for medical services and LTSS provided during the previous year through these arrangements. The dollar amounts that qualify toward meeting the VBP goals are as follows:

i. Performance based contracting – dollar value of performance (bonus) payments and direct payments made to the Provider for Participants attributed to the provider's panel during the calendar year.

ii. The CHC-MCOs will use the Nursing Facility Quality Measurement Program to evaluate nursing homes and develop a valued based incentive arrangement as detailed in Exhibit DD(2) Pay for Performance Nursing Facility Quality Measurement Program.

iii. Shared savings– dollar value of any performance (bonus) payments, direct payments made to the provider and total medical costs incurred by the CHC-MCO for Participants of the provider's panel during the time period of the calendar year the Participant was attributed to the provider's panel.

iv. Shared risk – dollar value of any performance (bonus) payments and penalty payments, direct payments made to the provider total medical costs incurred by the CHC-MCO for Participants of the provider's panel during the time period of the calendar year the Participant was attributed to the provider's panel.

v. Bundled payments– dollar value of bundled payments made to providers. The Department may add additional reporting requirements depending on the services being bundled.

vi. Global payments – dollar value of any performance (bonus) payments, direct payments made to the provider and total medical costs incurred by the CHC-MCO for Participants of the provider's panel inclusive of any previous (bonus) payments during the time period of the calendar year the Participant was attributed to the provider's panel.

e. New Agreements

If a new CHC-MCO Agreement is executed and effective during a calendar year, the reporting requirements are applicable to the calendar

year that crosses Agreements, and the Department will determine compliance for the complete calendar year.

f. Assessment

This section provides for an assessment against the CHC-MCO's revenue if an annual goal is not met.

Not later than 60 calendar days after receipt from the CHC-MCO of the annual report on VBP accomplishments, the Department will notify the CHC-MCO of its determination about compliance with the goal for the preceding year. The CHC-MCO may provide a response within 30 calendar days. After considering the response from the CHC-MCO, if any, the Department will notify the CHC-MCO of its final determination of compliance.

If the CHC-MCO fails to provide a timely and adequate report on VBP accomplishments, the Department may determine that the CHC-MCO is not compliant with the goal of the preceding year.

If the determination results in a finding of non-compliance, the Department may reduce the next monthly capitation payment by an amount equivalent to .5 percent (.5%) of the capitation it paid to the CHC-MCO for December of the prior calendar year.

g. Data Sharing

The CHC-MCOs must provide timely and actionable data to its providers participating in VBP arrangements. This data should include, but is not limited to, the following:

i. Identification of high risk patients;

ii. Comprehensive care gaps inclusive of gaps related to quality metrics used in the VBP arrangement; and

iii. Service utilization and claims data across clinical areas such as inpatient admissions, non-inpatient facility (Short Procedure Unit/Ambulatory Surgical Center), emergency department, radiology services, lab services, durable medical equipment and supplies, specialty physician services, home health services, nursing facilities, HCBS services and prescriptions,

iv. Care management information such as initial assessments and care plans, reassessments and updated

care plans, as well as transition of care information from nursing home to the community.

F. Third Party Liability

The CHC-MCO must comply with the TPL procedures implemented by the Department. Under this Agreement, the TPL responsibilities of the Department will be allocated between the Department and the CHC-MCO.

1. Cost-Avoidance Activities

a. The CHC-MCO will have primary responsibility for cost avoidance through the COB relative to federal and private health insurance-type resources, including, but not limited to, Medicare, private health insurance, ERISA plans, and workers compensation. Except as provided in subparagraph ii, the CHC-MCO must attempt to avoid initial payment of Claims, whenever possible, where federal or private health insurance-type resources are available. The CHC-MCO must report all funds that are cost-avoided by the CHC-MCO to the Department via Encounter Data submissions. The number of claims cost avoided by the CHC-MCO's claims system should be reported in Financial Report #8A, “Claims Cost Avoided.” The use of the appropriate HIPAA 837 Loop(s) for Medicare and Other Insurance Paid shall indicate that TPL has been pursued and the amount which has been cost-avoided. The CHC-MCO shall not be held responsible for any TPL errors in EVS or the Department's TPL file. The CHC-MCO must sign a Coordination of Benefits Agreement and participate in the automated claims crossover process administered by Medicare.

b. The CHC-MCO may not deny or delay approval of otherwise covered treatment or services based upon TPL considerations. The CHC-MCO may neither unreasonably delay payment nor deny payment of Claims unless the probable existence of TPL is established at the time the Claim is adjudicated.

2. Post-Payment Recoveries

a. Post-payment recoveries are categorized by (a) health-related insurance resources, and (b) Other Resources. Health-related insurance resources are ERISA health benefit plans, Blue Cross/Blue Shield subscriber contracts, Medicare, private health insurance, workers′ compensation, and health insurance contracts. Other Resources include but are not limited to recoveries from personal injury claims, liability insurance, first-party automobile medical insurance and accident indemnity insurance.

b. The Department's Division of TPL retains the sole and exclusive right to investigate, pursue, collect, and retain all Other Resources. The CHC-MCO assigns to the Department the CHC-MCO's subrogation rights to collect the Other Resources covered by this provision. The CHC-MCO must immediately forward to the Division of TPL any correspondence or Inquiry received by the CHC-MCO (by an attorney, Provider of service, insurance carrier, etc.) relating to a personal injury accident or trauma-related medical service, or which in any way indicates that there is, or may be, legal involvement regarding the Participant and the services which were provided. The CHC-MCO may neither unreasonably delay payment nor deny payment of Claims because they involve an injury stemming from an accident such as a motor vehicle accident, where the services are otherwise covered. Those funds recovered by the Department under the scope of these "Other Resources" shall be retained by the Department.

With respect to any third party payment received by the CHC-MCO from a Provider, the CHC-MCO shall return all casualty funds to the Department. CHC-MCOs will not instruct Providers to send funds directly to the Department. The CHC-MCO may not hold these third party payments more than thirty (30) days. If the casualty funds received by the Department must be returned to the CHC-MCO for any reason, for example, an outdated check or the amount of the check does not match supporting documentation, the CHC-MCO shall have ninety (90) days to return all casualty funds to the Department using the established format.

c. The CHC-MCO is responsible for pursuing, collecting, and retaining recoveries of a claim involving Workers' Compensation.

d. Due to potential time constraints involving casualty cases subject to litigation as well as estate cases, and due to the large dollar value of many claims which are potentially recoverable by the Department's Division of TPL, the Department must ensure that it identifies these cases and establishes its claim before a settlement has been negotiated for a casualty case or a final accounting has been approved for an estate. Should the Department fail to identify and establish a claim prior to settlement due to the CHC-MCO's untimely submission of notice of legal involvement where the CHC-MCO has received such notice, the amount of the Department's actual loss of recovery shall be assessed against the CHC-MCO. The Department's actual loss of recovery shall not include the attorney's fees or other costs which would not have been retained by the Department. If the Department fails to identify and establish a casualty or estate claim prior to settlement due to the CHC-MCO's untimely submitting of notice of legal involvement where the CHC-MCO has received such notice, the Department's actual loss of recovery shall be assessed against the CHC-MCO. The Department's assessment will not include the attorney's fees or other costs that the Department would not have retained

from the recovery.

e. The CHC-MCO has the sole and exclusive responsibility and right to pursue, collect and retain all health-related insurance resources for a period of nine (9) months from the date of service or six (6) months after the date of payment, whichever is later. The CHC-MCO must indicate its intent to recover on health-related insurance by providing to the Department an electronic file of those cases it will pursue. The cases must be identified, and a file provided to the Department by the CHC-MCO within the window of opportunity afforded by the nine (9) months from the date of service or six (6) months after the date of payment unless otherwise permitted by the Department. The Department's Division of TPL may pursue, collect and retain recoveries of all health-related insurance cases which are not identified by the CHC-MCO for recovery, after the later of nine (9) months from the date of service or six (6) months after the date of payment. Notification of intent to pursue, collect and retain health-related insurance is the sole responsibility of the CHC-MCO, and cases not identified for recovery will become the sole and exclusive right of the Department to pursue, collect and retain. In such cases where the CHC-MCO has identified the cases to be pursued, the CHC-MCO shall retain the exclusive responsibility for the cases for a period not to exceed eighteen (18) months. The calculation of the eighteen (18) month period shall commence with receipt of the file from the CHC-MCO identifying the cases to be pursued. Any case not completed within the eighteen (18) month period will become the sole and exclusive right of the Department to pursue, collect and retain. The CHC-MCO is responsible for notifying the Department through the prescribed electronic file process of all outcomes for those cases identified for pursuit. Cases included in Encounter files that were suspended will not be able to be included in the flagging process because the Claims cannot be adjusted in the Department’s automated processing system.

With respect to any third party payment received by the CHC-MCO from a Provider, the CHC-MCO shall ensure that the funds are within their right of recovery. If the funds are outside the allowable recovery window, the funds shall be returned to the Department. These third party payments shall not be held by the MCO for more than thirty (30) calendar days. If the provider funds received by the Department from the CHC-MCO must be returned to the CHC-MCO for any reason, for example, an outdated check or the amount of the check does not match supporting documentation, then the CHC-MCO shall have sixty (60) calendar days to return all provider funds to the Department using the established format.

f. Should the Department lose recovery rights to any Claim due to late or untimely filing of a Claim with the liable third party, and the untimeliness in filing that specific Claim is directly related to untimely submission of

Encounter Data or additional records under special request, or inappropriate denial of Claims for accidents or emergency care in casualty related situations, the amount of the unrecoverable claim shall be assessed against the CHC-MCO. The same will apply in any situation where the Department loses recovery rights on an estate due to the CHC-MCO's failure to timely supply the data necessary to perfect the Department's claim and meet the forty-five (45) day regulatory mandate.

g. Encounter Data that is not submitted to the Department in accordance with the data requirements and/or timeframes identified in this Agreement can possibly result in a loss of revenue to the Department. Strict compliance with these requirements and timeframes shall therefore be enforced by the Department and could result in the assessment of sanctions against the CHC-MCO.

h. Health Insurance Premium Payment (HIPP) Program. The HIPP Program pays for employment-related health insurance for Participants when it is determined to be cost effective.

3. Requests for Additional Data

The CHC-MCO must provide, at the Department's request, such information not included in the Encounter Data submissions that may be necessary for the administration of TPL activity, specifically casualty and estate recoveries. The CHC-MCO must provide casualty information within fifteen (15) calendar days of the Department's request. The CHC-MCO must provide information for urgent requests involving casualty and Encounter data for estate cases within forty-eight (48) hours. Such information may include, but is not limited to, individual medical records for the express purpose of determining TPL for the services rendered. Confidentiality of the information must be maintained as required by Federal and State regulations

4. Accessibility to TPL Data

The Department will provide the CHC-MCO with access to data maintained on the TPL monthly file.

5. Third Party Resource Identification

The CHC-MCO must supply the Department with TPL information identified by the CHC-MCO or its subcontractors, which does not appear on the Department's TPL database, as well as information on coverage for other household members, addition of a coverage type, changes to existing resources, including termination of coverage and changes to coverage dates. The method of reporting must be by electronic file or by any alternative method approved by the Department. TPL resource information must be submitted within two (2) weeks of its receipt by the CHC-MCO. A web-based referral is

only to be submitted in the following instances: the CHC-MCO is no longer the Participant's CHC-MCO; the Contract /Policy ID number is longer than 12 digits; or the referral is from the Pennsylvania Health Insurance Premium Payment Program. For web-based referrals, the CHC-MCO must use an exact replica of the TPL resource referral form supplied by the Department. For electronic submissions, the CHC-MCO must follow the required report format, data elements, and specifications supplied by the Department.

The Department will contact the CHC-MCO when the validity of a resource is in question. The CHC-MCO shall verify inconclusive resource information within two (2) business days of notification by the Department that the resource information is in dispute. However, if the verification notification is requested on the last business day of the week, the CHC-MCO must respond by the close of business that day to avoid a potential access to care issue for its Participant.

The CHC-MCO must use EVS and secured services on the Internet (previously known as POSNet) to identify insurance information the Participants have on file. If there is additional or different insurance information, the CHC-MCO or its subcontractors need to communicate the information as listed above.

6. Estate Recovery

The Department is required to recover MA costs paid on behalf of certain deceased individuals age fifty-five (55) and older who were receiving MA benefits for any of the following services:

a. Public or private NF services;

b. Residential care for home and community-based services;

c. Any hospital care and prescription drug services provided while receiving NF services or residential care for home and community-based services.

The Department's Division of TPL is solely responsible for administering the Estate Recovery Program. The CHC-MCO must supply all requested Encounter data timely to permit the Department's timely filing of a claim.

SECTION VIII: REPORTING REQUIREMENTS

A. Department Monitoring Requirements

To demonstrate compliance with 42 CFR § 438.66, State Monitoring Requirements, the Department must have in effect a monitoring system for CHC. The Department's system must address all aspects of the managed care

program, including the performance of each CHC-MCO as required in § 438.66 (b). The Department must use the data collected from its monitoring activities to improve the performance of its managed care program, including, at a minimum the areas noted in § 438.66 (c).

In addition, § 438.66 (e) requires the Department to submit to CMS, no later than 180 days after each contract year, a report on its managed care programs. The first annual report for CHC is due to CMS no later than June 29, 2023 for the 2022 calendar year. The annual program report must provide information on and an assessment of the operation of CHC on, at a minimum, the following areas:

- Financial performance of each CHC-MCO, including MLR experience.
- Encounter data reporting by each CHC-MCO.
- Enrollment and service area expansion (if applicable) of each CHC-MCO.
- Modifications to, and implementation of, MCO benefits covered under the contract with the Department.
- Grievance, appeals, and State fair hearings for CHC.
- Availability and accessibility of covered services within the CHC-MCO agreements, including network adequacy standards.
- Evaluation of the CHC-MCO's performance on quality measures, including as applicable, consumer report card, surveys, or other reasonable measures of performance.
- Results of any sanctions or corrective action plans imposed by the Department or other formal or informal intervention on a CHC-MCO to improve performance.
- Activities and performance of the beneficiary support system.
- Any other factors in the delivery of LTSS not otherwise addressed in § 438.66 (e)(2)(i)-(ix) as applicable.

The CHC-MCO must comply with all state and federal reporting requirements that are set forth in this Agreement and provided through Guidance from the Department. If the CHC-MCO fails to submit the required reports within timeframes specified, the Department shall assess sanctions upon the CHC-MCO as specified in Section VIII.I, Sanctions, and Section VII D.2, Sanctions, and Exhibits T, X, BB of this Agreement.

B. General

The CHC-MCO must comply with state and federal reporting requirements that are set forth in this Agreement and provided in guidance from the Department.

The CHC-MCO must certify and submit to the Department the data required to be certified under 42 C.F.R. § 438.604, whether in written or electronic form. Such certification must be submitted concurrently with the data and must be based on

the knowledge, information and belief of the Chief Executive Officer, Chief Financial Officer or an individual who has delegated authority to sign for, and who reports directly to, the CEO or CFO in accordance with 42 C.F.R. § 438.604.

The CHC-MCO will provide the certification in the manner prescribed by the Department.

The CHC-MCO must cooperate with the Department in all activities related to compliance with federal mental health parity requirements. The CHC-MCO must provide all information requested by the Department related to these activities within ten (10) days of the Department's request.

For critical and urgent issues, the CHC-MCO is required to respond to the Department the same day or within 12 hours. The CHC-MCO is required to respond to the Department's questions and issues within three business days of receiving questions and requests for clarification. The Department will determine the appropriate contact method, (e.g., phone call or email to the CHC-MCO Government Liaison or other CHC-MCO contact).

C. Systems Reporting

The CHC-MCO must submit electronic data as specified by the Department. Whenever possible, the Department will provide reasonable advance notice of modifications or additions to required electronic data submissions.

Information on the submission of the Department's data files is available on the Pennsylvania HealthChoices Extranet.

1. Encounter Data Reporting

The CHC-MCO must record Encounter Data for internal use and submit timely, complete, and accurate Encounter Data to the Department. The CHC-MCO shall only submit Encounter Data for Participants enrolled in its CHC plan on the date of service and must not submit duplicate records.

The CHC-MCO must maintain appropriate systems and mechanisms to obtain all data from its Providers needed to comply with Encounter Data and TMSIS reporting requirements.

The Department will provide a minimum of sixty (60) days advance written notice to the CHC-MCO regarding changes to Encounter Data requirements.

Failure of Providers or Subcontractors to submit Claims and Encounter Data to the CHC-MCO in a complete, timely, and accurate manner shall not excuse the CHC-MCO's noncompliance with this requirement.

The CHC-MCO must comply with all sections of 42 C.F.R. § 438.242, including, but not limited to, compliance with Section 6504(a) of the Affordable Care Act, which requires that Claims processing and retrieval systems collect data elements necessary to meet the requirements of section 1903(r)(1)(F) of the Act.

a. Data Format

The CHC-MCO must submit Encounter Data to the Department using established protocols. Prior to submission of production data, the CHC-MCO must pass Encounter Data certification for all transaction types.

i. The CHC-MCO must adhere to Encounter Data file specifications, including the collection and maintenance of sufficient Participant Encounter Data to identify the Provider who delivers any items or services to Participants.

ii. The CHC-MCO must adhere to the file size, format specifications, and file submission schedule provided by the Department. The CHC-MCO must submit Participant Encounter Data to the Department at a frequency and level of detail specified by CMS and the Department, based on program administration, oversight, and program integrity needs.

The CHC-MCO must provide Encounter Data files in the following ASC X12 transactions:

- 837P
  - Professional
  - Professional Crossover
  - Professional Drug
- 837I
  - Inpatient
  - Inpatient Crossover
  - Outpatient
  - Outpatient Crossover
  - Outpatient Drug
  - Long Term Care (LTC)
- 837D
  - Dental
- NCPDP D.0
  - NCPDP Pharmacy
  - Compound Pharmacy

b. Timing of Data Submittal

i. Provider Claims

The CHC-MCO must require Providers to submit claims ready for adjudication to the CHC-MCO within one hundred eighty (180) days after the date of service.

The CHC-MCO may include a requirement for more prompt submissions of Claims or Encounter Data in Provider Agreements and Subcontracts. Claims adjudicated by a third party vendor must be provided to the CHC-MCO by the end of the month following the month of adjudication.

ii. Encounter Submissions

All Encounter Data except NCPDP transactions must be submitted by the CHC-MCO and approved by the Department on or before the last calendar day of the third (3rd) month after the adjudication calendar month in which the CHC-MCO adjudicated the Claim.

NCPDP transactions must be submitted by the CHC-MCO and approved in the Department's MMIS within thirty (30) days following the adjudication date.

Encounter Data sent to the Department is considered approved when all Department edits are passed.

A file with Encounter Data records that deny due to Department edits will be returned to the CHC-MCO. These records must be corrected and resubmitted as "new" Encounter records within the timeframe referenced above.

Corrections and resubmissions must pass all edits before they are approved by the Department.

When Error Status Code (ESC) denials occur due to CHC-MCO, Subcontractor, or Provider system faults or limitations, it is the responsibility of the CHC-MCO to make every attempt to remediate the systems concerns within a reasonable amount of time. Based on the impact of the errors and the length of time to implement a solution, the CHC-MCO may be subject to assessments, Corrective Action, or both.

iii. Response Files

The CHC-MCO's Encounter Data system must be able to receive,

process, and reconcile the U277, NCPDP, and ESC Supplemental response files. The CHC-MCO must also store the Department's MMIS ICN associated with each processed Encounter Data record returned on the files.

c. Data Completeness

The CHC-MCO must submit Encounter Data each time a Participant has an Encounter with a Provider. The CHC-MCO must have a data completeness monitoring program in place that:

i. Demonstrates that all Claims and Encounters submitted to the CHC-MCO by its Providers and Subcontractors are submitted accurately and timely as Encounters and that denied Encounters are resolved and resubmitted,

ii. Evaluates Provider and Subcontractor compliance with contractual reporting requirements, and

iii. Demonstrates the CHC-MCO has processes in place to act on information from the monitoring program and takes appropriate action to ensure full compliance with Encounter Data reporting requirements.

Upon request of the Department, the CHC-MCO must submit a Data Completeness Plan for advance written review and approval. This Plan must include the three (3) elements listed above.

d. Financial Sanctions

The CHC-MCO must provide complete, accurate, and timely Encounter Data to the Department. In addition, the CH-MCO must maintain complete medical service history data.

The Department will request the CHC-MCO submit a Corrective Action Plan when areas of noncompliance are identified.

The Department may assess financial sanctions as provided in Exhibit X, Encounter Data Submission Requirements and Damages Applications, based on the identification of instances of non-compliance.

e. Data Validation

The CHC-MCO must assist the Department in its validation of Encounter Data by making medical records and Claims data available as requested. The validation may be completed by Department staff, independent

external review organizations, or both.

f. Release of Encounter Data

All Encounter Data for Participants is the property of the Department. The CHC-MCO may use this data for the sole purpose of operating the CHC Program under this Agreement.

g. Drug Rebate Supplemental File

The CHC-MCO must submit a complete, accurate, and timely monthly file containing supplemental data for NCPDP, 837P Professional Drug, and 837I Outpatient Drug transactions used for the purpose of drug rebate dispute resolution. The file must be submitted by the fifteenth (15^{th}) day of the month following the month in which the drug transaction was processed in the Department's MMIS as specified on the Pennsylvania HealthChoices Extranet.

The MCO Supplemental Data Status Report will be provided by the Department to the CHC-MCO on or after the 20th of each month following receipt of the Drug Rebate Supplemental File. CHC-MCOs must use this report to reconcile and correct any errors on Drug Rebate data that was submitted.

2. Third Party Liability Reporting

Third Party Resources identified by the CHC-MCO or its subcontractors, which do not appear on the Department's TPL database, must be supplied to the Department's Division of TPL within two (2) weeks of its receipt by the CHC-MCO. The Department will contact the CHC-MCO when the validity of a resource is in question. The CHC-MCO shall verify inconclusive resource information within two (2) business days of notification by the Department that the resource information is in dispute. However, if the verification notification is requested on the last business day of the week, the CHC-MCO must respond by the close of business that day to avoid a potential access to care issue for its member. The method of reporting shall be by electronic submission via a batch file or by hardcopy document, whichever is deemed most convenient and efficient by the CHC-MCO for its individual use. For electronic submissions, the CHC-MCO must follow the required report format, data elements, and specifications supplied by the Department. For hardcopy submissions, the CHC-MCO must use an exact replica of the TPL resource referral form supplied by the Department. Submissions lacking information key to the TPL database update process will be considered incomplete and will be returned to the CHC-MCO for correction and subsequent resubmission.

3. PCP Assignment

The CHC-MCO must provide a weekly file (EVS-PCP) to the Department's MMIS containing PCP assignments for all its Participants other than those who have a Medicare PCP. This file is used to update the Department's Eligibility Verification System.

The CHC-MCO must provide this file at least weekly or more frequently if requested by the Department. The CHC-MCO must confirm that the PCP assignment information is consistent with all requirements specified by the Department by utilizing the response report provided by the Department. The CHC-MCO must comply with the file submission requirements found on the Pennsylvania HealthChoices Extranet.

4. Provider Network

The CHC-MCO must provide a monthly Network Provider File (PRV640M) to the Department. The initial file must contain records for its entire Provider Network, including Subcontractors. Subsequent monthly files should contain only updates.

The CHC-MCO must confirm the information is consistent with all requirements by utilizing the response report (PRM640M) provided by the Department. The CHC-MCO must use this report to reconcile and correct any errors. The CHC-MCO must comply with file submission requirements found on the Pennsylvania HealthChoices Extranet.

5. Alerts

The CHC-MCO must report to the Department on a Weekly Enrollment/Disenrollment/Alert File: pregnancy (not on eCIS), death (not on eCIS), and returned mail.

The CHC-MCO must confirm the information is consistent with all requirements specified on the Pennsylvania HealthChoices Extranet.

D. Operations Reporting

The CHC-MCO is required to submit such reports as specified by the Department to enable the Department to monitor the CHC-MCO's internal operations and service delivery. These reports include, but are not limited to:

1. Operations and Quality Reporting Requirements

As a condition of approval of the Waivers for the operation of CHC, CMS has imposed specific reporting requirements related to the Home and Community

Based Waiver and overall CHC monitoring. OLTL has also established additional Operations and Quality Management Reports to oversee CHC. Required reports are identified on the Operations and Quality Management Reporting Requirements Submission Schedule. CHC-MCOs are required to meet identified due dates, submit accurate data, and provide requested documentation.

2. Fraud, Waste and Abuse,

The CHC-MCO must submit to the Department quarterly and annual statistical reports which relate to its Fraud, Waste and Abuse detection and sanctioning activities regarding Providers. The CHC-MCO must include information for all situations where a Provider action caused an overpayment to occur and must identify cases under review (including approximate dollar amounts), Providers terminated due to Medicare/Medicaid preclusion, provider terminations for good cause or best interest, overpayments recovered and cost avoidance issues related to identifying and/or identified fraud, waste, and abuse (42 CFR §438.608(a)(2)). The CHC-MCO must comply with all requirements regarding Operations Report format and timeframes provided on the DHS/CHC-MCO docuShare Reporting pages and on the HealthChoices Extranet at Managed Care Program/Fraud and Abuse.

E. Financial Reports

The CHC-MCO must submit such reports as specified by the Department to assist the Department in assessing the CHC-MCO's financial viability and compliance with this Agreement.

The Department will distribute financial reporting requirements to the CHC-MCO. The CHC-MCO must furnish all financial reports timely and accurately, with content in the format prescribed by the Department. This includes, but is not limited to, the CHC financial reporting requirements issued by the Department.

F. Equity

Not later than May 25, August 25, and November 25 of each Agreement year, the CHC-MCO must provide the Department with:

- A copy of quarterly reports filed with PID.
- A statement that its Equity is in compliance with the Equity requirements or is not in compliance with the Equity requirements.
- If Equity is not in compliance with the Equity requirements, the CHC-MCO must supply a report that provides an analysis of its fiscal health and steps that management plans to take, if any, to improve fiscal health.

Not later than March 10 of each Agreement year, the CHC-MCO must provide

the Department with:

- A copy of unaudited annual reports filed with PID.
- A statement that its Equity is in compliance with the Equity requirements or is not in compliance with the Equity requirements.
- If Equity is not in compliance with the Equity requirements, the CHC-MCO must supply a report that provides an analysis of its fiscal health and steps that management plans to take, if any, to improve fiscal health.

G. Claims Processing Reports

The CHC-MCO must provide the Department with monthly Claims processing reports with content in a format specified by the Department. The reports are due on the fifth (5^{th}) calendar day of the second (2^{nd}) subsequent month. Claims returned by a web-based clearinghouse (e.g., WebMD Envoy) are not considered as Claims received and would be excluded from Claims reports.

The Department may impose the following sanction for the CHC-MCO's failure to submit a timely Claims processing report that is accurate and fully compliant with the reporting requirements: Two Hundred Dollars ($200.00) per day for the first ten (10) calendar days from the date that the report is due, and One Thousand Dollars ($1,000.00) per day for each calendar day thereafter.

H. Presentation of Findings

The CHC-MCO must obtain advance written approval from the Department before publishing or making formal public presentations of statistical or analytical material based on its CHC Participant Population.

I. Sanctions

1. The Department may impose sanctions for noncompliance with the requirements under this Agreement and failure to meet applicable requirements in Sections 1932, 1903(m), and 1905(t) of the SSA in accordance with 42 C.F.R §§ 438.700; 438.702 and 438.704 in addition to any sanctions described in Exhibit B of this Agreement, Standard Terms and Conditions for Services, and in Exhibit B(1) of this Agreement, DHS Addendum to Standard Contract Terms and Conditions. The sanctions which can be imposed shall depend on the nature and severity of the breach, which the Department, in its reasonable discretion, will determine as follows:

    a. Imposing civil monetary penalties of a minimum of One Thousand Dollars ($1,000.00) per day for noncompliance;

    b. Requiring the submission of a corrective action plan;

c. Suspending or Limiting Enrollment of new Participants;

d. Suspension of payments;

e. Preclusion or exclusion of the CHC-MCO, its officers, managing employees or other individuals with direct or indirect ownership or control interest in accordance with 42 U.S.C. § 1320a-7, 42 C.F.R. Parts 1001 and 1002; 62 P.S. § 1407 and 55 Pa. Code §§ 1101.75 and 1101.77;

f. Temporary management subject to applicable Federal or State law; and/or

g. Termination of the Agreement

2. Where this Agreement provides for a specific sanction for a defined infraction, the Department may, at its discretion, apply the specific sanction provided for the noncompliance or apply any of the general sanctions set forth in this Section VIII.I, Sanctions. Specific sanctions contained in this Agreement include the following:

a. Claims Processing: Sanctions related to Claims processing are provided in Section VII D.2 of this Agreement, Sanctions.

b. Report or File, exclusive of Audit Reports: If the CHC-MCO fails to provide any report or file that is specified by this Agreement by the applicable due date, or if the CHC-MCO provides any report or file specified by this Agreement that does not meet established criteria, a subsequent payment to the CHC-MCO may be reduced by the Department. The reduction shall equal the number of days that elapse between the due date and the day that the Department receives a report or file that meets established criteria, multiplied by the average Per-Member, Per-Month Capitation rate that applies to the first (1^{st}) month of the Agreement year. If the CHC-MCO provides a report or file on or before the due date, and if the Department notifies the CHC-MCO after the fifteenth (15^{th}) calendar day after the due date that the report or file does not meet established criteria, no reduction in payment shall apply to the sixteenth (16^{th}) day after the due date through the date that the Department notifies the CHC-MCO.

c. Encounter Data Reporting: The sanctions related to the submission of Encounter Data are set forth in Section VIII.C of this Agreement, Systems Reports, and Exhibit X, Encounter Data Submission Requirements and Sanction Applications.

d. Marketing: The sanctions for engaging in unapproved marketing practices are described in Section V.O.3 of this Agreement, CHC-MCO Outreach Activities.

e. Access Standard: The sanction for noncompliance with the access standard is set forth in Exhibit T, Provider Network Composition/ Service Access.

f. Outpatient Drug Encounters: The sanctions for non-compliance with outpatient drug encounter data timeliness is set forth in Exhibit D, Drug Services.

J. Non-Duplication of Financial Penalties

If the Department assesses a financial sanction pursuant to one (1) of the provisions of Section VIII.I of this Agreement, Sanctions, it will not impose a financial sanction pursuant to Section VIII.I with respect to the same infraction.

SECTION IX: REPRESENTATIONS AND WARRANTIES OF THE CHC-MCO

A. Accuracy of Proposal

The CHC-MCO must notify the Department within ten (10) business days of any material fact, event, or condition which arises or is discovered subsequent to the date of the submission of its Proposal, which affects the truth, accuracy, or completeness of such representations and information.

B. Disclosure of Interests

The CHC-MCO must provide, on its behalf and for its subcontractors, written disclosure to the Department of information on ownership and control, business transactions, and persons convicted of crimes in accordance with 42 C.F.R. § 438.608 and with 42 C.F.R. Part 455, Subpart B.

The CHC-MCO shall make the disclosures required by 42 C.F.R. § 438.608 and by 42 C.F.R. Part 455, Subpart B at the following times:

1. when the CHC-MCO may submit a proposal in accordance with the Department's procurement process, if any;

2. when the CHC-MCO executes this Agreement; or

3. when the CHC-MCO may renew or extend this Agreement; or

4. within thirty-five (35) days after any change in ownership of the CHC-MCO.

The CHC-MCO must report to the Department a description of transactions between the CHC-MCO and a party in interest (as defined in 42 U.S.C. § 300e-17(b)), including the following transactions:

1. Any sale or exchange, or leasing of any property between the CHC-MCO and such a party.

2. Any furnishing for consideration of goods, services (including management services), or facilities between the CHC-MCO and such a party, but not including salaries paid to employees for services provided in the normal course of their employment.

3. Any lending of money or other extension of credit between the CHC-MCO and such a party.

The CHC-MCO shall make the forgoing information available to Participants upon reasonable request.

The CHC-MCO warrants that the members of its governing body and its officers and directors have no interest and will not acquire any interest, direct or indirect, which conflicts with the performance of its services hereunder. The CHC-MCO will not knowingly employ any person having such interest.

The Department may terminate this Agreement based on the CHC-MCO's failure to properly disclose required information and may recover as overpayments any payments improperly made by the CHC-MCO.

C. Disclosure of Change in Circumstances

Notwithstanding the disclosure requirements above, the CHC-MCO must notify the Department in writing of all changes affecting the delivery of care, the administration of its program, or its performance of Agreement requirements. The CHC-MCO must notify the Department in writing no later than ninety (90) days prior to any significant change to the manner in which services are rendered to Participants, including, but not limited to, reprocurement or termination of a Provider.

The CHC-MCO will report to the Department, as well as the DOH and PID, within ten (10) business days of the CHC-MCO's notice of same, circumstances that may have a material adverse effect upon financial or operational conditions of the CHC-MCO or CHC-MCO's parent(s), including, but not limited to, the following:

1. Suspension, or debarment, or exclusion from federally funded healthcare

programs of the CHC-MCO, CHC-MCO's parent(s), or any Affiliate or Related Party of either, by any state or the federal government;

2. Having a person who is debarred or suspended, or excluded act as a director, officer, or partner of the CHC-MCO with beneficial ownership of more than five percent (5%) of the CHC-MCO's Equity who has been debarred from participating in procurement activities under Federal regulations;
3. Notice of suspension, debarment, or exclusion from participation in healthcare programs or notice of an intent to suspend, debar, or exclude issued by any state or the federal government to CHC-MCO, CHC-MCO's parent(s), or any Affiliate or Related Party; and
4. Any lawsuits or investigations by any federal or state agency involving CHC-MCO, CHC-MCO's parent(s), or any Affiliate or Related Party.

SECTION X: TERMINATION AND DEFAULT

A. Termination by the Department

1. Termination for Convenience upon Notice

The Department may terminate this Agreement for convenience as provided in Section 18 of Exhibit B, Standard Terms and Conditions for Services. The Department is not required to provide advance notice of termination if this Agreement is replaced by another Agreement to operate a CHC Program in the zone.

2. Termination for Cause

The Department may terminate this Agreement for cause as provided in Section 18 of Exhibit B, Standard Terms and Conditions for Services. The Department is not required to provide advance written notice if it is terminating the Agreement based on:

a. An act of theft or Fraud against the Department, any state agency, or the Federal Government; or

b. An adverse material change in circumstances as described in Section IX.C, Disclosure of Change in Circumstances.

3. Termination Due to Unavailability of Funds or Approvals

In addition to Section 18 of Exhibit B, Standard Terms and Conditions for Services, the Department may terminate this Agreement immediately upon the occurrence of any of the following events:

a. Notification by the US DHHS of the withdrawal or disapproval of Federal Financial Participation in all or part of the cost for CHC Covered Services;

b. Notification of the unavailability of funds for the CHC Program; or

c. Notification that the federal approvals necessary to operate the CHC Program are not obtained or not retained; or

d. Notification by the PID or DOH that the authority under which the CHC-MCO operates is subject to suspension or revocation proceedings or sanctions, has been suspended, limited, or curtailed, has been revoked, or has expired and shall not be renewed.

B. Responsibilities of the CHC-MCO upon Termination

1. Continuing Obligations

Termination or expiration of this Agreement shall not discharge the CHC-MCO of obligations with respect to services or items furnished prior to termination, including retention of records and verification of overpayments or underpayments. The Department's payment obligations to the CHC-MCO and the CHC-MCO's payment obligations to its subcontractors and Providers for services provided prior to the termination or expiration survive the termination or expiration of the Agreement.

Upon any termination or expiration of this Agreement, the CHC-MCO must:

a. Provide the Department with all information deemed necessary by the Department within thirty (30) days of the request;

b. Be financially responsible for Claims with dates of service through the expiration or termination, except as provided below, including those submitted within time limits;

c. Be financially responsible for hospitalized patients through the date of discharge or thirty-one (31) days after termination or expiration, whichever is earlier;

d. Be financially responsible for services provided to NF Participants until the NF has completed a safe and orderly transfer of Participant care and records to another CHC-MCO in which the NF is operating after termination or expiration of this Agreement;

e. Be financially responsible for services rendered through 11:59 p.m. on the date of termination or expiration, except as provided below, for which payment is denied by the CHC-MCO and subsequently approved upon appeal;

f. Be financially responsible for Participant appeals of adverse decisions rendered by the CHC-MCO concerning services requested prior to termination or expiration that would have been provided but for a denial which is overturned at a DHS Fair Hearing or Grievance proceeding; and

g. Arrange for the orderly transfer of Participant care and records to those Providers who will be assuming care for the Participants.

2. Notice to Participants and Network Providers

If this Agreement is terminated, or expires without a new Agreement in place, the CHC-MCO must notify all Participants and Network Providers of such termination or expiration at least forty-five (45) days in advance of the effective date of termination or expiration, if practical. The CHC-MCO must make notices available in an accessible format and in the relevant language as required for Vital Documents. The CHC-MCO must coordinate the continuation of care prior to termination or expiration for Participants who are undergoing treatment for an acute condition.

3. Submission of Invoices

Upon termination or expiration, the CHC-MCO must submit to the Department all outstanding invoices for allowable services rendered prior to the date of termination or expiration in the form stipulated by the Department no later than forty-five (45) days from the effective date of termination or expiration. The Department will not make payment for invoices submitted after forty-five (45) days. This does not apply to submissions and payments in Appendices 3a – 3f.

4. Termination Requirements

Within one year (365 days) of expiration or termination of the Agreement, the CHC-MCO must provide the Department with all outstanding Encounter Data and Maternity Care Claims. The Department will withhold ten percent (10%) of one (1) month's Capitation payment until the Department determines that the CHC-MCO has complied with this requirement. The Department will not unreasonably delay or deny a determination of compliance. The Department will provide its determination to the CHC-MCO by the first (1^{st}) day of the fifth (5^{th}) month after the Agreement ends. If the Department determines that the CHC-MCO has not complied, the Department will provide subsequent

determinations by the first (1st) day of each subsequent month.

C. Transition at Expiration or Termination of Agreement

If the CHC-MCO and the Department have not entered into a new Agreement, the Department will develop a transition plan. During the transition period, the CHC-MCO must comply with the requirements of the plan and must cooperate with any subsequent CHC-MCO and the Department. The Department will consult with the CHC-MCO regarding the transition plan, including information requirements and the relationship between the CHC-MCOs. The length of the transition period shall be no less than three (3) months and no more than six (6) months in duration.

The CHC-MCO is responsible for the costs relating to the transfer of materials and responsibilities as a normal part of doing business with the Department.

SECTION XI: RECORDS

A. Financial Records Retention

1. The CHC-MCO must maintain and must cause its subcontractors to maintain all books, records, and other evidence pertaining to revenues, expenditures, and other financial activity pursuant to this Agreement in accordance with the standards and procedures specified in this Agreement, including Section V.X.3, Records Retention and Exhibit O, CHC Audit Clause.

2. The CHC-MCO will include the requirements set forth in Section XII, Subcontractual Relationships, in all Subcontracts it enters for the CHC Program, and will monitor subcontractors for compliance with these requirements.

B. Operational Data Reports

The CHC-MCO must maintain and must require its subcontractors to maintain all source records for data reports in accordance with the procedures specified in Section V.X.3., Records Retention.

C. Medical Records and Comprehensive Medical and Service Records Retention

The CHC-MCO must maintain and must cause its subcontractors to maintain all Comprehensive Medical and Service records in accordance with the procedures outlined in this Agreement, including Section V.X.3., Records Retention.

The CHC-MCO must provide Participants' Comprehensive Medical and Service Records to the Department or its representatives within twenty (20) business days

of the Department's request. The CHC-MCO will mail copies of such records to the Department if requested.

D. Review of Records

1. The CHC-MCO must make all records relating to the CHC Program, including, but not limited to, the records referenced in this Section, available for audit, review, or evaluation by the Department, the Pennsylvania Office of Attorney General Medicaid Fraud Control Section, federal agencies or their designees. Such records shall be made available on site, subject to the Department's approval, at any time or through the mail. The Department will, to the extent required by law, maintain as confidential any confidential information provided by the CHC-MCO.

2. In the event that the Department the Pennsylvania Office of Attorney General Medicaid Fraud Control Section, or federal agencies request access to records, subject to this Agreement, after the expiration or termination of this Agreement or at such time that the records no longer are required by the terms of this Agreement to be maintained at the CHC-MCO's location, but in any case, before the expiration of the period for which the CHC-MCO is required to retain such records, the CHC-MCO, at its own expense, must send copies of the requested records to the requesting entity within thirty (30) days of such request.

SECTION XII: SUBCONTRACTUAL RELATIONSHIPS

A. Compliance with Program Standards

With the exception of Provider Agreements, the CHC-MCO must comply with the procedures set forth in Section V.X.2. Contracts and Subcontracts and in Exhibit P, Required Contract Terms for Administrative Subcontractors.

Prior to the award of a contract or Subcontract, the CHC-MCO must disclose to the Department in writing information on ownership interests of five percent (5%) or more in the proposed Subcontractor.

The CHC-MCO’s contracts and Subcontracts for CHC must be in writing and must contain all items as required by this Agreement.

The CHC-MCO must require its subcontractors to provide written notification of a denial, partial approval, reduction, or termination of service or coverage, or a change in the level of care, according to the standards outlined in Exhibit F, Quality Management and Utilization Management Program Requirements, using the denial notice templates provided on the Pennsylvania HealthChoices Extranet. In addition, the CHC-MCO must include in its contracts or Subcontracts

that cover the provision of Covered Services to the CHC-MCO's Participants the following provisions:

1. A requirement for cooperation with the submission of all Encounter Data for all services provided within the timeframes required in Section VIII, Reporting Requirements, regardless of whether reimbursement for these services is made by the CHC-MCO either directly or indirectly through capitation.

2. Language which requires compliance with all applicable Federal and State laws, including applicable sub-regulatory guidance and contract provisions.

3. Language which prohibits gag clauses which would limit the subcontractor from disclosure of Medically Necessary or appropriate healthcare information or alternative therapies to Participants, other LTSS Providers, or to the Department.

4. Provides for access for Federal and State agencies and their designees to any and all documents and records of transactions, computer or other electronic systems pertaining to the provision of services to Participants or determinations of amounts payable under this Agreement.

5. The definition of Medically Necessary as outlined in Section II, Definitions.

6. The CHC-MCO must require, if applicable, that its Subcontractors adhere to the standards for Network composition and adequacy.

7. Should the CHC-MCO use a subcontracted utilization review entity, the CHC-MCO must require that its subcontractors process each request for benefits in accordance with Section V.B, General Prior Authorization Requirements.

8. Should the CHC-MCO subcontract with an entity to provide any information systems services, the Subcontract must include provisions for a transition plan in the event that the CHC-MCO terminates the Subcontract or enters into a Subcontract with a different entity. This transition plan must include information on how the data shall be converted and made available to the new subcontractor. The data must include all historical Claims and service data.

B. Consistency with Regulations

The CHC-MCO must require all Subcontracts to be consistent, as may be applicable, with DOH regulations governing HMO Contracting with Integrated Delivery Systems at 28 Pa. Code §§ 9.721 – 9.725 and PID regulations at 31 Pa. Code §§ 301.301 – 301.314.

SECTION XIII: CONFIDENTIALITY

A. The CHC-MCO must comply with all applicable Federal and State laws regarding the confidentiality of Participant records, including medical records. The CHC-MCO must also require each of its subcontractors to comply with all applicable Federal and State laws regarding the confidentiality of medical records.

B. The CHC-MCO will be liable for any State or Federal fines, sanctions, financial penalties, or damages levied upon the Department for a breach of confidentiality due to the negligent or intentional conduct of the CHC-MCO in relation to the CHC-MCO's systems, staff, or other area of responsibility.

C. The CHC-MCO will return all data and material obtained in connection with this Agreement and the implementation thereof, including confidential data and material, at the Department's request. The CHC-MCO is not permitted to use this material for any purpose after the expiration or termination of this Agreement.

D. The CHC-MCO is entitled to receive all information relating to the health status of its Participants in accordance with applicable confidentiality laws.

SECTION XIV: INDEMNIFICATION AND INSURANCE

A. Indemnification

1. In addition to Section 14 of Exhibit B, Standard Grant Terms and Conditions for Services, the CHC-MCO must indemnify and hold the Department and the Commonwealth of Pennsylvania, their respective employees, agents, designees and representatives harmless against any and all liabilities, losses, settlements, Claims, demands, and expenses of any kind (including, but not limited to, attorneys' fees) which may result or arise out of any dispute by and between the CHC-MCO and its subcontractors or Providers with Participants, agents, or clients in the performance or omission of any act or responsibility assumed by the CHC-MCO pursuant to this Agreement.

2. In addition to Section 14 of Exhibit B, Standard Grant Terms and Conditions for Services, the CHC-MCO must indemnify and hold harmless the Department and the Commonwealth of Pennsylvania from any audit disallowance imposed by the federal government resulting from the CHC-MCO's failure to follow Federal or State statutes, rules, regulations, or procedures unless prior approval was given by the Department. The Department shall provide timely notice of any disallowance to the CHC-MCO and allow the CHC-MCO an opportunity to participate in the disallowance appeal process and any subsequent judicial review to the extent permitted by law. Any payment required under this provision shall be due from the CHC-MCO upon notice from the Department. The indemnification provision hereunder shall not extend to disallowances which result from a determination by the federal government that the terms of this Agreement are not in

accordance with federal law. The obligations under this paragraph shall survive any termination or cancellation of this Agreement.

B. Insurance

The CHC-MCO must maintain for itself and each of its employees, agents, and representatives, general liability and all other types of insurance in such amounts as reasonably required by the Department and all applicable laws. In addition, the CHC-MCO must require that each of the Network Providers with which the CHC-MCO contracts maintains professional malpractice and all other types of insurance in such amounts as required by all applicable laws. The CHC-MCO must provide to the Department, upon the Department's request, certificates evidencing such insurance coverage.

SECTION XV: DISPUTES

In the event of a dispute between the parties to this Agreement, the Project Officer for the Department will make a determination in writing of his or her interpretation and will send the determination to the CHC-MCO. The determination is final and binding on the CHC-MCO and unreviewable unless the CHC-MCO files a written appeal with the Department's BHA. The CHC-MCO must file an appeal of an appealable agency action regarding this Agreement in accordance with 67 Pa.C.S. §§ 101-11006 and implementing regulations at 55 Pa. Code Chapter 41.

SECTION XVI: GENERAL

A. Suspension from Other Programs

If the CHC-MCO learns that a Network Provider is suspended or excluded from participation in any federally funded healthcare Program by another state or the or the federal government, the CHC-MCO must promptly notify the Department, in writing, of such suspension or exclusion.

The CHC-MCO may not employ, contract with, or make any payments to a Provider for services rendered during the period in which the Provider is suspended or excluded from participation in a federally funded healthcare program.

B. Rights of the Department and the CHC-MCO

The rights and remedies of the Department provided herein shall not be exclusive and are in addition to any rights and remedies provided by law.

Except as otherwise stated in Section XV, Disputes, the rights and remedies of the CHC-MCO provided herein shall not be exclusive and are in addition to any rights and remedies provided by law.

C. Invalid Provisions

Any provision of this Agreement which is in violation of any Federal or State law or regulation shall be deemed amended to conform with such law or regulation, pursuant to the terms of this Agreement, except that if such change would materially and substantially alter the obligations of the parties under this Agreement, any such provision shall be renegotiated by the parties. The invalidity or unenforceability of any terms or provisions hereof shall in no way affect the validity or enforceability of any other terms or provisions hereof.

D. Notice

Any written notice to any party under this Agreement shall be deemed sufficient if delivered personally, or by facsimile, telecopy, electronic or digital transmission (provided such delivery is confirmed), or by recognized overnight courier service (e.g., DHL, Federal Express, etc.), with confirmed receipt, or by certified or registered United States mail, postage prepaid, return receipt requested, sent to the address set forth below or to such other address as such party may designate by notice given pursuant to this section:

To the Department via U.S. Mail:
Department of Human Services
Deputy Secretary, Office of Long-Term Living
P.O. Box 8052
Harrisburg, Pennsylvania 17105

With a Copy to:

Department of Human Services
Office of Legal Counsel
3rd Floor West, Health and Welfare Building
625 Forster Street
Harrisburg, Pennsylvania 17120
Attention: Chief Counsel

To the CHC-MCO

E. Counterparts

This Agreement may be executed in counterparts, each of which shall be deemed an original for all purposes, and all of which, when taken together, shall constitute but one and the same instrument.

F. Headings

The section headings used herein are for reference and convenience only and shall not enter into the interpretation of this Agreement.

G. No Third Party Beneficiaries

This Agreement does not, nor is it intended to, create any rights, benefits, or interest to any third party, person, or organization.

APPENDIX 3a

Explanation of Capitation Payments

I. Base Waiver Capitation Rates

The schedule of Base Waiver Capitation Rates will be provided to the CHC-MCOs. The Department will provide the CHC-MCO with information on methodology and data used to develop the schedule of Base Waiver Capitation Rates.

II. Risk Adjusted Rates (RAR)

A. Applicability of RAR

The Department will risk adjust the Base Waiver Capitation Rates using an actuarially sound method to reflect differences in functional status and demographics of the Members enrolled in each CHC-MCO's program.

The Department may elect to terminate the risk adjustment of any or all Base Waiver Capitation Rates. If the Department makes this election, the Department will notify the CHC-MCO and will provide an effective date for this change. If the Department makes this election, the Department will enter into negotiations with the CHC-MCO on the subject of Base Waiver Capitation Rates that will apply on and after the effective date of the change.

B. RAR CHC-MCO Plan Factors

If Base Waiver Capitation Rates are risk adjusted, the Department and its actuarial consultant will develop each RAR CHC-MCO Plan Factor to reflect the functional status and demographics of Participants enrolled in the CHC-MCO's program within one Rate Cell and one Rating Region or combinations thereof.

The Department and its actuaries will recalculate the RAR CHC-MCO Plan Factors in accordance with a schedule determined by the Department.

C. MCO Assessment Amount

The Base Waiver Capitation Rates include an MCO Assessment Amount. The MCO Assessment Amount is the amount included in the Base Waiver Capitation Rates for the MCO Assessment fee inclusive of

a multiplier that accounts for the CHC-MCO's responsibility to pay the MCO Assessment fee for partial member months.

D. Risk-Adjusted Portion of the Base Waiver Capitation Rate

If the Base Waiver Capitation Rate is higher than the lowest Base Waiver Capitation Rate that the Department has calculated for a given Rate Cell and Rating Region for the applicable program month among all CHC-MCOs that operate in a zone, the difference is referred to as Amount A.

For each CHC-MCO, the following calculation will be made for each Rate Cell and Rating Region:

	Base Waiver Capitation Rate
MINUS	Acute Services Portion of Rate
MINUS	MCO Assessment Amount
MINUS	Amount A
TIMES	RAR CHC-MCO Plan Factor
EQUALS	Risk-Adjusted Portion of the Base Waiver Capitation Rate

E. Revised Base Waiver Capitation Rate

For each CHC-MCO, the following calculation will be made for each Rate Cell and Rating Region:

	Risk-Adjusted Portion of the Base Waiver Capitation Rate
PLUS	Acute Services Portion of Rate
PLUS	MCO Assessment Amount
PLUS	Amount A
EQUALS	Revised Base Waiver Capitation Rate

III. Capitation Payment Rate

The Capitation Payment Rate will include a Participant Enrollment Mix Adjustment, which is described in Appendix 3e. The Participant Enrollment Mix Adjustment calculation will utilize the Revised Base Waiver Capitation Rate.

In accordance with Section VII.B.2.ii of this Agreement, the Department will make capitation payments at per diem equivalents of the Capitation Payment Rates that are calculated and issued by the Department.

APPENDIX 3b

Medical Loss Ratio (MLR) Reporting and Remittance Requirements

This appendix establishes requirements for the CHC-MCO's responsibility to calculate and report their medical loss ratio (MLR) to the Department consistent with the 2016 Medicaid/CHIP Managed Care Final Rule requirements at 42 CFR §438.8. This appendix also establishes a requirement for remittance to the Department.

The reporting requirements apply collectively to all Agreements the CHC-MCO has with the Department to operate Community HealthChoices (CHC) programs during a CY. The CHC-MCO must provide one report inclusive of all zones, rating periods and Agreements within a CY. The CHC-MCO must not include revenue or costs that are not specific to the CHC program.

I. Timing

The CHC-MCO must submit the annual MLR report to the Department by November 30 of the following CY.

II. MLR Reporting Year

Consistent with 42 CFR §438.8, the MLR reporting year is a 12-month period that aligns with the Department's CHC rating period. The Department's current, standard rating period is a 12-month CY.

III. Contents of Annual MLR Report

The CHC-MCO is to submit their MLR report containing at least the information outlined herein for the current MLR reporting year, consistent with the requirements in 42 CFR §438.8(k) or subsequently modified by CMS. The Department reserves the right to request additional information and/or require the use of a MLR report template.

1. Total incurred claims (including fraud reduction efforts)
2. Expenditures on quality improving activities
3. Expenditures on fraud prevention activities (not applicable)
4. Non-claim costs
5. Premium revenue
6. Premium related taxes, licensing, and regulatory fees
7. Methodologies for allocation of expenditures
8. Any credibility adjustment applied
9. The calculated MLR (including numerator and denominator)
10. Any remittance potentially owed to the Department
11. A comparison of the MLR report information to the CHC-MCO's audited financial report(s)
12. The number of member months
13. A description of the aggregation method used to aggregate data for all Medicaid eligibility groups covered under this Agreement

IV. New Community HealthChoices CHC-MCOs

The Department, at its discretion, may exclude a CHC-MCO that did not previously have a CHC Agreement from these requirements for the first year of the CHC-MCO's operations. However, the new CHC-MCO will be required to comply with these requirements during the next MLR reporting year even if the first year of operations was not a full 12 months. For example, if a CHC-MCO is new on July 1, 2024, the Department may exclude the new CHC-MCO from completing and submitting the CY 2024 MLR report. The new CHC-MCO will be required to complete the subsequent CY 2025 MLR report. If a CHC-MCO exits CHC, a report will still be required, even if it is less than twelve months of experience.

V. MLR Numerator and Denominator

Detail of what is included and how the MLR numerator and denominator are computed can be found in 42 CFR §438.8(e) and (f) respectively. If an expenditure related to Social Determinants of Health is an "activity that improves health care quality" as specified in 42 CFR § 438.8(e)(3), the CHC-MCO may include the costs in the numerator of the MLR. The CHC-MCO is expected to comply with any additional requirements, guidance or instructions released by CMS that relate to the computation of the MLR as required in 42 CFR §438.8.

VI. Aggregate Medicaid Eligibility Groups

The Department requires the CHC-MCO's MLR report to be calculated as a single aggregated group across all populations. This aggregated group must represent all CHC Medicaid/Title XIX rate cells/populations and rating regions/zones combined that are covered under the CHC Agreements.

VII. Credibility Adjustment

Per 42 CFR §438.8(h), the CHC-MCO may add a credibility adjustment to the reported MLRs per Aggregate Medicaid Eligibility Group in section VI of this appendix if the CHC-MCO has sufficient member months to be partially credible, but not enough member months to be fully credible. The credibility adjustment is required for any remittance calculations. CMS will publish the table of credibility adjustments to be used. Fully credible plans may not use a credibility adjustment.

VIII. Remittance

Per 42 CFR §438.8(c) the Department has chosen a minimum MLR of 90.00 percent (90.00%). The Department will require a remittance in accordance with 42 CFR §438.8(j) for each Aggregate Medicaid Eligibility Group listed in section VI above. Settlement of any remittance obligation will be due 75 calendar days after the Department has issued a remittance notification to the CHC-MCO.

IX. Attestation

The CHC-MCO must provide an attestation of the accuracy of the information provided in their submitted MLR report as required in 42 CFR §438.8(n) and consistent with 42 CFR §438.606. The attestation is due on the report due date.

X. Sub-Regulatory Guidance and Capitation Adjustments

These requirements are subject to change as CMS releases sub-regulatory guidance. If there are retroactive capitation adjustments these MLR reports may need to be updated. For more information about MLR calculations, please see 42 CFR §438.8.

XI. Continuation

If CMS issues regulation that revises or replaces the citations in this appendix, the revised or replacement citations will apply.

APPENDIX 3c

Capitation Rates

This Appendix will be used for specifying the capitation rates that will be paid by the Department to the CHC-MCO.

APPENDIX 3d

Overview of Methodologies for Rate Setting

I. Rate Setting Methodology #1 – Use of Historical Fee-For-Service Data and Managed Care Encounter Data

To develop capitation rates on an actuarially sound basis for the Community HealthChoices (CHC) program using historical fee-for-service (FFS) data and managed care encounter data, the following general steps are performed:

- Summarize the FFS claims, managed care encounter and eligibility data
- Combine the Multiple Years of Data Together, If Applicable
- Project the Base Data Forward
- Include the Effect of Program/Policy Changes
- Adjust the FFS Data to Reflect Managed Care Principles
- Add an Appropriate Administration/Underwriting Gain Load
- Add an Amount for Taxes/Assessments

Summarize the FFS Claims, Managed Care Encounter and Eligibility Data — The Department provides summarized FFS claims, encounters and eligibility data for the recipients and services to be covered under the CHC program. Normally, multiple years of data are made available for rate-setting purposes; however, the actuary may choose one or more years of data to base rates upon. This data is then adjusted to account for items not included in the initial data collection process. These adjustments (positive and negative) generally include, but are not limited to: completion factors, legal settlements, gross adjustments, graduate medical education payments, pharmacy rebates, and other adjustments needed to improve the accuracy of the data.

Combine the Multiple Years of Each Data Source Together, If Applicable — To arrive at a single year of each data source to serve as the basis for rate setting, the multiple years of each data source can be combined together if more than one year of data was selected for the base. The blending of the base years of data may be on Participant months or other weighting factors selected by the actuary.

Project the Base Data Forward — The base data is then projected forward to the time period for which the capitation rates are to be paid. Trend factors are used to estimate the future costs of the services for the populations covered by the managed care program. These trend factors normally vary by service and/or population group.

Include the Effect of Program/Policy Changes — Changes from Commonwealth and/or federal policy may occur to the services or populations covered under the CHC program (e.g., expands dental care, restricts enrollment, or encourages innovations in service or workforce recruitment and retention). Material program changes are included in the capitation rates by either increasing or decreasing the base data by an appropriate adjustment.

Adjust the FFS Data to Reflect Managed Care Principles — Because Community HealthChoices is a managed care program and not FFS, the projected FFS data needs to be adjusted to reflect the typical changes that occur when changing from a FFS program to a managed care program. This generally involves increasing the cost/use of preventive services and decreasing hospital and emergency room cost/use. It may also include increasing the use of community services and transitioning individuals out of nursing facilities, as applicable.

Add an Appropriate Administration/Underwriting Gain Load — After the base data has been trended to the appropriate time period, adjusted for program/policy changes and adjusted to reflect managed care principles, an administration/underwriting gain load will be added to the service claims cost component to determine the overall capitation rates applicable to each population group. The administration/underwriting gain load may be applied as a percentage of the total capitation rate (i.e., percent of premium) and includes all reasonable and appropriate administrative expenses expected for a health plan operating the program in an efficient and effective manner. The underwriting gain component of the load includes consideration for the cost of capital and a risk margin.

Add an Amount for Taxes/Assessments — The final capitation rate, after all other components have been completed, is further adjusted to reflect legislatively mandated taxes/assessments as applicable. These taxes/fees can be applied as a percent of final premium or a PMPM adjustment added to the original final capitation rate. The Department will adjust the payment to the CHC-MCOs for the Medicaid portion of the MCO assessment cost based upon changes to the assessment fee in accordance with Act 92 of 2015 and any amendments thereto.

II. **Rate Setting Methodology #2 – Use of Managed Care Data**

To develop capitation rates on an actuarially sound basis for the CHC program using actual CHC program-specific managed care data, the following general steps are performed:

- Summarize, Analyze, and Adjust the Managed Care Data
- Project the Managed Care Base Data Forward
- Include the Effect of Program/Policy Changes
- Add an Appropriate Administration/Underwriting Gain Load
- Add an Amount for Taxes/Assessments
- Optional Rate Update

Summarize, Analyze, and Adjust the Managed Care Data — The Department collects data from each of the managed care organizations (MCOs) participating in the CHC program. This data is summarized, analyzed, and adjustments (positive and negative) are applied as needed to account for underlying differences between each MCO's management of the program. These adjustments can account for items such as collection of TPL/COB, over- or under- reserving of unpaid claims, management efficiency, and Provider contracting relations. After adjusting each MCO's data, each plan's specific service claim costs are aggregated together to arrive at a set of base data for each population group.

Project the Managed Care Base Data Forward — The aggregate base of managed care data is projected forward to the time period for which the capitation rates are to be paid. Trend factors are used to estimate the future costs of the services that the covered population would generate in the managed care program. These trend factors normally vary by service and/or population group.

Include the Effect of Program/Policy Changes — The Commonwealth occasionally changes, or Federal statutes or regulations will impact, the services or populations covered under the CHC (e.g., expands dental care, restricts enrollment). Any new, material program/policy changes that were not already reflected in the managed care data are included in the capitation rates by either increasing or decreasing the managed care data by an appropriate adjustment.

Add an Appropriate Administration/Underwriting Gain Load — After the base data has been trended to the appropriate time period, adjusted for program/policy changes, adjusted to reflect managed care principles, and blended into one data source, an administration/underwriting gain load will be added to the service claim cost component to determine the overall capitation rates applicable to each population group. The administration/underwriting gain load may be applied as a percentage of the total capitation rate (i.e., percent of premium) and includes all reasonable and appropriate administrative expenses expected for a health plan operating the program in an efficient and effective manner. The underwriting gain component of the load includes consideration for the cost of capital and a risk margin.

Add an Amount for Taxes/Assessments — The final capitation rate, after all other components have been completed, is further adjusted to reflect legislatively mandated taxes/assessments as applicable. These taxes/fees can be applied as a percent of final premium or a PMPM adjustment added to the original final capitation rate.

Optional Rate Update — In lieu of rebasing rates on newer experience base data, it is possible to update the prior year's rates for new, material program changes, trends and other adjustments following a similar process outlined above.

III. Rate Setting Methodology #3 – Blending of Prior Year's Rates and Managed Care Data

When updated FFS data is unavailable and actual CHC managed care experience first becomes available, capitation rates for the program can be developed on an actuarially sound basis using a blending of both data sources using the following two-track approach:

- Project the Prior Year's Rates Forward (Track 1)
- Summarize and Adjust the CHC Managed Care Data (Track 2)
- Include the Effect of New Program/Policy Changes (Track 1 and Track 2)
- Apply Credibility Factors to Each Track and Blend Together
- Add an Appropriate Administration/Underwriting Gain Load

- Add an Amount for Taxes/Assessments

Project the Prior Year's Rates Forward (Track 1) — The first step of Track 1 is to begin with the previous year's capitation rates. This data is projected forward to the time period for which the new capitation rates are to be paid. Trend factors are used to estimate the future costs of the services the covered population would generate under managed care. These trend factors normally vary by service and/or population group.

Include the Effect of New Program/Policy Changes (Track 1) — In Track 1, any new, material program/policy changes implemented by the Department or required by the federal government, which were not already accounted for in the previous year's rates, are included in the new capitation rates by either increasing or decreasing the rates by an appropriate adjustment.

Summarize and Adjust the CHC Managed Care Data (Track 2) — The more recent managed care data is collected from the MCOs, summarized, and analyzed to support rate setting. Adjustments (positive and negative) are applied to the managed care data as needed to account for underlying differences between each MCO's management of the CHC program. These adjustments can account for items such as collection of TPL/COB, over- or under-reserving of unpaid claims, management efficiency, and Provider contracting relations.

Include the Effect of Trend and New Program/Policy Changes (Track 2) — In Track 2, the managed care data is projected forward to the time period the capitation rates are to be paid. Trend factors may vary by service and/or population group, and are used to estimate the future costs of the services that the covered population would generate under managed care. Any new, material program/policy changes that were not already reflected in the managed care data are included in the rates by either increasing or decreasing the data by an appropriate adjustment.

Apply Credibility Factors to Each Track and Blend Together — After separately developing capitation rates using Track 1 and Track 2, the two sets of rates are combined together. This blending involves applying a credibility weight to each track and adding the two components together. The credibility weights may vary between the population groups.

Add an Appropriate Administration/Underwriting Gain Load — After the data has been trended to the appropriate time period, adjusted for program/policy changes, adjusted to reflect managed care principles, and blended into one data source, an administration/underwriting gain load will be added to the service claim cost component to determine the overall capitation rates applicable to each population group. The administration/underwriting gain load may be applied as a percentage of the total capitation rate (i.e., percent of premium) and includes all reasonable and appropriate administrative expenses expected for a health plan operating the program in an efficient and effective manner. The underwriting gain component of the load includes consideration for the cost of capital and a risk margin.

Add an Amount for Taxes/Assessments — The final capitation rate, after all other

components have been completed, is further adjusted to reflect legislatively mandated taxes/assessments as applicable. These taxes/fees can be applied as a percent of final premium or a PMPM adjustment added to the original final capitation rate. The Department will adjust the payment to the CHC-MCOs for the Medicaid portion of the MCO assessment cost based upon changes to the assessment fee in accordance with Act 92 of 2015 and any amendments thereto.

IV. Additional Information on Rate Development

The reimbursement provided under this Agreement is intended for Medically Necessary services covered under the Commonwealth's State Plan. For NFCE individuals, the reimbursement is also intended to cover HCBS services determined necessary based on the individual's assessed need. The MCO has the option to utilize this reimbursement to provide alternatives to the Medically Necessary services covered under the State Plan in order to meet the needs of the individual Participant in the most efficient manner. However, an adjustment may be required in the rate development process to incorporate only the cost of state plan and HCBS waiver services which would have been provided in the absence of alternative services. Cost effective in lieu of services may be addressed differently than other non-cost effective in lieu of services. The CHC-MCO may be required to provide documentation, supporting analyses and data related to the provision and justification of non-state plan services.

_

APPENDIX 3e

Participant Enrollment Mix Adjustment

The Department will apply a budget-neutral Participant Enrollment Mix Adjustment (PEMA) to adjust capitation payments based on the CHC-MCO's enrollment mix of nursing facility Participants and NFCE HCBS Participants.

I. Covered Participants

The PEMA applies collectively to all Participants for which the Department has made or will make a capitation payment under one of the eligible NFCE rate cells identified in Appendix 3c for the applicable rate period or rate year.

II. Timing of the PEMA Process

The PEMA will be applied once for each rate period and or rate year. Until the Department, in its sole discretion, either determines that the PEMA is no longer necessary or implements a substitute mechanism, the Department will apply the PEMA prospectively for each rate year.

III. Data and Computation

The PEMA is a budget neutral mix adjustment applied to the CHC-MCO payments for every CHC-MCO in a given zone.

The Department will adjust payment by a PEMA based on Participant location in November in the preceding calendar year. The Participant's status shall be the Participant's location in the given November.

APPENDIX 3f

Peer Group 13 Risk Pool

Overview

Starting 12 months after the Implementation Date, the Department will establish, administer and distribute funds from three quarterly Peer Group 13 Risk Pools per zone for costs associated with Peer Group 13 facilities.

The CHC-MCO will fund the quarterly risk pool based on Peer Group 13 Risk Pool Allocation Amounts developed annually by the Department's actuary. To determine the CHC-MCO-specific quarterly distributions based on the Peer Group 13 facility service costs, the Department will utilize encounter data, unless it notifies the CHC-MCO that it will utilize files submitted by the CHC-MCO with information on Participants and associated costs for Peer Group 13 facility services during the twelve-month period defined below. For each CHC zone, the Department will sum the amount spent by each CHC-MCO on Peer Group 13 facilities for the Defined Twelve-Month Period in order to determine what portion of the risk pool each CHC-MCO will receive. The Department will distribute the funds in the Peer Group 13 Risk Pool in proportion to each CHC-MCO's adjusted Peer Group 13 expenditures on all Covered Participants for the Defined Twelve-Month Period. The Department's payment to each CHC-MCO will be net of the CHC-MCO's Peer Group 13 Risk Pool Allocation Amount obligation for the quarter. If the CHC-MCO's Peer Group 13 Risk Pool Allocation Amount obligation exceeds its share of the Peer Group 13 Risk Pool, the Department will reduce a subsequent payment to the CHC-MCO by the amount of the difference.

Medicaid Eligible Group (MEG)

The Department will administer one budget-neutral risk pool per quarter per zone for each of the following groups, starting twelve months after CHC implementation in a zone:

- Nursing Facility Clinically Eligible (NFCE) Dual Eligibles (Duals)
- NFCE Non-Dual Eligibles
- Nursing Facility Ineligible (NFI) Dual Eligibles (Duals)

CHC-MCO Inclusion/exclusion in the Peer Group 13 Risk Pool

The Peer Group 13 Risk Pool threshold for Peer Group 13 facility claims is $0.00 for each of the above noted MEGs.

A CHC-MCO will participate in the quarterly Peer Group 13 Risk Pool if both of the following criteria are met:

- The Department has made or will make capitation payments to the CHC-MCO in the zone for all three months during the quarter; and
- The Department has made or will make capitation payments to the CHC-MCO for the zone for all three months of each of the four previous quarters.

If the CHC-MCO does not meet the criteria for inclusion in the quarterly Peer Group 13 Risk Pool, then:

- The CHC-MCO has no Peer Group 13 Risk Pool Allocation Amount obligation for that quarter; and
    - The CHC-MCO has no opportunity to receive a distribution from that quarterly Peer Group 13 Risk Pool; and
    - The CHC-MCO will not be required to contribute to that quarterly Peer Group 13 Risk Pool through a reduction to a subsequent payment.

The Department will determine each quarter which of the CHC-MCOs meet the criteria for inclusion in that quarter's Peer Group 13 Risk Pool.

DHS Calculation of Quarterly Funds in the Peer Group 13 Risk Pool

After each quarter has ended, the Department will determine the sum of the CHC-MCO's Peer Group 13 Risk Pool Allocation Amount obligation for the quarter, by multiplying the Peer Group 13 Risk Pool Allocation Amount by the number of member months included in the CHC-MCO during the quarter. The Department will use Participant data compiled as of one date for the purpose of determining each CHC-MCO's Peer Group 13 Risk Pool Allocation Amount obligation for the quarter. The Department will provide documentation to the CHC-MCO and will consider any issues the CHC-MCO brings to the Department's attention.

The sum of the Peer Group 13 Risk Pool Allocation Amount obligation for every CHC-MCO in the zone will be the total amount allocated to the Peer Group 13 Risk Pool for that quarter.

Covered Services

The CHC-MCO may include all claims paid by the CHC-MCO for Peer Group 13 facility services received by an enrolled Participant during the Defined Twelve-Month Period on files submitted to the Department unless the service is eligible in another risk sharing program. The Department may reprice each Peer Group 13 facility claim to the amount the Department would have paid for the same claim. The Department may elect to use CHC-MCO encounter data in lieu of Peer Group 13 Risk Pool-specific files submitted by the CHC-MCO, in whole or in part. The Department will apply the same criteria if it elects to use CHC-MCO encounter data in lieu of Peer Group 13 Risk Pool-specific files submitted by the CHC-MCOs.

For members for which a Peer Group 13 Risk Pool Allocation Amount was collected, this Arrangement covers services provided by Peer Group 13 facilities.

Defined Twelve-Month Period

The Defined Twelve-Month Period is the twelve months that ended the day before the quarter for which the Peer Group 13 Risk Pool is allocated to the quarterly risk pool.

Example: The Defined Twelve-Month Period for the Southwest zone for the January – March 2020 Peer Group 13 Risk Pool quarter is January 2019 – December 2019.

The Defined Twelve-Month Period encompasses dates of service, not the dates claims are paid.

The Defined Twelve-Month Period may include months that are covered by a different CHC-MCO agreement that applies to the same zone.

Data Source

The Department will use the Commonwealth's MMIS approved encounter data, unless the Department notifies the CHC-MCO that it will use different data. The Department will provide the run dates for extraction of encounter data to the CHC-MCO.

If the Department decides not to use encounter data, upon notification from the Department, the CHC-MCO will submit files in a format specified by the Department for the administration of the risk pool in lieu of encounter data.

For purposes of risk pool allocation, the Department will utilize information on Participants whose costs exceed the Peer Group 13 Risk Pool threshold during the Defined Twelve-Month Period, after repricing and other adjustments.

Calculation of Quarterly Distributions

The Department will utilize the Commonwealth's MMIS approved encounter data to administer the steps outlined in this Appendix and to determine the adjusted amount each CHC-MCO paid in excess of the Peer Group 13 threshold for each Participant for Covered Services provided during the Defined Twelve-Month Period. The CHC-MCO-specific sum will be the numerator in the calculation for the risk pool distribution. The denominator will be the applicable sum for all CHC-MCOs in the CHC zone. The resulting percentage figure will be multiplied by the amount in the risk pool. The CHC-MCO's uncollected Peer Group 13 Risk Pool Allocation Amount obligation for the quarter will be subtracted from this amount. If the result is a positive number, the Department will pay the amount to the CHC-MCO. If the result is a negative number, the Department will reduce a subsequent payment to the CHC-MCO by this amount.

Early Payment of a CHC-MCO's Peer Group 13 Risk Pool Allocation Amount Obligation

If the Department notifies the CHC-MCO of termination of this Agreement; or if the CHC-MCO notifies the Department of termination of this CHC Agreement; or if this Agreement expires within four months; or if an CHC-MCO fails to submit a required report or file to support the administration of a risk pool or risk-sharing arrangement within fifteen work days of the final due date:

- The Department may elect to reduce a subsequent monthly capitation payment by the total amount of the outstanding Peer Group 13 Risk Pool Allocation Amount obligation for current and previous program months; and
- The Department may reduce each subsequent monthly capitation payment by the CHC-MCO's Peer Group 13 Risk Pool Allocation Amount obligation for the same month.

APPENDIX 3g

COVID-19 VACCINE NON-RISK ARRANGEMENT

This appendix establishes a non-risk arrangement for the coverage and administration of COVID-19 vaccines, in accordance with 42 CFR 447.362. COVID-19 vaccines are the financial responsibility of the CHC-MCO during the January 1, 2024 to December 31, 2024 Calendar Year (CY 2024, hereinafter known as the Arrangement Year).

For the Arrangement Year, the following terms shall apply:

I. Covered Population

Any Participant that is eligible to receive a COVID-19 vaccine and is enrolled with the CHC-MCO during the Arrangement Year is potentially eligible for this Arrangement. To be included in this Arrangement, a Participant must have received a covered COVID-19 vaccine during the Arrangement Year.

II. Covered Services

Covered Services for this Arrangement will include any COVID-19 vaccine, as well as the associated cost to administer the vaccine, that ultimately becomes the financial responsibility of the CHC-MCO during the Arrangement Year. Only vaccines to specifically address COVID-19 will be included. To be eligible for this Arrangement, COVID-19 vaccines must be included on the MA Fee-for-Service Fee Schedule (hereinafter, Fee Schedule). The Fee Schedule is subject to change. Any changes to the Fee Schedule will be applicable to the terms of this Arrangement as of the effective date of those changes. The Non-Risk Arrangement only applies to Covered Services with dates of service during the Arrangement Year.

III. Quarterly Payment Process

There will be quarterly payments. Each payment will include covered services paid by the CHC-MCO for dates of service beginning with the start date of the Non-Risk Arrangement and limited to not more than eighteen (18) months prior to the end of the payment quarter. The payment for each covered service will be the lesser of the amount paid by the CHC-MCO or the MA Allowed Amount. Each payment will exclude any claim that was included in a prior quarter's payment. The Department will provide the CHC-MCO with the payment amount, and documentation not later than the last workday of the fourth month after the end of the quarter. The Department will utilize the Department's MMIS approved encounter data for the purpose of calculating payments for this Non-Risk Arrangement at least seventy-five (75) days after the last day in the quarter.

If the CHC-MCO does not operate a Community HealthChoices program in a zone under this Agreement throughout the complete quarter, then the payment quarter consists of the portion of the quarter in which the CHC-MCO operates the program under this Agreement.

IV. CMS Requirements

This Arrangement shall comply with all applicable CMS requirements and regulations pertaining to non-risk arrangements, and is subject to the CMS regulations for payments under non-risk managed care contracts at 42 CFR 447.362. Payments to the CHC-MCO are contingent upon CMS approval and participation of federal matching funds. The CHC-MCO agrees to provide DHS any supporting information or data that may be required to respond to CMS questions about this Arrangement. The CHC-MCO agrees to perform under the terms of this Appendix beginning on the effective date of this Appendix pending CMS approval. In the event that CMS rejects this Appendix, the parties shall work in good faith to propose an alternate arrangement to CMS within twenty (20) business days of notification of rejection by CMS. In the event that the parties fail to negotiate an acceptable proposed alternative within the twenty-day period specified herein, or in the event that CMS does not accept the alternative jointly submitted by the Parties pursuant to this paragraph, all obligations under this Appendix are immediately terminated without further recourse from either party. No payment obligation under this Arrangement shall arise prior to CMS approval of this Appendix.

Appendix 4

Community HealthChoices Revenue Sharing

This Appendix establishes a requirement for remittance to the Department of any Realized Revenue, as defined in this Appendix, earned by a CHC-MCO in excess of 3 percent.

The reporting requirements apply collectively to all Community HealthChoices (CHC) zone(s) in which the CHC-MCO operates under this Agreement or a previous Agreement with the Department during the applicable time period. This requirement is specific to the CHC program only and does not include revenue from any other MA managed care program in which the CHC -MCO may operate.

I. Time Period

The time period for purposes of reporting CHC program revenue aligns with the Department's CHC program year and the CHC program rating period. The applicable Time Period included in this Appendix will be CHC program year CY2024.

II. Extent of Calculation

Revenue sharing calculations will be based on CHC revenue and corresponding costs for all Rate Cells for each rating region and zone as identified in Appendix 3c. The CHC-MCO may not include revenue or costs that are not specific to the CHC program.

III. Calculation Process

The revenue sharing calculation will utilize information reported in each applicable annual Medical Loss Ratio Report (Annual Financial Report) for the Time Period. The Department will utilize the Department reviewed and approved Annual Financial Report for each applicable program year within the Time Period and will combine the reported amounts in each referenced section on the Annual Financial Report for each Aggregated Medicaid Eligibility Group for the applicable Time Period.

The following items reference Sections within the Annual Financial Report:

a. **Capitation Revenue** will be based on "Total Premium Revenue" as reported in Section 4 as follows:

   i. Capitation revenue will not include CHC-MCO quality incentive payments, such as any received CHC-MCO Nursing Facility Quality Incentive Program funds, as detailed in Exhibit DD(2), or any future Pay-for-Performance initiatives.
   ii. The MCO Assessment will be deducted from Capitation Revenue.
   iii. Applicable Federal and Pennsylvania State taxes will be deducted from Capitation Revenue.

iv. If the CHC-MCO paid a MLR Remittance amount to the Department as calculated on the Annual Financial Report, the MLR Remittance amount paid by the CHC-MCO will be deducted from the Capitation Revenue.

b. **Medical Expenses** will include paid claims and alternative method payments made by the CHC-MCO for allowable covered services rendered to Participants during the Time Period. Medical Expenses will be based on "Total Incurred Claims" as reported in Section 1. The Department may review a portion of or all of the reported Medical Expenses and may exclude Medical Expenses that do not constitute payment for State Plan services and/or allowed in lieu of services, including but not limited to:

    i. Any allowance for Unpaid Claim Liability (UCL). The Department has full discretion to modify UCL allowances that, in the professional judgment of the Department's Actuary, overstate projected liabilities; and
    ii. Payments to Related Parties.

c. **Activities that improve health care quality** are reported in Section 2 and will be considered in the revenue sharing calculation in a manner consistent with the Medical Loss Ratio calculation in Appendix 3b, as long as they meet one or more of the following criteria:

    i. CHC-MCO activity that meets requirements of 45 CFR § 158.150(b) and is not excluded under 45 CFR § 158.150(c).
    ii. CHC-MCO activity related to any External Quality Review related activity as described in 45 CFR § 438.358(b) and (c).
    iii. CHC-MCO expenditure that is related to Health Information Technology and meaningful use, under 45 CFR § 158.151.

d. **Administrative Expenses** will include those administrative expenses as reported in Section 6 and determined by the Department to be an allowable program expense.
    i. The Department will review all payments to parent companies and reserves the right to limit consideration for these payments in the profit calculation.
    ii. The Department reserves the right to limit total Administrative Expenses to an amount based on assumptions used in the capitation rate development process for this Agreement Period**.**

e. **Taxes and assessments** imposed on the CHC-MCO pursuant to law are to be included in Section 5.

f. **Prohibited Expenses** – the following expenses will not be included as expenses under this Appendix:
    i. Outreach activities as described in Section V.O.3 of this Agreement
    ii. Payments described in Section VII.E.14: Prohibited Payments of this Agreement

iii. Claims payments covered under a non-risk arrangement(s) included in this CHC Agreement
iv. Premium Deficiency Reserves
v. Cost of advertisements in mass media
vi. Start-up, development or RFA expenses incurred before the Start Date on which the CHC-MCO is responsible for the provision of services to Participants
vii. Any expense related to exiting or terminating operations in a given zone/region under this Agreement
viii. Donations
ix. Excessive allocation of corporate overhead, as determined by the Department (see also item IV.d.i).

g. **Percent Limit** will be the maximum retained percentage of certain CHC revenue, which is 3 percent.

h. **Maximum Retained Revenue**, or the amount of revenue that may be retained by the CHC-MCO, will be calculated by multiplying Capitation Revenue by the Percent Limit.

i. **Realized Revenue -** the Department will calculate the Realized Revenue for the Time Period as follows:

	Capitation Revenue
LESS:	Medical Expenses
LESS:	Expenses for Activities that improve health care quality
LESS:	Administrative Expenses
EQUALS:	Realized Revenue

j. **Revenue Recovery Amount -** If the Realized Revenue is greater than the Maximum Retained Revenue, the Revenue Recovery Amount will be the difference between the Realized Revenue and Maximum Retained Revenue. If this amount is greater than zero (0), then the Revenue Recovery Amount is an obligation due from the CHC-MCO to the Department. The Department will recover this obligation due from the CHC-MCO by offsetting a future payment due to the CHC-MCO under this Agreement. The Department will notify the CHC -MCO of the future payment that will be offset in advance of that scheduled payment.

k. **Retention of Excess Revenue –** The CHC-MCO may retain fifty percent (50%) of the Realized Revenue in excess of the Maximum Retained Revenue with express written approval from the Department if the CHC-MCO agrees to expend the remaining fifty percent (50%) of funds in excess of the Maximum Retained Revenue on initiatives that align with the Department's goals of improving access and provider retention; investments in social determinants of health such as housing, employment and food

insecurity; achieving health equity; and programs that focus on community development.

i. A CHC-MCO shall submit to the Department a written expenditure proposal for any funds in excess of the Maximum Retained Revenue.

ii. This proposal shall be submitted within thirty (30) days of receiving the preliminary calculation per Section V, below.

iii. After the Department accepts the CHC-MCO's proposal, the Department will decrease the Revenue Recovery Amount to zero (0).

IV. Risk of Insolvency

If the CHC-MCO decides not to invest excess revenue as described in Section III.k of this Appendix, and the Department determines that payment of a Revenue Recovery Amount by the CHC-MCO would result in the CHC-MCO being put at significant risk of insolvency, the Department may at the Department's discretion, waive all or a portion of the Revenue Recovery Amount owed by the CHC-MCO.

V. Communication and Timing of Revenue Sharing Administration

The Department will notify each CHC-MCO of the preliminary revenue sharing calculation and associated Revenue Recovery Amount within ninety (90) days following the date the Department completes the review and approves the Annual Financial Report for CY2024. The CHC-MCO will have thirty (30) days from the notification date to provide additional documentation or supplemental information to the Department regarding the calculation, including the reported amounts in the Annual Financial Report. The Department will have up to sixty (60) days to review the additional documentation and supplemental information submitted by the CHC-MCO and to finalize the Revenue Recovery Amount calculation. If the Revenue Recovery Amount is greater than zero (0), the Department will recover this amount per Section IV of this Appendix.

VI. Final Revenue Sharing Notification and Remittance

The Department will provide the CHC-MCO with written notification of the final Revenue Recovery Amount and the date when the amount due to the Department will be recovered, if applicable.

VII. Documentation of CHC-MCO Expenses

At the request of the Department, the CHC-MCO shall make available all books, accounts, documents, files and information that relate to the CHC-MCO's transactions within ten (10) business days after the request was made. The CHC-MCO shall cooperate with the Department and any representatives of the Department.

VIII. Continuation

If CMS issues regulation(s) that revises or replaces the requirements in this appendix, the revised or replacement requirements will apply. The Department at its discretion may choose to waive any or all requirements of this Appendix. If the requirements of this Appendix are waived in full or in part, the Department will notify the CHC-MCO in writing of the waived Sections.

Appendix 5

In Lieu of Services (ILOS)

ILOS Definition. ILOS is a cost-effective, medically necessary service or setting that is offered to a Participant as a substitute for a State Plan service or setting in accordance with 42 CFR § 438.3(e)(2) and all future regulations and sub-regulatory federal guidance. All ILOS must be allowable under Medicaid State Plan or Section 1915(c) waiver rules and approved by the Department in advance.

Compliance With Federal Requirements. ILOSs must not violate any applicable federal requirements, including 42 CFR § 438.3(e)(2), general prohibitions on payment for room and board costs under Title XIX of the Social Security Act, the Americans with Disabilities Act, Section 504 of the Rehabilitation Act, and the Emergency Medical Treatment and Labor Act.

Department Approved ILOS. The services or settings listed below are determined by the Department to be a medically appropriate and cost-effective substitute for the named covered services or settings under the State Plan for the following clinically defined target populations. The CHC-MCO may provide ILOS only from this approved list to Participants during the contract year.

Pursuant to 42 CFR 438.3, CHC-MCOs may not provide ILOS without first applying to the Department and obtaining approval to offer the ILOS by demonstrating all requirements will be met. If the CHC-MCO identifies a potential ILOS that they would like to offer during a future contract period, the CHC-MCO must follow the process described in the ILOS development guidelines and request form documents as detailed in the In Lieu of Services Operations Memorandum.

ILOS Name	ILOS Definition	Substituted State Plan Service or Setting	Procedure Code(s) (e.g., HCPCS or CPT) That Identify ILOS	Clinically Defined Target Population(s)
Assisted Living	A group living situation, licensed under 55 PA Code Chapter 2800, for NFCE members that provides food, shelter, assistance with personal care and activities of daily living, health assessment and monitoring, and assistance or supervision of supplemental health care services.	Nursing Facility Services	T2030 and T2031	NFCE individuals in a nursing facility who are interested in transition to a less restrictive setting or individuals at risk of nursing facility placement who are interested in diversion from placement in a Nursing Facility.

ILOS Name	ILOS Definition	Substituted State Plan Service or Setting	Procedure Code(s) (e.g., HCPCS or CPT) That Identify ILOS	Clinically Defined Target Population(s)

Encounter Data. The CHC-MCO must utilize identified codes to submit encounter data on ILOS.

Clinical Determination of Appropriateness. For each approved ILOS, the Department determined a clinically defined target population as individuals who are medically appropriate for the ILOS and for whom the use of the ILOS is likely to result in lower costs than utilization of the substituted State Plan service and setting.

For a Participant to receive an ILOS, a determination of medical appropriateness must be made by the CHC-MCO using their professional judgement and assessing the Participant's presenting medical condition, preferred course of treatment, and current or past medical treatment. Prior to offering the ILOS, the CHC-MCO must develop a policy and procedure for determining whether an ILOS is medically necessary and the individual meets the targeted population to receive an ILOS and submit to the Department for review and approval.

The CHC-MCO shall document the determination of medical appropriateness within the Participant's records, which could include the Participant's PCSP, medical record (paper or electronic), or another record that details the Participant's level of care. The documentation must include how each ILOS is expected to address the Participant's needs. The Department must approve the CHC-MCO's documentation process before the CHC-MCO elects to provide the ILOS.

CHC-MCO Responsibilities:

1. **ILOS Option for the CHC-MCO.** The CHC-MCO is not required to offer an ILOS to Participants.
2. **Public Disclosure of ILOS Provided.** The CHC-MCO shall include in its Participant handbook the protections available to participants who receive ILOS, including a description of the process to determine eligibility for specific ILOS, the voluntary nature of ILOS, and the right to file a Complaint, Grievance or Fair Hearing with regards to the denial or receipt of an ILOS.
3. **Calculation of Cost of ILOS.** CHC-MCO shall supply any information needed by the Department to assist in calculating cost projections for approved or potential ILOS, including but not limited to, specific claims, cost information, encounter data, and other Participant data that will assist the Department in meeting and current or future CMS documentation requirements. The CHC-MCO will also comply with any standards detailed in the Community HealthChoices Financial Reporting Requirements documenting ILOS expenditures.

4. **Provision of ILOS Encounter Data to the Department.** Encounter data must be submitted to the Department by the CHC-MCO in accordance with Section VIII.A.1 for ILOS and, when available, include data necessary for the State to stratify ILOS utilization by sex (including sexual orientation and gender identity), race, ethnicity, disability status, and language spoken to inform health equity initiatives and efforts to mitigate health disparities.

   To the extent that existing health care codes do not accurately identify ILOS, the Department will provide specific codes and modifiers that the CHC-MCO shall use to ensure consistent use.

5. **Operations and Quality Reporting Requirements.** The CHC-MCO is required to comply with Operations and Quality Management Reporting requirements as specified in Section VIII:D.1 to enable the Department to monitor the CHC-MCO's in-lieu of program.

Participant Rights

1. **ILOS Option for Participants.** The CHC-MCO shall not require Participants to use an ILOS as a substitute for a State Plan Service.

2. **Participant Rights and Protections.** When receiving an ILOS, Participants retain all of the rights afforded to them in 42 CFR Part 438, including, for example, the right to make informed decisions about their health care and to receive information on available treatment options and alternatives per 42 CFR § 438.100(b)(2). In accordance with 42 CFR § 438.3(e)(2)(ii), the CHC-MCO shall not require Participants to utilize ILOS or from mandating replacement of a State Plan Service for an ILOS. ILOS may not be used to reduce, discourage, or jeopardize Participants'' access to covered State Plan Services or Settings. If a Participant chooses not to receive an ILOS, they always retain their right to receive the covered State Plan Service or Setting on the same terms as would apply if an ILOS were not an option. The CHC-MCO is not permitted to deny a Participant a medically appropriate State Plan Service or Setting on the basis that a Participant has been offered an ILOS, is currently receiving an ILOS, or has received an ILOS in the past.

   In accordance with 42 CFR § 438.10(g)(2)(ix), all of the CHC-MCO's Participant handbooks must contain information on Participant rights and responsibilities, including the Complaint, Grievance, and fair hearings requirements outlined in Exhibit G. Regardless of a Participant's 's utilization of an ILOS, the Participant retains all rights and privileges under Exhibit G. The Department will review and approve the ILOS language included in the Participant handbooks annually.

Oversight

Performance Monitoring The Department will include any ILOSs the CHC-MCO elects to provide in the overall quality monitoring structure detailed in Exhibit F- Quality Management and Utilization Management Program Requirements, to ensure that all ILOS received by Participants are medically appropriate, cost effective, and used at the option of the Participant and CHC-MCO.

Utilization and Cost The utilization and actual cost of ILOSs shall be taken into account in developing the component of the capitation rates that represents the covered State Plan services, unless a federal statute or regulation explicitly requires otherwise.

Network Adequacy The CHC-MCO must develop and maintain a network of ILOS providers that have the capacity and capability to deliver medically appropriate and cost effective ILOSs selected by the Participant.

Discontinuation of ILOS by the CHC-MCO The CHC-MCO may discontinue offering an approved ILOS with notice to the Department at least 60 calendar days prior to the discontinuation date. The CHC-MCO must ensure that any ILOS that were authorized for a Participant prior to the discontinuation of that specific ILOS are not disrupted by a change in ILOS offerings, either by completing the authorized service or by seamlessly transitioning the Participant into other medically necessary services or programs that meet the Participant's needs. The CHC-MCO's transition plan must be provided to the Department as part of the ILOS discontinuation process. The transition plan must identify the total number of Participants utilizing the ILOS through the discontinuation date and the alternative services that will be offered (either State Plan services or other approved ILOS). The CHC-MCO must not offer the ILOS after the date of discontinuation.

At least 45 calendar days before discontinuing an ILOS, the CHC-MCO must notify Participants affected by the discontinuation of the ILOS of the following:

- The discontinuance of the ILOS and the last date the Participant can receive the ILOS, and
- How the CHC-MCO will ensure that the Participant will receive the ILOS as authorized or the plan to transition the Participant to other comparable medically necessary services.

Discontinuation of ILOS by the Department In the event the Department or CMS determines an ILOS not to be medically appropriate or cost effective, the CHC-MCO will assist the Department in preparing a transition plan to phase out the applicable ILOS while ensuring access for affected Participants to contractually required services with minimal disruption of care. The transition plan will include a process to notify Participants of the termination of the ILOS that they are currently receiving as expeditiously as required by the Participants' health condition. If the Department discontinues an ILOS, the Department will amend the Agreement to remove the applicable ILOS.

EXHIBIT A

COVERED SERVICES LIST

In the event that a conflict arises between this Agreement and the content of the CHC Waivers approved by CMS, the CHC waivers shall take precedence.

CHC Covered Physical Health Services	
Category	**Category**
Inpatient Hospital Services	**Clinic Services**
Inpatient Acute Hospital	Independent Clinic
Inpatient Rehab Hospital	Maternity – Physician, Certified Nurse Midwives, Birth Centers
Outpatient Hospital Clinic	Renal Dialysis Services
Outpatient Hospital Clinic	Ambulatory Surgical Center (ASC) Services
Outpatient Hospital Short Procedure Unit	**Dental Services**
Federally Qualified Health Center / Rural Health Clinic	**Physical Therapy, Occupational Therapy, and Services for Individuals with Speech, Hearing, and Language Disorders**
Other Laboratory and X-ray Service	**Prescribed Drugs, Dentures, and Prosthetic Devices; and eyeglasses prescribed by a physician skilled in diseases of the eye or by an optometrist**
Laboratory	Prescribed Drugs
Radiology (For example: X- rays, MRIs, CTs)	Dentures
Nursing Facility Services	Prosthetic Devices
	Eyeglasses
Family Planning Clinic Services, and Supplies	**Diagnostic, Screening, Preventive, and Rehabilitative Services**
Physician Services	Tobacco Cessation
Primary Care Provider	Therapy (Physical, Occupational, Speech) - Rehabilitative
Physician Services and Medical and Surgical Services provided by a Dentist	**Certified Registered Nurse Practitioner Services**

Medical care and any other type of remedial care	Any other medical care and any other type of remedial care recognized under state law, specified by the Secretary
Podiatrist Services	Ambulance Transportation
Optometrist Services	Non-Emergency Medical Transport
Chiropractor Services	Emergency Room
Home Health Services	Hospice Care
Home Healthcare Including Nursing, Aide and Therapy	Limited Abortions*
Medical Supplies	
Durable Medical Equipment Including home accessibility durable medical equipment	
Therapy (Physical, Occupational, Speech)	Definitions for Physical Health Services may be found in the Pennsylvania Medicaid State Plan at: http://www.dhs.state.pa.us/publications/medicaidstateplan/
Personal Protective Equipment (PPE)	

CHC LTSS Benefits
Nursing Facility Services
Nursing Facility Services are professionally supervised nursing care and related medical and other health services furnished by a healthcare facility licensed by the Pennsylvania Department of Health as a long-term care nursing facility under Chapter 8 of the Healthcare Facilities Act (35 P.S. §§ 448.801-448.821) and certified as a nursing facility provider in the MA Program (other than a facility owned or operated by the Federal or State government or agency thereof). Nursing facility services include services that are skilled nursing and rehabilitation services under the Medicare Program and health-related care and services that may not be as inherently complex as skilled nursing or rehabilitation services but which are needed and provided on a regular basis in the context of a planned program or healthcare and management. A Participant must be NFCE to receive nursing facility services under the CHC Program. Nursing Facility Services includes at least the items and services specified in 42 CFR 483.10(f)(11)(i). Nursing facility services are covered as defined in 55 Pa. Code § 1187.51.
Exceptional DME for CHC Participants Residing in a Nursing Facility.
Home and Community-Based Services

Adult Daily Living	
Assistive Technology	Occupational Therapy
Behavior Therapy	Participant-Directed Community Supports
Benefits Counseling	Participant-Directed Goods and Services
Career Assessment	Personal Assistance Services
Cognitive Rehabilitation	
Community Integration	Personal Emergency Response System
Community Transition Services	Pest Eradication
Counseling	Physical Therapy
Employment Skills Development	Residential Habilitation
	Respite
Financial Management Services	Specialized Medical Equipment and Supplies
Home Adaptations	Speech and Language Therapy
Home Delivered Meals	Structured Day Habilitation
Home Health Aide	Telecare
Job Coaching	Vehicle Modifications
Job Finding	
Nursing	
Non-Medical Transportation	
Nutritional Consultation	

*Some services are included on the CHC Covered Physical Health Services list and the CHC LTSS Benefits list. The CHC LTSS Benefits are available only after the Participant's State Plan, Medicare or private insurance limitations have been reached, or the service is not covered under the State Plan, Medicare or private insurance.

Definitions for the LTSS listed above can be found in the 1915(c) Home and Community Based Services Waiver, and may be amended from time to time, found at: https://www.dhs.pa.gov/HealthChoices/HC-Services/Pages/CHC-Supporting-Documents.aspx

***An Abortion is a Covered Service only when a physician has found, and certified in writing to the Medicaid agency that, on the basis of that physician's professional judgment, the life of the mother would be endangered if the fetus were carried to term (which is in accordance with 42 CFR 441.202).**

EXHIBIT B

STANDARD TERMS AND CONDITIONS

1. TERM

The term of this Agreement shall commence on the effective date and shall end on the expiration date identified in the Agreement, subject to the other provisions of the Agreement. The Agreement shall not be a legally binding Agreement until fully executed by the CHC-MCO and by the Commonwealth and all approvals required by Commonwealth and federal procurement procedures have been obtained. No agency employee has the authority to verbally direct the commencement of any work under this Agreement. The Commonwealth may, upon notice to the CHC-MCO, extend the term of the Agreement for up to three (3) months upon the same terms and conditions, which will be utilized to prevent a lapse in Agreement coverage and only for the time necessary, up to three (3) months, to enter into a new Agreement.

2. PARTY RELATIONSHIP

In performing the services required by the Agreement, the CHC-MCO will act as an independent contractor and not as an employee or agent of the Commonwealth.

3. Reserved.

4. ENVIRONMENTAL PROVISIONS

In the performance of the Agreement, the CHC-MCO shall minimize pollution and shall strictly comply with all applicable environmental statutes and regulations.

5. Reserved.

6. COMPENSATION/EXPENSES

The CHC-MCO shall be required to perform the specified services at the prices provided for in the Agreement. All services shall be performed within the time periods specified in the Agreement. The CHC-MCO shall be compensated only for work performed to the satisfaction of the Commonwealth. The CHC-MCO shall not be paid travel or per diem expenses.

7. Reserved.

8. OFFSET

The Commonwealth may set off the amount of any state tax liability or other obligation of the CHC-MCO, or its subsidiaries, owed to the Commonwealth against any payments due the CHC-MCO under any Agreement between the Commonwealth and CHC-MCO.

9. TAXES

The Commonwealth is exempt from all excise taxes imposed by the Internal Revenue Service and has accordingly registered with the Internal Revenue Service to make tax-free

purchases under Registration No. 23740001-K. With the exception of purchases of the following items, no exemption certificates are required and none will be issued: undyed diesel fuel, tires, trucks, gas guzzler emergency vehicles, and sports fishing equipment. The Commonwealth is also exempt from Pennsylvania state sales tax, local sales tax, public transportation assistance taxes and fees and vehicle rental tax. The Department of Revenue regulations provide that exemption certificates are not required for sales made to governmental entities and none will be issued. Nothing in this paragraph is meant to exempt a construction Contractor from the payment of any of these taxes or fees which are required to be paid with respect to the purchase, use, rental, or lease of tangible personal property or taxable services used or transferred in connection with the performance of a construction Contract.

10. WARRANTY

The CHC-MCO warrants that all services performed by the CHC-MCO, its employees, representatives, agents and subcontractors shall be performed in a professional and workmanlike manner and in accordance with prevailing professional and industry standards. Unless otherwise stated in this Agreement, all services are warranted for a period of one (1) year following completion of performance by the CHC-MCO and acceptance by the Commonwealth. The CHC-MCO shall correct any problem with the service without any additional cost to the Commonwealth.

11. PATENT, COPYRIGHT, AND TRADEMARK INDEMNITY

The CHC-MCO warrants that it is the sole owner or author of, or has entered into a suitable legal agreement concerning either: a) the design of any product or process provided or used in the performance of the Agreement which is covered by a patent, copyright, or trademark registration or other right duly authorized by Federal or State law, or b) any copyrighted matter in any report document or other material provided to the Commonwealth. The CHC-MCO shall defend any suit or proceeding brought against the Commonwealth on account of any alleged patent, copyright or trademark infringement in the United States of any of the products provided or used in the performance of the Agreement. This is upon condition that the Commonwealth shall provide prompt notification in writing of such suit or proceeding; full right, authorization and opportunity to conduct the defense thereof; and full information and all reasonable cooperation for the defense of same. As principles of governmental or public law are involved, the Commonwealth may participate in or choose to conduct, in its sole discretion, the defense of any such action. If information and assistance are furnished by the Commonwealth at the CHC-MCO's written request, it shall be at the CHC-MCO's expense, but the responsibility for such expense shall be only that within the CHC-MCO's written authorization. The CHC-MCO shall indemnify and hold the Commonwealth harmless from all damages, costs, and expenses, including attorney's fees that the CHC-MCO or the Commonwealth may pay or incur by reason of any infringement or violation of the rights occurring to any holder of copyright, trademark, or patent interests and rights in any products provided or used in the performance of the Agreement. If any of the products provided by the CHC-MCO in such suit or proceeding are held to constitute infringement and the use is enjoined, the CHC-MCO shall, at its own expense and at its option, either procure the right to continue use of such infringement products, replace them with non-infringement equal performance products or modify them so that they are no longer infringing. If the CHC-MCO is unable to do any of the preceding, it will remove all the equipment or software which are obtained contemporaneously with the infringing product, or, at the option of the Commonwealth, only those items of

equipment or software which are held to be infringing, and to pay the Commonwealth: 1) any amounts paid by the Commonwealth towards the purchase of the product, less straight line depreciation; 2) any license fee paid by the Commonwealth for the use of any software, less an amount for the period of usage; and 3) the pro rata portion of any maintenance fee representing the time remaining in any period of maintenance paid for. The obligations of the CHC-MCO under this paragraph continue without time limit. No costs or expenses shall be incurred for the account of the CHC-MCO without its written consent.

12. OWNERSHIP RIGHTS

The Commonwealth shall have unrestricted authority to reproduce, distribute, and use any submitted report, data, or material, and any software or modifications and any associated documentation that is designed or developed and delivered to the Commonwealth as part of the performance of the Agreement.

13. ASSIGNMENT OF ANTITRUST CLAIMS

The CHC-MCO and the Commonwealth recognize that in actual economic practice, overcharges by the CHC-MCO's suppliers resulting from violations of Federal or State antitrust laws are in fact borne by the Commonwealth. As part of the consideration for the award of the Agreement, the CHC-MCO assigns to the Commonwealth all right, title and interest in and to any claims the CHC-MCO now has, or may acquire, under Federal or State antitrust laws relating to the products and services which are the subject of this Agreement.

14. INDEMNIFICATION

The CHC-MCO shall indemnify and defend the Commonwealth against all third-party claims, suits, demands, losses, damages, costs, and expenses, including without limitation, litigation expenses, attorneys' fees, and liabilities, arising out of or in connection with any activities performed by the CHC-MCO or its employees and agents pursuant to this Agreement, as determined by the Commonwealth in its sole discretion.

15. AUDIT PROVISIONS

In addition to its other audit requirements, the Commonwealth shall have the right, at reasonable times and at a site designated by the Commonwealth, to audit, review, or inspect the books, documents and records of the CHC-MCO to the extent that the books, documents and records relate to costs or pricing data for the Agreement. The CHC-MCO will maintain records which will support the prices charged and costs incurred for the Agreement. The CHC-MCO shall preserve books, documents, and records that relate to costs or pricing data for the Agreement for a period of five (5) years from date of final payment. The CHC-MCO shall give full and free access to all records to the Commonwealth and its authorized employees, agents, representatives, or designees.

16. DEFAULT

a. The Commonwealth may, subject to the provisions of Paragraph 17, Force Majeure, and in addition to its other rights under the Agreement, declare the CHC-MCO in default by written notice to the CHC-MCO, and terminate as provided in Paragraph 18, Termination Provisions, the whole or any part of this Agreement for any of the following reasons:

1) Failure to begin services within the time specified in the Agreement

or as otherwise specified;

2) Failure to perform the services with sufficient labor, equipment, or material to ensure the completion of the specified work in accordance with the Agreement terms;
3) Unsatisfactory performance of services;
4) Discontinuance of services without approval;
5) Failure to resume services, which has been discontinued, within a reasonable time after notice to do so;
6) Insolvency or bankruptcy;
7) Assignment made for the benefit of creditors;
8) Failure or refusal within ten (10) days after written notice, to make payment or show cause why payment should not be made, of any amounts due for materials furnished, labor supplied or performed, for equipment rentals, or for utility services rendered;
9) Failure to protect, to repair, or to make good any damage or injury to property;
10) Theft, fraud, waste, or abuse involving the Commonwealth or the federal government;
11) An adverse material change in circumstances as describe in Section IX of the Agreement;
12) Notification by PID or DOH that the CHC-MCO's authority to operate has been suspended, limited or revoked or has expired and will not be renewed;
13) Failure to obtain NCQA certification; or
14) Breach of any provision of the Agreement.

b. In the event that the Commonwealth terminates this Agreement in whole or in part, the Commonwealth may procure, upon such terms and in such manner as it determines, services similar or identical to those so terminated, and the CHC-MCO shall be liable to the Commonwealth for any reasonable excess costs for such similar or identical services included within the terminated part of the Agreement.

c. If the Agreement is terminated, the Commonwealth, in addition to any other rights provided in this paragraph, may require the CHC-MCO to transfer title and deliver immediately to the Commonwealth in the manner and to the extent directed by the Department, such partially completed work, including, where applicable, reports, working papers and other documentation, as the CHC-MCO has specifically produced or specifically acquired for the performance of such part of the Agreement as has been terminated. Except as provided below, payment for completed work accepted by the Commonwealth shall be at the Agreement price. Except as provided below, payment for partially completed work including, where applicable, reports and working papers, delivered to and accepted by the Commonwealth shall be in an amount agreed upon by the CHC-MCO and the Department. The Commonwealth may withhold from amounts otherwise due the CHC-MCO for such completed or partially completed works such sum as the Department determines to be necessary to protect the Commonwealth against loss.

d. The rights and remedies of the Commonwealth provided in this paragraph are not exclusive and are in addition to any other rights and remedies provided by

law or under the Agreement.

17. FORCE MAJEURE

Neither party will incur any liability to the other if its performance of any obligation under this Agreement is prevented or delayed by causes beyond its control and without the fault or negligence of either party. Causes beyond a party's control may include, but are not limited to, acts of God or war, changes in controlling statutes, regulations, orders, or the requirements of any governmental entity, severe weather conditions, civil disorders, natural disasters, fire, epidemics and quarantines, general strikes throughout the trade, and freight embargoes.

The CHC-MCO shall notify the Commonwealth orally within five (5) days and in writing within ten (10) days of the date on which the CHC-MCO becomes aware, or should have reasonably become aware, that such cause would prevent or delay its performance. Such notification shall (i) describe fully such cause(s) and its effect on performance, (ii) state whether performance under the Agreement is prevented or delayed, and (iii) if performance is delayed, state a reasonable estimate of the duration of the delay. The CHC-MCO shall have the burden of proving that such cause(s) delayed or prevented its performance despite its diligent efforts to perform and shall produce such supporting documentation as the Commonwealth may reasonably request. After receipt of such notification, the Commonwealth may elect either to cancel the Agreement or to extend the time for performance as reasonably necessary to compensate for the delay.

In the event of a declared emergency by competent governmental authorities, the Commonwealth by notice to the CHC-MCO, may suspend all or a portion of the Agreement.

18. TERMINATION PROVISIONS

a. The Commonwealth has the right to terminate the Agreement for any of the following reasons. Termination shall be effective upon written notice to the CHC-MCO and in accordance with the Agreement terms.

1) **TERMINATION FOR CONVENIENCE:** Upon one hundred twenty (120) days written notice, the Commonwealth may terminate the Agreement for its convenience if the Commonwealth determines termination to be in its best interest. The effective date of the termination will be the last day of the month in which the one hundred-twentieth (120^{th}) day fall. The CHC-MCO shall be paid for services satisfactorily completed prior to the effective date of the termination, but in no event shall the CHC-MCO be entitled to recover loss of profits.

2) **NON-APPROPRIATION:** The Commonwealth's obligation to make payments during any Commonwealth fiscal year succeeding the current fiscal year shall be subject to availability and appropriation of funds. When funds (state and/or federal) are not appropriated or otherwise made available to support continuation of performance in a subsequent fiscal year period, the Commonwealth shall have the right to terminate the Agreement. The CHC MCO shall be reimbursed for the reasonable value of any nonrecurring costs incurred but not amortized in the price of the supplies or services delivered under this Agreement. Such reimbursement shall not include loss of profit, loss of use of money, or administrative or overhead

costs. The reimbursement amount may be paid for any appropriations available for that purpose.

3) **TERMINATION FOR CAUSE:** The Commonwealth may terminate the Agreement for default under Paragraph 16, Default, or other cause as specified in the Agreement or by law, by providing written notice of default to the CHC-MCO. Except as provided in Section X.A.2 of the Agreement, the Commonwealth will provide forty-five (45) days written notice setting forth the grounds for termination and provide the CHC-MCO with forty-five (45) days or such longer time as approved by the Commonwealth in which to implement a corrective action plan and cure the deficiency. If corrective action is not implemented to the satisfaction of the Commonwealth within the approved cure period, the termination shall be effective at the expiration of the approved cure period. If it is later determined that the Commonwealth erred in terminating the Agreement for cause, then, at the Commonwealth's discretion, the Agreement shall be deemed to have been terminated for convenience under the Subparagraph 18.a.

19. Reserved.

20. ASSIGNABILITY AND SUBGRANTING

a. Subject to the terms and conditions of this Paragraph 20, this Agreement shall be binding upon the parties and their respective successors and assigns.

b. The CHC-MCO shall not subcontract with any person or entity to perform all or any part of the services to be performed without the prior written consent of the Department, which consent may be withheld at the sole and absolute discretion of the Department.

c. The CHC-MCO may not assign, in whole or in part, the Agreement or its rights, duties, obligations, or responsibilities hereunder without the prior written consent of the Department, which consent may be withheld at the sole and absolute discretion of the Department.

d. The CHC-MCO may, without the consent of the Department, assign its rights to payment to be received under the Agreement, provided that the CHC-MCO provides written notice of such assignment to the Department together with a written acknowledgement from the assignee that any such payments are subject to all of the terms and conditions of the Agreement.

e. For the purposes of this Agreement, the term "assign" shall include, but shall not be limited to, the sale, gift, assignment, pledge, or other transfer of any ownership interest in the CHC-MCO, provided, however, that the term shall not apply to the sale or other transfer of stock of a publicly traded company.

f. Any assignment consented to by the Department shall be evidenced by a written assignment Agreement executed by the CHC-MCO and its assignee in which the assignee agrees to be legally bound by all of the terms and conditions of the Agreement and to assume all duties, obligations, and responsibilities being assigned.

g. A change of name, following which the CHC-MCO's federal identification number remains unchanged, shall not be considered to be an assignment. The CHC-MCO shall give the Department written notice of any such change of name.

21. NONDISCRIMINATION/SEXUAL HARASSMENT

a. **Representations.** The CHC-MCO represents that it is presently in compliance with and will remain in compliance with all applicable federal, state, and local laws, regulations, and policies relating to nondiscrimination and sexual harassment for the term of the agreement. The CHC-MCO shall, upon request and within the time periods requested by the Commonwealth, furnish all necessary employment documents and records, including EEO-1 reports, and permit access to its books, records, and accounts by the Commonwealth for the purpose of ascertaining compliance with provisions of this Nondiscrimination/Sexual Harassment Clause.

b. **Nondiscrimination/Sexual Harassment Obligations.** The CHC-MCO shall not:

i. in any manner discriminate in the hiring of any employee(s) for the performance of the activities required under this agreement or any subgrant agreement, contract, or subcontract, by reason of race, gender, creed, color, sexual orientation, gender identity or expression, or in violation of the Pennsylvania Human Relations Act ("PHRA") and applicable federal laws, against any citizen of this Commonwealth who is qualified and available to perform the work to which the employment relates.

ii. in any manner discriminate by reason of race, gender, creed, color, sexual orientation, gender identity or expression, or in violation of the PHRA and applicable federal laws, against or intimidate any of its employees.

iii. in any manner discriminate by reason of race, gender, creed, color, sexual orientation, gender identity or expression, or in violation of the PHRA and applicable federal laws, in the provision of services under this agreement or any subgrant agreement, contract, or subcontract.

iv. in any manner discriminate by reason of race, gender, creed, color, sexual orientation, gender identity or expression, or in violation of PHRA and applicable federal laws, against any subgrantee, contractor, subcontractor, or supplier who is qualified to perform the work to which this agreement relates.

v. in any manner discriminate against employees by reason of participation in or decision to refrain from participating in labor activities protected under the Public Employee Relations Act, Pennsylvania Labor Relations Act, or National Labor Relations Act, as applicable, and to the extent determined by entities charged with the Acts' enforcement and shall comply with any provision of law establishing organizations as employees' exclusive representatives.

c. **Establishment of CHC-MCO Policy.** The CHC-MCO shall establish and

maintain a written nondiscrimination and sexual harassment policy that complies with the applicable law and these Nondiscrimination/Sexual Harassment provisions and shall inform its employees in writing of the policy. The policy must contain a provision that states that sexual harassment will not be tolerated and employees who practice it will be disciplined. For the entire period of this agreement, the CHC-MCO shall: (1) post its written nondiscrimination and sexual harassment policy or these Nondiscrimination/Sexual Harassment provisions conspicuously in easily accessible and well-lighted places customarily frequented by employees at or near where the grant activities are performed; or (2) provide electronic notice of the policy or this clause to its employees not less than annually.

d. **Notification of Violations.** The CHC-MCO's obligations pursuant to these provisions are ongoing from the effective date and through the termination date of the agreement. Accordingly, the CHC-MCO shall notify the Commonwealth if, at any time during the term of this agreement, it becomes aware of any actions or occurrences that would result in violation of these provisions.

e. **Cancellation or Termination of Agreement.** The Commonwealth may cancel or terminate this agreement and all money due or to become due under this agreement may be forfeited for a violation of the terms and conditions of these Nondiscrimination/Sexual Harassment provisions. In addition, the Department may proceed with debarment or suspension and may place the CHC-MCO in the Contractor Responsibility File.

f. **Subgrant Agreements, Contracts, and Subcontracts**. The CHC-MCO shall include these Nondiscrimination/Sexual Harassment provisions in its subgrant agreements, contracts, and subcontracts with all subgrantees, contractors, and subcontractors providing goods or services under this agreement. The incorporation of these provisions in the Department's subgrants, contracts, or subcontracts does not create privity of contract between the Commonwealth and any subgrantee, contractor, or subcontractor, and no third-party beneficiaries are created by those provisions. If the CHC-MCO becomes aware of a subgrantee's, contractor's, or subcontractor's violation of these provisions, the CHC-MCO shall use its best efforts to ensure the subgrantee's, contractor's, or subcontractor's compliance with these provisions.

22. CHC-MCO INTEGRITY

a. **Definitions.** For purposes of these CHC-MCO Integrity Provisions, the following definitions apply:

i. "Affiliate" means two or more entities where (a) a parent entity owns more than 50% of the voting stock of each of the entities; (b) a common shareholder or group of shareholders owns more than 50% of the voting stock of each of the entities; or (c) the entities have a common proprietor or general partner.

ii. "CHC-MCO" means the individual or entity, that has entered into this agreement with the Commonwealth.

iii. "CHC-MCO Related Parties" means any Affiliates of the CHC-MCO and the CHC-MCO's executive officers, Pennsylvania officers and directors, or owners of five percent or more interest in the CHC-MCO.

iv. "Financial Interest" means ownership of more than a five percent interest in any business or holding a position as an officer, director, trustee, partner, employee, or holding any position of management.

v. "Gratuity" means tendering, giving, or providing anything of more than nominal monetary value including, but not limited to, cash, travel, entertainment, gifts, meals, lodging, loans, subscriptions, advances, deposits of money, services, employment, or contracts of any kind. The exceptions set forth in the Governor's Code of Conduct, Executive Order 1980-18, as may be amended, 4 Pa. Code §7.153(b), apply.

vi. "Non-Solicitation Award Process" means a method of awarding grants based on predetermined criteria, without the solicitation of grant applications.

b. **Representations and Warranties.**

i. **CHC-MCO Representation and Warranties.** The CHC-MCO represents, to the best of its knowledge and belief, and warrants that within the last five years neither the CHC-MCO nor CHC-MCO Related Parties have:

1. been indicted or convicted of a crime involving moral turpitude or business honesty or integrity in any jurisdiction;
2. been suspended, debarred, or otherwise disqualified from entering into any contract with any governmental agency;
3. had any business license or professional license suspended or revoked;
4. had any sanction or finding of fact imposed as a result of a judicial or administrative proceeding related to fraud, extortion, bribery, bid rigging, embezzlement, misrepresentation or anti-trust; and
5. been, and are not currently, the subject of a criminal investigation by any federal, state, or local prosecuting or investigative agency or civil anti-trust investigation by any federal, state, or local prosecuting or investigative agency.

ii. **Contractor Explanation**. If the CHC-MCO cannot make the representations and warranties set forth above at the time of its submission of its grant application or if the agreement is awarded pursuant to a Non-Solicitation Award Process at the time of the execution of the agreement, the CHC-MCO shall submit a written

explanation outlining the reasons why it cannot make those representations and warranties. The Commonwealth may, based on its evaluation of the explanation provided, determine whether it is in the Commonwealth's best interest to execute the agreement.

iii. **Further Representations**. By submitting any bills, invoices, or requests for payment pursuant to the agreement, the CHC-MCO further represents that it has not violated any of these CHC-MCO Integrity Provisions during the term of the agreement.

iv. **Notice.** The CHC-MCO shall immediately notify the Commonwealth, in writing, if at any time during the term of the agreement it becomes aware of any event that would cause the Contractor's certification or explanation to change. The CHC-MCO acknowledges that the Commonwealth may, in its sole discretion, terminate the agreement for cause if it learns that any of the certifications made in these CHC-MCO Integrity Provisions are currently false or misleading due to intervening factual circumstances or were false or misleading or should have been known to be false or misleading when entering into the agreement.

c. **CHC-MCO Responsibilities.** During the term of this agreement, the CHC-MCO shall:

i. maintain the highest standards of honesty and integrity.

ii. take no action in violation of any applicable laws, regulations, or other requirements applicable to the CHC-MCO that govern Commonwealth contracting or grant administration.

iii. establish and implement a written business integrity policy that includes, at a minimum, the requirements of these CHC-MCO Integrity Provisions as they relate to the CHC-MCO's activity with the Commonwealth and Commonwealth employees and ensure that its employees comply with the policy.

iv. not accept, agree to give, offer, confer, agree to confer, or promise to confer, directly or indirectly, any gratuity or pecuniary benefit to any person, or to influence or attempt to influence any person in violation of any federal or state law, regulation, executive order, statement of policy, management directive, or bulletin applicable to the award of grants or the administration of this agreement.

v. not have a financial interest in any other subgrantee, contractor, subcontractor, or supplier providing services, labor, or material under this agreement, unless the financial interest is disclosed to the Commonwealth in writing and the Commonwealth consents to CHC-MCO's financial interest. The CHC-MCO must disclose the financial interest to the Commonwealth at the time of submission of its grant application, or if a Non-Solicitation Award Process is used, no later

than the date the CHC-MCO signs the agreement. The Commonwealth shall be deemed to have consented if the required disclosure is received and all of the required Commonwealth signatures are affixed.

vi. comply with the requirements of the Lobbying Disclosure Act (65 Pa.C.S. § 13A01 et seq.) regardless of the method of award.

vii. comply with the requirements of Section 1641 of the Pennsylvania Election Code (25 P.S. § 3260a) if this agreement was awarded pursuant to a Non-Solicitation Award Process.

viii. immediately notify the Commonwealth or the Office of the State Inspector General, in writing, when the CHC-MCO has reason to believe that any breach of ethical standards as set forth in law, the Governor's Code of Conduct, or these CHC-MCO Integrity Provisions has occurred or may occur, including, but not limited to, contact by a Commonwealth officer or employee, which, if acted upon, would violate the ethical standards.

d. **Investigations.** If a State Inspector General investigation is initiated, the CHC-MCO shall:

i. reimburse the Commonwealth for the reasonable costs of investigation incurred by the Office of the State Inspector General for investigations of the CHC-MCO's compliance with the terms of this or any other agreement between the CHC-MCO and the Commonwealth that results in the suspension or debarment of the CHC-MCO. The CHC-MCO shall not be responsible for investigative costs for investigations that do not result in the CHC-MCO's suspension or debarment.

ii. cooperate with the Office of the State Inspector General in its investigation of any alleged Commonwealth agency or employee breach of ethical standards and any alleged CHC-MCO non-compliance with these CHC-MCO Integrity Provisions and make identified CHC-MCO employees and volunteers available for interviews at reasonable times and places.

iii. upon the inquiry or request of an Inspector General, provide, or if appropriate, make promptly available for inspection or copying, any information of any type or form deemed relevant by the Office of the State Inspector General to CHC-MCO's integrity and compliance with these provisions. This information may include, but is not be limited to, the CHC-MCO's business or financial records, documents or files of any type or form that refer to or concern this agreement.

e. **Termination.** For violation of any of these CHC-MCO Integrity Provisions, the Commonwealth may terminate this agreement and any other contract with the CHC-MCO, claim liquidated damages in an amount equal to the value of anything received in breach of these CHC-MCO Integrity provisions, claim

damages for all additional costs and expenses incurred in obtaining another grantee to complete performance under this agreement, and debar and suspend the CHC-MCO from doing business with the Commonwealth. These rights and remedies are cumulative, and the use or non-use of any one does not preclude the use of all or any other. These rights and remedies are in addition to those the Commonwealth may have under law, statute, regulation, or otherwise.

f. **Subcontracts.** The CHC-MCO shall include these CHC-MCO Integrity Provisions in its subgrant agreements, contracts, and subcontracts with all subgrantees, contractors, and subcontractors providing goods or services under this agreement. The incorporation of this provision in the CHC-MCO's subgrant agreements, contracts, and subcontracts shall not create privity of contract between the Commonwealth and any subgrantee, contractor, or subcontractor, and no third-party beneficiaries are created by the inclusion of these provisions. If the CHC-MCO becomes aware of a subgrantee's, contractor's, or subcontractor's violation of these provision, the CHC-MCO shall use its best efforts to ensure their compliance with these provisions.

23. CONTRACTOR RESPONSIBILITY PROVISIONS

a. **Definition**. For the purpose of these provisions, the term "Contractor" means as any person, including, but not limited to, a bidder, offeror, loan recipient, grantee or lessor, who has furnished or performed or seeks to furnish or perform, goods, supplies, services, leased space, construction or other activity, under a contract, grant, lease, purchase order or reimbursement agreement with the Commonwealth. The term also includes a permittee, licensee, or any agency, political subdivision, instrumentality, public authority, or other public entity in the Commonwealth.

b. **Contractor Representations.**

i. The Contractor represents for itself and its subgrantees, contractors, and subcontractors required to be disclosed or approved by the Commonwealth, that as of the date of its execution of this agreement, that neither the Contractor, nor any of its subgrantees, contractors, and subcontractors, are under suspension or debarment by the Commonwealth or any governmental entity, instrumentality, or authority and, if the Contractor cannot make this representation, the Contractor shall submit, along with the agreement, a written explanation of why the certification cannot be made.

ii. The Contractor represents that, as of the date of its execution of this agreement, it has no tax liabilities or other Commonwealth obligations, or has filed a timely administrative or judicial appeal, if any liabilities or obligations exist, or is subject to a duly approved deferred payment plan if any liabilities exist.

c. **Notification.** The Contractor shall notify the Commonwealth if, at any time during the term of the agreement, it becomes delinquent in the payment of taxes, or other Commonwealth obligations, or if it or, to the best of its knowledge, any of its

subgrantees, contractors, or subcontractors are suspended or debarred by the Commonwealth, the federal government, or any other state or governmental entity. The Contractor shall provide this notification within 15 days of the date of suspension or debarment.

d. **Default.** The Contractor's failure to notify the Commonwealth of its suspension or debarment by the Commonwealth, any other state, or the federal government constitutes an event of default of the agreement with the Commonwealth.

e. **Reimbursement.** The Contractor shall reimburse the Commonwealth for the reasonable costs of investigation incurred by the Office of State Inspector General for investigations of the Contractor's compliance with the terms of this agreement or any other agreement between the Contractor and the Commonwealth that results in the suspension or debarment of the Contractor. These costs include, but are not limited to, salaries of investigators, including overtime; travel and lodging expenses; and expert witness and documentary fees. The Contractor shall not be responsible for investigative costs for investigations that do not result in the Contractor's suspension or debarment.

f. **Suspension and Debarment List.** The Contractor may obtain a current list of suspended and debarred Commonwealth contractors by visiting the eMarketplace website at http://www.emarketplace.state.pa.us and clicking the Debarment list tab.

24. AMERICANS WITH DISABILITIES ACT

a. **No Exclusion.** Pursuant to the Americans with Disabilities Act, 42 U.S. Code § 12101, et seq., no qualified individual with a disability may, on the basis of the disability, be excluded from participation in this contract or from activities provided for under this agreement.

b. **Compliance.** For all goods and services provided pursuant to this agreement, the CHC-MCO shall comply with Title II of the Americans with Disabilities Act, the "General Prohibitions Against Discrimination" set forth in 28 C. F. R. § 35.130, and all other regulations promulgated under Title II of the Americans with Disabilities Act that apply to state and local governments.

c. **Indemnification.** The CHC-MCO shall indemnify the Commonwealth against all third-party claims, suits, demands, losses, damages, costs, and expenses, including without limitation, litigation expenses, attorneys' fees, and liabilities, arising out of or in connection with the CHC-MCO's failure or its employee's or agent's failure to comply with the provisions of paragraph a, as determined by the Commonwealth in its sole discretion.

25. Reserved.

26. COVENANT AGAINST CONTINGENT FEES

The CHC-MCO warrants that no person or selling agency has been employed or retained to solicit or secure this Agreement upon an agreement or understanding for a commission, percentage, brokerage, or contingent fee, except bona fide employees or bona fide established commercial or selling agencies maintained by the CHC-MCO for the purpose

of securing business. For breach or violation of this warranty, the Commonwealth may terminate this Agreement without liability or in its discretion to deduct from the Agreement price or consideration, or otherwise recover the full amount of such commission, percentage, brokerage, or contingent fee.

27. APPLICABLE LAW AND FORUM

This Agreement is governed by and must be interpreted and enforced in accordance with the laws of the Commonwealth of Pennsylvania (without regard to any conflict of laws provisions) and the decisions of the Pennsylvania courts. The Contractor consents to the jurisdiction of any court of the Commonwealth of Pennsylvania and any federal courts in Pennsylvania and waives any claim or defense that such forum is not convenient or proper. Any Pennsylvania court or tribunal has in personam jurisdiction over the Contractor, and the Contractor consents to service of process in any manner authorized by Pennsylvania law. This provision may not be interpreted as a waiver or limitation of the Commonwealth's rights or defenses.

28. INTEGRATION

The Agreement, including all referenced documents, constitutes the entire agreement between the parties. No agent, representative, employee or officer of either the Commonwealth or the CHC-MCO has authority to make, or has made, any statement, agreement or representation, oral or written, in connection with this Agreement, which in any way can be deemed to modify, add to or detract from, or otherwise change or alter its terms and conditions. No negotiations between the parties, nor any custom or usage, shall be permitted to modify or contradict any of the terms and conditions of the Agreement. No modifications, alterations, changes, or waiver to this Agreement or any of its terms shall be valid or binding unless accomplished by a written amendment signed by both parties.

29. CHANGE ORDERS

The Commonwealth may issue change orders at any time during the term of the Agreement or any renewals or extensions thereof: 1) to increase or decrease the quantities resulting from variations between any estimated quantities in the Agreement and actual quantities; 2) to make changes to the services within the scope of the Agreement; 3) to notify the CHC-MCO that the Commonwealth is exercising any renewal or extension option; or 4) to modify the time of performance that does not alter the scope of the Agreement to extend the completion date beyond the Expiration Date of the Agreement or any renewals or extensions thereof. Any such change order shall be in writing signed by the Project Officer. The change order shall be effective as of the date appearing on the change order, unless the change order specifies a later effective date. Such increases, decreases, changes, or modifications will not invalidate the Agreement, nor, if performance security is being furnished in conjunction with the Agreement, release the security obligation. The CHC-MCO will provide the service in accordance with the change order.

30. RIGHT TO KNOW LAW

a. **Applicability**. The Pennsylvania Right-to-Know Law, 65 P.S. §§ 67.101-3104, ("RTKL") applies to this Agreement.

b. **CHC-MCO Assistance.** If the Commonwealth needs the CHC-MCO's

assistance in any matter arising out of the RTKL related to this Agreement, the Commonwealth shall notify the CHC-MCO that it requires the CHC-MCO's assistance, and the CHC-MCO shall provide to the Commonwealth:

i. access to, and copies of, any document or information in the CHC-MCO's possession (Requested Information) arising out of this Agreement that the Commonwealth reasonably believes is a public record under the RTKL, within ten calendar days after receipt of written notification; and

ii. any other assistance as the Commonwealth may reasonably request, in order to comply with the RTKL with respect to this Agreement.

c. **Trade Secret or Confidential Proprietary Information.** If the CHC-MCO considers the Requested Information to include a Trade Secret or Confidential Proprietary Information, as those terms are defined by the RTKL, or other information that the Contractor considers exempt from production under the RTKL, the CHC-MCO shall notify the Commonwealth and provide, within seven calendar days of receipt of the written notice a written statement, signed by a representative of the CHC-MCO, that explains why the requested material is exempt from public disclosure under the RTKL. If the Commonwealth determines that the Requested Information is clearly not exempt from disclosure, the CHC-MCO shall provide the Requested Information to the Commonwealth within five business days of receipt of written notice of the Commonwealth's determination.

d. **Reimbursement**

i. **Commonwealth Reimbursement.** If the CHC-MCO fails to provide the Requested Information and the Commonwealth is ordered to produce the Requested Information, the CHC-MCO shall reimburse the Commonwealth for any damages, penalties, or costs that the Commonwealth may incur as a result of the CHC-MCO's failure, including any statutory damages assessed against the Commonwealth.

ii. **Contractor Reimbursement**. The Commonwealth will reimburse the CHC-MCO for any costs that the CHC-MCO incurs as a direct result of complying with these provisions only to the extent allowed under the fee schedule established by the Office of Open Records or as otherwise provided by the RTKL.

e. **Challenges of Commonwealth Release.** The CHC-MCO may file a legal challenge to any Commonwealth decision to release a record to the public with the Office of Open Records, or in the Pennsylvania Courts, however, the CHC-MCO shall reimburse the Commonwealth for any legal expenses incurred by the Commonwealth as a result of the challenge, including any damages, penalties or costs that the Commonwealth may incur as a result of the CHC-MCO's legal challenge, regardless of the outcome.

f. **Waiver.** As between the parties, the CHC-MCO waives all rights or remedies that may be available to it as a result of the Commonwealth's disclosure of Requested Information pursuant to the RTKL.

g. **Survival.** The CHC-MCO's obligations contained in this Section survive the termination or expiration of this Agreement.

31. WORKER PROTECTION AND INVESTMENT

The CHC-MCO shall comply with all applicable Pennsylvania state labor laws and worker safety laws including, but not limited to, the following:

a. Construction Workplace Misclassification Act;
b. Employment of Minors Child Labor Act;
c. Minimum Wage Act;
d. Prevailing Wage Act;
e. Equal Pay Law;
f. Employer to Pay Employment Medical Examination Fee Act;
g. Seasonal Farm Labor Act;
h. Wage Payment and Collection Law;
i. Industrial Homework Law;
j. Construction Industry Employee Verification Act;
k. Act 102: Prohibition on Excessive Overtime in Healthcare;
l. Apprenticeship and Training Act; and
m. Inspection of Employment Records Law.

EXHIBIT B(1)

DEPARTMENT OF HUMAN SERVICES
ADDENDUM TO STANDARD CONTRACT
TERMS AND CONDITIONS

A. APPLICABILITY

This Addendum is intended to supplement the Standard Terms and Conditions. To the extent any of the terms contained herein conflict with terms contained in the Standard Contract Terms and Conditions, the terms in the Standard Contract Terms and Conditions shall take precedence. Further, it is recognized that certain terms contained herein may not be applicable to all the services which may be provided through Department contracts.

B. CONFIDENTIALITY

The parties shall not use or disclose any information about a Participant of the services to be provided under this Agreement for any purpose not connected with the parties' Agreement responsibilities except with written consent of such Participant, Participant's attorney, or Participant's parent or legal guardian.

C. INFORMATION

During the period of this Agreement, all information obtained by the CHC-MCO through work on the project will be made available to the Department immediately upon demand. If requested, the CHC-MCO shall deliver to the Department background material prepared or obtained by the CHC-MCO incident to the performance of this Agreement. Background material is defined as original work, papers, notes and drafts prepared by the CHC-MCO to support the data and conclusions in final reports, and includes completed questionnaires, materials in electronic data processing form, computer programs, other printed materials, pamphlets, maps, drawings and all data directly related to the services being rendered.

D. CERTIFICATION AND LICENSING

CHC-MCO agrees to obtain all licenses, certifications and permits from Federal, State and Local authorities permitting it to carry on its activities under this Agreement.

E. PROGRAM SERVICES

Definitions of service, eligibility of recipients of service and other limitations in this Agreement are subject to modification by amendments to Federal, State, and local statutes, regulations, and program requirements without further notice to the CHC-MCO hereunder.

F. CHILD PROTECTIVE SERVICE LAWS

In the event that the Agreement calls for services to minors, the CHC-MCO shall comply with the provisions of the Child Protective Services Law (Act of November 26, 1975, P.L. 438, No. 124; 23 P.S. §§ 6301-6384, and all regulations promulgated thereunder at 55 Pa. Code chapter 3490.

G. PRO-CHILDREN ACT OF 1994

The CHC-MCO agrees to comply with the requirements of the Pro-Children Act of 1994, as amended; Public Law 103- 277, Part C-Environment Tobacco Smoke (also known as the Pro-Children Act of 1994), which requires that smoking not be permitted in any portion of any indoor facility owned or leased or

contracted by an entity and used routinely or regularly for the provision of healthcare services, day care and education to children under the age of 18, if the services are funded by Federal programs whether directly or through State and Local governments. Federal programs include grants, cooperative agreements, loans or loan guarantees and contracts. The law does not apply to children's services provided in private residences, facilities funded solely by Medicare or Medicaid funds, and portions of facilities used for inpatient drug and alcohol treatment.

H. MEDICARE/MEDICAID REIMBURSEMENT

1. To the extent that services are furnished by contractors, subcontractors, or organizations related to the CHC-MCO and such services may in whole or in part be claimed by the Commonwealth for Medicare/Medicaid reimbursements, the CHC-MCO agrees to comply with 42 C.F.R. Part 420, including:

    a. Preservation of books, documents, and records until the expiration of four (4) years after the services are furnished under this Agreement.

    b. Full and free access to (i) the Commonwealth, (ii) the US Comptroller General, (iii) the US DHHS, and their authorized representatives.

2. The CHC-MCO's authorized representative's signature on the proposal certifies under penalty of law that the CHC-MCO has not been suspended or terminated from the Medicare or Medicaid Program and will notify the contracting DHS Facility or DHS Program Office immediately should a suspension or termination occur during the Agreement period.

I. TRAVEL AND PER DIEM EXPENSES

The CHC-MCO shall not be allowed or paid travel or per diem expenses except as provided for in CHC-MCO's Budget and included in the Agreement amount. Any reimbursement to the CHC-MCO for travel, lodging, or meals under this Agreement shall be at or below state rates as provided in Management Directive 230.10, Commonwealth Travel Policy, as may be amended, unless the CHC-MCO has higher rates which have been established by its offices or officials, and published prior to entering into this Agreement. Higher rates must be supported by a copy of the minutes or other official documents, and submitted to the Department. Documentation in support of travel and per diem expenses will be the same as required of Commonwealth employees.

J. INSURANCE

1. The CHC-MCO shall accept full responsibility for the payment of premiums for Workers' Compensation, Unemployment Compensation, Social Security, and all income tax deductions required by law for its employees who are performing services under this Agreement. As required by law, an independent contractor is responsible for Malpractice Insurance for healthcare personnel. CHC-MCO shall provide the insurance Policy Number and Provider Name, or a copy of the policy with all renewals for the entire Agreement period.

2. The CHC-MCO shall, at its expense, procure and maintain during the term of the Agreement the following types of insurance, issued by companies acceptable to the Department and authorized to conduct such business under the laws of the Commonwealth of Pennsylvania:

    a. Worker's Compensation Insurance for all of the CHC-MCO's employees and those of any subcontractor engaged in work at the site of the project as required by law.

    b. Public liability and property damage insurance to protect the Commonwealth, the CHC-MCO, and any and all subcontractors from claim for damages for personal injury (including bodily injury), sickness or disease, accidental death and damage to property, including loss of use resulting from any property damage, which may arise from the activities performed under this Agreement or the failure to perform under this Agreement whether such performance or nonperformance be by the

CHC-MCO, by any subcontractor, or by anyone directly or indirectly employed by either. The limits of such insurance shall be in an amount not less than $500,000 each person and $2,000,000 each occurrence, personal injury and property damage combined. Such policies shall be occurrence rather than claims-made policies and shall name the Commonwealth of Pennsylvania as an additional insured. The insurance shall not contain any endorsements or any other form designated to limit or restrict any action by the Commonwealth, as an additional insured, against the insurance coverage in regard to work performed for the Commonwealth.

Prior to commencement of the work under the Agreement and during the term of the Agreement, the CHC-MCO shall provide the Department with current certificates of insurance. These certificates shall contain a provision that the coverages afforded under the policies will not be cancelled or changed until at least thirty (30) days' written notice has been given to the Department.

K. PROPERTY AND SUPPLIES

1. The CHC-MCO agrees to obtain all supplies and equipment for use in the performance of this Agreement at the lowest practicable cost and to purchase by means of competitive bidding whenever required by law.

2. Title to all property furnished in-kind by the Department shall remain with the Department.

3. The CHC-MCO has title to all personal property acquired by the CHC-MCO, including purchase by lease/purchase agreement, for which the CHC-MCO is to be reimbursed under this Agreement. Upon cancellation or termination of this Agreement, disposition of such purchased personal property which has a remaining useful life shall be made in accordance with the following provisions.

    a. The CHC-MCO and the Department may agree to transfer any item of such purchased property to another contractor designated by the Department. Cost of transportation shall be borne by the CHC-MCO receiving the property and will be reimbursed by the Department. Title to all transferred property shall vest in the designated CHC-MCO. The Department will reimburse the CHC-MCO for its share, if any, of the value of the remaining life of the property in the same manner as provided under subclause b of this paragraph.

    b. If the CHC-MCO wishes to retain any items of such purchased property, depreciation tables shall be used to ascertain the value of the remaining useful life of the property. The CHC-MCO shall reimburse the Department in the amount determined from the tables.

    c. When authorized by the Department in writing, the CHC-MCO may sell the property and reimburse the Department for its share. The Department reserves the right to fix the minimum sale price it will accept.

4. All property furnished by the Department or personal property acquired by the CHC-MCO, including purchase by lease/purchase contract, for which the CHC-MCO is to be reimbursed under this Agreement shall be deemed "Department Property" for the purposes of subsection 5, 6 and 7 of this section.

5. The CHC-MCO shall maintain and administer in accordance with sound business practice a program for the maintenance, repair, protection, preservation and insurance of Department Property so as to assure its full availability and usefulness.

6. Department property shall, unless otherwise approved in writing by the Department, be used only for the performance of this Agreement.

7. In the event that the CHC-MCO is indemnified, reimbursed or otherwise compensated for any loss, destruction or damage to Department Property, it shall use the proceeds to replace, repair or renovate the property involved, or shall credit such proceeds against the cost of the work covered by the Agreement, or shall reimburse the Department, at the Department's direction.

L. DISASTERS

If, during the terms of this Agreement, the Commonwealth's premises are so damaged by flood, fire or other Acts of God as to render them unfit for use; then the Agency shall be under no liability or obligation to the CHC-MCO hereunder during the period of time there is no need for the services provided by the CHC-MCO except to render compensation which the CHC-MCO was entitled to under this Agreement prior to such damage.

M. SUSPENSION OR DEBARMENT

In the event of suspension or debarment, 4 Pa. Code Chapter 60, as it may be amended, shall apply.

N. COVENANT AGAINST CONTINGENT FEES

The CHC-MCO warrants that no person or selling agency has been employed or retained to solicit or secure this Agreement upon an Agreement or understanding for a commission, percentage, brokerage or contingent fee (excepting bona fide employees or bona fide established commercial or selling agencies maintained by the CHC-MCO for the purpose of securing business). For breach or violation of this warranty, the Department shall have the right to annul this Agreement without liability or, in its discretion, to deduct from the consideration otherwise due under the Agreement, or otherwise recover, the full amount of such commission, percentage, and brokerage or contingent fee.

O. CHC-MCO'S CONFLICT OF INTEREST

The CHC-MCO hereby assures that it presently has no interest and will not acquire any interest, direct or indirect, which would conflict in any manner or degree with the performance of its services hereunder. The CHC-MCO further assures that in the performance of this Agreement, it will not knowingly employ any person having such interest. CHC-MCO hereby certifies that no member of the Board of the CHC-MCO or any of its officers or directors has such an adverse interest.

P. INTEREST OF THE COMMONWEALTH AND OTHERS

No officer, member or employee of the Commonwealth and no member of its General Assembly, who exercises any functions or responsibilities under this Agreement, shall participate in any decision relating to this Agreement which affects his or her personal interest or the interest of any corporation, partnership or association in which he or she is, directly or indirectly, interested; nor shall any such officer, member or employee of the Commonwealth or member of its General Assembly have interest, direct or indirect, in this Agreement or the proceeds thereof.

Q. CONTRACTOR RESPONSIBILITY TO EMPLOY CASH ASSISTANCE BENEFICIARIES
(Applicable to contracts Twenty-Five Thousand Dollars ($25,000.00) or more)

1. The CHC-MCO, within ten (10) days of receiving the notice to proceed, must contact the Department's Contractor Partnership Program (CPP) to present, for review and approval, the CHC-MCO's plan for recruiting and hiring recipients currently receiving cash assistance. If the contract was not procured via Request for Proposal (RFP); such plan must be submitted on Form PA-778. The plan must identify a specified number (not percentage) of hires to be made under this Agreement. If no employment opportunities arise as a result of this Agreement, the CHC-MCO must identify other employment opportunities available within its organization that are not a result of this Agreement. The entire completed plan (Form PA-778) must be submitted to the Bureau of Employment and Training Programs (BETP)**:** Attention CPP Division. (Note: Do not keep the pink copy of Form PA-778). The approved plan will become a part of the Agreement.

2. The CHC-MCO's CPP approved recruiting and hiring plan shall be maintained throughout the term of the Agreement and through any renewal or extension of the Agreement. Any proposed change must be submitted to the CPP Division, which will make a recommendation to the Contracting Officer

regarding course of action. If an Agreement is assigned to another CHC-MCO, the new CHC-MCO must maintain the CPP recruiting and hiring plan of the original Agreement.

3. The CHC-MCO, within (10) days of receiving the notice to proceed, must register in the Commonwealth Workforce Development System (CWDS). In order to register, the CHC-MCO must provide business, location, and contact details by creating an Employer Business Folder for review and approval, within CWDS at https://www.cwds.state.pa.us. Upon CPP review and approval of Form PA-778 and the Employer Business Folder in CWDS, the CHC-MCO will receive written notice (via the pink CHC-MCO's copy of Form PA-778) that the plan has been approved.

4. Hiring under the approved plan will be monitored and verified by Quarterly Employment Reports (Form PA-1540) submitted by the CHC-MCO to the Central Office of Employment and Training – CPP Division. A copy of the submitted Form PA-1540 must also be submitted by the CHC-MCO to the Department's Contract Monitor (i.e., Contract Officer). The reports must be submitted on the DHS Form PA-1540. The form may not be revised, altered, or re-created.

5. If the CHC-MCO is non-compliant, CPP Division will contact the Contract Monitor to request corrective action. The Department may cancel this Agreement upon thirty (30) days written notice in the event of the CHC-MCO's failure to implement or abide by the approved plan.

R. TUBERCULOSIS CONTROL

Recommendations of the Centers for Disease Control and Prevention (CDC), United States Department of Health and Human Services (HHS) shall be followed in screening, testing and surveillance for TB and in treating and managing persons with confirmed or suspected TB. Currently the CDC recommends:

1) TB screening with an individual risk assessment and symptom evaluation at baseline (preplacement); 2) TB testing with an interferon-gamma release assay (IGRA) or a tuberculin skin test (TST) for persons without documented prior TB disease or latent TB infection (LTBI); 3) no routine serial TB testing at any interval after baseline in the absence of a known exposure or ongoing transmission; 4) encouragement of treatment for all health care personnel with untreated LTBI, unless treatment is contraindicated; 5) annual symptom screening for health care personnel with untreated LTBI; and 6) annual TB education of all health care personnel. In the event that a CHC-MCO employee is unwilling to submit to the test due to previous positive reading, allergy to testing material, or refusal, the risk assessment questionnaire must be completed. If a CHC-MCO employee refuses to be tested in accordance with this policy, the facility will not be able to contract with this provider and will need to procure the services from another source.

S. ACT 13 APPLICATION TO CHC-MCO

The CHC-MCO shall be required to submit with its bid information obtained within the preceding one-year period for any personnel who will have or may have direct contact with residents from the facility or unsupervised access to their personal living quarters in accordance with the following:

1. Pursuant to 18 Pa. C.S. Chap. 91 (relating to criminal history record information), a report of criminal history information from the Pennsylvania State Police or a statement from the State Police that its central repository contains no such information relating to that person. The criminal history record information shall be limited to that which is disseminated pursuant to 18 Pa. C.S. § 9121(b)(2) (relating to general regulations).

2. Where the applicant is not, and for the two (2) years immediately preceding the date of application has not been, a resident of this Commonwealth, the Department shall require the applicant to submit with the application a report of Federal criminal history record information pursuant to the Federal Bureau of Investigation's under Department of State, Justice, and Commerce, the Judiciary, and Related Agencies Appropriation Act, 1973 (Public Law 92-544, 86 Stat. 1109). For the purpose of this paragraph, the applicant shall submit a full set of fingerprints to the State Police, which shall forward them to the Federal Bureau of Investigation for a national criminal history check. The information obtained from the criminal record check shall be used by the Department to determine the applicant's

eligibility. The Department shall ensure confidentially of the information.

3. The Pennsylvania State Police may charge the applicant a fee of not more than $10 to conduct the criminal record check required under subsection 1. The State Police may charge a fee of not more than the established charge by the Federal Bureau of Investigation for the criminal history record check required under subsection 2.

The CHC-MCO shall apply for clearance using the State Police Background Check (SP4164) at its own expense. The forms are available from any State Police Substation. When the State Police Criminal History Background Report is received, it must be forwarded to the Department. State Police Criminal History Background Reports not received within sixty (60) days may result in cancellation of the Agreement.

T. LOBBYING CERTIFICATION AND DISCLOSURE

(applicable to agreements $100,000 or more)

Commonwealth agencies will not contract with outside firms or individuals to perform lobbying services, regardless of the source of funds. With respect to an award of a federal contract, grant, or cooperative agreement exceeding $100,000 or an award of a federal loan or a commitment providing for the United States to insure or guarantee a loan exceeding $150,000, all recipients must certify that they will not use federal funds for lobbying and must disclose the use of non-federal funds for lobbying by filing required documentation. The CHC-MCO will be required to complete and return a “Lobbying Certification Form” and a “Disclosure of Lobbying Activities form” with their signed Agreement, which forms will be made attachments to the Agreement.

U. AUDIT CLAUSE

(applicable to Agreements $100,000 or more)

This Agreement is subject to audit in accordance with Exhibit O, the Audit Clause.

EXHIBIT C

MANAGED LONG-TERM SERVICES AND SUPPORTS REGULATORY COMPLIANCE GUIDELINES

The CHC-MCO must comply with all applicable Federal and State laws (including, but not limited to, applicable regulations found in 55 Pa. Code Chapters 52, 1101 through 1249) and policy bulletins issued, by the Department.

As a general manner, regulatory provisions that no longer apply relate to Early and Periodic Screening, Diagnosis, and Treatment requirements (EPSDT) and to the calculation of MA provider payment rates and fees.

The following is a non-exhaustive outline of regulations in Title 55 of the Pennsylvania Code and policy bulletins relating to those regulations that do not apply to the CHC-MCO:

Chapter 52. Long-term Living Home and Community-Based Services

- Subsection 52.26(e) (relating to service coordination entity as Organized Healthcare Delivery System (OHCDS))
- Section 52.27 (relating to service coordinator qualifications and training)
- Sections 52.41 and 52.42 (relating to billing and payment policies)
- Section 52.45 (relating to fee schedule rates)
- Sections 52.51 and 52.52 (relating to vendor goods and services)
- Section 52.53 (relating to OHCDS)
- Section 52.64 (relating to payment sanctions)

Chapter 1101. General Provisions

- Section 1101.21 (relating to the following definitions: Prior Authorization; Shared Health Facility)
- Subsection 1101.31(b)(13) (relating to dental services)
- Subsection 1101.31(f) (relating to program exception process)
- Subsection 1101.33(a) (relating to recipient eligibility)
- Subsection 1101.33(b) (relating to a single-provider exception)
- Section 1101.51(a) (relating to freedom of choice)
- Section 1101.61 (relating only to fees and payments)
- Section 1101.62 (relating to maximum fees)
- Subsections 1101.63(b)(1) through (9) (relating to cost payments)
- Subsection 1101.63(c) (relating to MA deductibles)
- Subsection 1101.64(b) (only as to the reference to rates and fees)
- Section 1101.65 (relating to method of payment)
- Section 1101.67 (relating to prior authorization)
- Section 1101.68 (relating to invoices)
- Section 1101.69 (relating to overpayments and underpayments)

- Section 1101.72 (relating to invoice adjustments)
- Section 1101.83 (relating to restitution and repayment)

Chapter 1121. Pharmaceutical Services

- Section 1121.2 (relating to the definitions of: CAP; Compounded Prescription; Pricing Service; Federal Upper Limit; CMS Multisource Drug; State MAC; and Usual and Customary Charge)
- Subsections 1121.52(a)(6) and (b) (relating to payment conditions)
- Subsections 1121.53(a), (b)(1), (b)(2), (c), and (f) (relating to limitations on payment)
- Section 1121.55 (relating to the Department's payment to pharmacies)
- Section 1121.56 (relating to Drug Cost Determination)

Chapter 1123. Medical Supplies

- Section 1123.1 (only as to the reference to MA Fee Schedule)
- Subsections 1123.13(a) and (b) (relating to inpatient services)
- Subsection 1123.22(1) and (2) (relating to medical supplies which have been prescribed through the school medical program and EPSDT)
- Section 1123.51 (only as to the reference to MA Fee)
- Section 1123.53 (relating to hemophilia products)
- Section 1123.54 (relating to Orthopedic shoes)
- Section 1123.55 (relating to oxygen and related equipment)
- Section 1123.56 (relating to vision aids)
- Section 1123.57 (relating to hearing aids)
- Subsections 1123.58 (relating to prostheses and orthoses)
- Section 1123.60 (relating to limitations on payment)
- Section 1123.61 (relating to non-compensable services and items)
- Section 1123.62 (relating to method of payment)
- MA Bulletin 05-86-02
- MA Bulletin 05-87-02
- MA Bulletin 1123-91-01

Chapter 1126. Ambulatory Surgical Center and Hospital Short Procedure Unit Services

- Subsections 1126.51(f) through (h), and (k) through (m) (relating to payment for same-day surgical services)
- Subsections 1126.52 (relating to maximum reimbursement and developed fees)
- Subsection 1126.53(b) (relating to limitations on covered procedures)
- Subsection 1126.54(a)(7) (relating to sex reassignment)
- Subsections 1126.54(b) (relating to non-compensable services and items)

Chapter 1127. Birth Center Services

- Subsection 1127.51(d) (relating to claims submissions)
- Subsections 1127.52(a) through (c) (relating to fees and payment methodology)
- Subsection 1127.52(d) (relating to termination of birth center services during

prenatal care)
- Subsection 1127.52(e) (relating to payment if complications develop during labor and patient is transferred to a hospital)
- Subsection 1127.53(c) (relating to limitations on payment)

Chapter 1128. Renal Dialysis Facilities
- Subsection 1128.51(a) – (d) (only as it relates to payment provisions)
- Subsection 1128.51(f) through (m) (only as it relates to fees)
- Subsection 1128.51(n) (relating to payment to Out-of-State dialysis facilities)
- Section 1128.52 (relating to payment criteria)
- Subsection 1128.53(a) though (e) (relating to limitations on payment)
- Subsection 1128.53(f) (only as it relates to payment for back up visits)
- Subsection 1128.53(g) (relating to limitations on payment)

Chapter 1129. Rural Health Clinic Services
- Subsection 1129.51(b) and (c) (only as it relates to billings to, and payments from, the Department to payment to Rural Health Clinics)
- Sections 1129.52 and 1129.53 (relating to payment policies for Rural Health Clinics)

Chapter 1130. Hospice Services
- Subsections 1130.22(4), 1130.41(a), 1130.41(c) and Subsection 1130.42(a) (only as it relates to the use of the specific form; however, the provider must have a form that is substantively the same)
- Subsection 1130.63(b) (relating to limitations on coverage)
- Subsection 1130.63(c) (to the extent it provides that bereavement counseling is not reimbursable)
- Subsection 1130.63(e) (relating to limitations on coverage)
- Subsection 1130.71(d) through (h) (as those provisions relate to MA payments process)
- Section 1130.72 (relating to services performed by hospice physicians)
- Section 1130.73 (relating to additional payment to nursing facility residents)

Chapter 1140. Healthy Beginnings Plus Program
- Subsections 1140.52(2), 1140.53 and 1140.54(1) (as those provisions relate to billing, payment process and non-compensable services and items)

Chapter 1141. Physicians' Services
- Subsection 1141.53(a) through (c) (relating to payment made in an approved short procedure unit only if the service could not appropriately and safely be performed in the physician's office, clinic or ED of a hospital; prior authorization requirements for specialists' examinations and consultations; and services provided to recipients in skilled and intermediate care facilities by the physician administrator or medical director)
- Subsection 1141.53(f) and (g) (relating to all covered outpatient physicians' services billed to the Department shall be performed by such physician personally or by a registered nurse, physician's assistant, or a midwife under the physician's

direct supervision; and payment by the Department of a Ten Dollar ($10.00) per month fee to physicians who are approved by the Department to participate in the restricted recipient program)

- Subsection 1141.54(a)(1) through (3) (relating to when a physician is eligible to bill the Department for services provided to a hospitalized recipient)
- Subsection 1141.54(f) (relating to inpatient physicians' services billed to the Department shall be performed by the physician, an RN, physician's assistant or midwife under the physician's direct supervision)
- Subsection 1141.55(b)(1) (only as it relates to the Department's forms)
- Subsections 1141.55(c), 1141.55(c)(2) and Subsection 1141.55(c)(3) and 1141.56(a)(3) (to the extent those provisions referenced the Provider Handbook)
- Subsection 1141.57(a)(2) (only to the extent that the incident must be reported within seventy-two (72) hours)
- Subsection 1141.57(a)(1)(i) (to the extent of the invoice and report)
- Subsection 1141.57(a)(2)(i) (to the extent of the invoice and report)
- Subsections 1141.59(1) through (5), 1141.59(7) and (8), and 1141.59(10) and (11) and 1141.59(14) through (16) (relating to non-compensable services)
- Section 1141.60 (relating to payment for medications dispensed or ordered in the course of an office visit)

Chapter 1142. Midwives' Services

- Section 1142.51 (only as to MA payment fees)
- Subsection 1142.52(2) (only as to MA billing)
- Subsection 1142.55 (relating to non-compensable services)

Chapter 1143. Podiatrists' Services

- Section 1143.2 (only as to the definition of Medically Necessary)
- Section 1143.51 (only as to the MA fee schedule)
- Section 1143.53 (relating to payment conditions for outpatient services)
- Section 1143.54 (relating to payment conditions for inpatient hospital services)
- Subsection 1143.55 (relating to payment conditions for diagnostic services)
- Section 1143.56 (relating to payment conditions for orthopedic shoes, molded shoes and shoe inserts)
- Section 1143.57 (relating to limitations on payment for podiatrist visits and x-rays)
- Subsection 1143.58(a)(1) through (12) (relating to non-compensable services and items for podiatry services)
- Subsection 1143.58(b) (relating to non-compensable services and items)

Chapter 1144. Certified Registered Nurse Practitioner Services

- Subsection 1144.42(b) (only as to the reference to the Department)
- Subsection 1144.52 (relating to payment conditions)
- Subsection 1144.53 (relating to non-compensable services)

Chapter 1145. Chiropractor's Services

- Subsections 1145.11 through 1145.14 (relating to services and payment

limitations)

- Section 1145.51 (only as to the MA fee schedules and billing)
- Section 1145.54 (relating to non-compensable services)

Chapter 1147. Optometrists' Services

- Section 1147.2 (only as to remove "untinted" from the definition of "Eyeglasses")
- Section 1147.11 (only as to MA)
- Section 1147.12 (only as to MA fee schedules)
- Section 1147.13 (only as to MA fee Schedules)
- Subsection 1147.14(1) (relating to orthoptic training)
- Section 1147.23 (to the extent of "only" and "They are not eligible for eyeglasses, low vision aids or eye prostheses. However, State Blind Pension recipients are eligible for eye prostheses if they are also categorically needy.")
- Section 1147.51 (relating to limitations on payment; and non-compensable services and items; Medical Assistance Program fee schedule; and Optometric services shall be billed in the name of the optometrist providing the service)
- Section 1147.53 (relating to limitations on payments for optometric services)
- Section 1147.54 (relating to non-compensable optometric services and items)

Chapter 1149. Dentists' Services

- Section 1149.1 (only as to MA fee schedule)
- Subsection 1149.43(6) (relating to radiographs are requested by the Department for prior authorization purposes)
- Subsection 1149.43(9) through (11) (relating to pathology reports are required for surgical excision services; pre- operative X-rays are required for surgical services; and postoperative X-rays are required for endodontic procedures)
- Section 1149.51 (relating to general payment policy)
- Section 1149.52 (relating to payment conditions for various dental services)
- Section 1149.54 (relating to payment policies for orthodontic services)
- Subsection 1149.55(1) and Subsections 1149.55(5) through (8) (relating to payment policies for orthodontic services)
- Section 1149.56 (relating to payment limitations for orthodontic services)
- Section 1149.57 (relating to non-compensable dental services and items)

Chapter 1150. Medical Assistance Program Payment Policies

- Section 1150.2 (only as to definitions of place of service review (PSR) and Second Opinion program)
- Subsections 1150.51 (relating to general Medical Assistance Program payment policies)
- Section 1150.52 (relating to payment for Anesthesia services)
- Section 1150.54 (relating to payment for surgical services)
- Section 1150.55 (relating to payment for obstetrical services)
- Section 1150.56 (relating to payment for medical services)
- Section 1150.56a (relating to payment policy for consultations)

- Section 1150.57 (relating to payment for diagnostic services and radiation therapy)
- Section 1150.58 (relating to prior authorization)
- Section 1150.59 (relating to the PSR Program)
- Section 1150.60 (relating to the Second Opinion Program)
- Section 1150.61 (relating to guidelines for fee schedule changes)
- Section 1150.62 (relating to payment levels and notices of rate setting changes)
- Section 1150.63 (only as to references to the Department and CAO)

Chapter 1151. (relating to inpatient psychiatric services)

Chapter 1153. (relating to outpatient psychiatric services)

Chapter 1163. Inpatient Hospital Services, Subchapter A, Acute Care General Hospitals under the Prospective Payment System

- Section 1163.32 (relating to hospital units excluded from the DRG prospective payment system)
- Subsections 1163.51 (relating to payment for hospital services)
- Sections 1163.52 through 1153.59 (relating to prospective payment methodology, assignment of DRG, prospective capital reimbursement system, payments for direct medical education, outliers, payment policy for readmissions and transfers, and non-compensable services and items and outlier days)
- Subsection 1163.60(b)(1), Subsection 1163.60(c)(2), and Subsection 1163.60(c)(3) (only as to references to the Provider Handbook)
- Subsections 1163.62(a)(2) through 1163.65 (relating to payment conditions for abortions , billing, cost reports, and payment for out-of-state services)
- Subsection 1163.66(b) through (g) (relating to third party liability)
- Section 1163.67 (relating to disproportionate share payments)
- Sections 1163.70 (relating to changes of ownership or control)
- Subsections 1163.72(a), (c) through (g) (relating to general utilization review, admissions, day and cost outliers)
- Sections 1163.73 (relating to hospital utilization review plan)
- Subsections 1163.75 (6) and (12) (relating to, the Department's forms and manual)
- Sections 1163.76 through 1163.77 (only as to the written plan of care within two (2) days of admission and admission review requirements within twenty-four (24) hours of admission)
- Section 1163.78a and 1163.78b (relating to review requirements for day outliers and cost outliers)
- Subsections 1163.92(a) through (f) (relating to administrative sanctions)
- Subsection 1163.101(a) (relating to right to appeal under Chapter 1101 (relating to general provisions))
- Section 1163.122 (relating to determination of DRG relative values)
- Section 1163.126 (relating to computation of hospital specific computation rates)

Chapter 1163. Inpatient Hospital Services, Subchapter B, Hospitals and Hospital Units Under Cost Reimbursement Principles

- Section 1163.402 (only as to definition of “certified day”)
- Subsections 1163.451 (relating to general payment policies)
- Section 1163.452 (relating to payment methods and rates)
- Subsections 1163.453(a) and (c) (relating to allowable and non-allowable costs, allowable costs for inpatient services, payment not higher than hospital’s customary charge)
- Subsections 1163.453(d) (2) through (9) (relating to costs not allowable under the Medical Assistance Program)
- Subsections 1163.453(e) and (f) (relating to allowable costs)
- Section 1163.454 (relating to limitations on payment)
- Subsection 1163.455 (a)(1) through (5) and (7) through (16) (relating to non-compensable inpatient services)
- Subsection 1163.455 (b) and (c) (relating to non-compensable inpatient services)
- Section 1163.457 (relating to payment policies relating to out-of-state hospitals)
- Section 1163.458 (relating to payment policies relating to same calendar day admissions and discharges)
- Section 1163.459 (relating to disproportionate share payments)
- Section 1163.472 (relating to concurrent hospital review)
- Section 1163.476 and 1163.477 (only as to the written plan of care within two (2) days of admission and admission review requirements within twenty-four (24) hours of admission)
- Subsection 1163.481(b) and (c) (relating to utilization review sanctions)
- Section 1163.501 (relating to provider right to appeal)
- Section 1163.511 (relating to change of ownership or control)

Chapter 1181. Nursing Facility Care

- Subchapter A (related to nursing facility care)
- Subchapter B (related to manual for allowable cost reimbursement for skilled nursing and intermediate care facilities)

Chapter 1187. Private Nursing Facility Services

- Section 1187.2 (for definitions relating to payment calculation)
- Subsection 1187.21(4) (only as to "Payment will be based on criteria found in § 1187.101(b) (relating to general payment policy)")
- Section 1187.23 (relating to nursing facility incentives and adjustments)
- Subsections 1187.33(b)(1)-(3) (relating to sanctions)
- Subchapter E (relating to allowable program cost policies)
- Subchapter F, except for 1187.78 (relating to accountability requirements related to resident personal fund management) and 1187.79 (relating to auditing requirements related to resident personal fund management)
- Subchapter G
- Subsection 1187.102(e) (only as to reporting allowable Medicare Part B-type

costs)
- Section 1187.103 (relating to cost finding and allocation of costs)
- Section 1187.104 (only as to payment rates)
- Section 1187.105 (relating to limitations on payment for prescription drugs)
- Section 1187.106 (relating to limitations on payment during strike or disaster situations requiring resident evacuation)
- Sections 1187.107 through 1187.117, including 1187.113a and 1187.113b (relating to payment provisions)
- Subchapter J (relating to NF right of appeal)
- Subchapter K (relating to exceptional payments for nursing facility services)

Chapter 1189. County Nursing Facility Services

- Sections 1189.1 and 1189.2 (relating to policy and definitions)
- Section 1189.2C (relating to payment calculations)
- Subchapter B (relating to allowable program costs and policies)
- Section 1189.75 (related to auditing requirements for MA Cost Reports)
- Subchapter D (relating to rate setting)
- Subsection 1189.102(e) (relating to reporting allowable Medicare Part B-type costs)
- Subsection 1189.71 (related to cost reporting) and 1189.72 (related to cost reporting for Medicare Part B type services)
- Section 1189.103 (only as to payment)
- Section 1189.104 (relating to limitations on payment during strike or disaster situations requiring resident evacuation)
- Section 1189.105 (relating to incentive payments)
- Section 1189.106 (relating to adjustments relating to sanctions and fines)
- Section 1189.107 (relating to adjustment relating to errors and corrections of NF payments)
- Section 1189.108 (relating to supplemental payments)
- Subchapter F (relating to county facility right of appeal)

Chapter 1221. Clinic and Emergency Room Services

- Sections 1221.43 through 1221.44 (relating to participation requirements for hospital clinics and emergency rooms for higher reimbursement rates, and additional participation requirements for independent clinics)
- Sections 1221.51 and 1221.52 (relating to general payment policy for clinic and emergency room services and payment conditions for various services)
- Subsection 1221.55(b)(1) (except that an informed consent form is required)
- Subsections 1221.57(a)(2) and 1221.57(c) (except that the CHC-MCO must comply with Medical Assistance Bulletin 99- 95-09)
- Sections 1221.58 and 1221.59 (relating to limitations on payments and non-compensable services and items)
- MA Bulletin 11-95-04

- MA Bulletin 11-95-10
- MA Bulletin 11-95-12

Chapter 1223. Outpatient Drug and Alcohol Clinic Services

Chapter 1225. Family Planning Clinic Services

- Sections 1225.1 and 1225.51 (only as to MA fees)
- Subsection 1225.54(2) (relating to non-compensable family planning services)

Chapter 1230. Portable X-Ray Services

- Sections 1230.1, 1230.51 and 1230.52(b) (only as to MA fees)
- Subsection 1230.53 (relating to portable x-ray services, provider maximum payment, payment for transportation of portable x-ray equipment, and electrocardiogram services)
- Subsection 1230.54 (relating to non-compensable)

Chapter 1239. Medical Assistance Case Management Services for Recipients under the Age of 21

- MA Bulletin 99-94-08

Chapter 1241. Early and Periodic Screening, Diagnosis, and Treatment Program

Chapter 1243. Outpatient Laboratory Services

- Section 1243.1 and 1243.51 (only as to MA fees)
- Subsection 1243.52(b) (only as to billing)
- Subsection 1243.53(a) (relating to limitations on payment)
- Subsection 1243.54(1)(2) (relating to non-compensable services)

Chapter 1245. Ambulance Transportation

- Section 1245.1 (only as to MA fees)
- Subsection 1245.52(1) (relating to payment conditions for ambulance services)
- Subsections 1245.52(3) through (5) (relating to transportation to the nearest appropriate medical facility and medical services/supplies invoice)
- Section 1245.53 (relating to limitations on payment for ambulance service when more than one patient is transported. Payment is made for transportation of the patient whose destination is the greatest distance. No additional payment is allowed for the additional person)
- Subsections 1245.54(1) through (7) (relating to non-compensable services)

Chapter 1249. Home Health Agency Services

- Section 1249.1 and 1249.51 (only as to MA fee schedule)
- Section 1249.52 (relating to payment conditions for various services.)
- Subsection 1249.55(a) (only as to MA fee schedule) and (b) (relating to reimbursement for supplies)
- Section 1249.57(a) (relating to payment conditions for maternal/child services) and 1249.57 (b).
- Section 1249.58 (relating to payment conditions for travel costs)
- Section 1249.59 (relating to limitations on payment)

EXHIBIT D

DRUG SERVICES

1. General Requirements

a. All requirements in this Exhibit apply to all Covered Drugs regardless of the setting in which the drug is dispensed or administered the billing provider type, or how the CHC-MCO makes payment for the drug (pharmacy benefit and medical benefit).

b. The amount, duration, and scope of Covered Drugs must be consistent with coverage under the Fee-for-Service (FFS) program. The CHC-MCO must cover all Covered Drugs listed on the CMS Quarterly Drug Information File when determined to be Medically Necessary, unless otherwise excluded from coverage. (See Section 2, Coverage Exclusions, below for exclusions.) This includes brand-name and generic drugs, and over-the-counter drugs (OTCs), prescribed by licensed Providers enrolled in the Medical Assistance program, and sold or distributed by drug manufacturers that participate in the Medicaid Drug Rebate Program.

c. The CHC-MCO must provide coverage for all medically accepted indications, as described in Section 1927(k)(6) of the Social Security Act, 42 U.S.C.A. § 1396r-8(k)(6). This includes any use which is approved under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C.A. §§ 301 et seq., or whose use is supported by the nationally recognized pharmacy compendia, or peer-reviewed medical literature.

d. Unless financial responsibility is otherwise assigned, all Covered Drugs are the payment responsibility of the Participant's CHC-MCO. The only exception is that the behavioral health managed care organization (BH-MCO) is responsible for the payment of methadone when used in the treatment of substance abuse disorders and when prescribed and dispensed by BH-MCO Service Providers.

e. All Covered Drugs must be dispensed through CHC-MCO Network Providers. This includes Covered Drugs prescribed by both the CHC-MCO and the BH-MCO Providers.

f. Under no circumstances will the CHC-MCO permit the therapeutic substitution of a drug by a pharmacist without explicit authorization from the licensed prescriber.

g. All proposed Covered Drug policies, programs and drug Utilization Management programs, such as but not limited to Prior Authorization, Step Therapy, partial fills, specialty pharmacy, pill-splitting, mail order, 90-day supply programs, limited pharmacy networks, medication therapy management

programs, etc., must be submitted to the Department for review and written approval prior to implementation, prior to implementation of any changes, and annually thereafter.

h. The CHC-MCO must include in its written policies and procedures an assurance that all requirements and conditions governing coverage and payment for Covered Drugs, such as, but not limited to, Prior Authorization (including Step Therapy), medical necessity guidelines, age edits, drug rebate Encounter submission, reporting, notices of decision, etc., will:

   i. Apply, regardless of whether the Covered Drug is provided as an drug benefit or as a "medical benefit" incident to a medical service and billed by the prescribing Provider using codes such as the Healthcare Common Procedure Coding System (HCPCS).

   ii. Ensure access for all medically accepted indications as documented by package labeling, nationally recognized pharmacy compendia, peer-reviewed medical literature, Statewide Preferred Drug List (PDL) prior authorization guidelines, if applicable, and FFS guidelines to determine medical necessity of drugs that require Prior Authorization in the Medical Assistance FFS Program, when designated by the Department.

i. The CHC-MCO must submit for review and approval a policy for each section of Exhibit D that includes the requirements in the respective section and the CHC-MCO's procedures to demonstrate compliance.

j. The CHC-MCO must agree to adopt the same requirements for prior authorization and some or all of the same guidelines to determine medical necessity of selected drugs or classes of drugs as those adopted by the Medical Assistance FFS Program when designated by the Department.

k. The CHC-MCO must comply with Section 2117 of Article XXI of the Insurance Company Law of 1921, 40 P.S. § 991.2117 regarding continuity of care requirements and 28 Pa. Code Chapter 9. The CHC-MCO must also comply with the procedures outlined in Medical Assistance Bulletin # 99-03-13 and Medical Assistance Bulletin # 99-96-01. The CHC-MCO policy and procedures for continuity of care for drugs, and all subsequent changes to the Department-approved policy and procedures, must be submitted to the Department for review and approval prior to implementation. The policy and procedures must address how the CHC-MCO will ensure no interruption in drug therapy and the course of treatment, and continued access to drugs that the Participant was prescribed before enrolling in the CHC-MCO.

l. The CHC-MCO must allow access to all new drugs approved by the Food and Drug Administration (FDA) and meet the definition of a Covered Drug either by addition to the Statewide PDL or MCO Formulary or through prior authorization, within 10 days from their availability in the marketplace.

m. The CHC-MCO must comply with 1902(a)(85); Section 1004 of the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act). The CHC-MCO will implement prospective safety edits on subsequent fills of opioid prescriptions, as specified by the state, which may include edits to address days' supply, early refills, duplicate fills and quantity limitations for clinical appropriateness.

2. Coverage Exclusions

a. In accordance with Section 1927 of the Social Security Act, 42 U.S.C.A. § 1396r-8, the CHC-MCO must exclude coverage for any drug marketed by a drug company (or labeler) that does not participate in the Medicaid Drug Rebate Program. The CHC-MCO is not permitted to provide coverage for any drug product, brand name or generic, legend or non-legend, sold or distributed by a company that did not sign an agreement with the federal government to provide rebates to the Medicaid agency. This requirement does not apply to vaccines, compounding materials, certain vitamins and minerals or diabetic supplies.

b. The CHC-MCO may not provide coverage for Drug Efficacy Study Implementation (DESI) drugs under any circumstances.

c. The CHC-MCO must exclude coverage of noncompensable drugs in accordance with 55 Pa. Code § 1121.54

3. Formularies and Preferred Drug Lists (PDLs)

a. The CHC-MCO must utilize the Statewide PDL developed by the Department's Pharmacy and Therapeutics (P&T) Committee.

   If the CHC-MCO fails to meet Statewide PDL quarterly compliance of 95% (excluding TPL) a financial sanction consistent with the difference in net cost using CHC-MCO actual compliance rate and the net cost if compliance rate was 95%. The minimum penalty of $25,000 per quarter will be imposed. The CHC-MCO is responsible for submitting prior authorization approval and denial information in a format designated by the Department.

b. The CHC-MCO must implement use of the Statewide PDL, any changes to the Statewide PDL, the Statewide PDL prior authorization guidelines, and any changes to the Statewide PDL prior authorization guidelines on the effective date provided by the Department.

c. The CHC-MCO must apply Statewide PDL prior authorization guidelines to all drugs and products included on the Statewide PDL. The CHC-MCO may not impose additional prior authorization requirements for drugs and products included on the Statewide PDL. Quantity limits can be no more restrictive than the Department's quantity limits.

   The CHC-MCO must submit the policies, procedures, and guidelines to determine

medical necessity of drugs included on the Statewide PDL to the Department. Submissions must occur prior to the effective date of the changes as determined by the Department and at least annually.

d. The CHC-MCO may use a Formulary or PDL to manage MA covered drugs and products that are outside the scope of the Statewide PDL as long as the Department has prior approved it and the Formulary or PDL meets the clinical needs of the MA population.

   The Formulary or PDL must be developed and reviewed at least annually by the CHC-MCO's P&T Committee, as defined in Section 6 of this Exhibit.

e. The CHC-MCO must allow access to all non-formulary or non-preferred drugs that are included in the CMS Quarterly Drug Information File, other than those excluded from coverage by the Department, when determined to be Medically Necessary through a process such as Prior Authorization (including Step Therapy), in accordance with Section V. B.1., Prior Authorization of Services, and Exhibit E, Prior Authorization Guidelines for the CHC-MCO, and this Exhibit.

f. The CHC-MCO must receive written approval from the Department of the Formulary or PDL, the list of specialty drugs, quantity limits, age edits, and the policies, procedures and guidelines to determine medical necessity of drugs and products not included on the Statewide PDL that require Prior Authorization, including drugs that require Step Therapy and drugs that are designated as non-formulary or non-preferred, prior to implementation of the Formulary or PDL, the designation of specialty, and the requirements. CHC-MCOs may add drugs to the specialty drug list that are in therapeutic classes already included on the specialty drug list prior to receiving approval from the Department. However, these additions must be included in the specialty drug designations submitted to the Department for written approval. Submissions for annual reviews must occur at least 30 days before the effective date of the updated information.

g. The CHC-MCO must submit all Formulary or PDL deletions for drugs and products outside the scope of the Statewide PDL to the Department for review and written approval prior to implementation.

h. The CHC-MCO must submit written notification of any Formulary or PDL additions for drugs and products outside the scope of the Statewide PDL to the Department within fifteen (15) days of implementation.

i. In addition to providing a link to the Statewide PDL on the CHC-MCO's website, the CHC-MCO must make available on the website in electronic format, information about its drug Formulary or PDL, listing which medications are covered, including both brand and generic names.

4 Prior Authorization of Drugs

a. For Covered Drugs that require Prior Authorization (including Step Therapy) as a condition of coverage or payment:

   i. The CHC-MCO must provide a response to the request for Prior Authorization by telephone or other telecommunication device to approve or deny the prescription within twenty-four (24) hours of the request; and

   ii. If a Participant's prescription for a medication is not filled when a prescription is presented to the pharmacist due to a Prior Authorization requirement, the CHC-MCO must instruct the pharmacist to dispense either:

      1) A fifteen (15) day supply if the prescription qualifies as an Ongoing Medication.

      2) A seventy-two (72) hour supply of a new medication.

b. For drugs not able to be divided and dispensed into individual doses, the CHC-MCO must instruct the pharmacist to dispense the smallest amount that will provide at least a seventy-two (72) hour or fifteen (15) day supply, whichever is applicable.

c. The requirement that the Participant be given at least a seventy-two (72) hour supply for a new medication or a fifteen (15) day supply for an Ongoing Medication does not apply when a pharmacist determines that the taking of the prescribed medication, either alone or along with other medication that the Participant may be taking, would jeopardize the health or safety of the Participant. The CHC-MCO and/or its subcontractor must require that its participating dispensing Provider make good faith efforts to contact the prescriber.

d. If the CHC-MCO denies the request for Prior Authorization, the CHC-MCO must issue a written denial notice to the Participant and the Provider, using the appropriate Drug Denial Notice template within twenty-four (24) hours of receiving the request for Prior Authorization. The specific reason(s) for denial must be included in the notice of decision. If additional information is required to approve the request, the specific documentation needed must be listed in the notice. If the requested drug is non-preferred/non-formulary and within the scope of the Statewide PDL or the CHC-MCO's Formulary, the CHC-MCO must list preferred alternatives appropriate for the beneficiary's diagnosis and clinical condition in the denial notice.

e. If the CHC-MCO approves the request for prior authorization, the CHC-MCO must issue a written approval notice to Participant and Provider including the drug name and strength, effective and end dates of the approval within twenty-four (24) hours of receiving the request for prior authorization.

f. If the Participant files a Grievance or DHS Fair Hearing request from a denial of an Ongoing Medication, the CHC-MCO must authorize the medication until the Grievance or DHS Fair Hearing request is resolved.

g. When medication is authorized due to the obligation to cover pre-existing services while a Grievance or DHS Fair Hearing is pending, a request to refill that prescription, made after the Grievance or DHS Fair Hearing has been finally concluded in favor of the MCO, is not an Ongoing Medication.

h. Requests for Prior Authorization will not be denied for lack of Medical Necessity unless a physician reviews the request for a Medical Necessity determination. Such a request for Prior Authorization must be approved when, in the professional judgment of the physician reviewer, the services are Medically Necessary to meet the medical needs of the Participant.

i. When medication is authorized due to the CHC-MCO's obligation to continue services while a Participant's Grievance or Fair Hearing is pending, and the final binding decision is in favor of the CHC-MCO, a request for subsequent refill of the prescribed medication does not constitute an Ongoing Medication.

j. The CHC-MCO guidelines to determine Medical Necessity of Covered Drugs outside the scope of the Statewide PDL cannot be more stringent than the FFS guidelines. The CHC-MCO must follow the Statewide PDL Prior Authorization guidelines for drugs and products included on the Statewide PDL.

k. The CHC-MCO must comply with the requirements of Section V. B. 1. Of the Agreement, Prior Authorization of Services, and Exhibit E, Prior Authorization Guidelines for CHC-MCOs, and receive written approval from the Department prior to implementation and annually thereafter. If a CHC-MCO covers a specific drug through both their medical and pharmacy benefits, the CHC-MCO must apply the same Department approved prior authorization guidelines to prior authorization requests.

5. Provider and Participant Notification

The CHC-MCO must have policies and procedures for notification to Providers and Participants of changes to the Statewide PDL or Formulary used by the CHC-MCO for drugs and products outside the scope of the Statewide PDL, Prior Authorization requirements, and other requirements for Covered Drugs such as, but not limited to, specialty program requirements.

a. Written notification for changes to the requirements must be provided to all affected Providers and Participants at least thirty (30) days prior to the effective date of the change.

b. The CHC-MCO must provide all other Providers and Participants written notification of changes to the requirements upon request.

c. The CHC-MCO also must generally notify Providers and Participants of changes through Participant and Provider newsletters, its website, or other regularly published media of general distribution.

d. Participant notices must be submitted to the Department for review and approval prior to mailing.

6. CHC-MCO Pharmacy & Therapeutics (P&T) Committee

a. The P&T Committee membership must include physicians (including a minimum of two (2) behavioral health physicians), pharmacists, Medical Assistance Program Participants and other appropriate clinicians. Medical Assistance Program Participant representative membership must include the following:

   i. One (1) physical health Participant representative. The physical health Participant representative must be a Participant enrolled in the CHC-MCO, or a physician, a pharmacist, or a physical health Participant advocate designated by Participants enrolled in the CHC-MCO to represent them.

   ii. One (1) behavioral health Participant representative. The behavioral health Participant representative must be a Participant enrolled in the CHC-MCO, or a physician, a pharmacist, a behavioral health Participant advocate, or a family member designated by Participants enrolled in the CHC-MCO to represent them.

   iii. One (1) LTSS Participant representative. The LTSS Participant representative must be a Participant enrolled in the CHC-MCO, or a physician, a pharmacist, a LTSS Participant advocate, or a family member designated by Participants enrolled in the CHC-MCO to represent them.

b. The CHC-MCO must submit a P&T Committee membership list for Department review and approval upon request.

c. When the P&T Committee addresses specific drugs or entire drug classes requiring medical expertise beyond that of the P&T Committee membership, specialists with knowledge appropriate to the drug(s) or class of drugs being addressed must be added as non-voting, ad hoc members.

d. The minutes from each CHC-MCO P&T Committee meeting must be posted for public view on the CHC-MCO's website within thirty (30) days of the date of the meeting at which the minutes are approved. Minutes will include vote totals.

7. Pharmacy Provider Network and Payment

a. The CHC-MCO or Subcontractor must contract on an equal basis with any pharmacy qualified to participate in the Medical Assistance program that is willing to comply with the CHC-MCO's payment rates and terms and to adhere to quality standards established by the CHC-MCO as required by 62 P.S. § 449.

   i. The provisions for any willing pharmacy apply if the CHC-MCO or Subcontractor enters into agreements with specific pharmacies to provide defined drugs or services, such as but not limited to, specialty, mail order, and 90-day supplies. CHC-MCOs are required to contract on an equal basis with any pharmacy qualified to participate in the Medical Assistance program that is willing to accept the same payment rate(s) and comply with the same terms and conditions for quality standards and reporting.

   ii. Subcontracts and agreements with specific pharmacies contracted to provide defined drugs or services must be submitted to the Department for advance written approval. Any changes to subcontracts or agreements must also be submitted to the Department for advance written approval.

   iii. The CHC-MCO must submit annually the list of specific pharmacies contracted to provide defined drugs or services, and a list of the drugs or services each pharmacy is contracted to provide, to the Department for review and written approval. Submissions for annual reviews must occur at least thirty (30) days before the effective date of the updated information.

   iv. The CHC-MCO must notify the Department on an ongoing basis of the following: (1) specific pharmacies that are no longer contracted to provide defined drugs or services and the reason why, (2) pharmacies that request contracting to provide defined drugs or services but are not admitted into the specific pharmacy network and the reason why, (3) any pharmacies that are only contracted to provide a limited scope of defined drugs or services and the reason why.

b. The CHC-MCO and any subcontractor must develop, implement, and maintain a process that ensures the amount paid to all network pharmacies reflects the pharmacy’s acquisition cost, professional services and cost to dispense the prescription to a Medicaid beneficiary. The CHC-MCO must submit to the Department the policies and procedures for development of network pharmacy payment methodology including the process to ensure that brand and generic payment rates reflect the pharmacy’s acquisition cost (from a readily available distributor doing business in Pennsylvania) and the professional dispensing fee accurately reflects the pharmacist’s professional services and cost to dispense the prescription to a Medicaid beneficiary.

c. The CHC-MCO or subcontractor must submit to the Department for review and approval all changes to the payment methodology prior to implementation.

d. The CHC-MCO or subcontractor must report all changes to the payment methodology, rates, and dispensing fee in advance to network pharmacy providers.

e. The CHC-MCO or subcontractor must report all changes to the maximum allowable cost rates in real-time to network pharmacy providers.

f. (1) If a network pharmacy's claim is approved through the adjudication process, the CHC-MCO and any subcontractor may not retroactively deny or modify the payment unless any of the following:

i. The claim was fraudulent.
ii. The claim was duplicative of a previously paid claim.
iii. The pharmacy did not render the service.

(2) Nothing in 7.e.(1) shall be construed to prohibit the modification of or recovery of an adjudicated claim that was determined to be an overpayment or underpayment resulting from audit, review or investigation by a federal or state agency or CHC-MCO.

g. The CHC-MCO and any subcontractor will not charge a fee related to a network pharmacy's claim unless the amount of the fee is disclosed and applied at the time of the claim adjudication.

h. The CHC-MCO and any subcontractor shall not utilize an effective rate for reimbursement to a network pharmacy, including, but not limited to, generic effective rates, brand effective rates, dispensing fee effective rates, and direct and indirect renumeration fees. For the purposes of this Exhibit, an "effective rate contract" allows for adjustment of reimbursements over time so the overall reimbursement averages out to a guaranteed amount; the result is some claims are paid below the effective rate and others are paid above the effective rate. For the purposes of this Exhibit, "direct and indirect remuneration fees" are any fees charged by PBMs to pharmacies that are outside of administration fees and are generally collected after the point of sale.

8. Drug Rebate Program

a. The CHC-MCO must report the necessary Drug Encounter Data in order for the Department to invoice drug manufacturers for rebates for all Covered Drugs. This includes physician-administered drugs, drugs dispensed by 340B covered entities or contract pharmacies, and drugs dispensed to Participants with private or public pharmacy coverage and CHC-MCO secondary coverage.

b. The CHC-MCO must report all Drug information, including National Drug Codes (NDCs) and accurate NDC units for all drug claim types, NCPDP, 837 Professional, 837 Institutional, etc., as designated by the Department.

If the CHC-MCO fails to submit Drug Encounter Data, then the Department shall impose a sanction of Twenty-Five Thousand Dollars ($25,000.00) per quarter until the CHC-MCO is compliant.

The CHC-MCO or subcontractor may not negotiate rebates and discounts for Covered Drugs. The CHC-MCO or subcontractor may not negotiate rebates and discounts for non-drug products included on the Statewide PDL. If the CHC-MCO negotiates and collects its own rebates and discounts for non-drug products that are not included on the Statewide PDL, the CHC-MCO must report to the Department the full value of the rebates and discounts in a format designated by the Department. If the CHC-MCO assigns responsibility for negotiating and/or collecting the rebates and discounts for non-drug products not included on the Statewide PDL to a subcontractor, the subcontractor must pass the full value of all rebates and discounts on drugs dispensed to the CHC-MCO's Participants back to the CHC-MCO. The subcontractor may not retain any portion of the rebates or discounts. The CHC-MCO must report the full value of the rebates and discounts to the Department in a format designated by the Department.

9. Drug Encounters

a. The CHC-MCO shall submit all Drug Encounters to the Department within thirty (30) days (for NCPDP) and 90 days (for 837P and 837I) of the adjudication date of the claim to the CHC-MCO for payment.

b. The CHC-MCO shall provide all Pharmacy Drug Encounter Data and supporting information as specified below for the Department to collect rebates through the Medicaid Drug Rebate Program and the Statewide PDL. For all Drug Encounter Data, including pharmacy point-of-sale (NCPDP), physician-administered drugs (837P), hospital drugs (837I), and drugs dispensed by 340B-covered entities and contract pharmacies, the following data elements are required:

i. Valid NDC for the drug or product dispensed.

1. The CHC-MCO shall also include the HCPCS code associated with the NDC for all 837P and 837I Encounters where payment was made by the CHC-MCO based on the HCPCS code and HCPCS code units.
2. The CHC-MCO shall also include the diagnosis codes associated with the NDC for all 837P and 837I Encounters where payment was made by the CHC-MCO based on the HCPCS code and HCPCS code units.

ii. Valid NDC units for the drug or product dispensed.

1. The CHC-MCO shall also include the HCPCS units associated with the NDC for all 837P and 837I Encounters where payment was made by the CHC-MCO based on the HCPCS code and HCPCS code units.

iii. Actual paid amount by the CHC-MCO to the Provider for the drug

dispensed.

iv. Actual TPL amount paid by the Participant's primary pharmacy coverage to the Provider for the drug dispensed.

v. Actual copayment paid by the Participant to the Provider for the drug dispensed.

vi. Actual dispensing fee paid by the CHC-MCO to the Provider for the drug dispensed.

vii. The billing Provider's:

1. NPI and/or Medical Assistance Identification Number.

2. Full address and phone number associated with the NPI.

viii. The prescribing Provider's:

1. NPI and/or Medical Assistance Identification Number.

2. Full address and phone number associated with the NPI.

ix. The date of service for the dispensing of the drug by the billing Provider.

x. The date of payment by the CHC-MCO, or the CHC-MCO's PBM, to the Provider for the drug.

xi. Any other data elements identified by the Department to invoice for drug rebates.

c. The CHC-MCO shall edit and validate claim transaction submissions and Drug Encounter Data for completeness and accuracy in accordance with claim standards such as NCPDP. The actual paid amount by the CHC-MCO to the dispensing Provider must be accurately submitted on each pharmacy Encounter to the Department.

d. The CHC-MCO shall ensure that the NDC on all Drug Encounters is appropriate for the HCPCS code based on the NDC and units billed.

e. The Department will review the Drug Encounters and remove applicable 340B covered entity Encounters from the drug rebate invoicing process.

f. The CHC-MCO shall meet Drug Encounter Data accuracy requirements by submitting CHC-MCO paid pharmacy Encounters with no more than a three percent (3%) error rate, calculated for a month's worth of Encounter submissions. The Department will monitor the CHC-MCO's corrections to denied Encounters by random sampling performed quarterly and over the term of this Agreement. The CHC-MCO shall have corrected and resubmitted

seventy-five percent (75%) of the denied Encounters for services covered under this Agreement included in the random sample within thirty (30) calendar days of denial.

g. If the CHC-MCO fails to submit Drug Encounter data within timeframes specified, the Department shall assess civil monetary penalties upon the CHC-MCO. These penalties shall be Two Thousand Dollars ($2,000.00) for each calendar day that the Drug Encounter Data is not submitted. The Department may waive these sanctions if it is determined that the CHC-MCO was not at fault for the late submission of the data.

10. Prospective Drug Utilization Review (Pro-DUR)

a. The CHC-MCO must provide for a review of drug therapy before each prescription is filled or delivered to a Participant at the point-of-sale or point-of-distribution. The review shall include screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions and clinical abuse/misuse.

b. The CHC-MCO must provide for counseling of Participants receiving benefits from pharmacists in accordance with State Board of Pharmacy requirements.

11. Retrospective Drug Utilization Review (Retro-DUR)

a. The CHC-MCO must, through its drug claims processing and information retrieval system, examine claims data and other records to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and Participants.

b. The CHC-MCO shall, on an ongoing basis, assess data on drug use against explicit predetermined standards (using nationally recognized compendia and peer-reviewed medical literature), including but not limited to monitoring for therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, and clinical abuse/misuse, and, as necessary, introduce remedial strategies, in order to improve the quality of care.

c. The CHC-MCO shall provide for active and ongoing educational outreach programs to educate practitioners on common drug therapy problems aimed at improving prescribing or dispensing practices.

12. Annual DUR Report

The CHC-MCO must submit an annual report on the operation of its Pennsylvania Medicaid Drug Utilization Review (DUR) program in a format designated by the Department. The format of the report will include a description of the nature and scope of the prospective and retrospective drug use review programs, a summary of the interventions used, an assessment of the impact of these educational interventions on quality of care, and an estimate of the cost savings generated as a result of the DUR program.

13. Drug Utilization Review Board (DUR Board)

The Department maintains a DUR Board that reflects the structure of the healthcare delivery model that includes both a managed care and a Fee-for-Service delivery system. Each CHC-MCO that does not already include a PH-MCO representative and each BH-MCO is required to include a representative to serve as a member of the DUR Board. The DUR Board is a standing advisory committee that recommends the application of predetermined standards related to Pro-DUR, Retro-DUR, and related administrative and educational interventions designed to protect the health and safety of the Medical Assistance Program Participants. The Board reviews and evaluates pharmacy claims data and prescribing practices for efficacy, safety, and quality against predetermined standards using nationally recognized drug compendia and peer-reviewed medical literature as a source. The Board recommends appropriate utilization controls and protocols, including Prior Authorization, automated Prior Authorization, system edits, guidelines to determine medical necessity, generic substitution, and quantity limits for individual medications or for therapeutic categories.

14. Pharmacy Benefit Manager (PBM)

The CHC-MCO may use a PBM to process prescription Claims only if the PBM Subcontract complies with the provisions in Section XII, Subcontractual Relationships, Exhibit P: Required Contract Terms for Administrative Subcontractors, and has received advance written approval by the Department. The standards for Network composition and adequacy for Covered Drug services includes the requirements for any willing pharmacy as described above. The CHC-MCO must indicate the intent to use a PBM, identify the proposed PBM Subcontract and the ownership of the proposed PBM subcontractor.

The PBM subcontract must be submitted in unredacted format to the Department for review and written approval prior to implementation, prior to implementation of any changes, and annually thereafter. Changes that only impact non-Community HealthChoices lines of business do not need to be submitted for Department approval. The final Department-approved, fully executed, and unredacted CHC-MCO and PBM subcontract must be submitted to the Department.

If the PBM is owned wholly, in part, or by the same parent company as a CHC-

MCO, retail pharmacy Provider, chain drug store or pharmaceutical manufacturer, the CHC-MCO must submit a written description of the assurances and procedures that will be put in place under the proposed PBM Subcontract, such as an independent audit, to assure confidentiality of proprietary information. These assurances and procedures must be submitted and receive advance written approval by the Department prior to initiating the PBM Subcontract. The Department will allow the continued operation of existing PBM Subcontracts while the Department is reviewing new contracts.

The CHC-MCO must:

a. Report the PBM's payment methodology, or methodologies for actual payment to all network pharmacy providers of covered drugs, including community pharmacies, long-term care pharmacies, network pharmacies contracted to provide specialty drugs, and dispensing prescribers for existing PBM Subcontractors and new PBM Subcontractors.

b. Submit unredacted PBM contracts with the CHC-MCO's network pharmacies upon request.

c. Include on each drug encounter the PBM received amount (amount paid to the PBM by the CHC-MCO [ingredient cost and dispensing fee]) and the provider received amount (the actual amount paid by the PBM [ingredient cost and dispensing fee] to the dispensing pharmacy or prescribing provider.

d. Report any differences between the amount paid by the CHC-MCO to the PBM and the amount paid by the PBM to the providers of covered drugs as other fees.

e. Report all PBM fees charged to the CHC-MCO and to the pharmacy provider, in a format designated by the Department.

f. Submit a written description of the procedures that the CHC-MCO will put in place to monitor the PBM for compliance with the term and conditions of the Agreement related to covered drugs and actual payments to the providers of covered drugs.

g. Upon request by the Department, conduct an independent audit of the PBM's transparent pricing arrangement in compliance with the provision in Exhibit O CHC Audit Clause.

h. Ensure that the PBM is fully compliant with the requirements in Section V. T. Provider Dispute Resolution System.

i. Develop, implement, and maintain a Second Level PBM Provider Pricing Dispute Resolution Process that provides for settlement of a PBM network Provider's pricing dispute with the PBM, on the condition that the PBM's network Provider exhausted all of its remedies against the PBM.

j. Submit to the Department, prior to implementation, the CHC-MCO's policies and procedures relating to the resolution of PBM Provider pricing disputes.

i. The CHC-MCO must submit any changes to the policies and procedures to the Department for approval prior to implementation of the changes.

ii. The CHC-MCO's submission of new or revised policies and procedures for review and approval by the Department shall not act to void any existing policies and procedures that have been prior approved by the Department for operation in a CHC zone. Unless otherwise required by law, the CHC-MCO may continue to operate under such existing policies and procedures until the Department approves the new or revised version.

k. At a minimum, include in the CHC-MCO's Second Level PBM Provider Pricing Dispute Resolution policies and procedures the following:

i. The process for submission and settlement of Second Level PBM Provider Pricing Disputes;

ii. A requirement that the PBM Provider must exhaust all of its remedies against the PBM before requesting a CHC-MCO Second Level PBM Provider Pricing Dispute Resolution;

iii. Acceptance and usage of the Department's definition/delineation of Provider Disputes;

iv. Timeframes for submission and resolution of Second Level PBM Provider Pricing Disputes;

v. Processes to ensure equal treatment of all PBM providers in the resolution of pricing disputes.

vi. Process to ensure the paid amount reflects the pharmacy's drug acquisition cost, professional services, and cost to dispense the prescription to an MA beneficiary.

vii. A requirement for both the PBM Provider and the PBM to provide documentation supporting each entity's position(s) related to the pricing dispute;

viii. Designation of CHC-MCO staff responsible for resolution of the PBM Provider Pricing Dispute who have:

- The knowledge and expertise to address and resolve PBM Provider Pricing Disputes;
- Access to data and documentation of the informal resolution of the PBM Provider Dispute and the formal PBM Provider

Appeal and decisions necessary to assist in making decisions; and

ix. Mechanisms and time-frames for reporting CHC-MCO PBM Provider Pricing Dispute decisions to the PBM Provider, the PBM and the Department. If the dispute is denied by the CHC-MCO, the Provider Pricing Dispute decisions must include the specific rationale for the denial;

l. Require the PBM and the PBM provider to abide by the final decision of the CHC-MCO. If the Provider Pricing Dispute is overturned by the CHC-MCO, adjustment must be made to the appealed claim and to future claims for the appealed drug. The PBM/CHC-MCO must update their payment methodology for the appealed drug; and

m. Require the PBM to inform all PBM providers of the process and conditions to request a Second Level PBM Provider Pricing Dispute.

15. Requirements for CHC-MCO and BH-MCO Interaction and Coordination of Drug Services

a. BH-MCO prescribing Providers must comply with the CHC-MCO requirements for Utilization Management of behavioral health drugs.

b. The BH-MCO will be required to issue an initial list of BH-MCO Providers to the CHC-MCO, and quarterly updates that include additions and terminations. Should the CHC-MCO receive a request to dispense medication prescribed by a BH Provider not listed on the BH-MCO's Provider file, the CHC-MCO must work through the appropriate BH-MCO to identify the Provider. The CHC-MCO is prohibited from denying prescribed medications solely on the basis that the BH-MCO Provider is not clearly identified on the BH-MCO Provider file.

c. Payment for inpatient pharmaceuticals during a BH admission is the responsibility of the BH-MCO and is included in the hospital charge.

d. The CHC-MCO may deny payment of a Claim for a Covered Drug prescribed by a BH-MCO Provider only if one of the following occurs:

i. The drug is not being prescribed for the treatment of substance use disorder or mental illness and any side effects of psychopharmacological agents. Those drugs are to be prescribed by the CHC-MCO's PCP or specialists in the Participant's CHC-MCO Network.

ii. The prescription has been identified as a case of Fraud, Abuse, or gross

overuse, or the dispensing pharmacist determined that taking the medication either alone or along with other medications that the Participant may be taking would jeopardize the health and safety of the Participant.

e. The CHC-MCO must receive written approval from the Department of the policies and procedures for the CHC-MCO and BH-MCO to:

   i. When deemed advisable, require consultation between practitioners before prescribing medication, and sharing complete, up-to-date medication records.

   ii. Comply with any CHC-BH MCO drug data exchange procedures specified by the Department.

   iii. Timely resolve disputes which arise from the payment for or use of drugs, including a mechanism for timely, impartial mediation when resolution between the CHC-MCO and BH-MCO does not occur.

   iv. Share independently developed Quality Management/Utilization Management information related to drug services, as applicable.

   v. Collaborate in adhering to a drug utilization review program approved by the Department. Collaborate in identifying and reducing the frequency of patterns of Fraud, Abuse, gross overuse, inappropriate or medically unnecessary care among physicians, pharmacists and Participants associated with specific drugs.

EXHIBIT E

PRIOR AUTHORIZATION GUIDELINES FOR THE CHC-MCO

A. GENERAL REQUIREMENT

The CHC-MCOs must submit to the Department all written policies and procedures for the Prior Authorization of services. Prior authorization is not required for Family Planning services (V.A.6), Emergency Services (see V.A.8), or services for which Medicare is the primary payor except where Medicare has denied the service. The CHC-MCO may require Prior Authorization for any services that require Prior Authorization in the Medical Assistance Fee-for-Service (FFS) Program. The CHC-MCO must notify the Department of the FFS authorized services they will continue to prior authorize and the basis for determining if the service is Medically Necessary. The CHC-MCO must receive advance written approval from the Department to require the Prior Authorization of any services not currently required to be Prior Authorized under the FFS Program. For each service to be Prior Authorized, the CHC-MCO must submit for the Department's review and approval the written policies and procedures in accordance with the guidelines described below. The policies and procedures must:

- Be submitted in writing, for all new and revised criteria, prior to implementation;
- Be approved by the Department in writing prior to implementation;
- Adhere to specifications of the CHC RFP, this Agreement, the CHC 1915(c) Waiver, federal regulations, and Department regulations, including 55 Pa. Code Chapter 1101;
- Ensure that Covered Services are Medically Necessary and provided in an appropriate, effective, timely, and cost-efficient manner;
- Adhere to the applicable requirements of Centers for Medicare and Medicaid Services (CMS) Guidelines for Internal Quality Assurance Programs of Health Maintenance Organizations (HMOs), Health Insuring Organizations, and Prepaid Health Plans (PHPs), contracting with Medicaid/Quality Assurance Reform Initiative (QARI);
- Include an expedited review process to address those situations when an item or service must be provided on an urgent basis;
- Specify that Person-Centered Service Plans serve as Prior Authorization for the services outlined therein.

Future changes in State and Federal statutes, regulations, or court cases may require re-evaluation of any previously approved Prior Authorization proposal. Any deviation from the policies and procedures approved by the Department, including time frames for decisions, is considered to be a change and requires a new request for approval. Failure of the CHC-MCO to comply may result in sanctions and/or penalties by the Department.

The Department defines Prior Authorization as a determination made by a CHC-MCO to approve or deny payment for a Provider's request to provide a service or course of treatment of a specific duration and scope to a Participant prior to the Provider's initiation or continuation of the requested service.

The Department's Prior Authorization Review Panel (PARP) has the sole responsibility to review and approve all Prior Authorization proposals from the CHC-MCOs.

B. GUIDELINES FOR REVIEW

1. Basic Requirements:

   a. The CHC-MCO must identify individual service(s), medical item(s), and/or therapeutic categories of drugs to be Prior Authorized.

   b. If the Prior Authorization is limited to specific populations, the CHC-MCO must identify all populations who will be affected by the proposal for Prior Authorization.

2. Medically Necessary Requirements:

   a. The CHC-MCO must describe the process to validate medical necessity for:

      - covered care and services;
      - procedures and level of care;
      - medical or therapeutic items.

   b. The CHC-MCO must identify the source of the criteria used to review the request for Prior Authorization of services. The criteria must be consistent with the CHC Agreement definition for a service or benefit that is Medically Necessary. All criteria must be submitted to the Department for evaluation and approval under Utilization Review Criteria Assessment Process (URCAP).

   c. For CHC-MCOs, if the criteria being used are:

      - Purchased and licensed, the CHC-MCO must identify the vendor;
      - Developed/recommended/endorsed by a national or state Provider association or society, the CHC-MCO must identify the association or society;
      - Based on national best practice guidelines, the CHC-MCO must identify the source of those guidelines;
      - Based on the medical training, qualifications, and experience of the CHC-MCO's Medical Director, Dental Director, or other qualified and trained practitioners, the CHC-MCO must identify the individuals who will determine if the service or benefit is Medically Necessary.

d. CHC-MCO guidelines to determine medical necessity of all drugs that require Prior Authorization must be posted for public view on the CHC-MCO's website. This includes, but is not limited to, guidelines to determine medical necessity of both specific drugs and entire classes of drugs that require Prior Authorization for health and safety reasons, non-formulary designations, appropriate utilization, quantity limits, or mandatory generic substitution. The guidelines must specify all of the conditions that the CHC-MCO reviewers will consider when determining medical necessity, including requirements for step therapy.

e. The CHC-MCO must identify the qualification of staff that will determine if the service is Medically Necessary.

   Requests for service will not be denied for lack of Medical Necessity unless a physician or other healthcare professional with appropriate clinical expertise in treating the Participant's condition or disease determines:

   - That the prescriber did not make a good faith effort to submit a complete request, or

   - That the service or item is not Medically Necessary, after making a reasonable effort to consult with the prescriber. The reasonable effort to consult must be documented in writing.

f. The CHC-MCO must outline how the Service Planning process with PCPT approach will ensure that Medically Necessary services specified in the Person-Centered Service Plan are authorized by virtue of inclusion in the Person-Centered Service Plan and processed into all appropriate systems.

g. In accordance with Section V.I., the CHC-MCO must outline which PCSP changes during the period covered by the PCSP may be made by the Participant and Service Coordinator without PCPT involvement and which must be made by the CHC-MCO in accordance with the CHC-MCO Prior Authorization plan and must outline the timeframes specified in V.B.2.

h. For LTSS in home and community-based settings, Covered Services will be authorized in accordance with the requirements of the CHC 1915(c) Waiver.

3. <u>Administrative Requirements</u>

a. The CHC-MCO's written policies and procedures must identify the time frames for review and decisions and the CHC-MCO must demonstrate that the time frames are consistent with the requirements specified in V.B.2 and Exhibit D for drug services.

b. The CHC-MCO's written policies and procedures must demonstrate how the CHC-MCO will ensure adequate care management and overall continuity of care among all levels and specialty areas.

c. The CHC-MCO's written policies and procedures must explain how Prior

Authorization data will be incorporated into the CHC-MCO's overall Quality Management plan.

4. Notification, Grievance, and DHS Fair Hearing Requirements

   The CHC-MCO must demonstrate how written policies and procedures for requests for Prior Authorization comply and are integrated with the Participant and Provider notification requirements and Participant Grievance and DHS Fair Hearing requirements of the RFP and Agreement.

5. Requirements for Care Management/Care Coordination of Non Prior Authorized Service(s)/Items(s)

   For purposes of tracking care management/identification of certain diagnoses or conditions, and with advance written approval from the Department, the CHC-MCO may choose to establish a process or protocol requiring notification prior to service delivery. This process must not involve any approvals/denials or delays in receiving the service. The CHC-MCO must notify Providers of this notification requirement. This process may not be administratively cumbersome to Providers and Participants. These situations need not comply with the other Prior Authorization requirements contained in this Exhibit.

EXHIBIT F

QUALITY MANAGEMENT AND UTILIZATION MANAGEMENT PROGRAM REQUIREMENTS

The Department will monitor the QM and UM programs of the CHC-MCO and retains the right of advance written approval of all QM and UM activities. The CHC-MCO's QM and UM programs must incorporate all the requirements outlined in this Agreement and must be designed to assure and improve the accessibility, availability, and quality of care and services being provided to its Participants. The CHC-MCO's QM and UM programs must, at a minimum:

A. Contain a written program description, work plan, evaluation and policies/procedures that meet requirements outlined in this Agreement;

B. Allow for the development and implementation of an annual work plan of activities that focuses on areas of importance as identified by the CHC-MCO in collaboration with the Department;

C. Be based on statistically valid clinical and financial analysis of Encounter Data, Participant demographic information, HEDIS, CAHPS, Pennsylvania Performance Measures and other data that allows for the identification of prevalent medical conditions, barriers to care and services and racial/ethnic disparities to be targeted for quality improvement, case and disease management initiatives;

D. Allow for the continuous evaluation of its activities and adjustments to the program based on these evaluations;

E. Submit all reports on data elements and quality measures as required, and in the manner to be required by the Department;

F. Demonstrate sustained improvement for clinical performance over time;

G. Allow for the timely, complete, and accurate reporting of Encounter Data and other data required to demonstrate clinical and service performance, including HEDIS and CAHPS as outlined in Exhibit W(2), Healthcare Effectiveness Data and Information Set (HEDIS®) and Consumer Assessment of Healthcare Providers and Systems (CAHPS®);

H. Include processes for the investigation and resolution of individual performance or quality of care issues whether identified by the CHC-MCO or the Department that:

   1) Allow for the tracking and trending of issues on an aggregate basis pertaining to patterns of care and services;

   2) Allow for submission of improvement plans, as determined by and within time frames established by the Department. Failure by the CHC-MCO to comply with

the requirements and improvement actions requested by the Department may result in the application of penalties and/or sanctions as outlined in Section VIII.I, Sanctions, of the Agreement.

I. Obtain accreditation by a nationally recognized organization, such as National Committee for Quality Assurance (NCQA);

J. Obtain NCQA Health Equity or the Health Equity Plus accreditation by July 1, 2024. ; and

K. Comply with National Quality Forum or other LTSS quality requirements as designated by the Department.

L. Determine whether algorithms used for case management, disease management, quality management, or decisions about which enrollees receive additional services from the CHC-MCO, contain inadvertent racial bias. If any racial bias is identified, the CHC-MCO must take steps to eliminate that bias to the satisfaction of the Department. As part of the determination of whether the algorithms contain racial bias and the elimination of racial bias, the CHC-MCO will work with entities designated by the Department to identify bias and the actions that can be taken to eliminate or mitigate bias.

Standard I: The scope of the QM and UM programs must be comprehensive in nature, allow for improvement and be consistent with the Department's goals related to access, availability, and quality of care and services. At a minimum, the CHC-MCO's QM and UM programs must:

A. Adhere to current Medicaid CMS guidelines.

B. Be developed and implemented by professionals with adequate and appropriate experience in QM/UM and techniques of peer review.

C. Ensure that that all QM and UM activities and initiatives undertaken by the CHC-MCO are based upon clinical and financial analysis of Encounter Data, Participant demographic information, HEDIS, CAHPS, Pennsylvania Performance Measures and/or other identified areas.

D. Contain policies and procedures which provide for the ongoing review of the entire scope of care and services provided by the CHC-MCO, assuring that all demographic groups, races, ethnicities, disabilities, care and service settings and types and models of services are addressed.

E. Contain a written program description that addresses all standards, requirements and objectives established by the Department and that describes the goals, objectives, and structure of the CHC-MCO's QM and UM programs. The written program description must, at a minimum:

1) Include standards and mechanisms for ensuring the accessibility of primary care services, specialty care services, urgent care services, and Participant services in accordance with timeframes outlined in Exhibit T, Provider Network Composition/Service Access.

2) Distinct policies and procedures regarding how Service Coordinators will authorize LTSS and communicate those authorizations to providers.

3) Include mechanisms for planned assessment and analysis of the quality of care and services provided and the utilization of services against formalized standards, including but not limited to:

   a) Primary, secondary, and tertiary care;
   b) Preventive care and wellness programs;
   c) Acute and/or chronic conditions;
   d) Emergency Department utilization and ED diversion efforts;
   e) Dental care;
   f) LTSS;
   g) Service Coordination; and
   h) Continuity of care.

4) Allow for the timely, accurate, complete collection and clinical and financial analysis of Encounter Data and other data including, but not limited to, HEDIS, CAHPS, and Pennsylvania Performance Measures.

5) Allow for systematic analysis and re-measurement of barriers to care and services, the quality of care and services provided to Participants, and utilization of services over time.

F. Provide a comprehensive written evaluation, completed on at least an annual basis, that details all QM and UM program activities including, but not limited to:

   a) Studies and activities undertaken, including the rationale, methodology and results;
   b) Subsequent improvement actions; and
   c) Aggregate clinical and financial analysis of Encounter, HEDIS, CAHPS, Pennsylvania Performance Measures, and other data on the quality of care rendered to Participants and utilization of services.

G. Include a work plan and timetable for the coming year which clearly identifies target dates for implementation and completion of all phases of all QM activities, including, but not limited to:

   1) Data collection and analysis;
   2) Evaluation and reporting of findings;
   3) Implementation of improvement actions where applicable; and
   4) Individual accountability for each activity.

H. Provide for aggregate and individual analysis and feedback of Provider

performance and CHC-MCO performance in improving access to Covered Services, the quality of care and services provided to Participants and utilization of Covered Services.

I. Include mechanisms and processes which ensure that related and relevant operational components, activities, and initiatives from the QM and UM programs are integrated into activities and initiatives undertaken by other departments within the CHC-MCO including, but not limited to, the following:

1) Provider Relations;
2) Participant Services; and
3) Management Information Systems.

J. Include procedures for informing both physician and non-physician Providers about the written QM and UM programs, and for securing cooperation with the QM and UM programs in all physician and non-physician Provider Agreements.

K. Include procedures for feedback and interpretation of findings from analysis of quality and utilization data to Providers, health professionals, CHC-MCO staff, and Medical Assistance Consumers/family members.

L. Include mechanisms and processes which allow for the development and implementation of CHC-MCO-wide and Provider-specific improvement actions in response to identified barriers to care and services, quality of care and services concerns; and overutilization, underutilization, and misutilization of services.

M. The CHC-MCO shall provide for methods of assuring the appropriateness of inpatient care. Such methodologies as described below shall be based on individualized determinations of medical necessity in accordance with UM policies and procedures.

- Pre-admission certification process for non-emergency admissions;
- A concurrent review program to monitor and review continued inpatient hospitalization, length of stay, or diagnostic ancillary services regarding their appropriateness and medical necessity. In addition, the CHC-MCO shall have a process in place to determine for emergency admissions, based upon medical criteria, if and when a Participant can be transferred to a contract facility in the network, if presently in a non-contract facility;
- Admission review for urgent and/or emergency admissions, on a retroactive basis when necessary, in order to determine if the admission is medically necessary and if the requested length of stay for the admission is reasonable based upon an individualized determination of medical necessity. Such reviews shall not result in delays in the provision of medically necessary urgent or emergency care;
- Restrictions against requiring pre-admission certification for admissions for the normal delivery of children; and
- Prospective review of same day surgery procedures.

N. The CHC-MCO shall ensure that reimbursement of nursing facility care is provided for Participants who have been determined to be eligible for reimbursement of nursing facility care for the period specified. The CHC-MCO shall monitor the Participant's condition for ongoing care and potential discharge back to community living.

O. The CHC-MCO shall utilize the following guidelines in identifying and managing care for Participants who are determined to have excessive and/or inappropriate ED utilization:

- Review ED utilization data, at a minimum, every six (6) months to identify Participants with utilization exceeding the threshold defined as six (6) or more visits in the defined six (6) month period (January through June, and July through December);
- For Participants whose utilization exceeds the threshold of ED visits defined above in the previous six (6) month period, the CHC-MCO shall conduct appropriate follow-up to identify the issues causing frequent ED utilization and determine appropriate next steps.
- As appropriate, make contact with Participants whose utilization exceeded the threshold of ED visits in the previous six (6) month period and their primary care providers for the purpose of providing education on appropriate ED utilization.
- Assess the most likely cause of high utilization and develop a PCSP based on results of the assessment for each Participant.

P. The CHC-MCO shall comply with any applicable Federal and State laws or rules related to length of hospital stay.

Q. In addition to meeting the reporting requirement for oversight and monitoring of the program, the CHC-MCO must report all information required for early implementation evaluation, as outlined by the Department. The CHC-MCO must also comply with all implementation, monitoring, and oversight requirements. The CHC-MCO must comply with any program policy changes resulting from the Department's rapid cycle, implementation monitoring, or other evaluation of the CHC Program.

Standard II: The organizational structures of the CHC-MCO must ensure that:

A. The Governing Body:

1) Has formally designated an accountable entity or entities within the CHC-MCO to provide oversight of QM and UM program activities or has formally decided to provide such oversight as a committee, e.g., Quality Management Committee.

2) Regularly receives written reports on the QM and UM program activities that describe actions taken, progress in meeting objectives and improvements made. The governing body formally reviews, on at least an annual basis, a

written evaluation of the QM and UM program activities that includes studies undertaken, results of studies, and subsequent improvement actions taken. The written evaluation must include aggregate clinical and financial analysis of quality and utilization data, including HEDIS, CAHPS, and Pennsylvania Performance Measures.

3) Documents actions taken by the governing body in response to findings from QM and UM program activities.

B. The Quality Management Committee (QMC):

1) Must contain policies and procedures which describe the role, structure and function of the QMC that:

a) Demonstrate that the QMC has oversight responsibility and input, including review and approval, on all QM and UM program activities;

b) Ensure membership on the QMC and active participation by individuals representative of the composition of the CHC-MCO's Providers; and

c) Provide for documentation of the QMC's activities, findings, recommendations, and actions.

2) Meets at least monthly, and otherwise as needed.

C. The Director of LTSS ensures the provision of LTSS in home and community-based settings is provided in accordance with the requirements outlined in this Agreement and the CHC 1915(c) Waiver.

D. The Director of Quality Management serves as liaison and is accountable to the governing body and Quality Management Committee for all QM and UM activities and initiatives.

E. The Senior Medical Director must be directly accountable to and act as liaison to the Department's Chief Medical Officer.

F. The Medical Director:

1) Is available to the CHC-MCO's medical staff for consultation on referrals, denials, Complaints and problems;

2) Is directly involved in the CHC-MCO's recruiting and credentialing activities;

3) Is familiar with local standards of medical practice and nationally accepted standards of practice, including those for LTSS and with "most integrated setting" requirements under the ADA;

4) Has knowledge of due process procedures for resolving issues between Network Providers and the CHC-MCO administration, and between

participants and the CHC-MCO, including those related to medical decision making and utilization review;

5) Is available to review, advise and take action on questionable hospital admissions, Medically Necessary days and all other medical care and medical cost issues;

6) Is directly involved in the CHC-MCO's process for prior authorizing or denying services and is available to interact with Providers on denied authorizations;

7) Has knowledge of current peer review standards and techniques;

8) Has knowledge of risk management standards;

9) Is directly accountable for all Quality Management and Utilization Management activities; and

10) Oversees and is accountable for:

a) Referrals to the Department and appropriate agencies for cases involving quality of care and services that have adverse effects or outcomes; and

b) The processes for potential Fraud, Waste, and Abuse audit, investigation, review, sanctioning, and referral to the appropriate oversight agencies.

G. The CHC-MCO must have sufficient material resources, and staff with the appropriate education, experience and training, to effectively implement the written QM and UM programs and related activities.

Standard III: The QM and UM programs must include methodologies that allow for the objective and systematic monitoring, measurement, and evaluation of the quality and appropriateness of care and services provided to Participants through quality of care studies and related activities with a focus on identifying and pursuing opportunities for continuous and sustained improvement.

A. The QM and UM programs must include professionally developed practice guidelines/standards of care and services that are:

1) Written in measurable and accepted professional formats;
2) Based on scientific evidence; and
3) Applicable to Providers for the delivery of certain types or aspects of healthcare or LTSS.

B. The QM and UM programs must include clinical/quality Indicators in the form of written, professionally developed, objective and measurable variables of a specified clinical or health services delivery area, which are reviewed over a period

of time to screen delivered healthcare and/or monitor the process or outcome of care delivered in that clinical area.

C. Practice guidelines and clinical indicators must address the full range of healthcare and LTSS needs of the populations served by the CHC-MCO. The areas addressed must include but are not limited to:

1) Adult preventive care;
2) LTSS;
3) Service Coordination provision;
4) Obstetrical care, including a requirement that Participants be referred to obstetricians or certified nurse midwives at the first visit during which pregnancy is determined;
5) Selected diagnoses and procedures relevant to the CHC-MCO's Participant population;
6) Selected diagnoses and procedures relevant to racial and ethnic subpopulations within the CHC-MCO's Participant population; and
7) Preventive dental care.

D. The QM and UM programs must provide practice guidelines, clinical indicators, and medical record keeping standards to all Providers, appropriate subcontractors, and to potential Participants upon request. This information must also be provided to Participants upon request.

E. The CHC-MCO must develop methodologies for assessing performance of PCPs/PCP sites, high risk/high volume specialists, dental Providers, LTSS Providers, and Providers of ancillary services not less than every two (2) years (i.e., medical record audits). These methodologies must, at a minimum:

1) Demonstrate the degree to which PCPs, specialists, and dental Providers are complying with clinical and preventive care guidelines adopted by the CHC-MCO;

2) Demonstrate the degree to which LTSS Providers are complying with requirements of the Department and the CHC-MCO;

3) Allow for the tracking and trending of individual and CHC-MCO-wide Provider performance over time;

4) Include active mechanisms and processes that allow for the identification, investigation and resolution of quality of care and services concerns, including events such as Healthcare-Associated Infections, medical errors, and adverse patient outcomes; and

5) Include mechanisms for detecting instances of overutilization, underutilization, and misutilization.

F. The QM and UM program must have policies and procedures for implementing and monitoring improvement plans. These policies and procedures must include

the following:

1) Processes that allow for the identification, investigation and resolution of quality of care and services concerns, including Healthcare-Associated Infections, medical errors, and adverse patient outcomes;

2) Processes for tracking and trending patterns of care and services;

3) Use of progressive sanctions as indicated;

4) Person(s) or body responsible for making the final determinations regarding quality problems; and

5) Types of actions to be taken, such as:

   a) Education;
   b) Follow-up monitoring and re-evaluation;
   c) Changes in processes, structures, forms;
   d) Informal counseling;
   e) Procedures for terminating the affiliation with the physician or other health professional or Provider;
   f) Assessment of the effectiveness of the actions taken; and
   g) Recovery of inappropriate expenditures (e.g., related to Healthcare-Associated Infections, medical errors, and other inappropriate expenditures).

G. The QM and UM programs must include methodologies that allow for the identification, verification, and timely resolution of inpatient and outpatient quality of care and services concerns, Participant quality of care and services complaints, overutilization, underutilization, and/or misutilization, access/availability issues, and quality of care and services referrals from other sources;

H. The QM and UM programs must contain procedures for Participant satisfaction surveys that are conducted on at least an annual basis, including the collection of annual Participant satisfaction data through application of the CAHPS instrument as outlined in Exhibit W(2), Healthcare Effectiveness Data and Information Set (HEDIS®) and Consumer Assessment of Healthcare Providers and Systems (CAHPS®). The Department will continue to monitor the development of evidence-based LTSS satisfaction surveys and reserves the right to implement a CAHPS, CAHPS-like, or other survey at a later date.

I. The QM and UM programs must contain procedures for Provider satisfaction surveys to be conducted on at least an annual basis. Surveys are to include PCPs, specialists, LTSS Providers, Nursing Facilities, dental Providers, hospitals, and Providers of ancillary services.

J. Each CHC-MCO will be required to comply with requirements for Performance Improvement Projects (PIPs) as outlined in Exhibit W, External Quality Review.

K. The QM and UM programs must contain procedures for measuring Participant and Provider satisfaction with LTSS Service delivery.

Standard IV: The QM and UM programs must objectively and systematically monitor and evaluate the appropriateness and cost effectiveness of care and services provided to Participants through utilization review activities with a focus on identifying and correcting instances and patterns of overutilization, underutilization and misutilization.

A. Semi-annually, or more frequently as appropriate, the QM and UM programs must provide for production and distribution to Providers, (in either hard copy or web-based electronic formats) profiles comparing the average medical care utilization rates of the Participants of each PCP to the average utilization rates of all CHC-MCO Participants. The CHC-MCO must develop statistically valid methodologies for data collection (Denominator must be ≥ 30 participants) regarding Provider profiling. PCP can be defined as individual PCP or can be group practices identified by group tax ID or NPI numbers. Profiles shall include, but not be limited to:

1) Utilization information on Participant Encounters with PCPs;
2) Specialty Claims;
3) Prescriptions;
4) Inpatient stays;
5) Nursing Facility use;
6) Community-based LTSS use;
7) Emergency room use; and
8) Clinical indicators for preventive care services (i.e., mammograms, immunizations, pap smears, etc.).

B. The CHC-MCO must have mechanisms and processes for profiling all Providers using risk-adjusted diagnostic data for profiles.

C. The CHC-MCO must have mechanisms and processes for aggregate trending of changes to services and reporting aggregate data to the Department.

D. The QM and UM programs must implement statistically valid methodologies for analysis and follow-up of semi-annual practitioner utilization profiles for patterns and instances of overutilization, underutilization, and misutilization across the continuum of care and services, as well as trending of Provider utilization patterns over time. Follow up includes but is not limited to Provider education, Provider improvement plans, and Provider sanctions as necessary.

E. The QM and UM programs must, at least annually, provide for verification of Encounter reporting rates and accuracy and completeness of Encounter information submitted by PCPs.

Standard V: The CHC-MCO must develop mechanisms for integration of case/disease and health management programs that rely on wellness promotion, prevention of complications, and treatment of chronic conditions for Participants identified. The CHC-MCO must have a Complex Case Management Program and a Disease Management Program that must:

A. Include mechanisms and processes that ensure the active collaboration and coordination of care and services for identified Participants.

B. Include mechanisms and processes that allow for the identification of conditions to be targeted for case/disease and health management programs and that allow for the assessment and evaluation of the effectiveness of these programs in improving outcomes for and meeting the needs of individuals with targeted conditions.

C. Include care guidelines and/or protocols for appropriate and effective management of individuals with specified conditions. These guidelines must be written in measurable and accepted professional formats and be based on scientific evidence.

D. Include performance indicators that allow for the objective measurement and analysis of individual and CHC-MCO-wide performance in order to demonstrate progress made in improving access and quality of care and services.

E. Include mechanisms and processes that lead to healthy lifestyles such as weight loss program memberships, gym memberships and asthma camps.

F. Include collaboration with the Department and Health Information Organizations (HIOs) to develop, adopt and disseminate a resource and referral tool.

G. Include meaningful participation in the DOH Health Equity Action Team for each region in which the CHC-MCO operates.

Standard VI: The QM and UM programs must have mechanisms to ensure that Participants receive seamless, continuous, and appropriate care and services throughout the continuum of care and services, including transitions between care setting and coverage, by means of coordination of care and services, benefits, and quality improvement activities between:

A. PCPs and specialty care practitioners and other Providers**;**

B. Other CHC-MCOs;

C. The CHC-MCO and Medicare D-SNPs whether aligned or not aligned;

D. The CHC-MCO and Medicare FFS or Medicare Advantage;

E. The CHC-MCO and HealthChoices BH-MCOs;

F. The CHC-MCOs and Physical Health HealthChoices MCOs;

G. The CHC-MCO and the Department's FFS Program;

H. The CHC-MCO and other third party insurers;

I. The CHC-MCOs and LIFE providers;

J. The CHC-MCOs and State Lottery-funded services;

K. The CHC-MCOs and Hospitals or Nursing Facilities; and

L. The CHC-MCO and any other agency providing services to the Participant.

Standard VII: The CHC-MCO must demonstrate that it retains accountability for all QM and UM program functions, including those that are delegated to other entities. The CHC-MCO must:

A. Have a written description of the delegated activities, the delegate's accountability for these activities, and the frequency of reporting to the CHC-MCO.

B. Have written procedures for monitoring and evaluating the implementation of the delegated functions and for verifying the actual quality of care and services being provided.

C. Document evidence of continuous and ongoing evaluation of delegated activities, including approval of quality improvement plans and regular specified reports.

D. Make available to the Department and its authorized representatives any and all records, documents, and data detailing its oversight of delegated QM and UM program functions.

E. Ensure that delegated entities make available to the Department and its authorized representatives any and all records, documents and data detailing the delegated QM and UM program functions undertaken by the entity of behalf of the CHC-MCO.

F. Compensation and payments to individuals or entities that conduct Utilization Management activities may not be structured so as to provide incentives for the individual or entity to deny, limit, or discontinue Medically Necessary services to any Participant.

Standard VIII: The QM/UM program must have standards for credentialing/ recredentialing Providers to determine whether all Providers who provide healthcare services or LTSS under contract to the CHC-MCO are qualified to perform their services.

A. The CHC-MCO must establish and maintain minimum credentialing and recredentialing criteria for all Provider types that satisfies the Department's requirements outlined in this Agreement and through the credentialing framework to be provided to plans. Recredentialing activities must be conducted by the CHC-MCO at least every five (5) years. Criteria must include, but not be limited to, the

following as applicable to the Provider type:

1) Appropriate license or certification as required by Pennsylvania state law;

2) Verification that each Provider has not been suspended, terminated, or party to a settlement for voluntary withdrawal from the Medicaid or Medicare Programs;

3) Verification that each Provider and subcontractor has a current Provider Agreement and an active MMIS Provider ID number issued by the Department;

4) Evidence of malpractice/liability insurance;

5) A valid Drug Enforcement Agency (DEA) certification;

6) Adherence to the Principles of Ethics of the American Medical Association, the American Osteopathic Association, or any appropriate professional organization involved in a multidisciplinary approach;

7) Consideration of quality issues such as Participant Complaint and/or Participant satisfaction information, sentinel events, and quality of care concerns.

B. For purposes of credentialing and recredentialing, the CHC-MCO must perform a check on all PCPs and other physicians by contacting the National Practitioner Data Bank (NPDB). If the CHC-MCO does not meet the statutory requirements for accessing the NPDB, then the CHC-MCO must obtain information from the Federation of State Medical Boards

C. Appropriate PCP qualifications:

1) Seventy-five to one hundred percent (75-100%) of the Network consists of PCPs who have completed an approved primary care residency in family medicine, osteopathic general medicine, internal medicine or geriatrics;

2) No more than twenty-five percent (25%) of the Network consists of PCPs without appropriate residencies but who have, within the past seven (7) years, five (5) years of post-training clinical practice experience in family medicine, osteopathic general medicine, internal medicine or geriatrics. Post-training experience is defined as having practiced at least as a half (0.5) full-time equivalent in the practice areas described;

3) No more than ten percent (10%) of the Network consists of PCPs who were previously trained as specialist physicians and changed their areas of practice to primary care, and who have completed Department-approved primary care retraining programs;

4) A PCP must have the ability to perform or directly supervise the ambulatory primary care services of Participants;

5) Membership of the medical staff with admitting privileges of at least one (1) general hospital or an acceptable arrangement with a PCP with admitting privileges;

6) Evidence of continuing professional medical education;

7) Attendance at least one CHC-MCO sponsored Provider education training session as outlined in Section V.AA.2, Provider Education;

8) Assurance that any CRNP, Certified Registered Midwife, or physician's assistant, functioning as part of a PCP team, is performing under the scope of his or her respective license.

D. As part of the Provider release form, the potential Provider must agree to release all MA records pertaining to sanctions and/or settlement to the CHC-MCO and the Department.

E. The Department will recoup from the CHC-MCO any and all payments made to a Provider that does not meet the enrollment and credentialing criteria for participation or is used by the CHC-MCO in a manner that is not consistent with the Provider's licensure.

F. The CHC-MCO must notify its PCPs and all subcontractors of the prohibitions and sanctions for the submission of false Claims and statements.

G. The CHC-MCO shall evaluate a Provider's professional qualifications through objective measures of competence and quality. Providers should be given the opportunity to have input on the CHC-MCO's credentialing practices.

H. Any economic profiles used by the CHC-MCOs to credential Providers should be adjusted to adequately account for factors that influence utilization independent of the Provider's clinical management, including Participant age, Participant sex, Provider case-mix and Participant severity. The CHC-MCO must report any utilization profile that it utilizes in its credentialing process and the methodology that it uses to adjust the profile to account for non-clinical management factors at the time and in the manner requested by the Department.

I. In the event that a CHC-MCO renders an adverse credentialing decision, the CHC-MCO must provide the affected Provider with a written notice of the decision. The notice should include a clear and complete explanation of the rationale and factual basis for the determination. The notice shall include any utilization profiles used as a basis for the decision and explain the methodology for adjusting profiles for non-clinical management factors. All credentialing decisions made by the CHC-MCO are final and may not be appealed to the Department.

J. The CHC-MCO must meet the following standards related to timeliness of processing new Provider applications for credentialing:

1) The CHC-MCO must begin its credentialing process upon receipt of a

Provider's credentialing application if the application contains all required information.

2) The CHC-MCO may not delay processing the application if the Provider does not have an MAID number that is issued by the Department. However, the CHC-MCO cannot complete its process until the Provider has received its MAID number from the Department.

3) Provider applications submitted to the CHC-MCO for credentialing must be completed within sixty (60) days of receipt of the application packet if the information is complete.

Standard IX: The CHC-MCO's UM program must have policies and procedures that describe the scope of the program, mechanisms, and information sources used to make decisions on Covered Services in conjunction with the requirements in Exhibit E, Prior Authorization Guidelines for the CHC-MCO.

A. The UM program must contain policies and procedures for Prospective, Concurrent, and Retrospective review and coverage decisions on Covered Services.

B. A PCSP shall be developed and implemented for all NFCE Participants and others who request or require Service Coordination. The CHC-MCO shall audit a Department-approved sample size of the PCSPs to demonstrate compliance with the requirements of the QM/UM program and the CHC monitoring report requirements. The CHC-MCO must use a protocol to select the PCSPs that either has been submitted to and reviewed and approved by the Department or that has been provided by the Department. Audit results must be submitted to the Department as part of the Annual QAPI Program Evaluation or the applicable CHC monitoring report.

C. The UM program must allow for coverage decisions about Covered Services that are consistent with the CHC definition of Medically Necessary found in Section II, Definitions, and the requirements of the CHC 1915(c) Waiver.

Coverage decisions for Covered Services, whether made on a Prior Authorization, Concurrent Review, or Retrospective Review basis, shall be documented in writing. The CHC-MCO shall base its determination on information provided by the Participant, the Participant's family/caretaker and the PCP, as well as any other Providers, programs and agencies that have evaluated the Participant. Medical necessity determinations must be made by qualified and trained Providers. A Provider who makes such determinations of Medical Necessity is not considered to be providing a healthcare service under this Agreement.

D. If the CHC-MCO wishes to require Prior Authorization of any services, it must establish and maintain written policies and procedures for the Prior Authorization review process as required under Section V.B., Prior Authorization of Services, and Exhibit E, Prior Authorization Guidelines for the CHC-MCO.

E. The CHC-MCO must provide all Licensed Proprietary Products that it will use in evaluating Medical Necessity for medical services. Licensed Proprietary Products may include but are not limited to Interqual and Milliman. All Utilization Review Guidelines and/or policies and procedures that contain Utilization Review Guidelines used to determine Medical Necessity must:

1) Require definitions of Medical Necessity that are consistent with the CHC definition of Medically Necessary;

2) Require that clinical reviewers make determinations of Medical Necessity that are consistent with the CHC definition of Medically Necessary;

3) Require that clinical reviewers assess the Participant's current condition and response to treatment and/or co-morbidities, psychosocial, environmental, and other needs that influence the need for care and services;

4) Provide direction to clinical reviewers on how to use clinical information gathered in making a determination to approve, deny, continue, reduce, or terminate a service;

5) Be developed using a scientific based process;

6) Be reviewed at least annually and updated as necessary; and

7) Provide for evaluation of the consistency with which clinical reviewers implement the guidelines on at least an annual basis.

F. The CHC-MCO must ensure that Prior Authorization and Concurrent review decisions:

1) Are made by an individual who has appropriate expertise in addressing the enrollee's medical, behavioral health, or LTSS needs;

2) That result in a denial may only be made by an individual who has appropriate expertise in addressing the enrollee's medical, behavioral health, or long-term services and supports needs;

3) Are made in accordance with established timeframes outlined in this Agreement for routine, urgent, or emergency care; and

4) Are made by clinical reviewers using the CHC definition of medical necessity.

G. The CHC-MCO must provide twenty-four (24) hour staff availability to authorize weekend services, including but not limited to: home healthcare, pharmacy, DME, LTSS, and medical supplies. The CHC-MCO must have written policies and procedures that address how Participants and Providers can make contact with the CHC-MCO to receive instruction or Prior Authorization, as necessary

H. Additional Prior Authorization requirements can be found in Exhibit E, Prior Authorization Guidelines for the CHC-MCO.

I. The CHC-MCO must ensure that utilization records document efforts made to obtain all pertinent clinical information and efforts to consult with the prescribing Provider before issuing a denial based upon medical necessity.

J. The CHC-MCO must ensure that sources of utilization criteria are provided to Participants and Providers upon request.

K. The UM program must contain procedures for providing written notification to Participants of denials of medical necessity and terminations, reductions and changes in level of care or placement, which clearly document and communicate the reasons for each denial. These procedures must:

1) Meet requirements outlined in Exhibit G, Complaint, Grievance, and DHS Fair Hearing Processes.

2) Provide for written notification to Participants of denials, terminations, reductions and changes in medical services at least ten (10) days before the effective date of the denial, termination, reduction or change.

3) Include notification to Participants of their right to file a Complaint, Grievance or DHS Fair Hearing as outlined in Exhibit G, Complaint, Grievance, and DHS Fair Hearing Processes.

L. The CHC-MCO must agree to comply with the Department's quality monitoring and utilization review monitoring processes, including, but not limited to:

1) Submission of a log of all denials issued using formats to be specified by the Department.

2) Submission of denial notices for review as requested by the Department.

3) Submission of utilization review records and documentation as requested by the Department.

4) Ensure that all staff who have any level of responsibility for making determinations to approve or deny services for any reason have completed a utilization review training program.

5) Development of an internal quality assurance process designed to ensure that all denials issued by the plan and utilization review record documentation meet Department requirements. This process must be approved by the Department.

Standard X: The CHC-MCO must have a mechanism in place for Provider Appeals and Provider Disputes related to the following:

A. Denials of Claims and payment of Claims at an alternate level of care than what was provided, i.e., acute versus skilled days. This includes the appeal by a Provider of a CHC-MCO's decision to deny payment for services already rendered by the Provider to a Participant.

B. QM/UM sanctions.

C. Adverse credentialing/recredentialing decisions.

D. Provider Terminations.

Standard XI: The CHC-MCO must ensure that findings, conclusions, recommendations, and actions taken as a result of QM and UM program activities are documented and reported to appropriate individuals within the CHC-MCO for use in other management activities.

A. The QM and UM program must have procedures which describe how findings, conclusions, recommendations, actions taken, and the results of actions taken are documented and reported to individuals within the CHC-MCO for use in conjunction with other related activities, such as:

1) CHC-MCO Provider Network changes;
2) Benefit changes;
3) Medical management systems (e.g., pre-certification);
4) Practices feedback to Providers; and
5) Service Coordination or Service Planning changes.

Standard XII: The CHC-MCO must have written policies and procedures for conducting prospective and retrospective DUR that meet requirements outlined in Exhibit D, Drug Services.

Standard XIII: The CHC-MCO must have written standards for maintaining Comprehensive Medical and Service Record (including PCSPs) record keeping. The CHC-MCO must ensure that the Comprehensive Medical and Service Records contain written documentation of the medical necessity of a rendered, ordered or prescribed service.

A. The CHC-MCO must have written policies and procedures for the maintenance of Comprehensive Medical and Service Records so that those records are documented accurately and in a timely manner, are Readily Accessible and permit prompt and systematic retrieval of information. Written policies and procedures for the CHC-MCO and its Network Providers must contain standards for medical records that promote maintenance of medical records in a legible, current, detailed, organized and comprehensive manner that permits effective patient care and quality review.

B. Medical record standards for the CHC-MCO and its Network Providers must meet or exceed medical record keeping requirements contained in at 55 Pa. Code § 1101.51(d)(e) of the Medical Assistance Manual and in medical record keeping

standards adopted by DOH.

C. Comprehensive Medical and Service Records must, at a minimum, include the following information to the extent related to CHC-MCO Covered Services or related to other services coordinated by the CHC-MCO but covered by a Participant's Medicare or other source of coverage:

1) History and physical that is appropriate to the patient's current condition;
2) Treatment plan, progress and changes in treatment plan;
3) Diagnostic tests and results
4) Therapies and other prescribed regimens;
5) Disposition and follow-up;
6) Referrals and results thereof;
7) Hospitalizations;
8) Reports of operative procedures and excised tissues;
9) Medication record\PCSP, where applicable;
10) Services provided as per the PCSP for Participants who have one;
11) Service Coordination contact notes; and
12) All other aspects of patient care or Participant service delivery.

D. The CHC-MCO must have written policies and procedures to assess the content of Comprehensive Medical and Service Records for legibility, organization, completion and conformance to its standards.

E. The CHC-MCO must ensure access of the Participant to his or her Comprehensive Medical and Service Records at no charge and upon request.

F. The Department and/or its authorized agents (i.e., any individual or corporation or entity employed, contracted or subcontracted with by the Department) shall be afforded prompt access to all Participants' Comprehensive Medical and Service Records, whether electronic or paper. All Comprehensive Medical and Service Records copies are to be forwarded to the requesting entity within fifteen (15) calendar days of such request and at no expense to the requesting entity. The Department is not required to obtain written approval from a Participant before requesting the Participant's Comprehensive Medical and Service Records from the CHC-MCO, PCP or any other agency.

G. Comprehensive Medical and Service Records must be preserved and maintained for a minimum of ten (10) years from expiration of the CHC-MCO's contract. Comprehensive Medical and Service Records must be made available in paper form upon request.

H. When a Participant changes PCPs, the CHC-MCO must facilitate the transfer of his or her medical records or copies of medical records to the new PCP within five (5) business days from receipt of the request. In emergency situations, the CHC-MCO must facilitate the transfer of medical records as soon as possible from receipt of the request.

I. When a Participant changes CHC-MCOs, the CHC-MCO must facilitate the

transfer of his or her Comprehensive Medical and Service Records or copies of the Comprehensive Medical and Service Records to the new CHC-MCO within five (5) business days from the Start Date in the receiving CHC-MCO. In emergency situations, the CHC-MCO must facilitate the transfer of Comprehensive Medical and Service Records as soon as possible from receipt of the request.

Standard XIV: The QM and UM program must demonstrate a commitment to ensuring that Participants are treated in a manner that acknowledges their defined rights and responsibilities.

A. The CHC-MCO must have a written policy that recognizes the rights of Participants outlined in Exhibit L, Participant Rights.

B. The CHC-MCO must have a written policy that addresses Participant's responsibility for cooperating with those providing healthcare services. This written policy must address Participant's responsibility for:

1) Providing, to the extent possible, information needed by professional staff in caring for the Member; and

2) Following instructions and guidelines given by those providing healthcare services.

3) Participants shall be asked to provide consent to the CHC-MCO, Providers, and their respective designees for the purpose of providing patient care management, outcomes improvement and research. For these purposes, Participants will remain anonymous to the greatest extent possible.

C. The CHC-MCO's policies on Participant rights and responsibilities must be provided to all Network Providers.

D. Upon enrollment, Participants must be provided with a written statement that includes information on the following:

1) Rights and responsibilities of Participants as outlined in Exhibit L, Participant Rights.

2) A Participant Handbook fulfilling the Participant Handbook requirements of this Agreement.

3) All other items outlined in Section V.O., Exhibit M, and requirements of that section for distribution to Participants upon Enrollment.

E. The CHC-MCO must have policies and procedures for resolving Participant Complaints and Grievances that meet all requirements outlined in Exhibit G, Complaint, Grievance, and DHS Fair Hearing Processes. These procedures must include mechanisms that allow for the review of all Complaints and Grievances to determine if quality of care and services issues exists and for

appropriate referral of identified issues.

F. Opportunity must be provided for Participants to offer suggestions for changes in policies and procedures.

G. The CHC-MCO must take steps to promote accessibility of services offered to Participants. These steps must include identification of the points of access to primary care, specialty care, LTSS, and hospital services. At a minimum, Participants must be given information about:

- How to obtain services during regular hours of operation;
- How to obtain after-hours, urgent and emergency care; and
- How to obtain the names, qualifications, and titles of the Healthcare or LTSS Provider providing and/or responsible for their care.

H. The CHC-MCO must develop and maintain policies and procedures to ensure that Participant information (e.g., Participant brochures, announcements, and handbooks) is provided in language that is readable and easily understood.

Standard XV: The CHC-MCO must maintain systems, which document implementation of the written QM and UM program descriptions.

A. The CHC-MCO must document that it is monitoring the quality of care and services across all services, all treatment modalities, and all sub-populations according to its written QM and UM programs.

B. The CHC-MCO must adhere to all systems requirements as outlined in Section V.X.6, Management Information Systems, and Section VIII.C, Systems Reporting, of the Agreement and in Management Information System and Systems Performance Review Standards provided by the Department on the Pennsylvania HealthChoices Extranet.

C. The CHC-MCO must adhere to all Encounter Data requirements as outlined in Section VIII.C.1, Encounter Data Reporting, of the Agreement.

Standard XVI: The QM and UM systems must ensure timely, complete, and regular Assessments for Participants who so require and must oversee development and implementation of PCSPs. They must also measure Participant satisfaction with quality of services, quality of life, experience of care, community integration, and quality of Service Coordination.

A. The CHC-MCO must document that it is monitoring the Assessment process across all populations. Assessments must comply with the content and timeline requirements outlined in this Agreement and must be provided to the populations outlined in Section V.E.

B. The CHC-MCO must demonstrate that it is complying with its Department-approved service coordination staffing, communications, and Participant contact plan as required in this Agreement.

C. The CHC-MCO must demonstrate that Participants who require it are provided person-centered service planning with input into who participates in their PCPTs and into the content of their PCSPs.

D. The CHC-MCO must demonstrate how PCSPs are implemented and how they are monitored to ensure that services outlined are being provided or coordinated across coverages, systems, or agencies.

E. The CHC-MCO must conduct annual Participant surveys using a survey tool approved by the Department to obtain feedback on quality of services, quality of life, experience of care, community integration, and quality of Service Coordination services provided.

Standard XVII: CHC-MCOs must help establish a nursing facility (NFs) Learning Network (LN) with a vendor approved by the Department. The LN will be established in conjunction with each of the MCOs and the Department to provide NFs a consistent approach to quality improvement and infection control as referenced in the NF Quality Incentive Program. The LN will help establish training modules, and regional meetings that will assist NFs in clinical and technical assistance. MCOs will collaborate and coordinate with the Department on the following activities of the LN:

1) Participate in regional and statewide trainings and meetings to support NF personnel to enhance and improve quality measures as defined in the NF Quality Incentive Program.

2) Increase BH services within NFs.

3) Help drive quality improvement by helping to collect data, perform rapid PDCA cycles, and share best practices.

4) Work with local health systems to better enhance transitions of care from the emergency department and inpatient discharges.

5) Implement and/or participate in regional quarterly quality meetings for NFs to share best practices, identify and help resolve NF operational issues that affect quality, and share quality improvement results.

6) Participate in an annual statewide quality meeting that will bring all regions together to share regional experiences and report on the effectiveness of the LN.

EXHIBIT G

COMPLAINT, GRIEVANCE, AND DHS FAIR HEARING PROCESSES

A. General Requirements

1. The CHC-MCO must obtain the Department's prior written approval of its Complaint, Grievance, and Fair Hearing policies and procedures.

2. The CHC-MCO must have written policies and procedures for registering, responding to, and resolving Complaints and Grievances as they relate to the MA population and must make these policies and procedures available to Participants upon request.

3. The CHC-MCO must maintain an accurate written record of each Complaint and Grievance and the actions taken by the CHC-MCO to resolve each Complaint and Grievance. The record must include at least the following:
    a. The name of the Participant on whose behalf the Complaint or Grievance was filed;
    b. The date the Complaint or Grievance was received;
    c. A description of the reason for the Complaint or Grievance;
    d. The date of each review or review meeting;
    e. The date of resolution of the Complaint or Grievance and how the Complaint or Grievance was resolved; and
    f. A Copy of any documents or records reviewed.

    The CHC-MCO must provide the record of each Complaint and Grievance and the actions taken by the CHC-MCO to resolve each Complaint and Grievance to the Department and CMS upon request.

4. The CHC-MCO must submit a log of all Complaint and Grievance decisions in a format specified by the Department and must include review of the Complaint and Grievance processes in its QM and UM programs as outlined in Exhibit F Quality Management and Utilization Management Program Requirements.

5. The CHC-MCO must have a data system to process, track, and trend all Complaints and Grievances.

6. The CHC-MCO must designate and train sufficient staff as reported in the Operating Procedures Report (OPS) 11 Provider Education, to be responsible for receiving, processing, and responding to Participant Complaints and Grievances in accordance with the requirements specified in this Exhibit.

7. CHC-MCO staff performing Complaint and Grievance reviews must have the necessary orientation, clinical training, and experience to make an informed and impartial determination regarding issues assigned to them.

8. The CHC-MCO must provide information about the Complaint and Grievance process to all Providers and subcontractors when the CHC-MCO enters into a contract or agreement with the Provider or subcontractor.

9. The CHC-MCO may not use the timeframes or procedures of the Complaint or Grievance process to avoid the medical decision process or to discourage or prevent a Participant from receiving Medically Necessary care in a timely manner.

10. The CHC-MCO must require that anyone who participates in making the decision on a Complaint or Grievance was not involved in and is not a subordinate of an individual who was involved in any previous level of review or decision-making on the issue that is the subject of the Complaint or Grievance.

11. The CHC-MCO may not charge Participants a fee for filing a Complaint or a Grievance.

12. CHC-MCOs must permit both a Participant or Participant's representative, which may include the Participant's Provider, with proof of the Participant's written authorization for the representative to be involved and/or act on the Participant's behalf, to file a Complaint or Grievance. If a Complaint or Grievance is received by a CHC-MCO from a representative on behalf of the Participant that does not include the Participant's authorization the CHC-MCO must contact the Participant to obtain authorization.

13. The CHC-MCO must allow the Participant and the Participant's representative to have access to all relevant documentation pertaining to the subject of the Complaint or Grievance free of charge and sufficiently in advance of the time frame for resolution of the Complaint or Grievance outlined in this Exhibit.

14. The CHC-MCO must maintain the following information in the Participant's case file:
    a. Medical records;
    b. Any documents or records relied upon or generated by the CHC-MCO in connection with the Complaint or Grievance, including any Medical Necessity criteria used to make a decision or information on coverage limits relied upon to make a decision; and
    c. Any new or additional evidence considered, relied upon, or generated by the CHC-MCO in connection with the Complaint or Grievance.

15. The CHC-MCO must ask the Participant if the Participant needs interpreter services. The CHC-MCO must provide language interpreter services at no cost when requested by a Participant. The CHC-MCO must include in the Complaint or Grievance record documentation that the Participant was asked if the Participant needed an interpreter and if an interpreter was provided.

16. The CHC-MCO must accept Complaints and Grievances from individuals with disabilities which are in alternative formats including: TTY/Videophone/TDD for telephone inquiries and Complaints and Grievances from Participants who are deaf or hearing impaired; Braille; tape; computer disk; and other commonly accepted alternative forms of communication. The CHC-MCO must make its employees who receive telephone Complaints and Grievances aware of the speech limitations of Participants with disabilities so they treat these individuals with patience, understanding, and respect.

17. The CHC-MCO must provide Participants with disabilities assistance in presenting their case at Complaint or Grievance reviews at no cost to the Participant. This includes but is not limited to:
    a. Providing qualified sign language interpreters for Participants who are deaf or hearing impaired;
    b. Providing information submitted on behalf of the CHC-MCO at the Complaint or Grievance review in an alternative format accessible to the Participant filing the Complaint or Grievance. The alternative format version must be supplied to the Participant at or before the review, so the Participant can discuss and/or refute the content during the review; and
    c. Providing personal assistance to a Participant filing the Complaint or Grievance who has other physical limitations in copying and presenting documents and other evidence.

18. The CHC-MCO must offer Participants the assistance of a CHC-MCO staff member throughout the Complaint and Grievance processes at no cost to the Participant.

19. The CHC-MCO must provide Participants with a toll-free number to file a Complaint or Grievance, request information about the Complaint or Grievance process, and ask any questions the Participant may have about the status of a Complaint or a Grievance.

20. The CHC-MCO must, at a minimum, hold in-person reviews of Complaints and Grievances at one location within each of its zones of operation. If a Participant requests an in-person review, the CHC-MCO must notify the Participant of the location of the review and who will be present at the review, using the template specified by the Department.

21. The CHC-MCO must ensure that any location where it will hold in-person reviews is physically accessible for persons with disabilities.

22. The CHC-MCO must notify the Participant when the CHC-MCO fails to decide a first level Complaint or a Grievance within the time frames specified in this Exhibit, using the

template specified by the Department. The CHC-MCO must mail this notice to the Participant one (1) day following the date of the decision (day 31).

23. The CHC-MCO must notify the Participant when it denies payment after a service or item has been delivered because the service or item was provided without authorization by a provider not enrolled in the MA Program, using the template specified by the Department. The CHC-MCO must mail this notice to the Participant on the day the decision is made to deny payment.

24. The CHC-MCO must notify the Participant when it denies payment after a service or item has been delivered because the service or item provided is not a Covered Service for the Participant, using the template specified by the Department. The CHC-MCO must mail this notice to the Participant on the day the decision is made to deny payment.

25. The CHC-MCO must notify the Participant when it denies payment after a service or item has been delivered because the CHC-MCO determined that the service or item was not Medically Necessary, using the template specified by the Department. The CHC-MCO must mail this notice to the Participant on the day the decision is made to deny payment.

26. The CHC-MCO must notify the Participant when it denies the Participant's request to dispute a financial liability, including cost sharing, copayments, premiums, deductibles, coinsurance, and other enrollee financial liabilities using the template specified by the Department. The CHC-MCO must mail this notice to the Participant on the day the decision is made to deny payment.

27. If a Participant continued to receive services at the previously authorized level because the Participant filed a Complaint, Grievance, or Fair Hearing to dispute a decision to discontinue, reduce, or change a service that the Participant has been receiving within fifteen (15) days from the mail date on the written notice of decision, the CHC-MCO must pay for the services pending resolution of the Complaint, Grievance, or Fair Hearing.

28. The CHC-MCO must use all templates specified by the Department, which are available in DocuShare. The CHC-MCO may not modify the templates. The CHC-MCO must follow the instructions in the templates for including detailed, specific information related to the Complaint or Grievance.

B. Complaint Requirements

Complaint: A dispute or objection regarding a particular Provider or the coverage operations, or management of a CHC-MCO, which has not been resolved by the CHC-MCO and has been filed with the CHC-MCO or with PID's Bureau of Managed Care (BMC), including but not limited to:

- a denial because the requested service or item is not a Covered Service; which does not include BLE;

- the failure of the CHC-MCO to provide a service or item in a timely manner, as defined by the Department;

- the failure of the CHC-MCO to decide a Complaint or Grievance within the specified time frames;

- a denial of payment by the CHC-MCO after a service or item has been delivered because the service or item was provided without authorization by a provider not enrolled in the MA Program;

- a denial of payment by the CHC-MCO after a service or item has been delivered because the service or item provided is not a Covered Service for the Participant; or

- a denial of a Participant's request to dispute a financial liability, including cost sharing, copayments, premiums, deductibles, coinsurance, and other Participant financial liabilities.

The term does not include a Grievance.

1. First Level Complaint Process

a. A CHC-MCO must permit a Participant or Participant's representative, which may include the Participant's Provider, with proof of the Participant's written authorization for the representative to be involved and/or act on the Participant's behalf, to file a first level Complaint either in writing or orally. The CHC-MCO must commit oral requests to writing if not confirmed in writing by the Participant and must provide the written Complaint to the Participant or Participant's representative for signature. The signature may be obtained at any point in the process, and failure to obtain a signed Complaint may not delay the Complaint process.

b. If the first level Complaint disputes one of the following, the Participant must file a Complaint within sixty (60) days from the date of the incident complained of or the date the Participant receives written notice of a decision:

- a denial because the service or item is not a Covered Service;
- the failure of the CHC-MCO to provide a service or item in a timely manner, as defined by the Department;
- the failure of the CHC-MCO to decide a Complaint or Grievance within the specified time frames;
- a denial of payment after the service or item has been delivered because the service or item was provided without authorization by a provider not enrolled in the MA Program;
- a denial of payment after the service or item has been delivered because the service or item provided is not a Covered Service for the Participant; or
- a denial of a Participant's request to dispute a financial liability, including cost sharing, copayments, premiums, deductibles, coinsurance, and other Participant financial liabilities,

For all other Complaints, there is no time limit for filing a first level Complaint.

c. A Participant who files a first level Complaint to dispute a decision to discontinue, reduce, or change a service or item that the Participant has been receiving on the basis that the service or item is not a Covered Service must continue to receive the disputed service or item at the previously authorized level pending resolution of the first level Complaint, if the first level Complaint is made verbally, hand delivered, faxed, submitted electronically (via secure e-mail or secure web portal, if available), or post-marked within fifteen (15) days from the mail date on the written notice of decision.

d. Upon receipt of the Complaint, the CHC-MCO must send the Participant and Participant's representative, if the Participant has designated one in writing, a first level Complaint acknowledgment letter using the template specified by the Department. The first level Complaint acknowledgement letter must be sent no later than three (3) business days after the receipt of the Complaint.

e. The first level Complaint review for Complaints **not involving a clinical issue** must be conducted by a first level Complaint review committee, which must include one or more employees of the CHC-MCO who were not involved in and are not the subordinates of an individual involved in any previous level of review or decision-making on the issue that is the subject of the Complaint.

f. The first level Complaint review for Complaints **involving a clinical issue** must be conducted by a first level Complaint review committee, which must include one or more employees of the CHC-MCO who were not involved in and are not the subordinates of an individual involved in any previous level of review or decision-making on the issue that is the subject of the Complaint. The first level Complaint review committee must include a licensed physician or licensed dentist in the same or similar specialty that typically manages or consults on the service or item in question. Other appropriate providers may participate in the review, but the licensed physician or licensed dentist in the same or similar specialty that typically manages or consults on the service or item in question must decide the first level Complaint.

g. A committee member who does not personally attend the first level Complaint review meeting may not be part of the decision-making process unless that member actively participates in the review by telephone or videoconference and has the opportunity to review all information presented during the review.

h. The CHC-MCO must afford the Participant a reasonable opportunity to present evidence and testimony and make legal and factual arguments, in person as well as in writing.

i. The CHC-MCO must give the Participant at least ten (10) days advance written notice of the first level Complaint review date, using the template specified by the Department. The CHC-MCO must be flexible when scheduling the review to facilitate the Participant's attendance. If the Participant cannot appear in person at the review, the CHC-MCO must provide an opportunity for the Participant to communicate with the first level Complaint review committee by telephone or videoconference.

j. The Participant may elect not to attend the first level Complaint review meeting, but the meeting must be conducted with the same protocols as if the Participant was present. All Complaint review meetings must be recorded and transcribed and the recording and transcription must be maintained as part of the Complaint record.

k. If a Participant requests an in-person first level Complaint review, at a minimum, a member of the first level Complaint review committee must be physically present at the location where the first level Complaint review is held and the other members of the first level Complaint review committee must participate in the review through the use of videoconferencing.

l. The decision of the first level Complaint review committee must take into account all comments, documents, records, and other information submitted by

the Participant or the Participant's representative without regard to whether such information was submitted or considered in the initial determination of the issue.

m. Prior to the start of the first level Complaint review meeting, the Participant must be told that the testimony will be recorded. If the Participant agrees to the testimony taken by the Complaint review committee (including the Participant's comments) being recorded, the testimony must be recorded and transcribed verbatim and maintained as part of the Complaint record. If the Participant objects to the testimony being recorded, the Participant's objection must be documented in the Complaint record and the first level Complaint review meeting must proceed without the testimony being recorded.

n. The first level Complaint review committee must complete its review of the Complaint as expeditiously as the Participant's health condition requires.

o. The first level Complaint review committee must prepare a summary of the issues presented and decisions made, which must be maintained as part of the Complaint record.

p. The CHC-MCO must send a written notice of the first level Complaint decision, using the template specified by the Department, to the Participant, Participant's representative, if the Participant has designated one, service Provider and prescribing Provider, if applicable, within thirty (30) days from the date of receipt of the Complaint unless the time frame for deciding the Complaint has been extended by up to fourteen (14) days at the request of the Participant.

q. If the Complaint disputes one of the following, the Participant may file a request for a Fair Hearing, a request for an external review, or both a request for a Fair Hearing and a request for an external review:

    - a denial because that the service or item is not a Covered Service;

    - the failure of the CHC-MCO to provide a service or item in a timely manner, as defined by the Department;

    - the failure of the CHC-MCO to decide the Complaint or Grievance within the specified time frames;

    - a denial of payment by the CHC-MCO after the service or item has been delivered because the service or item was provided without authorization by a provider not enrolled in the MA Program;

    - a denial of payment by the CHC-MCO after the service or item has been delivered because the service or item provided is not a Covered Service for the Participant; or

- a denial of a Participant's request to dispute a financial liability, including cost sharing, copayments, premiums, deductibles, coinsurance, and other Participant financial liabilities.

The Participant or Participant's representative may file a request for a Fair Hearing within one hundred and twenty (120) days from the mail date on the written notice of the CHC-MCO's first level Complaint decision.

The Participant or Participant's representative, which may include the Participant's Provider, with proof of the Participant's written authorization for the representative to be involved and/or act on the Participant's behalf, may file a request for an external review in writing with PID's BMC within fifteen (15) days from the date the Participant receives written notice of the CHC-MCO's first level Complaint decision.

For all other Complaints, the Participant or Participant's representative, which may include the Participant's Provider, with proof of the Participant's written authorization for the representative to be involved and/or act on the Participant's behalf, may file a second level Complaint either in writing or orally within forty-five (45) days from the date the Participant receives written notice of the CHC-MCO's first level Complaint decision.

2. Second Level Complaint Process

a. A CHC-MCO must permit a Participant or Participant's representative, which may include the Participant's Provider, with proof of the Participant's written authorization for the representative to be involved and/or act on the Participant's behalf, to file a second level Complaint either in writing or orally for any Complaint for which a Fair Hearing and external review is not available.

b. Upon receipt of the second level Complaint, the CHC-MCO must send the Participant and Participant's representative, if the Participant has designated one in writing, a second level Complaint acknowledgment letter using the template specified by the Department. The second level Complaint acknowledgement letter must be sent no later than three (3) business days after the receipt of the second level Complaint.

c. The second level Complaint review for Complaints **not involving a clinical issue** must be performed by a second level Complaint review committee made up of three (3) or more individuals who were not involved in and are not the subordinates of an individual involved in any previous level of review or decision-making on the issue that is the subject of the Complaint.

d. The second level Complaint review for Complaints **involving a clinical issue** must be conducted by a second level Complaint review committee made up of three (3) or more individuals who were not involved in and are not the subordinates of an individual involved in any previous level of review or

decision-making on the issue that is the subject of the Complaint. The second level Complaint review committee must include a licensed physician or licensed dentist in the same or similar specialty that typically manages or consults on the service or item in question. Other appropriate providers may participate in the review, but the licensed physician or licensed dentist in the same or similar specialty that typically manages or consults on the service or item in question must decide the second level Complaint.

e. At least one-third of the second level Complaint review committee members may not be employees of the CHC-MCO or a related subsidiary or Affiliate.

f. A committee member who does not personally attend the second level Complaint review may not be part of the decision-making process unless that member actively participates in the review by telephone or videoconference and has the opportunity to review all information introduced during the review.

g. The CHC-MCO must afford the Participant a reasonable opportunity to present evidence and testimony and make legal and factual arguments, in person as well as in writing.

h. The CHC-MCO must give the Participant at least fifteen (15) days advance written notice of the second level review date, using the template specified by the Department. If the Participant cannot appear in person at the review, the CHC-MCO must provide an opportunity for the Participant to communicate with the second level Complaint review committee by telephone or videoconference. The CHC-MCO must be flexible when scheduling the review to facilitate the Member's attendance.

i. The Participant may elect not to attend the second level Complaint review meeting, but the meeting must be conducted with the same protocols as if the Participant was present. All second level Complaint review meetings must be recorded and transcribed verbatim and the recording and transcription must be maintained as part of the second level Complaint record.

j. If a Participant requests an in-person second level Complaint review, at a minimum, a member of the second level Complaint review committee must be physically present at the location where the second level Complaint review is held and the other members of the second level Complaint review committee must participate in the review through the use of videoconferencing.

k. The decision of the second level Complaint review committee must take into account all comments, documents, records, and other information submitted by the Participant or the Participant's representative without regard to whether such information was submitted or considered previously. The decision of the

second level Complaint review committee must be based solely on the information presented at the review.

l. Prior to the start of the second level Complaint review meeting, the Participant must be told that the testimony will be recorded. If the Participant agrees to the testimony taken by the second level Complaint review committee (including the Participant's comments) being recorded, the testimony must be tape-recorded and transcribed verbatim and maintained as part of the second level Complaint record. If the Participant objects to the testimony being recorded, the Participant's objection must be documented in the second level Complaint record and the second level Complaint review meeting must proceed without the testimony being recorded

m. The second level Complaint review committee must complete its review of the second level Complaint as expeditiously as the Participant's health condition requires.

n. The CHC-MCO must send a written notice of the second level Complaint decision, using the template specified by the Department, to the Participant, Participant's representative, if the Participant has designated one in writing, service Provider, and prescribing Provider, if applicable, within forty-five (45) days from the date of receipt of the second level Complaint.

o. The Participant or the Participant's representative, which may include the Participant's Provider, with proof of the Participant's written authorization of the representative to be involved and/or act of the Participant's behalf, may file in writing a request for an external review of the second level Complaint decision with PID's BMC within fifteen (15) days from the date the Participant receives the written notice of the CHC-MCO's second level Complaint decision.

3. **External Complaint Process**

a. If a Participant files a request directly with PID's BMC for an external review of a Complaint decision that disputes a decision to discontinue, reduce, or change a service or item that the Participant has been receiving on the basis that the service or item is not a Covered Service, the Participant must continue to receive the disputed service or item at the previously authorized level pending resolution of the external review, if the request for external review is hand-delivered, faxed, or post-marked within fifteen (15) days from the mail date on the written notice of the CHC-MCO's first or second level Complaint decision.

b. Upon the request of PID's BMC, the CHC-MCO must transmit all records from the CHC-MCO's Complaint review to PID's BMC within thirty (30) days from

the request in the manner prescribed by PID's BMC. The Participant, the Provider, or the CHC-MCO may submit additional materials related to the Complaint.

4. **Expedited Complaint Process**

a. The CHC-MCO must conduct expedited review of a Complaint if the CHC-MCO determines that the Participant's life, physical or mental health, or ability to attain, maintain, or regain maximum function would be placed in jeopardy by following the regular Complaint process or if a Participant or Participant's representative, with proof of the Participant's written authorization for the representative to be involved and/or act on the Participant's behalf, provides the CHC-MCO with a certification from the Participant's Provider that the Participant's life, physical or mental health, or ability to attain, maintain, or regain maximum function would be placed in jeopardy by following the regular Complaint process. The certification must include the Provider's signature.

b. A request for an expedited review of a Complaint may be filed in writing via mail, by fax, submitted electronically (via secure email or secure web portal, if available), or orally.

c. Upon receipt of an oral or written request for expedited review, the CHC-MCO must inform the Participant of the right to present evidence and testimony and make legal and factual arguments in person as well as in writing and of the limited time available to do so.

d. If the Provider certification is not included with the request for an expedited review and the CHC-MCO cannot determine based on the information provided that the Participant's life, physical or mental health, or ability to attain, maintain, or regain maximum function would be placed in jeopardy by following the regular Complaint process, the CHC-MCO must inform the Participant that the Provider must submit a certification as to the reasons why the expedited review is needed. The CHC-MCO must make a reasonable effort to obtain the certification from the Provider. If the Provider certification is not received within seventy-two (72) hours of the Participant's request for expedited review, the CHC-MCO must decide the Complaint within the standard time frames as set forth in this Exhibit, unless the time frame for deciding the Complaint has been extended by up to fourteen (14) days at the request of the Participant. If the CHC-MCO decides that expedited consideration within the initial or extended time frame is not warranted, the CHC-MCO must make a reasonable effort to give the Participant prompt oral notice that the Complaint is to be decided within the standard time frame and send a written notice within two (2) business days of the decision to deny expedited review, using the template specified by the Department.

e. A Participant who files a request for expedited review of a Complaint to dispute a decision to discontinue, reduce, or change a service or item that the Participant has been receiving on the basis that the service or item is not a Covered Service must continue to receive the disputed service or item at the previously authorized level pending resolution of the Complaint, if the request for expedited review is made orally, hand delivered, faxed, submitted electronically (via secure email or secure web portal, if available), or post-marked within fifteen (15) days from the mail date on the written notice of decision.

f. Expedited review of a Complaint must be conducted by a Complaint review committee that includes a licensed physician or licensed dentist in the same or similar specialty that typically manages or consults on the service or item in question. If the Complaint is related to dental services, the expedited Complaint review committee must include a dentist. Other appropriate providers may participate in the review, but the licensed physician or licensed dentist in the same or similar specialty that typically manages or consults on the service or item in question must decide the Complaint. The members of the expedited Complaint review committee may not have been involved in and not be the subordinates of an individual involved in any previous level of review or decision-making on the issue that is the subject of the Complaint.

g. Prior to the start of the expedited Complaint review meeting, the Participant must be told that the testimony will be recorded. If the Participant agrees to the testimony taken by the Complaint review committee (including the Participant's comments) being recorded, the testimony must be recorded and transcribed verbatim and maintained as part of the Complaint record. If the Participant objects to the testimony being recorded, the Participant's objection must be documented in the Complaint record and the expedited review meeting must proceed without the testimony being recorded.

h. The CHC-MCO must issue the decision resulting from the expedited review in person or by phone to the Participant, the Participant's representative, if the Participant has designated one in writing, service Provider and prescribing Provider, if applicable, within either forty-eight (48) hours of receiving the Provider certification or seventy-two (72) hours of receiving the Participant's request for an expedited review, whichever is shorter, unless the time frame for deciding the expedited complaint has been extended by up to fourteen (14) days at the request of the Participant. In addition, the CHC-MCO must mail written notice of the decision to the Participant, the Participant's representative, if the Participant has designated one in writing, the Participant's service Provider, and prescribing Provider, if applicable, within two (2) business days of the decision, using the template specified by the Department.

i. The Participant or the Participant's representative may file a request for a Fair Hearing within one hundred and twenty (120) days from the mail date on the written notice of the CHC-MCO's expedited Complaint decision.

j. A request for an expedited Fair Hearing may be filed verbally, or in writing via mail, fax, or secure email.

k. The Participant, or the Participant's representative, which may include the Participant's Provider, with proof of the Participant's written authorization for the representative to be involved and/or act on the Participant's behalf, may file a request for an expedited external Complaint review with the CHC-MCO within two (2) business days from the date the Participant receives the CHC-MCO's expedited Complaint decision. A Participant who files a request for an expedited Complaint review that disputes a decision to discontinue, reduce, or change a service or item that the Participant has been receiving must continue to receive the disputed service or item at the previously authorized level pending resolution of the request for expedited Complaint review.

l. The CHC-MCO must follow PID's BMC guidelines relating to submission of requests for expedited external Complaint reviews.

m. The CHC-MCO may not take punitive action against a Provider who requests expedited resolution of a Complaint or supports a Participant's request for expedited review of a Complaint.

C. Grievance Requirements

Grievance: A request to an MA Managed Care Plan by a Participant or a health care provider (with the written consent of the Participant), or a Participant's authorized representative to have an MA Managed Care Plan reconsider a decision solely concerning the medical necessity, appropriateness, health care setting, level of care or effectiveness of a health care service. If the MA Managed Care Plan is unable to resolve the matter, a grievance may be filed regarding the decision that:

(1) disapproves full or partial payment for a requested health care service;

(2) approves the provision of a requested health care service for a lesser scope or duration than requested; or

(3) disapproves payment for the provision of a requested health care service but approves payment for the provision of an alternative health care service

(4) reduces, suspends, or terminates a previously authorized service.

The term does not include a complaint.

1. Grievance Process

a. A CHC-MCO must permit a Participant or Participant's representative, which may include the Participant's Provider, with proof of the Participant's written authorization for the representative to be involved and/or act on the Participant's behalf, to file a Grievance either in writing or orally. The CHC-MCO must commit oral requests to writing if not confirmed in writing by the Participant and must provide the written Grievance to the Participant or the Participant's representative for signature. The signature may be obtained at any point in the process, and the failure to obtain a signed Grievance may not delay the Grievance process.

b. A Participant must file a Grievance within sixty (60) days from the date the Participant receives written notice of decision.

c. A Participant who files a Grievance to dispute a decision to discontinue, reduce, or change a service or item that the Participant has been receiving must continue to receive the disputed service or item at the previously authorized level pending resolution of the Grievance, if the request for review of the Grievance is made orally, hand delivered, faxed, submitted electronically (via secure email or secure web portal, if available), or post-marked within fifteen (15) days from the mail date on the written notice of decision.

d. Upon receipt of the Grievance, the CHC-MCO must send the Participant and Participant's representative, if the Participant has designated one in writing, a Grievance acknowledgment letter using the template specified by the Department. The Grievance acknowledgement letter must be sent no later than three (3) business days after receipt of the Grievance.

e. A Participant who consents to the filing of a Grievance by a Provider may not file a separate Grievance. The Participant may rescind consent throughout the process upon written notice to the CHC-MCO and the Provider.

f. In order for the Provider to represent the Participant in the conduct of a Grievance, the Provider must obtain the written consent of the Participant and submit the written consent with the Grievance. A Provider may obtain the Participant's written permission at the time of treatment. The CHC-MCO must assure that a Provider does NOT require a Participant to sign a document authorizing the Provider to file a Grievance as a condition of treatment. The written consent must include:

    i. The name and address of the Participant, the Participant's date of birth and identification number;

    ii. If the Participant is legally incompetent, the name, address, and relationship to the Participant of the person who signed the consent;

iii. The name, address, and CHC-MCO identification number of the Provider to whom the Participant is providing consent;

iv. The name and address of the CHC-MCO to which the Grievance will be submitted;

v. An explanation of the specific service or item which was provided or denied to the Participant to which the consent will apply;

vi. The following statement: "The Participant or the Participant's representative may not submit a Grievance concerning the service or item listed in this consent form unless the Participant or the Participant's representative rescinds consent in writing. The Participant or the Participant's representative has the right to rescind consent at any time during the Grievance process.";

vii. The following statement: "The consent of the Participant or the Participant's representative shall be automatically rescinded if the Provider fails to file a Grievance or fails to continue to prosecute the Grievance through the review process.";

viii. The following statement: "The Participant or the Participant's representative, if the Participant is legally incompetent, has read, or has been read, this consent form, and has had it explained to his/her satisfaction. The Participant or the Participant's representative understands the information in the Participant's consent form."; and

ix. The dated signature of the Participant, or the Participant's representative, and the dated signature of a witness.

g. The Grievance review must be conducted by a Grievance review committee made up of three (3) or more individuals who were not involved in and are not the subordinates of an individual involved in any previous level of review or decision-making on the issue that is the subject of the Grievance.

h. At least one-third of the Grievance review committee may not be employees of the CHC-MCO or a related subsidiary or Affiliate.

i. The Grievance review committee must include a licensed physician or licensed dentist in the same or similar specialty that typically manages or consults on the service or item in question. If the Grievance is related to dental

services, the Grievance review committee must include a dentist. Other appropriate providers may participate in the review, but the licensed physician or licensed dentist in the same or similar specialty that typically manages or consults on the service or item in question must decide the Grievance.

j. A committee member who does not personally attend the Grievance review may not be part of the decision-making process unless that member actively participates in the review by telephone or videoconference and has the opportunity to review all information introduced during the review.

k. The CHC-MCO must afford the Participant a reasonable opportunity to present evidence and testimony and make legal and factual arguments, in person as well as in writing.

l. The CHC-MCO must give the Participant at least ten (10) days advance written notice of the review date, using the template specified by the Department. The CHC-MCO must be flexible when scheduling the review to facilitate the Participant's attendance. If the Participant cannot appear in person at the review, the CHC-MCO must provide an opportunity for the Participant to communicate with the Grievance review committee by telephone or videoconference.

m. The Participant may elect not to attend the Grievance review meeting, but the meeting must be conducted with the same protocols as if the Participant was present. All Grievance review meetings must be recorded and transcribed verbatim and the recording and transcription must be maintained as part of the Grievance record.

n. If a Participant requests an in-person Grievance review, at a minimum, a member of the Grievance review committee must be physically present at the location where the Grievance review is held and the other members of the Grievance review committee must participate in the review through the use of videoconferencing.

o. The decision of the Grievance review committee must take into account all comments, documents, records, and other information submitted by the Participant or the Participant's representative without regard to whether such information was submitted or considered in the initial determination of the issue. The decision of the Grievance review committee must be based solely on the information presented at the review.

p. Prior to the start of the Grievance review meeting, the Participant must be told that the testimony will be recorded. If the Participant agrees to the testimony taken by the Grievance review committee (including the Participant's comments) being recorded, the testimony must be recorded and transcribed

verbatim and a written transcription prepared and maintained as part of the Grievance record. If the Participant objects to the testimony being recorded, the Member's objection must be documented in the Grievance record and the Grievance review meeting must proceed without the testimony being recorded.

q. The Grievance review committee must complete its review of the Grievance as expeditiously as the Participant's health condition requires.

r. The CHC-MCO must send a written notice of the Grievance decision, using the template specified by the Department, to the Participant, Participant's representative, if the Participant has designated one in writing, service Provider and prescribing Provider, if applicable, within thirty (30) days from the date the CHC-MCO received the Grievance, unless the time frame for deciding the Grievance has been extended by up to fourteen (14) days at the request of the Participant.

s. The Participant may file a request for a Fair Hearing, a request for an external review, or both a request for a Fair Hearing and a request for an external review.

t. The Participant or Participant's representative may file a request for a Fair Hearing within one hundred and twenty (120) days from the mail date on the written notice of the CHC-MCO's Grievance decision.

u. The Participant or Participant's representative, which may include the Participant's Provider, with proof of the Participant's written authorization for a representative to be involved and/or act on the Participant's behalf, may file a request with the CHC-MCO for an external review of a Grievance decision by a IRO appointed by PID's BMC. The request must be filed in writing or orally within fifteen (15) days from the date the Participant receives the written notice of the CHC-MCO's Grievance decision.

2. External Grievance Process:

a. The CHC-MCO must process all requests for external Grievance review. The CHC-MCO must follow the protocols established by PID's BMC in meeting all time frames and requirements necessary in coordinating the request and notification of the decision to the Participant, Participant's representative, if the Participant has designated one in writing, service Provider, and prescribing Provider.

b. A Participant who files a request for an external Grievance review that disputes a decision to discontinue, reduce, or change a service or item that the

Participant has been receiving must continue to receive the disputed service or item at the previously authorized level pending resolution of the external Grievance review, if the request for external Grievance review is made orally, hand delivered, faxed, or post-marked within fifteen (15) days from the mail date on the written notice of the CHC-MCO's Grievance decision.

c. Within five (5) business days of receipt of the request for an external Grievance review, the CHC-MCO must notify the Participant, the Participant's representative, if the Participant has designated one in writing, the Provider if the Provider filed the request for the external Grievance, and PID's BMC that the request for external Grievance review has been filed.

d. The external Grievance review must be conducted by a IRO not affiliated with the CHC-MCO.

e. Within two (2) business days from receipt of the request for an external Grievance review, PID's BMC will randomly assign a IRO to conduct the review and notify the CHC-MCO and assigned IRO of the assignment.

f. Within the same two (2) business day timeframe, PID's BMC shall notify the Participant or the Participant's authorized representative of the name, address, e-mail address, fax number and telephone number of the IRO assigned under this subsection. The notice shall inform the Participant and the Participant's authorized representative of the right to submit additional written information to the IRO within twenty (20) days of the date the IRO assignment notice was mailed and shall include instructions for submitting additional information to the IRO by mail, fax, or electronically.

g. If PID's BMC fails to select an IRO within two (2) business days from receipt of a request for an external Grievance review, the CHC-MCO may designate an IRO to conduct a review from the list of IROs approved by PID's BMC. The CHC-MCO may not select an IRO that has a current contract or is negotiating a contract with the CHC-MCO or its Affiliates or is otherwise affiliated with the CHC-MCO or its Affiliates.

h. The CHC-MCO must forward all documentation regarding the Grievance decision, including all supporting information, a summary of applicable issues, and the basis and clinical rationale for the Grievance decision, to the IRO conducting the external Grievance review. The CHC-MCO must transmit this information within fifteen (15) days from receipt of the Participant's request for an external Grievance review.

i. Within fifteen (15) days from receipt of the request for an external Grievance review by the CHC-MCO, the Participant or the Participant's representative, or the Participant's Provider, may supply additional information to the IRO

conducting the external Grievance review for consideration. Copies must also be provided at the same time to the CHC-MCO so that the CHC-MCO has an opportunity to consider the additional information.

j. Within sixty (60) days from the filing of the request for the external Grievance review, the IRO conducting the external Grievance review must issue a written decision to the CHC-MCO, the Participant, the Participant's representative, PID's BMC and the Provider (if the Provider filed the Grievance with the Participant's consent), that includes the basis and clinical rationale for the decision. The standard of review must be whether the service or item is Medically Necessary and appropriate under the terms of this Agreement.

k. The external Grievance decision may be appealed by the Participant, the Participant's representative, or the Provider to a court of competent jurisdiction within sixty (60) days from the date the Participant receives notice of the external Grievance decision.

3. Expedited Grievance Process

a. The CHC-MCO must conduct expedited review of a Grievance if the CHC-MCO determines that the Participant's life, physical or mental health, or ability to attain, maintain, or regain maximum function would be placed in jeopardy by following the regular Grievance process or if a Participant or Participant representative, with proof of the Participant's written authorization for a representative to be involved and/or act on the Participant's behalf, provides the CHC-MCO with a certification from the Participant's Provider that the Participant's life, physical or mental health, or ability to attain, maintain, or regain maximum function would be placed in jeopardy by following the regular Grievance process. The certification must include the Provider's signature.

b. A request for expedited review of a Grievance may be filed either in writing via mail, by fax, electronically (via secure email or secure web portal, if available), or orally.

c. The expedited review process is bound by the same rules and procedures as the Grievance review process with the exception of timeframes, which are modified as specified in this section.

d. Upon receipt of an oral or written request for expedited review, the CHC-MCO must inform the Participant of the right to present evidence and testimony and make legal and factual arguments in person as well as in writing and of the limited time available to do so.

e. If the Provider certification is not included with the request for an expedited review and the CHC-MCO cannot determine based on the information provided that the Participant's life, physical or mental health, or ability to attain, maintain, or regain maximum function would be placed in jeopardy by following the regular Grievance process, the CHC-MCO must inform the Participant that the Provider must submit a certification as to the reasons why the expedited review is needed. The CHC-MCO must make a reasonable effort to obtain the certification from the Provider. If the Provider certification is not received within seventy-two (72) hours of the Participant's request for expedited review, the CHC-MCO must decide the Grievance within the standard time frames as set forth in this Exhibit unless the time frame for deciding the Grievance has been extended by up to fourteen (14) days at the request of the Participant. If the CHC-MCO decides that expedited consideration with the initial or extended time frame is not warranted, the CHC-MCO must make a reasonable effort to give the Participant prompt oral notice that the Grievance is to be decided within the standard time frame and send a written notice within two (2) business days of the decision to deny expedited review, using the template specified by the Department.

f. A Participant who files a request for expedited review of a Grievance to dispute a decision to discontinue, reduce or change a service or item that the Participant has been receiving must continue to receive the disputed service or item at the previously authorized level pending resolution of the Grievance, if the request for expedited review of a Grievance is made verbally, hand delivered, submitted electronically (via secure email or secure web portal, if available), or post-marked within fifteen (15) days from the mail date on the written notice of decision.

g. Expedited review of a Grievance must be conducted by a Grievance review committee made up of three (3) or more individuals who were not involved in and are not the subordinates of an individual involved in any previous level of review or decision-making on the issue that is the subject of the Grievance.

h. At least one-third of the expedited Grievance review committee may not be employees of the CHC-MCO or a related subsidiary or Affiliate.

i. The expedited Grievance review committee must include a licensed physician or licensed dentist in the same or similar specialty that typically manages or consults on the service or item in question. If the Grievance is related to dental services, the expedited Grievance review committee must include a dentist. Other appropriate providers may participate in the review, but the licensed physician or licensed dentist in the same or similar specialty that typically manages or consults on the service or item in question must decide the Grievance.

j. Prior to the start of the expedited Grievance review meeting, the Participant must be told that the testimony will be recorded. If the Participant agrees to

the testimony taken by the Grievance review committee (including the Participant's comments) being recorded, the testimony must be recorded and transcribed verbatim and a written transcription prepared and maintained as part of the Grievance record. If the Participant objects to the testimony being recorded, the Participant's objection must be documented in the expedited Grievance record and the expedited Grievance review meeting must proceed without the testimony being recorded.

k. The CHC-MCO must issue the decision resulting from the expedited review in person or by phone to the Participant, to the Participant's representative if the Participant has designated one in writing, to the service Provider, and to the prescribing Provider within either forty eight (48) hours of receiving the Provider certification or seventy-two (72) hours of receiving the Participant's request for an expedited review, whichever is shorter, unless the time frame for deciding the expedited Grievance has been extended by up to fourteen (14) days at the request of the Participant. In addition, the CHC-MCO must mail written notice of the decision to the Participant, to the Participant's representative, if the Participant has designated one in writing, to the service Provider, and to the prescribing Provider, if applicable, within two (2) business days of the decision, using the template specified by the Department.

l. The Participant or the Participant's representative may file a request for a Fair Hearing within one hundred and twenty (120) days from the mail date on the written notice of the CHC-MCO's expedited Grievance decision.

m. A request for an expedited Fair Hearing may be filed with the Department's Bureau of Hearings and Appeals verbally, or in writing via mail, fax, or secure email.

n. The Participant, or Participant's representative, which may include the Participant's Provider, with proof of the Participant's written authorization for the representative to be involved and/or act on the Participant's behalf, may file a request for an expedited external Grievance review with the CHC-MCO within two (2) business days from the date the Participant receives the CHC-MCO's expedited Grievance decision. A Participant who files a request for an expedited external Grievance review to dispute a decision to discontinue, reduce, or change a service or item that the Participant has been receiving must continue to receive the disputed service or item at the previously authorized level pending resolution of the request for expedited Grievance review.

o. The CHC-MCO must follow PID's BMC guidelines relating to submission of requests for expedited external reviews.

p. The CHC-MCO may not take punitive action against a Provider who requests expedited resolution of a Grievance or supports a Participant's request for expedited review of a Grievance.

D. Department's Fair Hearing Requirements

Fair Hearing: A hearing conducted by the Department's Bureau of Hearings and Appeals (BHA) or a Department designee.

1. Fair Hearing Process

a. A Participant or Participant's representative must file a Complaint or Grievance with the CHC-MCO and receive a decision on the Complaint or Grievance before filing a request for a Fair Hearing. If the CHC-MCO fails to provide written notice of a Complaint or Grievance decision within the time frames specified in this Exhibit, the Participant is deemed to have exhausted the Complaint or Grievance process and may request a Fair Hearing.

b. The Participant or the Participant's representative may request a Fair Hearing within one hundred and twenty (120) days from the mail date on the written notice of the CHC-MCO's first level Complaint decision or Grievance decision for any of the following:

i. the denial, in whole or part, of payment for a requested service or item based on lack of Medical Necessity;

ii. the denial of a requested service or item because the service or item is not a Covered Service;

iii. the reduction, suspension, or termination of a previously authorized service or item;

iv. the denial of a requested service or item but approval of an alternative service or item;

v. the failure of the CHC-MCO to provide a service or item in a timely manner, as defined by the Department;

vi. the failure of a CHC-MCO to decide a Complaint or Grievance within the specified time frames;

vii. the denial of payment after a service or item has been delivered because the service or item was provided without authorization by a provider not enrolled in the MA Program;

viii. the denial of payment after a service or item has been delivered because the service or item is not a Covered Service for the Participant;

ix. the denial of a Participant's request to dispute a financial liability, including cost sharing, copayments, premiums, deductibles, coinsurance, and other Participant financial liabilities.

c. The request for a Fair Hearing must include a copy of the written notice of decision that is the subject of the request unless the CHC-MCO failed to provide written notice of the Complaint or Grievance decision within the time frames specified in this Exhibit. Requests must be sent to:

Department of Human Services
OLTL/Forum Place 6th Floor
Complaint, Grievance and Fair Hearings
P.O. Box 8025
Harrisburg, Pennsylvania 17105-8025

d. A Participant who files a request for a Fair Hearing that disputes a decision to discontinue, reduce, or change a service or item that the Participant has been receiving must continue to receive the disputed service or item at the previously authorized level pending resolution of the Fair Hearing, if the request for a Fair Hearing is hand delivered, emailed, faxed, or post-marked within fifteen (15) days from the mail date on the written notice of decision.

e. Upon receipt of the request for a Fair Hearing, BHA or the Department's designee will schedule a hearing. The Participant and the CHC-MCO will receive notification of the hearing date by letter at least ten (10) days before the hearing date, or a shorter time if requested by the Participant. The letter will outline the type of hearing, the location of the hearing (if applicable), and the date and time of the hearing.

f. The CHC-MCO is a party to the hearing and must be present. The CHC-MCO, which may be represented by an attorney, must be prepared to explain and defend the issue on appeal. BHA's decision is based solely on the evidence presented at the hearing. The absence of the CHC-MCO from the hearing will not be reason to postpone the hearing.

g. The CHC-MCO must provide Participants, at no cost, with records, reports, and documents, relevant to the subject of the Fair Hearing.

h. BHA will issue an adjudication within ninety (90) days of the date the Participant filed the first level Complaint or the Grievance with the CHC-MCO, not including the number of days before the Participant requested the Fair Hearing. If BHA fails to issue an adjudication within ninety (90) days of receipt of the initial request for the Fair Hearing, the CHC-MCO must comply with the requirements at 55 Pa. Code § 275.4 regarding the provision of interim assistance upon the request for such by the Participant. When the Participant is responsible for delaying the hearing process, the time limit by which BHA must issue the adjudication prior to interim assistance being afforded will be extended by the length of the delay attributed to the Participant.

i. BHA's adjudication is binding on the CHC-MCO unless reversed by the Secretary of Human Services. Either party may request reconsideration from the Secretary within fifteen (15) days from the date of the adjudication. Only the Participant may appeal to Commonwealth Court within thirty (30) days from the date of the BHA adjudication or from the date of the Secretary's final order, if reconsideration was granted. The decisions of the Secretary and the Court are binding on the CHC-MCO.

2. Expedited Fair Hearing Process

a. A Participant or the Participant's representative may file a request for an expedited Fair Hearing with the Department either in writing or orally.

b. A Participant must exhaust the Complaint or Grievance process prior to filing a request for an expedited Fair Hearing.

c. BHA will conduct an expedited Fair Hearing if a Participant or a Participant's representative provides the Department with a signed written certification from the Participant's Provider that the Participant's life, physical or mental health, or ability to attain, maintain, or regain maximum function would be placed in jeopardy by following the regular Fair Hearing process or if the Provider provides testimony at the Fair Hearing which explains why using the usual time frames would place the Participant's health in jeopardy.

d. A Participant who files a request for an expedited Fair Hearing to dispute a decision to discontinue, reduce, or change a service or item that the Participant has been receiving must continue to receive the disputed service or item at the previously authorized level pending resolution of the Fair Hearing, if the request for an expedited Fair Hearing is made verbally, hand

delivered, emailed, faxed, or post-marked within fifteen (15) days from the mail date on the written notice of decision.

e. Upon the receipt of the request for an expedited Fair Hearing, BHA or the Department's designee will schedule a hearing.

f. The CHC-MCO is a party to the hearing and must be present. The CHC-MCO, which may be represented by an attorney, must be prepared to explain and defend the issue on appeal. The absence of the CHC-MCO from the hearing will not be reason to postpone the hearing.

g. The CHC-MCO must provide the Participant, at no cost, with records, reports, and documents relevant to the subject of the Fair Hearing.

h. BHA has three (3) business days from the receipt of the Participant's oral or written request for an expedited review to process final administrative action.

i. BHA's adjudication is binding on the CHC-MCO unless reversed by the Secretary of Human Services. Either party may request reconsideration from the Secretary within fifteen (15) days from the date of the adjudication. Only the Participant may appeal to Commonwealth Court within thirty (30) days from the date of adjudication or from the date of the Secretary's final order, if reconsideration was granted. The decisions of the Secretary and the Court are binding on the CHC-MCO.

E. Provision of and Payment for Service or Item Following Decision

1. If the CHC-MCO, BHA, or the Secretary reverses a decision to deny, limit, or delay a service or item that was not furnished during the Complaint, Grievance, or Fair Hearing process, the CHC-MCO must authorize or provide the disputed service or item as expeditiously as the Participant's health condition requires but no later than seventy-two (72) hours from the date it receives notice that the decision was reversed. If the CHC-MCO requests reconsideration, the CHC-MCO must authorize or provide the disputed service or item pending reconsideration unless the CHC-MCO requests a stay of the BHA decision and the stay is granted.

2. If the CHC-MCO, BHA, or the Secretary reverses a decision to deny authorization of a service or item, and the Participant received the disputed service or item during the Complaint, Grievance, or Fair Hearing process, the CHC-MCO must pay for the service or item that the Participant received.

3. If a Participant requests both an external appeal/review and a Fair Hearing, and

if the decisions rendered as a result of the external review and Fair Hearing are in conflict with one another, the CHC-MCO must abide by the decision most favorable to the Participant. In the event of a dispute or uncertainty regarding which decision is most favorable to the Participant, the CHC-MCO must submit the matter to DHS' the Department's Grievance and Appeals Coordinator for review and resolution.

EXHIBIT H

COORDINATION WITH

BEHAVIORAL HEALTH MANAGED CARE ORGANIZATIONS

Written agreements between the CHC-MCO and the BH-MCO must reflect the requirements for how the CHC-MCO and BH-MCO will coordinate services for all Participants, including those in NFs and those receiving LTSS at home. A sample coordination agreement (which does not include all required procedures) is available on the Intranet supporting CHC. The written agreements must include, but not be limited to:

- Procedures which govern referral, collaboration, and coordination of diagnostic assessment and treatment, prescribing practices, the provision of ED services, and other treatment issues necessary for optimal health and prevention of disease. The CHC-MCO and the BH-MCO must collaborate in relation to the provision of ED services. Emergency services provided in general hospital EDs are the responsibility of the CHC-MCO, regardless of the diagnosis or services provided. The only exception is for ED evaluations for voluntary or involuntary commitment pursuant to the 1976 Mental Health Procedures Act, 50 P.S. §§ 7107 - 7116, which are the responsibility of the BH-MCO. Responsibility for inpatient admission will be based upon the Participant's primary diagnosis. Procedures must define and explain how payment will be shared when the Participant's primary diagnosis changes during a continuous hospital stay;

- Procedures, including Prior Authorization, which govern reimbursement by the BH- MCO to the CHC-MCO for BH services provided by the CHC-MCO or vice versa. Procedures must include provisions for differential diagnosis of persons with coexisting physical and BH disorders, as well as provisions for cost-sharing when both physical and BH services are provided to a Participant;

- Procedures for the exchange of enrollment and health-related information among the BH-MCO, the CHC-MCO, the PCP, and Providers of BH and Covered Services in accordance with Federal and State confidentiality statutes and regulations (e.g., periodic treatment updates with identified primary and relevant specialty Providers);

- Policy and procedures for obtaining releases to share clinical information and providing health records to each other as requested, consistent with Federal and State confidentiality requirements;

- Procedures for training and consultation to each other to facilitate continuity of care and cost-effective use of resources;

- A mechanism for timely resolution of any clinical and fiscal payment disputes, including procedures for entering into binding arbitration to obtain final resolution;

- Procedures for serving on interagency teams, as necessary;

- Procedures for the development of adequate Provider Networks to serve special needs populations and coordination of specialized service plans between the BH-MCO service managers, BH service provider(s) and the PCP for Participants with special health needs (e.g., older adults with coexisting physical and behavioral health disorders);

- Procedures for the coordination and payment of emergency and non-emergency Medically Necessary ambulance transportation of Participants. All emergency and non-emergency Medically Necessary ambulance transportation for both physical and BH services Covered Services is the responsibility of the CHC-MCO, including for a BH diagnosis.

- Procedures for the coordination of laboratory services;

- Mechanisms and procedures to ensure coordination between the BH-MCO service managers, Participant services staff and BH-MCO network providers with the CHC-MCO's Service Coordination unit. The effectiveness of these mechanisms shall be included as an area for review by the BH-MCO's Quality Assurance Program and the CHC-MCO's QM Program;

- Procedures for the CHC-MCO to provide physical examinations required for the delivery of BH services, within designated time frames for each service;

- Procedures for the interaction and coordination of pharmacy services.

To ensure that there is support for the coordination of care between the PCP and the BH provider, appropriate county contacts can be found at the following Internet addresses:

County MH/ID Administrators:
https://www.dhs.pa.gov/providers/Providers/Pages/County-Mental-Health-System.aspx
Single County Authorities (SCAs):
https://www.ddap.pa.gov/Get%20Help%20Now/Pages/County-Drug-and-Alcohol-Offices.aspx

EXHIBIT I

GUIDELINES FOR CHC-MCO ADVERTISING, SPONSORSHIPS, AND OUTREACH

I. Overview

The CHC-MCO must submit a plan for advertising, sponsorship, and outreach procedures to the Department for advance written approval in accordance with the guidelines outlined in this exhibit. This plan must address how the CHC-MCO will market its D-SNP to Participants.

II. Community HealthChoices Outreach Procedures

The CHC-MCO must adhere to the following guidelines and all the requirements specified in Section V.O.2, CHC-MCO Outreach Materials, and V.O.3, CHC-MCO Outreach Activities, of the Agreement when submitting outreach materials, policies and procedures to the Department.

A. Submission of CHC-MCO Outreach Materials

Purpose: To obtain Department approval of new or revised outreach materials, plans or procedures.

Objectives:

1. To assure that CHC-MCO outreach materials are accurate.

2. To prevent the CHC-MCO from distributing outreach materials that mislead, confuse or defraud either the Participant or the Department.

Process:

1. The CHC-MCO submits outreach materials to the Department for prior approval using the CHC Educational Materials Approval Form (form attached).

2. The Department's contract monitoring Core Team will review and forward to the CHC-MCO a preliminary response within thirty (30) calendar days from date of receipt of the request form.

   Exception: Should the materials require comments or approval from offices outside the Department contract monitoring Core Team, the turnaround time would be as soon as possible.

3. The CHC-MCO will submit a final copy of the outreach materials to the Department contract monitoring Core Team for a final written approval prior to circulating the materials.

4. The Department review agency will forward a final written approval to the CHC-MCO within ten (10) business days.

5. Outreach material usage:

   a. Direct outreach materials will be used only by the IEB personnel after final written approval is received by the CHC-MCO from the Department.

   b. Indirect outreach materials (i.e., advertisements) may be utilized immediately after final written approval is received by the CHC-MCO from the Department.

B. Criteria for Review of CHC-MCO Outreach Materials

Purpose: To ensure that printed materials, advertising, promotional activities, and new Participant orientations coordinated through the IEB are designed to enable Participants to make an informed choice.

Objectives:

1.To ensure that the information complies with all Federal and State requirements.

2.To determine if the information is grammatically correct and appropriate for Pennsylvania's Medical Assistance population.

3. To ensure that outreach materials are accurate and do not mislead, confuse, or defraud the Participant or the Department with the assertion or statement that the Participant must enroll in the CHC-MCO in order to obtain Medical Assistance benefits, or in order to not lose Medical Assistance benefits.

4. To ensure that the outreach materials do not contain assertions or statements that a Participant must enroll in the aligned D-SNP of the CHC-MCO.

5. To ensure that there are no assertions or statements that the CHC-MCO is endorsed by CMS, the Federal or State government, or similar entity.

Process:

1. Receive a written overall outreach plan annually if the CHC-MCO anticipates participation in outreach activities. Requests for specific indirect advertising must be submitted thirty (30) calendar days in advance for written Department approval.
2. Determine if approval is necessary from other offices.
3. Review the information with the following criteria:

    a. Is the CHC-MCO identified?
    b. Does the information comply with all Federal and State regulations?
    c. Is the information presented in grammatically correct, precise, appropriate and unambiguous language, easily understood by the target audience (i.e., age and language) and does it avoid the use of industry jargon?
    d. Is the information fair, relevant, accurate and not misleading or disparaging to competitors?
    e. Can the information be easily understood by a person with a sixth grade education?
    f. Does the information include symbols or pictures that are discriminating because of race, color, creed, age, religion, sex, sexual orientation, gender identity, national origin, ancestry, marital status, income status, health status, physical or mental disability, or otherwise?
    g. Does the information create a negative image of the traditional FFS system?

4. The Department will forward a final written response to the CHC-MCO within ten (10) business days.

C. CHC-MCO Participating In or Hosting an Event

The CHC-MCO may submit requests to sponsor or participate in health fairs or community events; the request should demonstrate that the CHC-MCO will participate in such fairs or events through activities, including approved outreach activities that are primarily health-care related. The CHC-MCO must receive advance written approval from the Department prior to the event date. All requests must be submitted to the Department at least thirty (30) calendar days in advance of the event, on the forms which are included as part of this attachment.

Purpose: To clarify for CHC-MCOs that Pennsylvania laws and regulations prohibit certain kinds of offers or payments to Participants as inducements or incentives for Participants to use the CHC-MCO's services.

Objectives:

1. To provide amenities that create an environment that is comfortable and convenient for Participants but is not offered as an artificial outreach inducement or incentive.

2. To eliminate fraudulent, abusive and deceptive practices that may occur as incentives or inducements to obtain specific Covered Services from the CHC-MCO.

Process:

1. The CHC-MCO must submit a request, using the applicable Community HealthChoices CHC-MCO Outreach Approval Form or the Community HealthChoices Educational Materials Approval Form, to the appropriate Department review agency thirty (30) calendar days in advance of the event (see attached). Should the event require approval from other offices, the approval process may extend beyond thirty (30) calendar days.

2. The Department review agency considers the request as confidential.

D. Community HealthChoices CHC-MCO Outreach Approval Form

E. Community HealthChoices Educational Materials Approval Form

COMMUNITY HEALTHCHOICES EDUCATIONAL MATERIALS APPROVAL FORM

CHC-MCO Name:_____ Tracking #: _____

Contact Person:_____ Date: _____

Request Received By DHS: _____

Subject: _____

Who: _____

What: _____

When: _____

Where: _____

Any Fees: _____

Confirmation Letter Attached: Yes ☐ No ☐

Discussion:

DHS USE ONLY:

Approved: ☐ Denied: ☐

Reviewer:_____ Final Approval Date: _____

COMMUNITY HEALTHCHOICES CHC-MCO OUTREACH APPROVAL FORM

CHC-MCO Name:_____ Tracking #: _____

Contact Person:_____ Date: _____

Request Received By DHS: _____

Subject: _____

Who: _____

What: _____

When: _____

Where: _____

Any Fees: _____

Confirmation Letter Attached: Yes ☐ No ☐

Discussion:

DHS USE ONLY:

Approved: ☐ Denied: ☐

Reviewer:_____ Final Approval Date: _____

EXHIBIT J

PARTICIPANT CHC-MCO SELECTION AND ASSIGNMENT

IEB Responsibilities for Advance Plan Selections and Plan Assignments

During the pre-transition period, the IEB will contact Potential Participants to offer them information about CHC and the CHC-MCOs and assist the individual to choose a CHC-MCO before being assigned to one. If an individual does not select a CHC-MCO, the individual will be assigned to a CHC-MCO according to the hierarchy criteria described below. If none of the hierarchy criteria applies to an individual, the individual will be assigned to a CHC-MCO using the automatic assignment process described below. Participants who are enrolled in a CHC-MCO through either mechanism may select a different CHC-MCO at any time. The IEB will assist Participants in choosing a different CHC-MCO.

After the CHC transition date, all eligible Participants will be enrolled in a CHC-MCO using the automatic assignment process described below.

Potential Participants who are NFI Dual Eligibles. In making CHC-MCO assignments, the IEB will use the following hierarchy:

- First, if the individual is enrolled in a D-SNP, the individual will be enrolled in the CHC-MCO aligned with that D-SNP;
- Second, if the individual is transferring from Health Choices and is a member of a Physical Health HealthChoices MCO that is also a CHC-MCO, the individual will be enrolled in that CHC-MCO; and
- Last, if the individual's PCP is a Network Provider with only one CHC-MCO, the individual will be enrolled in that CHC-MCO.

Potential Participants who are NFCE. In making CHC-MCO assignments, the IEB will use the following hierarchy:

- First, if on the Enrollment Date the individual is residing in a NF that is a Network Provider in only one CHC-MCO, the individual will be enrolled in that CHC-MCO;
- Second, if the individual is enrolled in a D-SNP, the individual will be enrolled in the CHC-MCO that is aligned with that D-SNP;
- Third, if the individual is transferring from HealthChoices and is a member of a Physical Health HealthChoices MCO that is also a CHC-MCO, the individual will be enrolled in that CHC-MCO;
- Last, if the individual's PCP is a Network Provider with only one CHC-MCO, the individual will be enrolled in that CHC-MCO.

Automatic Assignments

If a Participant does not select a CHC-MCO and none of the hierarchy criteria described above applies to the individual, the Participant will be enrolled in a CHC-

MCO using the following auto-assignment process:

- If the Participant's case record includes another active Participant in the case who is enrolled in a CHC-MCO, the Participant will be enrolled in that same CHC-MCO. Participants in a family unit will be enrolled in the same CHC-MCO. These Participants will not be included in the percentages designated for auto-assignment.
- All remaining Participants will be included in the pool of Participants who will be auto-assigned to CHC-MCOs using an algorithm that directs a monthly distribution of Participants in the auto-assignment pool in all Zones based on the number of CHC-MCOs in the Zone. .

A CHC-MCO may not receive auto-assignments if it does not have the capacity to take on additional Participants or if it is subject to sanctions.

A CHC Participant who is auto-assigned to a CHC-MCO may select a different CHC-MCO at any time. The IEB will assist Participants in choosing a different CHC-MCO.

Participant Re-Assignment Following Resumption of Eligibility

A Participant who becomes ineligible and becomes eligible again within six (6) months will automatically be re-enrolled in the Participant's previously selected CHC-MCO, as long as the Participant's eligibility status and geographical residence are still valid for enrollment in that same CHC-MCO.

If a Participant becomes ineligible and becomes eligible again after six (6) months, the Participant may be enrolled in the same CHC-MCO as the payment name, the case payment name, or any other Participant in the case that is enrolled in the CHC-MCO. If there is no active CHC-MCO record in the case, the Participant will be enrolled in a CHC-MCO through the auto-assignment process. Prior to the Start Date of the auto-assigned CHC-MCO, the Participant may select a different CHC-MCO and override the auto-assigned CHC-MCO by contacting the IEB. When the Participant contacts the IEB to make this change, the IEB will enroll the Participant in the CHC-MCO of choice through the weekly enrollment process.

Continued Enrollment When Moving Between Zones

A Participant who moves from one CHC zone to another will remain in the CHC-MCO in which he or she was enrolled prior to the move, if the CHC-MCO is also operational in the zone to which the Participant moved.

The Department may reassess the distribution process, modify it in accordance with sound programmatic management principles, and institute any modifications at any time following appropriate written notification to the CHC-MCO.

EXHIBIT K

CHC-MCO PARTICIPANT COVERAGE DOCUMENT

This Participant Coverage Document (PCD) includes descriptions of policies supported by the Department's data systems and processes. In cases where policies in this document conflict with another provision of the CHC-MCO Agreement, the Agreement will take precedence.

CHC-MCO coverage as detailed in this document does not imply coverage under a BH-MCO. Refer to the BH-MCO Recipient Coverage Document for behavioral health coverage guidelines.

The Department will provide sufficient information to each CHC-MCO to reconcile CHC-MCO Participant data and amounts paid to and recovered from the CHC-MCO. The Department will pay capitation to only one CHC plan per-Participant, per-month.

Coverage Rules

A CHC-MCO is responsible for a Participant if coverage is determined by applying the general rules found in paragraph A or B below, subject to exceptions and clarifications in paragraphs C, D, E, and F.

Refer to the Community HealthChoices Intranet site for additional information on Participant coverage, clarifications, examples, and Participant Enrollment/Disenrollment procedures.

A. **Responsibility to Provide MA Benefits**. Unless otherwise specified, each CHC-MCO is responsible for providing MA benefits to its Participants in accordance with eligibility information included on the Daily or Monthly 834 Eligibility File, which is provided by the Department to each CHC-MCO.

B. **Participant Files/Coverage Dates/Eligibility**. Daily and Monthly 834 Eligibility Files are provided to each CHC-MCO containing information and changes that apply to its Participants. The CHC-MCO is responsible for providing services for each non-LTSS CHC-MCO Participant identified on the Daily or Monthly 834 Eligibility File from the first day of the calendar month or the CHC-MCO Start Date, whichever is later, through the last day of the calendar month or the CHC-MCO coverage end date, if different. The Department will pay prorated Capitation to the CHC-MCO from the first day of coverage in a month through the last day of the calendar month. CHC-MCO coverage dates beyond the last day of the month are preliminary information that is subject to change.

   For LTSS participants, the CHC-MCO is responsible for providing services starting the day after MA eligibility determination. The Department will provide information about these individuals to the CHC-MCOs on a Daily or Monthly 834 Eligibility File.

eCIS will retain a Participant's CHC-MCO selection for six (6) months after a Participant becomes ineligible for MA. These Participants will become the responsibility of the same CHC-MCO if they regain MA eligibility during that six-month period and their category of assistance and geographic location are valid for that CHC-MCO. Upon regaining MA eligibility, the CHC-MCO Start Date will be the MA eligibility Start Date on Client Information System (eCIS) or the date MA eligibility was reopened in eCIS, whichever is later.

C. Exceptions and Clarifications. The Department will recover Capitation payments made for Participants who the Department has determined the CHC-MCO was not responsible for providing services.

The CHC-MCO will not be responsible for nor paid when the Department notifies the CHC-MCO of Participants for whom they are not responsible.

1. Errors in CHC-MCO coverage identified from any source must be reported to the Department within forty-five (45) days of receipt of the Daily 834 Eligibility File for changes to be considered.

   If a Participant is enrolled in a CHC-MCO in error, that CHC-MCO is responsible for covering the Participant until the Department is notified and the correction is applied to the eCIS eligibility record.

   If at the time of notification to the Department, the Participant was disenrolled in error from a CHC-MCO and then enrolled in a different CHC-MCO, the Participant will be reenrolled in the previous CHC-MCO effective the first of the next month. However, if at the time of notification, the Participant is covered by FFS, the Participant will be reenrolled into the same CHC-MCO effective the day following notification to the Department.

2. If eCIS shows an exemption code or a facility/placement code that precludes CHC-MCO coverage, the Participant will not be enrolled in a CHC-MCO.

3. If eCIS shows Fee-For-Service (FFS) coverage that coincides with CHC-MCO coverage, the Participant may elect to use either coverage and there will be no monetary adjustment between the Department and the CHC-MCO. (This is subordinate to #7 below.)

4. If a CHC-MCO has actual knowledge that a Participant is deceased, and if such Participant shows on either the Daily or Monthly 834 Eligibility File as active, the CHC-MCO is required to notify the County Assistance Office (CAO) and the Department. The Department will recover Capitation payments made for up to twenty-one (21) months after the service month in which the date of death occurred.

5. The Department will recover Capitation payments for Participants who were later determined to be ineligible for CHC-MCO coverage or who were placed in a setting that results in the termination of CHC-MCO coverage by the Department. The Department will recoup payments back to the month following the month in which the termination of coverage occurred, for up to twelve (12) months afterwards. For example, today's date is 9/18/2022 and central office staff end-dated managed care coverage 9/30/2021 – payments are recouped for 10/2021 through 9/2022. See Section E for examples of placements that result in termination of coverage.

6. A Participant's change of residence out of a CHC-MCO's service area does not necessarily exempt the CHC-MCO from the responsibility to provide MA benefits. It is the CHC-MCO's responsibility to inform the CAO of the address change upon receipt of information that a Participant is residing outside the CHC-MCO service area.

7. Pursuant to the rules outlined in this PCD, the absence of MA eligibility indicated on eCIS for a particular date does not necessarily exempt the CHC-MCO from its responsibility to provide MA benefits for that date. Refer to Section D, Change in CHC-MCO Coverage during Inpatient Hospital Stays, for applicable rules.

8. The Department reserves the right to intercede in requests for expedited enrollments when Medically Necessary. The Department's determination for the expedited enrollment will be final. The Capitation rate will be retroactively adjusted for the CHC-MCO based on the expedited Start Date.

9. The CHC-MCO must provide Out-of-Area Covered Services for a Participant as long as they remain a resident of the Commonwealth and the zone. The CHC-MCO remains responsible for a Participant who is:
    - attending a college or university in a state other than Pennsylvania,
    - attending a college or university in a zone other than their zone of residence, or
    - traveling outside of the zone.

10. If eCIS shows Living Independence for the Elderly (LIFE) coverage that coincides with CHC-MCO coverage due to a Participant transfer from CHC to LIFE, the LIFE program will receive a Capitation payment, and the CHC-MCO will not be entitled to a Capitation payment for the consecutive month(s) after the transfer in which the LIFE and CHC-MCO coverages coincide. The Department will recover Capitation payments received by the CHC-MCO for month(s) the LIFE coverage and CHC-MCO coverage coincide due to a Participant transfer from CHC to LIFE.

11. If a Participant transfers from LIFE to CHC and coverage coincides, the CHC-MCO will receive a Capitation payment, and the LIFE program will not be entitled to a Capitation payment for the consecutive month(s) after the transfer

in which the CHC-MCO and LIFE coverages coincide. The Department will recover Capitation payments received by the LIFE program for month(s) the CHC-MCO coverage and LIFE coverage coincide due to a Participant transfer from LIFE to CHC.

D. Change in CHC-MCO Coverage during Inpatient Hospital Stays. Payment responsibility when an MA Participant has CHC coverage during part of a hospital stay is detailed in the Rules below. Note that one or more of these rules may apply during a particular hospital stay.

RULE: D-1.	
Condition	**A Participant who is covered by FFS when admitted to a hospital becomes eligible for CHC-MCO coverage while still in the hospital.**
CHC-MCO Coverage Responsibility	As of the CHC-MCO Start Date, the CHC-MCO is responsible for physician, DME, and all other Covered Services not included in the hospital bill.
MA FFS Coverage Responsibility	The FFS program is responsible for the hospital bill through the date of discharge. Note: If the Participant is discharged from the initial hospital and admitted to another hospital (acute or rehabilitation) after the CHC-MCO Start Date, FFS is only responsible for the stay in the initial hospital through the date of discharge. The CHC-MCO is responsible for the stay in the subsequent hospital upon admission.

RULE: D-2	
Condition	**A Participant who is covered by a CHC-MCO when admitted to a hospital loses CHC-MCO coverage and assumes FFS coverage while still in the hospital.**
CHC-MCO Coverage Responsibility	The CHC-MCO is responsible for the hospital stay with the following exceptions: EXCEPTION #1: If the Participant is still in the hospital on the FFS coverage begin date, and the Participant's FFS coverage begin date is the first (1st) day of the month, the CHC-MCO is financially responsible for the stay through the last day of that month. Example: If a Participant covered by the CHC-MCO is admitted to a hospital on June 21 and the FFS coverage begin Date is July 1, the FFS program assumes payment responsibility for the stay on August 1. The CHC-MCO remains financially responsible for the stay through July 31. EXCEPTION #2: If the Participant is still in the hospital on the FFS coverage begin date, and the Participant's FFS coverage begin date is any day other than the first day of the month, the CHC-MCO is financially responsible for the stay through the last day of the following month.

	Example: If a Participant covered by a CHC-MCO is admitted to a hospital on June 21 and the FFS program coverage begin date is July 15, the FFS program assumes payment responsibility for the stay on September 1. The CHC-MCO program remains financially responsible for the stay through August 31.
MA FFS **Coverage Responsibility**	Starting with the FFS coverage begin date, FFS is responsible for physician, DME, and other bills not included in the hospital bill. EXCEPTION #1: The FFS program is financially responsible for the stay beginning on the first day of the next month. EXCEPTION #2: The FFS program is financially responsible for the stay beginning on the first day of the month following the next month.

RULE: D-3	
Condition	**A Participant covered by a CHC-MCO when admitted to a hospital transfers to another CHC-MCO while still in the hospital.**
CHC-MCO **Coverage Responsibility**	The surrendering CHC-MCO is responsible for the hospital stay with the exceptions below. As of the gaining CHC-MCO's Start Date, it is responsible for the physician, DME, and all other Covered Services not included in the hospital bill. EXCEPTION #1: If the Participant is still in the hospital on the receiving CHC-MCO Start Date, and the Participant's gaining CHC-MCO Start Date is the first day of the month, the surrendering CHC-MCO is financially responsible for the stay through the last day of that month. The gaining CHC-MCO is financially responsible for the stay beginning on the first day of the next month. Example: If a Participant is admitted to a hospital on June 21 and the receiving CHC-MCO Start Date is July 1, the gaining CHC-MCO assumes payment responsibility for the stay on August 1. The surrendering CHC-MCO remains financially responsible for the stay through July 31. EXCEPTION #2: If the Participant is still in the hospital on the gaining CHC-MCO Start Date, and the gaining CHC-MCO Start Date is any day other than the first day of the month, the surrendering CHC-MCO is financially responsible for the stay through the last day of the following month. The gaining CHC-MCO is financially responsible for the stay beginning on the first day of the month following the next month. Example: If a Participant is admitted to a hospital on June 21 and the receiving CHC-MCO Start Date is July 15, the gaining CHC-MCO assumes payment responsibility for the stay on September 1. The surrendering CHC-MCO remains financially responsible for the stay through August 31.

MA FFS **Coverage Responsibility**	There is no FFS coverage in this example.

RULE: D-4	
Condition	**A Participant covered by a CHC-MCO when admitted to a hospital loses and regains MA eligibility while in the hospital (Participant is not discharged), resulting in a break in CHC-MCO coverage. The Department's Division of Medicaid Management Information Systems (MMIS) Operations becomes aware of the break in CHC-MCO coverage by the end of the month following the month in which it is lost.**
CHC-MCO **Coverage Responsibility**	MMIS Operations will reopen the Participant's CHC-MCO coverage retroactive to the day it was end-dated on eCIS and adjust the Capitation payment accordingly. The CHC-MCO continues to be financially responsible for the stay, including the physician, DME, and all other Covered Services. Example: A Participant who is admitted to the hospital on March 10 loses MA eligibility effective March 22 and regains it on April 9 retroactive to March 22. The CHC-MCO coverage on eCIS shows the Participant was end-dated March 31 and reopened in the CHC-MCO with a new CHC-MCO Start Date of April 9. On April 25, MMIS Operations becomes aware of the situation. Because MMIS Operations is aware of the loss of MA eligibility within the month following the month in which it was lost, MMIS Operations reopens the CHC-MCO coverage retroactive to April 1, the day after the CHC-MCO end-date is posted on eCIS (March 31). The CHC-MCO continues to be financially responsible for the stay, including the physician, DME, and all other Covered Services.
MA FFS **Coverage Responsibility**	There would be no FFS coverage in this example.

RULE: D-5	
Condition	**A Participant covered by a CHC-MCO when admitted to a hospital loses and regains MA eligibility while in the hospital (Participant is not discharged), resulting in a break in CHC-MCO coverage. MMIS Operations does not become aware of the break in CHC-MCO coverage by the end of the month following the month in which it is lost.**
CHC-MCO **Coverage Responsibility**	Example: A recipient who is admitted to the hospital on March 10 loses MA eligibility effective March 22 and regains it on April 9 retroactive to March 22. The CHC-MCO coverage on eCIS shows the recipient as end-dated March 31 and reopened in the CHC-MCO with a new begin date of April 9. Because MMIS Operations was not aware of the break in CHC-MCO coverage by the end of the month following the month in which it was lost, the CHC-MCO coverage is not reopened retroactive to the day it was end-dated on eCIS (March 31). The CHC-MCO is only responsible for covering the Participant through the end of March, then again starting April 9 with a prorated

	capitation payment for the remainder of April.
MA FFS **Coverage Responsibility**	FFS is responsible effective April 1 through April 8.

RULE: D-6.	
Condition	**A Participant covered by a CHC-MCO when admitted to a hospital loses MA eligibility while in the hospital (Participant is not discharged). The Participant regains MA eligibility retroactively after the month following the month in which the MA eligibility was ended, regardless of when MMIS Operations became aware of the action.**
CHC-MCO **Coverage Responsibility**	Example: A Participant who is admitted to the hospital on March 10 loses MA eligibility effective March 22. The Participant regains MA eligibility on May 15 retroactive to March 22. The CHC-MCO coverage on eCIS shows the Participant was end-dated March 31 and reopened in the CHC-MCO with a new Start Date of May 15. Because the MA eligibility was not reopened within the month following the month in which it was lost, the CHC-MCO coverage is not reopened retroactive to the day it was end-dated on eCIS (March 31). The CHC-MCO is only responsible for covering the Participant through the end of March.
MA FFS **Coverage Responsibility**	FFS is responsible effective April 1st.

RULE: D-7.	
Condition	**A Participant covered by a CHC-MCO when admitted to a hospital loses MA eligibility while in the hospital. The Participant is discharged from the hospital after the month in which the MA eligibility was lost but before the MA eligibility is regained by the Participant and reopened retroactively, regardless of when MMIS Operations became aware of the situation.**
CHC-MCO **Coverage Responsibility**	Example: A Participant who is admitted to the hospital on March 10 loses MA eligibility effective March 22. The Participant is discharged from the hospital April 3. The Participant regains MA eligibility on April 22 retroactive to March 22. The CHC-MCO coverage on eCIS shows the Participant was end-dated March 31 and reopened in the CHC-MCO with a new Start Date of April 22. Because the Participant was discharged from the hospital before the MA eligibility was reopened, which resulted in a three (3)-day period of FFS coverage on eCIS, MMIS Operations does not reopen the CHC-MCO coverage retroactive to April 1. The CHC-MCO is only responsible for the stay through the end of March.
MA FFS	FFS is responsible effective April 1.

Coverage Responsibility	

RULE: D-8	
Condition	**A hospitalized Participant never regains MA eligibility.**
CHC-MCO **Coverage Responsibility**	If the Participant is never determined retroactively eligible for MA, the CHC-MCO is only responsible to cover the Participant through the end of the month in which MA eligibility ended.
MA FFS **Coverage Responsibility**	FFS is not responsible for coverage since the Participant has not regained MA eligibility.

RULE: D-9	
Condition	**A Participant who is covered by a PH-MCO when admitted to a hospital loses PH-MCO and assumes CHC-MCO while still in the hospital.**
CHC-MCO **Coverage Responsibility**	The surrendering PH-MCO is responsible for the hospital stay with the exceptions below. As of the gaining CHC-MCO's Start Date, the gaining CHC-MCO is responsible for the physician, DME, and all other Covered Services not included in the hospital bill. EXCEPTION #1: If the Participant is still in the hospital on the gaining CHC-MCO Start Date, and the Participant's gaining CHC-MCO Start Date is the first (1st) day of the month, the surrendering PH-MCO is financially responsible for the stay through the last day of the month. The gaining CHC-MCO is financially responsible for the stay beginning on the first day of the next month. Example: If a Participant is admitted to a hospital on June 21 and the gaining CHC-MCO Start Date is July 1, the gaining CHC-MCO assumes payment responsibility for the stay on August 1. The surrendering PH-MCO remains financially responsible for the stay through July 31. EXCEPTION #2: If the Participant is still in the hospital on the gaining CHC-MCO Start Date, and the Participant's gaining CHC-MCO Start Date is any day other than the first day of the month, the surrendering PH-MCO is financially responsible for the stay through the last day of the following month. The gaining CHC-MCO is financially responsible for the stay beginning on the first day of the month following the next month. Example: If a Participant is admitted to a hospital on June 21 and the gaining CHC-MCO Start Date is July 15, the gaining CHC-MCO assumes payment responsibility for the stay on September 1. The surrendering PH-MCO remains financially responsible for the stay through August 31.

MA FFS **Coverage Responsibility**	There is no FFS coverage in this example.

RULE: D-10	
Condition	**A Participant who is covered by a CHC-MCO when admitted to a hospital loses CHC-MCO and assumes PH-MCO while still in the hospital.**
CHC-MCO **Coverage Responsibility**	The surrendering CHC-MCO is responsible for the hospital stay with the exceptions below. Starting with the gaining PH-MCO's Start Date, the gaining PH-MCO is responsible for the physician, DME, and all other Covered Services not included in the hospital bill. EXCEPTION #1: If the Participant is still in the hospital on the gaining PH-MCO Start Date, and the Participant's gaining PH-MCO Start Date is the first (1st) day of the month, the surrendering CHC-MCO is financially responsible for the stay through the last day of the month. The gaining PH-MCO is financially responsible for the stay beginning on the first day of the next month. Example: If a Participant is admitted to a hospital on June 21 and the gaining PH-MCO Start Date is July 1, the gaining PHC-MCO assumes payment responsibility for the stay on August 1. The surrendering CHC-MCO remains financially responsible for the stay through July 31. EXCEPTION #2: If the Participant is still in the hospital on the gaining PH-MCO Start Date, and the Participant's gaining PH-MCO Start Date is any day other than the first day of the month, the surrendering CHC-MCO is financially responsible for the stay through the last day of the following month. The gaining PH-MCO is financially responsible for the stay beginning on the first day of the month following the next month. Example: If a Participant is admitted to a hospital on June 21 and the gaining PH-MCO Start Date is July 15, the gaining PH-MCO assumes payment responsibility for the stay on September 1. The surrendering CHC-MCO remains financially responsible for the stay through August 31.
MA FFS **Coverage Responsibility**	There is no FFS coverage in this example.

E. Other Causes for Coverage Termination and Involuntary Disenrollment. If a condition described in the following sections occurs, the CHC-MCO must notify the Department. In accordance with the Department's disenrollment guidelines, MMIS Operations will take action to disenroll the Participant. The Department will recoup payments back to the month following the month in which the termination of coverage occurred, for up to twelve (12) months afterwards. For example, today's date is 9/18/2022 and central office staff end date managed care coverage 9/30/2021 – payments are recouped for 10/2021 through 9/2022).

If a Participant is placed in a setting listed in these sections and is under FFS prior to the CHC-MCO's Start Date, CHC-MCO coverage will be voided and adjustments will be processed for any Capitation payments made.

The CHC-MCO must notify the Department within sixty (60) days following the satisfaction of the Department's disenrollment guidelines for MMIS Operations to end-date the Participant's enrollment. Failure on the part of the CHC-MCO to notify MMIS Operations within the sixty (60) days will result in the end-date being delayed, thereby extending the CHC-MCO's responsibility for covering the Participant. The CHC-MCO should not hold and then later submit the notifications.

RULE: E-1	
Condition	**A Participant is admitted to an out-of-state Nursing Facility (regardless of who places the Participant in the facility).**
CHC-MCO Coverage Responsibility	The CHC-MCO is not responsible for Participants who are placed in a Nursing Facility outside of Pennsylvania. A Participant who is placed in an out-of-state Nursing Facility is disenrolled from the CHC-MCO the day before the admission date.

RULE: E-2	
Condition	**A Participant is admitted to a Veteran's Home (MA Provider type/specialty 03/042).**
CHC-MCO Coverage Responsibility	The CHC-MCO is not responsible for Participants who are admitted to a Veteran's Home. A Participant who is admitted to a Veteran's Home is disenrolled from the CHC-MCO the day before the admission date.

RULE: E-3	
Condition	**A Participant is admitted to a State Facility (MA Provider Type/Specialty Codes 01/23 - Public Psychiatric Hospital and 03/37 - State LTC Unit located at State Mental Hospitals).**
CHC-MCO Coverage Responsibility	The CHC-MCO is not responsible for Participants in a state facility. A Participant admitted to a state facility is disenrolled from the CHC-MCO the day before the admission date.
MA FFS Coverage Responsibility	FFS coverage is effective on the admission date.

RULE: E-4	
Condition	**A Participant is incarcerated in a Penal Facility, Correctional Institution (including work release), or Youth Development Center.**
CHC-MCO **Coverage Responsibility**	The CHC-MCO is not responsible for coverage since the Participant is no longer eligible for MA upon placement in a correctional facility. The Participant is disenrolled from the CHC-MCO effective the day before incarceration in the facility or institution.
MA FFS **Coverage Responsibility**	FFS is not responsible for coverage since the Participant is no longer eligible for MA upon placement in a correctional facility, except for inpatient hospital services. Note: This rule is based upon section 392.2 of the MA Eligibility Handbook which states: "For purposes of MA eligibility, other than eligibility for inpatient hospital services, the needs of an inmate in a correctional institution are the responsibility of the governmental authority exercising administrative control over the facility."

RULE: E-5	
Condition	**A Participant is enrolled in the Living Independence for the Elderly Program (LIFE) (MA Provider Type/Specialty Code 07/70 – LIFE).** LIFE is Pennsylvania's managed care option for individuals who are Nursing Home Clinically Eligible (NFCE) and age 55 and older. It provides fully integrated acute care, long-term care, behavioral health, and pharmacy services to individuals who wish to remain in the community.
CHC-MCO **Coverage Responsibility**	A Participant enrolled in LIFE is disenrolled from the CHC-MCO effective the day before the Start Date in the LIFE program.
MA FFS **Coverage Responsibility**	LIFE coverage begins the day after the disenrollment date.

F. Other Facility Placement Coverage. The following rules provide information relating to CHC-MCO coverage of Participants placed in psychiatric facilities.

RULE: F-1	
Condition	**A Participant is admitted to an Extended Acute Psychiatric Care Hospital (MA Provider Type/Specialty Code 01/18 – Extended Acute Psych Inpatient Unit).**
CHC-MCO **Coverage Responsibility**	A Participant admitted to an extended acute psychiatric hospital remains covered by the selected CHC-MCO for all Covered Services. If the Participant is placed in the facility by the BH-MCO, then the BH-MCO is responsible for

	the residential and treatment costs.
MA FFS **Coverage Responsibility**	FFS is responsible for the residential and treatment costs.

RULE: F-2	
Condition	**A Participant is admitted to an Inpatient Private Psychiatric Facility (MA Provider Type/Specialty Code 01/11 – Private Psychiatric Hospital and 01/22 – Private Psychiatric Unit).**
CHC-MCO **Coverage Responsibility**	A Participant admitted to a private psychiatric hospital remains covered by the selected CHC-MCO for all Covered Services. The BH-MCO is responsible for the residential and treatment costs.
MA FFS **Coverage Responsibility**	FFS is responsible for the residential and treatment costs.

Exhibit L
PARTICIPANT RIGHTS AND RESPONSIBILITIES

PARTICIPANTS' RIGHTS

Each CHC-MCO must have written policies regarding the Participant rights specified in this Exhibit.

Each CHC-MCO must comply with any applicable Federal and State laws that pertain to Participant rights, and its staff and Network Providers must take those rights into account when furnishing services to enrollees.

A participant has the right to:

- Receive information in a manner and format that may be easily understood and is readily accessible to Participants and potential Participants.
- Receive accurate, easily understood information and assistance in making informed health care and LTSS decisions about his or her health plans, professionals, and facilities.
- A choice of healthcare and LTSS providers that is sufficient to ensure access to appropriate high-quality healthcare.
- Access emergency health care services when and where the need arises.
- Fully participate in all decisions related to his or her healthcare and LTSS. Participants who are unable to fully participate in treatment decisions have the right to be represented by parents, guardians, family members, or other conservators.
- Considerate, courteous and respectful care from all members of the healthcare and LTSS system at all times and under all circumstances.
- Communicate with Providers in confidence and to have the confidentiality of his or her individually identifiable healthcare and LTSS information protected. Participants also have the right to review and copy his or her own medical and LTSS records and request amendments or corrections to their records.
- A fair and efficient process for resolving differences with their health plans, healthcare and LTSS Providers, and the institutions that serve them, including a rigorous system of internal review and an independent system of external review.
- Be free from any form of restraint or seclusion used as a means of coercion, discipline, convenience or retaliation, as specified in other Federal regulations on the use of restraints and seclusion.

The information requirements for services that are not covered under the contract because of moral or religious objections are set forth in 42 C.F.R. §438.10(g)(2)(ii)(A) and (B).

Each Participant is free to exercise his or her rights, and the exercise of those rights may not adversely affect the way the CHC-MCO and its providers treat the enrollee.

Each CHC-MCO must comply with any other applicable Federal and State laws (such as: Title VI of the Civil Rights Act of 1964 as implemented by regulations at 45 CFR part 80; the Age Discrimination Act of 1975 as implemented by regulations at 45 CFR part 91; the Rehabilitation Act of 1973; and Titles II and III of the Americans with Disabilities Act..

PARTICIPANTS' RESPONSIBILITIES

CHC Participants have the following responsibilities:

- Take responsibility for maximizing healthy habits, such as exercising, not smoking, and eating a healthy diet.
- Become involved in specific health care decisions.
- Work collaboratively with healthcare and LTSS Providers in developing and carrying out agreed-upon treatment plans.
- Disclose relevant information and clearly communicate wants and needs.
- Use the health plan's internal complaint and appeal processes to address concerns that may arise.
- Avoid knowingly spreading disease.
- Recognize the reality of risks and limits of the science of medical care and the human fallibility of the health care professional.
- Be aware of a healthcare and LTSS Provider's obligation to be reasonably efficient and equitable in providing care to other patients and the community.
- Become knowledgeable about his or her health plan and LTSS coverage and health plan and LTSS options (when available) including all covered benefits, limitations, and exclusions, rules regarding use of network providers, coverage and referral rules, appropriate processes to secure additional information, and the process to appeal coverage decisions.
- Show respect for other patients, health workers, and LTSS workers.
- Make a good-faith effort to meet financial obligations.
- Abide by administrative and operational procedures of health plans, healthcare and LTSS Providers, and Government health benefit programs.
- Report wrongdoing and fraud to appropriate resources or legal authorities.

EXHIBIT M

PARTICIPANT HANDBOOK

The CHC-MCO must adhere to the following guidelines and all the requirements in section V.0.4, LEP requirements, V.O.5, Alternative Format Requirements, and V.O.16, Participant handbook. The CHC-MCO must utilize the Participant handbook template provided by the Department. The CHC-MCO must provide a Participant Handbook in the appropriate prevalent language, or alternative format, to all Participants within five (5) business days of being notified of a Participant's Enrollment.

At a minimum, the Participant handbook must include:

1. Information about the CHC-MCO, its Covered Services, excluded services, Network Providers, and the Participant's rights and responsibilities as outlined in Exhibit L, Participant Rights and Responsibilities.

2. Role of the PCP in directing and managing care and as a Participant advocate.

3. Information on the role of the IEB and how to access services, including but not limited to what services it provides to Participants and contact information.

4. Description of services, which should include assistance with changing CHC-MCOs, PCPs, and the right to request an updated Provider Directory.

5. Procedure to access after-hour, non-emergency care.

6. Description of the CHC-MCO ID card and the ACCESS card and their uses.

7. Statement that no balanced billing is allowed, Participants are not to be balanced billed by Providers, and are to be held harmless for any bills the CHC-MCO declines to pay, and a statement of what steps to take in the event the Participant is billed or balance billed.

8. Information about the right to contact the Long-Term Care ombudsman, and about how to contact Protective Services (to assist those at risk for abuse, neglect, financial exploitation, and abandonment).

9. Information about co-payments, Prior Authorization, service limits, and the Covered Services exception process.

10. An explanation of the Participant's financial responsibilities for payment of services provided by an Out-of-Network Provider, when an item or service that requires Prior Authorization is provided without Prior Authorization being obtained, or when an item or service is provided that is not covered by the CHC-MCO.

- An explanation that prescriptions for medications that are written by Out-of-Network Providers (whether or not they are presented at an out-of-network pharmacy) will be the Participant's

  Responsibility, with the following exceptions:

  - The Non-Participating Provider or non-network Provider arrangements were approved in advance by the CHC-MCO and any Prior Authorization requirements (if applicable) were met;
  - The Non-Participating Provider or non-network prescriber and the pharmacy are the Participant's Medicare Providers; or
  - The Participant is covered by a third party carrier, and the Non-Participating Provider or non-network prescriber and the pharmacy is the Participant's third party Provider.

11. Information that the Participant is not liable for payment of authorized Covered Services provided when a Medical Assistance participating Provider does not receive payment from the CHC-MCO.

12. Rights of the Participant regarding confidentiality of his or her medical records.

13. Rights of the Participant to request and receive a copy of his or her medical records and to request that they be corrected or amended as specified in 45 C.F.R. §§164.524 and 164.526.

14. Rights of Participants to receive information regarding the patient payment responsibilities related to NF services.

15. Information on the availability of and how to access or receive assistance in accessing, at no cost to the Participant, oral interpretation services for all services provided by the CHC-MCO in all non-English languages and translated Vital Documents, in prevalent languages identified by the Department.

16. Availability of and information on how to access or receive assistance in accessing, at no cost to the Participant, communication methods including TTY/Videophone and relay services and materials in alternative formats such as Braille, audio tape, large print, compact disc (CD), DVD, computer diskette, and/or electronic communication, including how the CHC-MCO will arrange for providing these alternative format Participant materials.

17. Table of contents.

18. Information about choosing and changing PCPs.

19. Information about choosing a primary dentist, if applicable.

20. Information on how to request a specialist as a PCP or a standing referral to a specialist.

21. Information on availability of specialists.

22. Information about Dual Eligibles' right to access Medicare providers for Medicare services regardless of whether the Medicare providers are in the CHC-MCO network and without having to obtain prior approval from the CHC-MCO for Medicare-covered services.

23. Information about what to do when family size, address, or phone number changes.

24. Information regarding appointment standards.

25. Information regarding Participants' rights and CHC-MCOs' responsibilities per Section 1867 of the SSA.

26. A description of all available Covered Services, including LTSS, and how to access those services, which services require Prior Authorization, and an explanation of any service limitations or exclusions from coverage, specific instructions on how transportation is provided, and a notice stating that the CHC-MCO will be liable only for those services that are the responsibility of the CHC-MCO.

27. A description of the services not covered if the CHC-MCO elects not to provide, reimburse for, or provide coverage of, a counseling or referral service because of an objection on moral or religious grounds and information on how to access the services.

28. Information on how to request guidelines, including utilization review and clinical practice guidelines.

29. An explanation of the procedures for obtaining benefits, including self-referred services, services requiring Prior Authorization, services requiring a Covered Service Limit Exception request, if applicable, and services requiring a referral.

30. Information on how to contact Participant Services, the Nurse Hotline, the Service Coordinator unit and a description of their functions.

31. Information regarding the Complaint, Grievance and DHS Fair Hearing processes, as set forth in the CHC Participant Handbook Template for Complaints, Grievances and Fair Hearings, and the right to interim relief within the relevant time frames of the process,55 Pa. Code § 275.4(d).

32. What to do in case of an Emergency Medical Condition and instructions for receiving advice on care in case of an emergency, including instructions to use the emergency medical services (EMS) available and/or activate EMS by dialing 9-1-1 in a life-threatening situation.

33. Information on how to obtain non-medical transportation, emergency transportation, and non-emergency medical transportation.

34. The names and telephone numbers for county MATP Providers.

35. Information on how and where to access Behavioral Health, Family Planning and vision services.

36. Information on how to obtain prescription drugs, including information on how to request a copy of the CHC-MCO's formulary or PDC, and how to obtain assistance with the benefit of enrolling in a Medicare Part D plan with a zero copay.

37. Information on what to do regarding out-of-county and out-of-state moves.

38. A description of wellness behaviors and activities the Participant can engage in to improve his or her own health, such as diet, exercise, and age-appropriate vaccinations and screenings.

39. Information regarding pregnancies which conveys the importance of prenatal care and continuity of care to promote optimum care for mother and infant, including the concept of remaining with the same CHC-MCO for the entire pregnancy.

40. Notification that the selection of certain PCP sites may result in medical residents, nurse practitioners, and physicians assistants providing care to Participants.

41. Information regarding the availability of second opinions and when and how to access them.

42. Information regarding the right to receive services from an Out-of-Network Provider when the CHC-MCO cannot offer a choice of two (2) qualified specialists, and an explanation of how to request authorization for Out-of-Network services.

43. Information on the availability and process for accessing MA Out-of-Plan Services which are not the responsibility of the CHC-MCO, but are available to Participants.

44. Information regarding the WIC Program (WIC) and how to access the program.

45. Information regarding HIV/AIDS Programs and how to access them.

46. Information on Tobacco Cessation Programs and how to access them.

47. Information about Estate Recovery.

48. Information about Assessment, Reassessment, and PSCP processes.

49. Information about Service Coordination.

50. Information on advance directives (durable healthcare power of attorney and living wills) for adult Participants, including:
    a. The description of State law, if applicable.
    b. The process for notifying the Participant of any changes in applicable State law as soon as possible, but no later than ninety (90) days after the effective date of the change.
    c. Any limitation the CHC-MCO has regarding implementation of advanced directives as a matter of conscience.
    d. The process for Participants to file a Complaint concerning noncompliance with the advanced directive requirements with the CHC-MCO and DOH.
    e. How to request written information on advance directive policies.

51. A statement that all Participants will be treated with respect and due consideration for their dignity and privacy.

52. A statement that Participants may receive, from a Provider, information on available treatment options and alternatives, presented in a manner appropriate to the Participant's condition and ability to understand.

53. A statement that Participants have the right to participate in decisions regarding their healthcare, including the right to refuse treatment.

54. A statement that Participants are guaranteed the right to be free from any form of restraint or seclusion used as a means of coercion, discipline, convenience, or retaliation.

55. A statement that each Participant is free to exercise his or her rights and that the exercise of those rights does not adversely affect the way the CHC-MCO and its Providers or the Department treat the Participant.

56. An explanation of the CHC-MCO's and Recipient Restriction Program, including how to request a DHS Fair Hearing regarding a restriction action and how to request a change of pharmacy or Provider.

57. A description of the Department's MA Provider Compliance Hotline telephone number.

58. A description of the Expanded Services or Value-Added Services the CHC-MCO has been approved by the Department to provide and the guaranteed period in which those services must be available to participants.

59. Information on how Participants can participate in CHC-MCO advisory

committees.

60. Procedures for disenrolling from the CHC-MCO and policies for transition of care.

61. Procedures for recommending changes in policies and services.

EXHIBIT N

PROVIDER DIRECTORY

The Provider Directory must include, at a minimum, the following information about PCPs, hospitals, specialists, or ancillary providers, Pharmacies, and LTSS providers:

- The names, addresses, website address, group practice names, email address if the Provider makes the address available to patients, and telephone numbers of Provider.

- The hospital affiliations of the Provider.

- Information on whether or not the Provider is accepting new patients.

- Identification of whether the Provider is a Doctor of Medicine or Osteopathy.

- Identification of whether the Providers are board-certified and, if so, in what area(s).

- Identification of whether a Provider dental is DDS or DMD, and whether the dentist is a periodontist.

- Identification of whether the dentist possesses anesthesia certificates.

- Identification of whether the dentist is able to serve adults with developmental disabilities.

- Identification of the specialty area of each specialist.

- Identification of the Provider's cultural and linguistic capabilities, including languages (including American Sign Language) offered by the provider or a certified medical interpreter at the Provider's office, and whether the Provider has completed cultural competence training

  Identification of sites which are wheelchair accessible for people with physical disabilities, including offices, exam room(s) and equipment

- Identification of the days of operation and the hours when the Provider's office is available to Participants.

  The CHC-MCO, at the request of the PCP or dentist, may include the PCP's or dentist's experience or expertise in serving individuals with particular conditions.

EXHIBIT O

CHC AUDIT CLAUSE

Annual Agreement Audits

The CHC-MCO shall cause, and bear the costs of, an annual agreement audit to be performed by an independent, licensed Certified Public Accountant. The agreement audit shall be completed using guidelines provided by the Department. Such audit shall be made in accordance with generally accepted government auditing standards. The contract audit shall be digitally submitted to OLTL, Bureau of Finance via the E-FRM system no later than June 30 after the contract year is ended.

> If circumstances arise in which the Department or the CHC-MCO invokes the termination clause or determines this Agreement will cease, the agreement audit for the period ending with the termination date or the last date the CHC-MCO is responsible to provide Covered Services to Participants shall be submitted to the Department within one hundred eighty (180) days after the termination date or the last date the CHC-MCO is responsible to provide Covered Services.

The CHC-MCO shall ensure that audit working papers and audit reports are retained by the CHC-MCO's auditor for a minimum of ten (10) years from the date of final payment under the Agreement, unless the CHC-MCO's auditor is notified in writing by the Commonwealth to extend the retention period. Audit working papers shall be made available, upon request, to authorized representatives of the Commonwealth or federal agencies. Copies of working papers deemed necessary shall be provided by the CHC-MCO's auditor.

Annual Entity-Wide Financial Audits

The CHC-MCO shall provide to the Department a copy of its annual entity-wide financial audit, performed by an independent, licensed Certified Public Accountant. Such audit shall be made in accordance with generally accepted auditing standards. Such audit shall be submitted to the OLTL, Bureau of Finance via E-FRM within thirty (30) days from the date it is made available to the CHC-MCO.

Other Financial and Performance Audits

The Commonwealth reserves the right for Federal and State agencies or their authorized representatives to perform additional financial or performance audits of the CHC-MCO, its subcontractors or Providers. Any such additional audit work will rely on work already performed by the CHC-MCO's auditor to the extent possible. The costs incurred by the Federal or State agencies for such additional work will be borne by those agencies.

Audits of the CHC-MCO, its subcontractors or Providers may be performed by the

Commonwealth or its designated representatives and include, but are not limited to:

1. Financial and compliance audits of operations and activities for the purpose of determining the compliance with financial and programmatic record keeping and reporting requirements of this Agreement.

2. Audits of automated data processing operations to verify that systems are in place to ensure that financial and programmatic data being submitted to the Department is properly safeguarded, accurate, timely, complete, reliable, and in accordance with contract terms and conditions.

3. Program audits and reviews to measure the economy, efficiency, and effectiveness of program operations under this Agreement.

4. The Commonwealth must periodically, but no less frequently than once every three (3) years, conduct or contract for the conducting of, an independent audit of the accuracy, truthfulness, and completeness of the encounter and financial data submitted by, or on behalf of, the CHC-MCO.

Audits performed by the Commonwealth shall be in addition to any federally-required audits or any monitoring or review efforts. Commonwealth audits of the CHC-MCO or its subcontractor's operations will generally be performed on an annual basis. However, the Commonwealth reserves the right to audit more frequently, to vary the audit period, and to determine the type and duration of these audits. Audits of subcontractors or Providers will be performed at the Commonwealth's discretion.

The following provisions apply to the CHC-MCO, its subcontractors, and Providers:

1. Except in cases where advance notice is not possible or advance notice may render the audit less useful, the Commonwealth will give the entity at least three (3) weeks advance written notice of the start date, expected staffing, and estimated duration of the audit. In the event of a claims processing audit, the Commonwealth will strive to provide advance written notice of a minimum of thirty (30) calendar days. While the audit team is on-site, the entity shall provide the team with adequate and secure workspace; access to a telephone, photocopier and facsimile machine; access to the Internet; electrical outlets; and privacy for conferences. The CHC-MCO shall also provide, at its own expense, necessary systems and staff support to timely extract and/or download information stored in electronic format, gather requested documents or information, complete forms or questionnaires, and respond to auditor inquiries. The entity shall cooperate fully with the audit team in furnishing, either in advance or during the course of the audit, any policies, procedures, job descriptions, contracts or other documents or information requested by the audit team.

2. Upon issuance of the final report to the entity, the entity shall prepare and submit, within thirty (30) calendar days after issuance of the report, a Corrective action plan for each observation or finding contained therein. The corrective action plan shall include a brief description of the finding, the specific steps to be taken to correct the situation or specific reasons why corrective action is not necessary, a timetable for performance of the corrective action steps, and a description of the monitoring to be performed to ensure that the steps are taken.

Record Availability, Retention and Access

The CHC-MCO shall, at its own expense, make all records available for audit, review or evaluation by the Commonwealth, its designated representatives or federal agencies. Access shall be provided either on-site during normal business hours or through the mail. During the contract and record retention period, these records shall be available at the CHC-MCO's chosen location, subject to approval of the Commonwealth. All records to be sent by mail shall be sent to the requesting entity within fifteen (15) calendar days of such request and at no expense to the requesting entity. Such requests made by the Commonwealth shall not be unreasonable.

The CHC-MCO shall maintain books, records, documents, and other evidence pertaining to all revenues, expenditures and other financial activity pursuant to this Agreement as well as to all required programmatic activity and data pursuant to this Agreement. Records other than medical records may be kept in an original paper state or preserved on micro media or electronic format. Medical records shall be maintained in a format acceptable by the Department. These books, records, documents and other evidence shall be available for review, audit or evaluation by authorized Commonwealth personnel or their representatives during the contract period and ten (10) years thereafter, except if an audit is in progress or audit findings are yet unresolved, in which case records shall be kept until all tasks are completed.

Audits of Subcontractors

The CHC-MCO shall include, in all risk sharing CHC-MCO subcontract agreements, clauses, which reflect the above provisions relative to "Annual Contract Audits," "Annual Entity-Wide Financial Audits," "Other Financial and Performance Audits" and "Record Availability, Retention, and Access."

The CHC-MCO shall include, in all contract agreements with other subcontractors or Providers, clauses which reflect the above provisions relative to "Other Financial and Performance Audits" and "Record Availability, Retention, and Access."

EXHIBIT P

REQUIRED CONTRACT TERMS FOR ADMINISTRATIVE SUBCONTRACTORS

All subcontracts must be in writing and must include, at a minimum, the following provisions:

- The specific activities and report responsibilities delegated to the subcontractor.
- A provision for revoking delegation or imposing other sanctions if the subcontractor's performance is inadequate.
- All applicable requirements of this Agreement.
- The applicable requirements of 42 C.F.R. § 434.6.
- Nondiscrimination provisions.
- The requirements of the Americans with Disabilities Act (42 U.S.C. §§ 12101 et seq.).
- In all subcontracts with any individual firm, corporation, or any other entity which provides medical services or LTSS and receives payment from the CHC-MCO either directly or indirectly through capitation, a requirement that data for all services provided will be reported timely to the CHC-MCO and that penalties and sanctions will be imposed for failure to comply. The data is to be included in the utilization and Encounter Data provided to the Department in the format required.
- In all subcontracts with any individual, firm, corporation, or any other entity which provides medical services or LTSS to CHC Participants, a requirement that the subcontractor will report all new third party resources to the CHC-MCO identified through the provision of medical services, which previously did not appear on the Department's Participant information files provided to the CHC-MCO.
- A hold harmless clause that stipulates that the CHC-MCO subcontractor agrees to hold harmless the Commonwealth, all Commonwealth officers and employees and all CHC-MCO Participants in the event of nonpayment by the CHC-MCO to the subcontractor. The subcontractor shall further indemnify and hold harmless the Commonwealth and its agents, representatives, officers, and employees against all injuries, death, losses, damages, claims, suits, liabilities, judgments, costs, and expenses which may in any manner accrue against the Commonwealth or its agents, representatives, officers or employees, through the intentional conduct, negligence or omission of the subcontractor, its agents, representatives, officers, or employees or the CHC-MCO.
- Compliance with all applicable Federal and State laws and policy and guidance issued by the Department.

- In all subcontracts with any individual firm, corporation or any other entity which provides medical services or LTSS to Community HealthChoices Participants, that prohibits gag clauses which limit the subcontractor from disclosure of Medically Necessary or appropriate healthcare information or alternate therapies to Participants, other healthcare professionals, or the Department.

- In all employee contracts prohibiting gag clauses which limit said employees from the disclosure of information pertaining to the Community HealthChoices Program.

- In all subcontracts with any individual, firm, corporation or any other entity which provides medical services or LTSS to Community HealthChoices Participants, that limits incentives to those permissible under the applicable federal regulation.

The CHC-MCO shall require as a written provision in all subcontracts that the Department has ready access to any and all documents and records of transactions pertaining to the provision of services to Participants.

The CHC-MCO and its subcontractor(s) must agree to maintain books and records relating CHC services and expenditures, including reports to the Department and source information used in preparation of these reports. These records include but are not limited to financial statements, records relating to quality of care, medical records and prescription files.

The CHC-MCO and its subcontractor(s) also must agree to comply with all standards for practice and medical records keeping specified by the Commonwealth.

The CHC-MCO and its subcontractor(s) shall, at their own expense, make all records available for audit, review or evaluation by the Commonwealth, its designated representatives or federal agencies. Access shall be provided either on-site during normal business hours or through the mail. During the contract and record retention period, these records shall be available at the CHC-MCO's chosen location, subject to approval of the Commonwealth. The CHC-MCO must fully cooperate with any and all reviews and/or audits by Federal or State agencies or their agents, such as the Independent Assessment Contractor, by assuring that appropriate employees and involved parties are available for interviews relating to reviews or audits. All records to be sent by mail shall be sent to the requesting entity in the form of accurate, legible paper copies, unless otherwise indicated, within fifteen (15) calendar days of such request and at no expense to the requesting entity. Such requests made by the Commonwealth shall not be unreasonable.

The CHC-MCO and its subcontractor(s) shall maintain books, records, documents and other evidence pertaining to all revenues, expenditures and other financial activity pursuant to this contract as well as to all required programmatic activity and data pursuant to this contract. Records other than medical records may be kept in an original paper state or preserved on micro media or electronic format. Medical records shall be maintained in a format acceptable by the Department. These books, records, documents and other evidence shall be available for review, audit or evaluation by authorized Commonwealth personnel or their representatives during the contract period and ten (10) years thereafter, except if an audit is in progress or audit findings are yet unresolved, in which case, records shall be kept until all tasks are completed.

The CHC-MCO shall require as a written provision in all subcontracts that the subcontractor recognize that payments made to the subcontractor are derived from Federal and State funds. Additionally, the CHC-MCO shall require, as a written provision in all contracts for services rendered to the Participant, that the subcontractor shall be held civilly and/or criminally liable to both the CHC-MCO and the Department in the event of nonperformance, misrepresentation, fraud, waste, or abuse. The CHC-MCO shall notify its PCPs and all subcontractors of the prohibition and sanctions for the submission of false claims and statements.

The CHC-MCO shall require as a written provision in all subcontracts that the subcontractor cooperate with Quality Management/Utilization Management Program requirements.

The CHC-MCO shall require Providers to comply with all Service Coordination program requirements, including, where applicable, cooperation with the PCPT approach for PCSP and Service Coordination.

The CHC-MCO shall monitor the subcontractor's performance on an ongoing basis and subject it to formal review according to a periodic schedule established by the Department, consistent with industry standards or State statutes and regulations. If the CHC-MCO identifies deficiencies or areas needing improvement, the CHC-MCO and the subcontractor must take corrective action.

EXHIBIT Q

REPORTING SUSPECTED FRAUD, WASTE, AND ABUSE

The following requirements are adapted from 55 Pa. Code Chapter 1101, General Provisions for the Medical Assistance Program, specifically 55 Pa. Code § 1101.75(a) and (b), Provider Prohibited Acts, which are directly adapted from 62 P.S. § 1407 (also referred to as Act 105 of 1980, Fraud and Abuse Control Act). The basis for Participant referrals is 55 Pa. Code § 1101.91 and § 1101.92, Recipient Mis-utilization and Abuse and Recipient Prohibited Acts. These regulations are available at http://www.pacode.com.

Reporting Requirements:

CHC-MCOs must report to the Department any act by any MA enrolled Providers, Participants, caregivers and employees that may affect the integrity of the CHC Program under the Medical Assistance Program. Specifically, if the CHC-MCO suspects that Fraud, Abuse or Waste, as discussed in Section V.X.4, Fraud and Abuse, may have occurred, the CHC-MCO must report the issue to the Department. The CHC-MCO must have a process to notify the Department of any adverse actions and/or Provider disclosures received during the credentialing/re-credentialing process. Depending on the nature or extent of the problem, it may also be advisable to place the individual Provider on prepayment review or suspend payments to avoid unnecessary expenditures during the review process.

In addition to referrals to the Department, the CHC-MCO is required to promptly submit any potential fraud directly to the Pennsylvania Office of Attorney General, Medicaid Fraud Control Section as provided in 42 CFR § 438.608(a)(7). The referrals to the Department shall be submitted using the Department's CHC-MCO Referral Form. Potential fraud referrals submitted to the Department using the CHC-MCO Referral Form will be forwarded by the Department to the Pennsylvania Office of Attorney General, Medicaid Fraud Control Section if it is determined by the Department that there is a credible allegation of fraud. After the referral form is submitted, the CHC-MCO is required to upload the supporting documentation to the Department using docuShare. The CHC-MCO is also required to upload the same supporting documentation of fraud to the Office of Attorney General, Medicaid Fraud Control Section through ShareFile.

CHC-MCOs are required to report quality issues to the Department for further investigation. Quality issues are those which, on an individual basis, affect the Participant's health (e.g., poor quality services, inappropriate and or potentially harmful treatment, and withholding of Medically Necessary services from the Participant).

All Confirmed Abuse, Waste, or quality referrals must be made with supporting documentation promptly, within thirty (30) calendar days of the identification of the problem/issue. For all Potential Fraud referrals, the CHC-MCO must conduct a preliminary investigation to the level of an indication of fraud. The CHC-MCO may

informally consult with other state agencies or law enforcement to reach this determination. The CHC-MCO must send to BPI all relevant documentation within thirty (30) calendar days after the preliminary allegations have been confirmed through the additional review and/or documentation, and there is now a potential credible allegation of fraud. Such information includes, but is not limited to, the materials listed on the "Checklist of Supporting Documentation for Referrals" located at the end of this exhibit. The Fraud and Abuse Coordinator, or the responsible party completing the referral, should check the appropriate boxes on the "Checklist of Supporting Documentation for Referrals" form indicating the supporting documentation information that is sent with each referral. A copy of the completed checklist and all supporting documentation should accompany each referral. Any egregious situation or act (e.g., those that are causing or imminently threaten to cause harm to a Participant or significant financial loss to the Department) must be referred immediately to the Department for further investigation.

The CHC-MCO must follow the reporting processes unless prior approval is received from the Department. Reports must be submitted online using the CHC-MCO Referral Form. The instructions and form templates are located at:

https://www.humanservices.state.pa.us/hc-extranet/forms/form_mcoreferral_chc.asp

Once completed, the CHC-MCO must electronically submit the form to BPI. Additionally, the following information must be submitted to BPI electronically using a docuShare page designated by BPI: Checklist of Supporting Documentation for Referrals, accessible on the CHC-MCO Referral Form. The same information must be uploaded to the Office of Attorney General, Medicaid Fraud Control Section ShareFile system.

- A copy of the confirmation page which will appear after “Submit” button is clicked, submitting the CHC-MCO Referral Form.
- All supporting documentation.

If docuShare is inaccessible for any reason at the time the CHC-MCO attempts to submit the form, then the CHC-MCO will note the unavailability of docuShare on the form and mail the supporting information above to the below address:

Attn: Division Director
Department of Human Services
Bureau of Program Integrity - DPPC
P.O. Box 2675
Harrisburg, PA 17105-2675

Checklist of Supporting Documentation for Referrals

- All referrals must have the confirmation page from online referral attached.
- Please check the appropriate boxes that indicate the supporting documentation included with your referral.

Example of materials for Provider or staff person referrals [***The below list is provided as examples of materials that could be relevant to an investigation of the referral. The list is not all-inclusive.]*** –

- ☐ confirmation page from online referral
- ☐ encounter forms (lacking signatures or forged signatures)
- ☐ timesheets
- ☐ attendance records of Participant
- ☐ written statement from parent, Provider, school officials or client that services were not rendered or a forged signature
- ☐ progress notes
- ☐ internal audit report
- ☐ interview findings
- ☐ sign-in log sheet
- ☐ complete medical records
- ☐ résumé and supporting résumé documentation (college transcripts, copy of degree)
- ☐ credentialing file (DEA license, CME, medical license, board certification)
- ☐ copies of complaints filed by Participants
- ☐ admission of guilty statement
- ☐ other: _____

Example of materials for pharmacy referrals –

- ☐ paid claims
- ☐ prescriptions
- ☐ signature logs
- ☐ encounter forms
- ☐ purchase invoices
- ☐ EOB's
- ☐ delivery slips
- ☐ licensing information
- ☐ other: _____

Example of materials for behavioral health referrals –

- ☐ complete medical and mental health record
- ☐ results of treatment rendered/ordered, including the results of all lab tests and diagnostic studies
- ☐ summaries of all hospitalizations all
- ☐ psychiatric examinations
- ☐ all psychological evaluations treatment
- ☐ plans
- ☐ all prior authorizations request packets and the resultant prior authorization number(s)
- ☐ encounter forms (lacking signatures or forged signatures) plan of care
- ☐ summaries
- ☐ documentation of treatment team or Interagency Service Planning Team meetings
- ☐ progress notes
- ☐ other: _____

Example of materials for DME referrals –

- ☐ orders, prescriptions, and/or certificates of medical necessity (CMN for the equipment)
- ☐ delivery slips and/or proof of delivery of equipment copies of checks
- ☐ or proof of copay payment by recipient diagnostic testing in the
- ☐ records
- ☐ copy of company's current licensure
- ☐ copy of the policy and procedure manual applicable to DME items
- ☐ other: _____

EXHIBIT R

Behavioral Health Mixed Services Protocol

Services	Payment/Clinical Responsibility
Ambulatory Care	
Assessment and treatment of a BH condition when provided by a BH provider	BH-MCO
Assessment and treatment of a BH condition when provided by a PCP	CHC-MCO
Assessment and treatment of dementia/Alzheimer's	CHC-MCO
Assessment and treatment of Asperger's/Autism Spectrum Disorder	BH-MCO or CHC-MCO depending on provider type and location of care
Methadone Maintenance Treatment	BH-MCO
Medication Assisted Treatment (MAT) for opioid addiction	CHC-MCO
Psychiatrist prescribed Medication Assisted Treatment (MAT) for opioid addiction	BH-MCO
24-Hour Care	
Admission to an acute care hospital, psychiatric facility or other specialty facility that is a licensed mental health inpatient facility for the treatment of a BH condition	BH-MCO
Admission to an inpatient drug and alcohol detoxification hospital that is licensed by DDAP	BH-MCO
Detoxification in a medical bed that is certified by DDAP for acute withdrawal, seizures, delirium tremens or medical instability	BH-MCO
Stabilization in a medical bed or in an intensive care unit for treatment of eating disorders or following attempted suicide or self-induced trauma/poisoning	CHC-MCO
Residential services for treatment of MH or SUD	BH-MCO
Emergency Department	
Facility and ancillary charges and professional fees for primary BH diagnoses	CHC-MCO
Facility and ancillary charges and professional fees for primary PH diagnosis, including medical stabilization for attempted suicide or self-induced trauma/poisoning	CHC-MCO

Services	Payment/Clinical Responsibility
Emergency room evaluations for voluntary and involuntary commitments pursuant to the Mental Health Procedures act of 1976	BH-MCO
All emergency and non-emergency medically necessary ambulance transportation for both PH and BH covered services, including BH diagnosis	CHC-MCO
Consults	
BH consultation specific to a BH diagnosis on medical surgical unit, nursing home or assisted living facility	BH-MCO
BH consultation not specific to a Serious Mental Illness (SMI) on medical surgical unit, nursing home or assisted living facility	CHC-MCO
Medical/surgical consult on a BH unit	CHC-MCO
Medical/surgical assessment on an inpatient admission with primary BH diagnoses	CHC-MCO
Psychological Testing	
Psychological/neuropsychological testing requested by a BH provider and/or used to clarify BH diagnosis.	BH-MCO
Psychological/neuropsychological testing when ordered by medical provider to rule out or clarify organic pathology	CHC-MCO
Miscellaneous	
Any BH service delivered through a federally qualified health center or rural health clinic	BH-MCO
Electroconvulsive therapy, including anesthesiology services	BH-MCO

EXHIBIT S

PROVIDER MANUAL

The CHC-MCO shall work with the Department to develop, distribute, and maintain a Provider manual. In addition, the CHC-MCO and/or CHC-MCO Subcontractors will be expected to distribute copies of all manuals and subsequent policy clarifications and procedural changes to Network Providers following advance written approval of the documents by the Department. Provider manuals must be updated to reflect any program or policy change(s) made by the Department via Medical Assistance bulletin within six (6) months of the effective date of the change(s), or within six (6) months of the issuance of the Medical Assistance bulletin, whichever is later, when such change(s) affect(s) information that the CHC-MCO is required to include in its Provider manual, as set forth in this exhibit. The Provider manual must include, at a minimum, the following information:

A. A description of the needs screening, Assessment and Reassessment, service planning system and protocols and a description of the Provider's role in Service Planning and Service Coordination.

B. A description of Service Coordination and how the Provider will fit into the Person-Centered Planning Team approach.

C. A description of the population being served through CHC.

D. A description of the accessibility requirements with which Providers are required to comply.

E. A description of the role of a PCP as described in Section II, Definitions, and Section V.BB.4, Primary Care Practitioner (PCP) responsibilities.

F. Information on how Participants may access specialists, including standing referrals and specialists as PCPs.

G. A summary of the guidelines and requirements of Title VI of the Civil Rights Act of 1964, as amended, and its guidelines, and how Providers can obtain qualified interpreters familiar with medical terminology.

H. Contact information to access the CHC-MCO, DHS, advocates, other related organizations, etc.

I. A copy of the CHC-MCO's Prior Authorization and program exception process.

J. A copy of the CHC-MCO's Formulary in the same machine readable file and format as made available to enrollees as specified under 42 C.F.R. § 438.10(i)(3).

K. Contact follow-up responsibilities for missed appointments.

L. Description of role of the Service Coordinator and how to contact them.

M. Description of drug and alcohol treatment available and how to make referrals.

N. Complaint, Grievance and DHS Fair Hearing information.

O. Information on Provider Disputes.

P. CHC-MCO policies, procedures, available services, and sample forms applicable to the Provider type.

Q. A full description of Covered Services, listing all Covered Services outlined in Exhibit A, Covered Services List.

R. Billing instructions.

S. Information regarding applicable portions of 55 Pa. Code, Chapter 1101, General Provisions.

T. Information on self-referred services and services which are not the responsibility of the CHC-MCO but are available to Participants on a Fee-for-Service basis.

U. Provider performance expectations, including disclosure of Quality Management and Utilization Management criteria and processes.

V. Information on procedures for sterilizations, hysterectomies and abortions (if applicable).

W. A description of certain Providers' obligations, under law, to follow applicable procedures in dealing with Participants on "Advanced Directives" (durable healthcare power of attorney and living wills). This includes notification and record keeping requirements.

X. Information on ADA and Section 504 of the Rehabilitation Act of 1973, other applicable laws, and available resources related to the same.

Y. A definition of “Medically Necessary” consistent with the language in this Agreement.

Z. Information on Participant confidentiality requirements.

AA. The Department’s Medical Assistance Provider Compliance Hotline (formerly the Fraud and Abuse Hotline) telephone number and explanatory statement.

BB. Explanation of CHC-MCO’s and the Department’s Recipient Restriction Program.

CC. Information regarding written translation and oral interpretation services for

Participants with LEP and alternate methods of communication for those requesting communication in alternate formats.

DD. List and scope of services for referral and Prior Authorization.

EE. Information about Recipient Restriction and how it works.

FF. All of the items in Section V AA.2- Provider Orientation and Ongoing Education.

The CHC-MCO is required to provide documented training to its Providers and their staffs and to Subcontractors regarding the contents and requirements of the Provider manuals.

EXHIBIT T

PROVIDER NETWORK COMPOSITION/SERVICE ACCESS

1. Network Composition

The CHC-MCO must consider the following in establishing and maintaining its Provider Network:

- The anticipated Medical Assistance Enrollment.
- The expected utilization of services, taking into consideration the characteristics and needs of specific Medical Assistance populations represented in the CHC-MCO.
- The number and types, in terms of training, experience, and specialization, of Providers required to furnish the contracted Medical Assistance services.
- All Providers operating within the Provider Network who provide services to Recipients must be enrolled in the Commonwealth's Medical Assistance program and possess an active MMIS Provider ID.
- The number of Network Providers who are not accepting new Medical Assistance Participants.
- The geographic location of Providers and Participants, considering distance, travel time, the means of transportation ordinarily used by Participants, and whether the location provides physical access for Participants with disabilities.

The CHC-MCO must ensure that its Provider Network is adequate to provide its Participants in this CHC zone with access to quality Participant care through participating professionals, in a timely manner, and without the need to travel excessive distances. Upon request from the Department, the CHC-MCO must supply geographic access maps using Participant-level data detailing the number, location, and specialties of its Provider Network in order to verify accessibility of Providers within its Network in relation to the location of its Participants. The Department may require additional numbers of specialists, ancillary, and LTSS Providers should it be determined that geographic access is not adequate. The CHC-MCO must also have a process in place which ensures that the CHC-MCO knows the capacity of its Network PCP panels at all times and have the ability to report on this capacity.

The CHC-MCO must make all reasonable efforts to honor a Participant's choice of Providers who are credentialed in the Network. If the CHC-MCO is unable to ensure a Participant's access to Provider or specialty Provider services within the Provider Network, within the travel times set forth in this exhibit, the CHC-MCO must make all reasonable efforts to ensure the Participant's access to these services within the travel times herein through Out-of-Network providers. In locations where the CHC-MCO can provide evidence that it has conducted all reasonable efforts to contract with Providers and specialists and can provide verification that no Providers or specialists exist to ensure a Participant's access

to these services within the travel times set forth in this exhibit, the CHC-MCO must work with Participants to offer reasonable Provider alternatives. Additionally, the CHC-MCO must ensure and demonstrate that the following Provider Network and access requirements are established and maintained for the entire CHC zone in which the CHC-MCO operates if Providers exist.

The Department will require annual submission of a GeoAccess Report and Gap Analysis to be done by the CHC-MCO. The CHC-MCO must demonstrate access to the provider types outlined below through application of the specified access criteria. The Network Gap Analysis must be detailed and include all reasonable efforts to fill network gaps.

a. PCPs

Make available to every Participant a choice of at least two (2) appropriate PCPs with open panels whose offices are located within a travel time no greater than thirty (30) minutes (Urban) and sixty (60) minutes (Rural). This travel time is measured via public transportation, where available.

Participants may, at their discretion, select PCPs located further from their homes.

b. Specialists

For the following Provider types, the CHC-MCO must ensure a choice of two (2) Providers who are accepting new patients within the travel time limits (thirty (30) minutes Urban, sixty (60) minutes Rural). This travel time is measured via public transportation, where available.

General Surgery
Optometry
Rehabilitation
Neurological Surgery
Urology
Dermatology
Oral Surgery
Orthopedic Surgery
Allergy and Immunology
Otolaryngology
Neurology
Cardiology
Gastroenterology
Podiatry
Common Laboratory and Diagnostic Service
Obstetrical and Gynecological Service

For the following provider types, the CHC-MCOs must ensure a choice of one (1) provider who is accepting new patients within the travel time limits (30 minutes Urban, 60 minutes Rural) and a second choice, within the CHC Zone.

Endocrinologist
Rheumatology
Nephrology
Hematology/Oncology
Speech Therapy

All Other Provider Types must meet the Participants needs through in-network or out-of-network arrangements. CHC-MCOs should make all reasonable efforts to offer two (2) or more Specialty Providers when possible.

c. Hospitals

Ensure at least one (1) hospital within the travel time limits (thirty (30) minutes Urban, sixty (60) minutes Rural) and a second (2nd) choice within the CHC zone. This travel time is measured via public transportation, where available.

d. LTSS Providers

LTSS network adequacy requirements are based on the full-time equivalent (FTE) calculations developed by the Department for services where the Provider is traveling to the Participant. FTE network adequacy data must be submitted by CHC zone. For services where the Participant is traveling to the Provider, the CHC-MCO must ensure a choice of two (2) Providers who are accepting new clients within the travel time limits (thirty (30) minutes Urban, sixty (60) minutes Rural). This travel time is measured via public transportation, where available.

e. Out-of-Network Access

Ensure the provision of Covered Services to all Participants such that if the CHC-MCO does not have at least two (2) specialists or sub-specialists qualified to meet the particular needs of the individuals who are accepting new patients and within the travel time requirements, then the CHC-MCO must allow Participants to pick an Out-of-Network Provider if not satisfied with the Network Provider. The CHC-MCO must develop a system to determine Prior Authorization for Out-of-Network Services through the Person-Centered Planning Team and UM, depending on the service for which the Out-of-Network Provider is being authorized, including provisions for informing the Participant of how to request this authorization for Out-of-Plan Services.

If the CHC-MCO is unable to ensure a Participant's access to Provider or specialty Provider services within the Provider Network, within the travel times set forth in this exhibit, the CHC-MCO must make all reasonable efforts to ensure the Participant's access to these services within the travel times herein through Out-of-Network Providers. In locations where the CHC-MCO can provide evidence that it has conducted all reasonable efforts to contract with Providers and specialists and can provide verification that no Providers or specialists exist to ensure a Participant's access to these

services within the travel times set forth in this exhibit, the CHC-MCO must work with Participants to offer reasonable Provider alternatives.

f. Medicare Network Compliance

If the Medicare Network standards would require more Providers for any Provider type or Service Area, the CHC-MCO must meet the Medicare standards in its CHC-MCO.

g. Anesthesiology and Anesthesia for Dental Care

CHC-MCOs must ensure there are two (2) anesthesiologists available for each location that performs medical procedures that require aesthesia.

For Participants needing anesthesia for dental care, the CHC-MCO must ensure a choice of at least two (2) dentists within the Provider Network with privileges or certificates to perform specialized dental procedures under general anesthesia or pay Out-of-Network.

h. Rehabilitation Facilities

Ensure a choice of at least two (2) rehabilitation facilities within the Provider Network, at least one (1) of which must be located within this CHC zone.

i. CNMs / CRNPs, Other Providers

Ensure access to Certified Nurse Midwives (CNMs), Certified Registered Nurse Practitioners (CRNPs) and other Providers. The CHC-MCO must demonstrate its attempts to contract in good faith with a sufficient number of CNMs, CRNPs and other Providers and maintain payment policies that reimburse CNMs, CRNPs and other Providers for all services provided within the scope of their practice and allow them to practice to the fullest extent of their education, training and licensing.

j. Qualified Providers

The CHC-MCO must limit its PCP Network to appropriately Qualified Providers. The CHC-MCO's PCP Network must meet the following:

- Seventy–five to one hundred percent (75-100%) of the Network consists of PCPs who have completed an approved Primary Care residency in family medicine, osteopathic general medicine, or internal medicine.

- No more than twenty-five percent (25%) of the Network consists of PCPs

without appropriate residencies but who have, within the past seven (7) years, five (5) years of post-training clinical practice experience in family medicine, osteopathic general medicine, internal medicine. Post-training experience is defined as having practiced at least as a 0.5 full-time equivalent in the practice areas described.

k. Participant Freedom of Choice

The CHC-MCO must demonstrate its ability to offer its Participants freedom of choice in selecting a PCP. At a minimum, the CHC-MCO must have or provide one (1) full-time equivalent (FTE) PCP who serves no more than one thousand (1,000) Participants. For the purposes of this section, a full-time equivalent PCP must be a physician involved in clinical care. The minimum weekly work hours for one (1.0) FTE is the number of hours that the practice considers to be a normal work week, which may be thirty-seven-and-one-half (37.5), forty (40), or fifty (50) hours. A physician cannot be counted as more than one (1.0) FTE regardless of the number of hours worked. If the PCP/PCP Site employs Certified Registered Nurse Practitioners (CRNPs)/Physician Assistants (PAs), then the Provider/Provider Site will be permitted to add an additional one thousand (1,000) Participants to the panel. The number of Participants assigned to a PCP may be decreased by the CHC-MCO if necessary to maintain the appointment availability standards.

l. PCP Composition and Location

The CHC-MCO and the Department will work together to avoid the PCP having a caseload or medical practice composed predominantly of Participants. In addition, the CHC-MCO must organize its PCP Sites so as to ensure continuity of care to Participants and must identify a specific PCP within the PCP site for each Participant. The CHC-MCO may apply to the Department for a waiver of these requirements on a PCP Site-specific basis. The Department may waive these requirements for good cause demonstrated by the CHC-MCO.

m. FQHCs/RHCs/Opioid Use Disorder Centers of Excellence (OUD-COE)

The CHC-MCO must contract with a sufficient number of Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) to ensure access to FQHC and RHC services. If the CHC-MCO's Primary care Network includes FQHCs and RHCs, these sites may be designated as PCP Sites. If a CHC-MCO cannot contract with a sufficient number of FQHCs and RHCs, the CHC- MCO must demonstrate in writing it has attempted to reasonably contract in good faith.

The CHC-MCO must make a good faith effort to contract with all Physical

Health Opioid Use Disorder Centers of Excellence (OUD-COE). If a CHC-MCO does not contract with a Physical Health OUD-COE, the CHC-MCO must provide an explanation for each Physical Health OUD-COE that the CHC-MCO does not contract with for CHC participants.

n. Medically Necessary Emergency Service

The CHC-MCO must comply with the provisions of Act 112 of 1996 (H.B. 1415, P.N. 3853, signed July 11, 1996), the Balanced Budget Reconciliation Act of 1997, as amended, and Act 68 of 1998, the Quality Healthcare Accountability and Protection Provisions, 40 P.S. §§ 991.2101 et seq. pertaining to coverage and payment of Medically Necessary Emergency Services. The definition of such services is set forth at Section IIt, Definitions.

o. ADA Accessibility Guidelines

The CHC-MCO must inspect the office of any Provider who provides services on site at the Provider's location and who seeks to participate in the Provider Network to determine whether the office is architecturally accessible to persons with mobility impairments. Architectural accessibility means compliance with ADA accessibility guidelines with reference to parking (if any), path of travel to an entrance, and the entrance to both the building and the office of the Provider, if different from the building entrance.

The CHC-MCO must submit quarterly reports to the Department, in a format to be specified by the Department, on the results of the inspections. OLTL will also utilize other reporting mechanisms, such as Physical Health HealthChoices reports and licensing visits.

If the office or facility is not accessible under the terms of this paragraph, the office or facility may participate in the Provider Network provided that the office or facility: 1) requests and is determined by the CHC-MCO to qualify for an exemption from this paragraph, consistent with the requirements of the ADA; or 2) agrees in writing to remove the barrier to make the office or facility accessible to persons with mobility impairments within one hundred-eighty (180) days after the CHC-MCO identified the barrier.

The CHC-MCO must document its efforts to determine architectural accessibility. The CHC-MCO must submit this documentation to the Department upon request.

p. Laboratory Testing Sites

The CHC-MCO must ensure that all laboratory testing sites providing

services have either a Clinical Laboratory Improvement Amendment (CLIA) certificate of waiver or a certificate of registration along with a CLIA Community HealthChoices Agreement identification number in accordance with CLIA 1988. Those laboratories with certificates of waiver will provide only the eight (8) types of tests permitted under the terms of their waiver. Laboratories with certificates of registration may perform a full range of laboratory tests. The PCP must provide all required demographics to the laboratory when submitting a specimen for analysis.

q. CHC-MCO Discrimination

The CHC-MCO may not discriminate with respect to participation, reimbursement, or indemnification as to any Provider who is acting within the scope of the Provider's license or certification under applicable State law, solely on the basis of such license or certification or on the basis that the provider serves high risks populations or specializes in conditions that require costly treatment. This paragraph must not be construed to prohibit a CHC-MCO from including Providers only to the extent necessary to meet the needs of the organization's Participants or from establishing any measure designed to maintain quality and control costs consistent with the responsibilities of the CHC-MCO.

r. Declined Providers

If the CHC-MCO declines to include individual Providers or groups of Providers in its Network, it must give the affected Providers written notice of the reason for its decision.

s. Second Opinions

The CHC-MCO must provide for a second opinion from a qualified Provider within the Network, at no cost to the Participant. If a qualified Provider is not available within the Network, the CHC-MCO must assist the Participant in obtaining a second opinion from a qualified Provider outside the Network, at no cost to the Participant, unless co-payments apply.

2. Appointment Standards

The CHC-MCO will require the PCP, dentist, or specialist to conduct or contact the Services Coordinator to conduct affirmative outreach whenever a Participant misses an appointment and to document this in the medical record. Such an effort shall be deemed to be reasonable if it includes three (3) attempts to contact the Participant. Such attempts may include, but are not limited to: written attempts, telephone calls and home visits. At least one (1) such attempt must be a follow-up telephone call.

Service Coordinators will evaluate any barriers to Participant attendance at appointments and develop any necessary plan to facilitate and improve Participant compliance with appointments scheduled.

a. General

PCP scheduling procedures must ensure that:

i. Emergency Medical condition cases must be immediately seen or referred to an emergency facility.

ii. Urgent Medical Condition cases must be scheduled within twenty- four (24) hours.

iii. Non-Urgent Sick Visits must be scheduled with a PCP within seventy-two (72) hours of request, as clinically indicated.

iv. Routine appointments must be scheduled within ten (10) business days. Health assessment/general physical examinations and first examinations must be scheduled within three (3) weeks of Enrollment.

v. The CHC-MCO must provide the Department with its protocol for ensuring that a Participant's average office waiting time for an appointment for Routine Care is no more than thirty (30) minutes or at any time no more than up to one (1) hour when the physician encounters an unanticipated Urgent Medical Condition visit or is treating a Participant with a difficult medical need. The Participant must be informed of scheduling timeframes through educational outreach efforts.

vi. The CHC-MCO must monitor the adequacy of its appointment processes and reduce the unnecessary use of ED visits.

b. Specialty Referrals

For specialty referrals, the CHC-MCO must be able to provide for:

i. Emergency Medical Condition appointments immediately upon referral.

ii. Urgent Medical Condition care appointments within twenty-four (24) hours of referral.

iii. Scheduling of appointments for routine care shall be scheduled to occur within thirty (30) days for all specialty Provider types.

c. Pregnant Women

Should the IEB or Participant notify the CHC-MCO that a new Participant is pregnant or there is a pregnancy indication on the files transmitted to the CHC-MCO by the Department, the CHC-MCO must contact the Participant within five (5) days of the Start Date to assist the woman in obtaining an appointment with an OB/GYN or Certified Nurse Midwife. For maternity care, the CHC-MCO must arrange initial prenatal care appointments for enrolled pregnant Participants as follows:

i. First trimester — within ten (10) business days of the Participant being identified as being pregnant.

ii. Second trimester — within five (5) business days of the Participant being identified as being pregnant.

iii. Third trimester — within four (4) business days of the Participant being identified as being pregnant.

iv. High-risk pregnancies — within twenty-four (24) hours of identification of high risk to the CHC-MCO or maternity care Provider, or immediately if an emergency exists.

3. Policies and Procedures for Appointment Standards

The CHC-MCO will comply with the program standards regarding service accessibility standards that are set forth in this exhibit and in Section V.BB.2. of the Agreement, Provider Agreements.

The CHC-MCO must have written policies and procedures for disseminating its appointment standards to all Participants through its Participant Handbook and through other means. In addition, the CHC-MCO must have written policies and procedures to educate its Provider Network about appointment standard requirements. The CHC-MCO must monitor compliance with appointment standards and must have a corrective action plan when appointment standards are not met.

4. Compliance with Access Standards

a. Mandatory Compliance

The CHC-MCO must comply with the access standards in accordance with this exhibit and Section V.BB.2 of the Agreement, Provider Agreements. If

the CHC-MCO fails to meet any of the access standards by the dates specified by the Department, the Department may terminate this Agreement. To the extent the Department designates new provider types in the future, the CHC-MCOs must adhere to distance standards for those new provider types when it promotes the objectives of the Medicaid program for the provider type to be subject to time and distance access standards, as determined by CMS, if the provider type is covered under the Agreement.

b. Reasonable Efforts and Assurances

The CHC-MCO must make reasonable efforts to honor a Participant's choice of Providers among Network Providers as long as:

i. The CHC-MCO's Agreement with the Network Provider covers the services required by the Participant.

ii. The CHC-MCO has not determined that the Participant's choice is clinically inappropriate.

The CHC-MCO must provide the Department adequate assurances that the CHC-MCO, with respect to this CHC zone, has the capacity to serve the expected Enrollment in this CHC zone. The CHC-MCO must provide assurances that it will offer the full scope of Covered Services as set forth in this Agreement and access to preventive and Primary Care services. The CHC-MCO must also maintain a sufficient number, mix and geographic distribution of Providers and services in accordance with the standards set forth in this exhibit and Section V.BB.2 of the Agreement, Provider Agreements.

c. Compliance with Access Standards

The CHC-MCO must continuously monitor its contracted networks throughout the contract year to ensure participant access to services within the access criteria set forth above. The CHC-MCO must obtain DHS approval for network exception requests to cover situations in which the CHC-MCO determines that Pennsylvania Medicaid Providers are not available within the access criteria established above. The network exception request must detail the specific service and provider type/specialist that the CHC-MCO has deemed as unavailable including identification of the geographic service area. DHS may consider exception requests for other provider types/specialties upon review of the evidence submitted by the CHC-MCO as part of the exception request. Each request will need to be submitted as part of the GeoAccess and Network Gap Analysis Report, when network access has changed due to closure or disenrollment of the service provider, and when the CHC-MCO has identified a gap in network access. The Department will review and

approve network exception requests based on the service type and provider type/specialist within the identified service area.

d. CHC-MCO's Corrective Action

The CHC-MCO must take all necessary steps to resolve, in a timely manner, any demonstrated failure to comply with the access standards. Prior to a termination action or other sanction by the Department, the CHC-MCO will be given the opportunity to institute a corrective action plan. The CHC-MCO must submit a corrective action plan to the Department for approval within thirty (30) days of notification of such failure to comply, unless circumstances warrant and the Department demands a shorter response time. The Department's approval of the CHC-MCO's corrective action plan will not be unreasonably withheld. The Department will make its best effort to respond to the CHC-MCO within thirty (30) days from the submission date of the corrective action plan. If the Department rejects the corrective action plan, the CHC-MCO shall be notified of the deficiencies of the corrective action plan. In such event, the CHC-MCO must submit a revised corrective action plan within fifteen (15) days of notification. If the Department does not receive an acceptable corrective action plan, the Department may impose sanctions against the CHC-MCO, in accordance with Section VIII.C. of the Agreement, Sanctions. Failure to implement the corrective action plan may result in the imposition of a sanction as provided in this Agreement.

EXHIBIT U

PROVIDER AGREEMENTS

The CHC-MCO is required to have written Provider Agreements with a sufficient number of Providers to ensure Participant access to all Medically Necessary Covered Services.

The CHC-MCO's Provider Agreements must include the following provisions:

a. A requirement that the Provider participate, as needed, in the needs screening, Assessment and Reassessment, service planning, and service coordination processes.

b. A requirement that the Provider comply with any accessibility, Cultural Competency, Linguistic Competency, and Disability Competency requirements the Department issues for meeting the needs of the CHC population.

c. A provision that the CHC-MCO may not exclude or terminate a Provider from participation in the CHC-MCO's Provider Network due to the fact that the Provider has a practice that includes a substantial number of patients with expensive medical conditions.

d. A provision that the CHC-MCO may not exclude a Provider from the CHC-MCO's Provider Network because the Provider advocated on behalf of a Participant for Medically Necessary and appropriate healthcare consistent with the degree of learning and skill ordinarily possessed by a reputable Provider practicing according to the applicable standard of care.

e. Notification of the prohibition and sanctions for submission of false Claims and statements.

f. The definition of Medically Necessary in Section II, Definitions.

g. A provision that the CHC-MCO may not prohibit or restrict a Provider acting within the lawful scope of practice from discussing Medically Necessary care and advising or advocating appropriate medical care with or on behalf of a Participant, including information regarding the nature of treatment options in order to decide among those options; the risks, benefits, and consequences of treatment and non-treatment; alternative treatments; or the availability of alternative therapies, consultation or tests that may be self-administered.

h. A provision that the CHC-MCO may not prohibit or restrict an LTSS Provider acting within the lawful scope of practice from discussing needed services and advising or advocating appropriate LTSS with or on behalf of a Participant, including information regarding the nature of LTSS options; risks; and the availability of alternative services.

i. A provision that the CHC-MCO may not terminate a contract or employment with a Provider for filing a Grievance on a Participant's behalf.

j. A provision which specifies that the agreement will not be construed as requiring the Provider to provide a counseling or referral service if the Provider objects to the provision of such services on moral or religious grounds.

k. A requirement that the Provider cooperate with the QM/UM Program standards outlined in Exhibit F, Quality Management and Utilization Management Program Requirements.

l. A requirement for cooperation for the submission of Encounter Data for all services provided within the time frames required in Section VIII, Reporting Requirements, no matter whether reimbursement for these services is made by the CHC-MCO either directly or indirectly through capitation.

m. A continuation of benefits provision which states that the Provider agrees that in the event of the CHC-MCO's insolvency or other cessation of operations, the Provider must continue to provide benefits to the CHC-MCO's Participants, including Participants in an inpatient setting, through the period for which the capitation has been paid.

n. A requirement that PCPs contact new Participants identified in the quarterly Encounter lists who have not had an Encounter during the first six (6) months of Enrollment or who have not complied with the scheduling requirements outlined in the RFP and this Agreement.

o. A requirement that should the Provider terminate its agreement with the CHC-MCO for any reason, the Provider must provide services to the Participants assigned to the Provider under the contract up to the end of the month in which the effective date of termination falls.

p. A requirement that each physician providing services to Participants must have a MMIS Provider ID Number.

q. A requirement that the Provider disclose annually any Physician Incentive Plan or risk arrangements it may have with physicians either within its group practice or other physicians not associated with the group practice, even if there is no Substantial Financial Risk between the CHC-MCO and the physician or physician group.

r. A requirement for cooperation with the CHC-MCO's and the Department's Recipient Restriction Program.

s. A requirement that healthcare facilities and ambulatory surgical facilities develop and implement, in accordance with P.L.154, No. 13, known as the Medical Care

Availability and Reduction of Error (Mcare) Act, an internal infection control plan that is established for the purpose of improving the health and safety of patients and healthcare workers and includes effective measures for the detection, control, and prevention of Healthcare-Associated Infections.

t. A provision that the Provider must agree to the CHC-MCO's QM/UM Department's monitoring of the appropriateness of a continued inpatient stay beyond approved days according to established Medical Necessity guidelines under the direction of the CHC-MCO's Medical Director, and to provide all clinical information on the inpatient stay in a timely manner which allows for decision and appropriate management of care.

u. Language requiring the Provider to hold harmless all Participants in the event of nonpayment by the CHC-MCO for failure to obtain Prior Authorization or failure to follow any other CHC-MCO rules. Participants may not be billed or balanced billed for Covered Services.

v. Requirements regarding coordination with BH Providers (if applicable):

- Comply with all applicable statutes and regulations pertaining to the confidentiality of Participant medical records, including obtaining any required written Participant consents to disclose confidential medical records.
- Make referrals for social, vocational, education, or human services when a need for such service is identified through assessment.
- Provide health records if requested by the BH Provider.
- Notify the BH Provider of all prescriptions and, when advisable, consult with the BH Provider before prescribing medication. Make certain the BH Provider has complete, up-to-date record of medications.
- Be available to the BH Provider on a timely basis for consultations.

w. A provision that requires the Provider to comply with the procedures for reporting suspected abuse and neglect under the Older Adult Protective Services Act and the Adult Protective Services Act and for performing exams for the county.

x. Requirements that Providers follow CHC-MCO requirements for ongoing communication with Participants' Service Coordinators.

y. Requirements that Providers return Participant calls within three (3) business days of receipt.

z. A requirement that the Providers must allow for and process voluntary payroll deductions of fringe benefits or wage supplements for any employee who requests it, in accordance with the Wage Payments and Collection Law (43 P.S. §§ 260.2a and 260.3).

aa. A provision that the Provider agrees that, as required by the Department, the CHC-MCO may offset any past due amount that Provider owes to the Department against any payments due to the Provider under the Provider Agreement; provided that the Department of the CHC-MCO first provides written notice of its intention to do so.

bb. A requirement that all Nursing Facilities in the CHC-MCOs network adhere to DOH regulations.

cc. A provision that Providers in the CHC-MCOs network are prohibited from soliciting Participants to receive services from the Provider including:

- Referring an individual for CHC evaluation with the expectation that, should CHC enrollment occur, the Provider will be selected by the Participant as the service provider;
- Communicating with existing CHC Participants via telephone, face-to-face or written communication for the purpose of petitioning the Participant to change Providers;
- Communicating with hospitals, discharge planners or other institutions for the purposes of soliciting potential CHC Participants. Providers in the CHC-MCOs network are allowed to outreach to hospitals, discharge planners or other institutions only to provide education and information about their agency/program, however, they cannot solicit for any potential CHC participants. The Provider cannot solicit for referrals of CHC participants, nor can they offer or provide any incentives to the hospital/institutions, discharge planner, or any other staff.

The CHC-MCO must make all necessary revisions to its Provider Agreements to be in compliance with the requirements set forth in this section. Revisions may be completed as Provider Agreements become due for renewal, provided that all Provider Agreements are amended within one (1) year of the effective date of this Agreement, with the exception of the Encounter Data requirements, which must be amended before the Implementation Date, if necessary, to ensure that all Providers are submitting Encounter Data to the CHC-MCO within the time frames specified in Section VIII.C.1, Encounter Data Reporting.

EXHIBIT V

CHC-MCO REQUIREMENTS FOR PROVIDER TERMINATIONS

1. Termination by the CHC-MCO

A. Notification to Department

The CHC-MCO must notify the Department in writing of its intent to terminate a Network Provider and services provided by a Network Provider (which includes, but is not limited to, a home care agency, nursing facility, hospital, specialty unit within a facility, and/or a large Provider group) ninety (90) days prior to the effective date of the termination.

The CHC-MCO must submit a Provider termination work plan and supporting documentation within ten (10) business days of the CHC-MCO notifying the Department of the termination and must provide weekly updates to this information. Workplans do not need to be submitted for Providers that have less than ten (10) Participants, unless specifically requested by the Department. The requirements for the work plan and supporting documentation are found in this Exhibit, under 3. Work plans and Supporting Documentation.

B. Continuity of Care

The CHC-MCO must comply with both this section and 28 Pa. Code § 9.684.

Unless the Provider is being terminated for cause as described in 40 P.S. § 991.2117(b), the CHC-MCO must allow a Participant to continue an ongoing course of treatment from the Provider for up to sixty (60) days from the date the Participant is notified by the CHC-MCO of the termination or pending termination of the Provider, or for up to sixty (60) days from the date of Provider termination, whichever is greater. A Participant is considered to be receiving an ongoing course of treatment from a Provider if during the previous twelve (12) months the Participant was treated by the Provider for a condition that requires follow-up care or additional treatment or the services have been Prior Authorized**.** Any adult Participant with a previously scheduled appointment shall be determined to be in receipt of an ongoing course of treatment from the Provider, unless the appointment is for a well adult check-up. Per 28 Pa. Code § 9.684(d), the transitional period may be extended by the CHC-MCO if the extension is determined to be clinically appropriate. The CHC-MCO shall consult with the Participant and the Provider in making the determination. The CHC-MCO must also allow a Participant who is pregnant to continue to receive care from the Provider that is being terminated through the completion of the Participant's postpartum care.

For a Participant who is receiving LTSS but whose LTSS Provider leaves the CHC-

MCO Provider Network, the CHC-MCO must continue to allow the Participant to receive services for a sixty (60) day period and must pay that Provider until such time as an alternative Network Provider can be identified and begins to deliver the same LTSS services as the former Provider.

The CHC-MCO must review each request to continue an ongoing course of treatment and notify the Participant of the decision as expeditiously as the Participant's health condition requires, but no later than two (2) business days. If the CHC-MCO determines what the Participant is requesting is not an ongoing course of treatment, the CHC-MCO must issue the Participant a denial notice using the template notice titled C(4) Continuity of Care Denial Notice found on the Intranet supporting CHC.

The CHC-MCO must also inform the Provider that to be eligible for payment for services provided to a Participant after the Provider is terminated from the Network, the Provider must agree to meet the same terms and conditions as Network Providers.

C. Notification to Participants

If the Provider that is being terminated from the Network is a PCP, the CHC-MCO, using the template notice titled C(1) Provider Termination Template For PCPs found on the Intranet supporting CHC, must notify all Participants who receive primary care services from the Provider forty-five (45) days prior to the effective date of the Provider's termination. Participants who are receiving an ongoing course of treatment from the Provider may continue to receive this treatment for up to sixty (60) days from the date the Participant is notified of the termination or pending termination of the Provider, or for up to sixty (60) days from the date of Provider termination, whichever is greater.

If the Provider that is being terminated from the Network is not a PCP or a hospital, the CHC-MCO, using the template notice titled C(3) Provider Termination Template for Specialist and FQHC Providers Who Are Not PCPs, found on the Intranet supporting CHC, must notify all Participants who have received services from the Provider during the previous twelve (12) months, as identified through referral and claims data; all Participants who are scheduled to receive services from the Provider; and all Participants who have a pending or approved Prior Authorization request for services from the Provider forty-five (45) days prior to the effective date of the Provider's termination. Participants who are receiving an ongoing course of treatment from the Provider may continue to receive this treatment for up to sixty (60) days from the date the Participant is notified of the termination or pending termination of the Provider, or for up to sixty (60) days from the date of Provider termination, whichever is greater.

If the Provider that is being terminated from the Network is a hospital (including a specialty unit within a facility or hospital), the CHC-MCO, using the template notice titled C(2) Hospital/Specialty Unit Within a Facility or Hospital Termination found on the Intranet supporting CHC, must notify all Participants assigned to a PCP with

admitting privileges at the hospital, all Participants assigned to a PCP that is owned by the hospital, and all Participants who have utilized the hospital's services within the past twelve (12) months forty-five (45) days prior to the effective date of the hospital's termination. The MCO must utilize claims data to identify these Participants.

If the CHC-MCO is terminating a specialty unit within a facility or hospital**,** the Department may require the CHC-MCO to provide forty-five (45) day advance written notice to a specific Participant population or to all of its Participants, based on the impact of the termination.

The Department, at its sole discretion, may allow exceptions to the forty-five (45) day advance written notice depending upon verified status of contract negotiations between the CHC-MCO and Provider.

The Department, in coordination with DOH, may require the CHC-MCO to include additional information in the notice of a termination to Participants.

The forty-five (45) day advance written notice requirement does not apply to terminations by the CHC-MCO for cause in accordance with 40 P.S. §991.2117(b). The CHC-MCO must notify Participants within five (5) business days using the template notice titled C(1) Provider Termination Template For PCPs, found on the Intranet supporting CHC.

The CHC-MCO must update hard copy and web-based Provider directories to reflect changes in the Provider Network as required in Section V.O.17, Provider Directories, of this Agreement.

D. Notification to the Provider

The CHC-MCO must notify Network Providers in writing of their intent to terminate the Provider's contract a minimum of forty-five (45) days in advance of termination.

2. Termination by the Provider

A. Notification to Department

If the CHC-MCO is informed by a Provider that the Provider intends to no longer participate in the CHC-MCO's Network, the CHC-MCO must notify the Department in writing ninety (90) days prior to the date the Provider will no longer participate in the CHC-MCO's Network. If the CHC-MCO receives less than ninety (90) days' notice that a Provider will no longer participate in the CHC-MCO's Network, the CHC-MCO must notify the Department by the next business day after receiving notice from the Provider.

The CHC-MCO must submit a Provider termination work plan within ten (10) business days of the CHC-MCO notifying the Department of the termination and must provide weekly status updates to the work plan. Workplans do not need to be submitted for Providers that have less than ten (10) Participants, unless specifically requested by the Department. The requirements for the work plan are found in this Exhibit, under 3. Work plans and Supporting Documentation.

The CHC-MCO must comply with both this section and 28 Pa. Code § 9.684.

B. Notification to Participants

If the Provider that is terminating its participation in the Network is a PCP, the CHC-MCO, using the template notice titled C(1) Provider Termination Template For PCPs, found on the Intranet supporting CHC, must notify all Participants who receive primary care services from the Provider.

If the Provider that is terminating its participation in the Network is not a PCP or a hospital, the CHC-MCO, using the template notice titled C(3) Provider Termination Template for Specialist and FQHC Providers Who Are Not PCPs, found on the Intranet supporting CHC, must notify all Participants who have received services from the Provider during the previous twelve (12) months, all Participants who were scheduled to receive services from the terminating Provider, and all Participants who have a pending or approved Prior Authorization request for services from the Provider forty-five (45) days prior to the effective date of the Provider's termination. The CHC-MCO must use referral and claims data to identify these Participants.

If the Provider that is terminating its participation in the Network is a hospital or specialty unit within a facility, the CHC-MCO, using the template notice titled C(2) Hospital/Specialty Unit Within a Facility or Hospital Termination, found on the Intranet supporting CHC, must, forty-five (45) days prior to the effective date of the hospital's termination, notify all Participants assigned to a PCP with admitting privileges at the hospital, all Participants assigned to a PCP that is owned by the hospital, and all Participants who have utilized the terminating hospital's services within the past twelve (12) months. The MCO must use referral and claims data to identify these Participants.

If the Provider that is terminating its participation in the Network is a specialty unit within a facility or hospital**,** the Department may require the CHC-MCO to provide forty-five (45) days advance written notice to a specific Participant population or to all of its Participants, based on the impact of the termination.

The Department, in coordination with DOH, may require additional information be included in the notice of a termination to Participants.

The CHC-MCO must update hard copy and web-based Provider directories to reflect changes in the Provider Network as required in Section V.O.17, Provider

Directories, of this Agreement.

3. Work plans and Supporting Documentation

A. Workplan Submission

The CHC-MCO must submit a Provider termination work plan within ten (10) business days of the CHC-MCO notifying the Department of the termination and must provide weekly updates to the work plan. Workplans do not need to be submitted for Providers that have less than ten (10) Participants, unless specifically requested by the Department. The work plan must provide detailed information on the tasks that will take place to ensure the termination is tracked from the time it is first identified until the termination effective date. The work plan should be organized by task, responsible person(s), target dates, completed dates, and status. The work plan should define the steps within each of the tasks. The tasks may include, but are not limited to:

- Commonwealth Notifications (DHS and DOH).
- Provider Impact and Analysis.
- Provider Notification of the Termination.
- Participant Impact and Analysis.
- Participant Notification of the Termination.
- Participant Transition.
- Participant Continuity of Care.
- Systems Changes.
- Provider Directory Updates for the IEB (include date when all updates will appear on Provider files sent to enrollment broker).
- CHC-MCO Online Directory Updates.
- Participant Service and Provider Service Script Updates.
- Submission of Required Documents to the Department (Participant notices and scripts for prior approval).
- Submission of Final Participant Notices to the Department (also include date that DOH received the final notices).
- Communication with the Public Related to the Termination.
- Termination Retraction Plan, if necessary.

B. Supporting Documentation

The Department is also requesting that the CHC-MCO submit the following supporting documentation, in addition to the work plan, within ten (10) business days of the CHC-MCO notifying the Department of the termination and must provide weekly updates as appropriate. The Department is not prescribing the format for the supporting documentation, but electronic means is preferable.

1) Background Information

a) Submit a summary of issues/reasons for termination.
b) Submit information on negotiations or outreach that has occurred between the CHC-MCO and the Provider including dates, parties present, and outcomes.

2) Participant Access to Provider Services

a) Submit information that identifies Providers remaining in the Network by Provider type and location that would be available within the appropriate travel times for those Participants once the termination is effective. Provide the travel times for the remaining Providers based upon the travel standards outlined in Exhibit T, Provider Network Composition/Service Access. For PCPs also list current panel sizes and the number of additional Participants that are able to be assigned to those PCPs.
b) Submit geographic access reports and maps documenting that all Participants currently accessing terminating Providers can access services being provided by the terminating Provider from remaining Network Providers who are accepting new Participants. This documentation must be broken out by Provider type.
c) Submit a comprehensive list of all Providers, broken out by Provider type, who are affected by the termination and that also indicates the current number of Participants either assigned (for PCPs) or utilizing these Providers.
d) Submit information that includes the admitting privileges at other hospitals or facilities for each affected Provider and whether each affected Provider can serve the CHC-MCO's Participants at another hospital or facility.
e) Submit a copy of the final Provider notices to the Department.

3) Participant Identification and Notification Process

a) Submit information that identifies the total number of Participants affected by the termination, i.e., assigned to an owned/affiliated PCP or utilizing the hospital or owned/affiliated Provider within the twelve (12) months preceding the termination date, broken down by Provider.
b) Submit information on the number of Participants with Prior Authorizations in place that will extend beyond the Provider termination date.

c) Submit draft and final Participant notices, utilizing the templates included as C(1) – C(4), Provider and Hospital Termination Templates and Continuity of Care Denial Notice, found on the Intranet supporting CHC, as appropriate, for Department review and prior approval.

4) Participant Services

a) Submit, for Department prior approval, the call center script to be used to respond to inquiries regarding the termination.
b) Identify a plan for handling increased call volume in the call center while maintaining call center standards.
c) Submit to the Department a call center report for the reporting of summary

call center statistics, if requested as part of the termination. This call center report should include, at a minimum, the following elements:

- Total Number of Inbound Participant services calls (broken out by PCP, Specialist, and Hospital).
- Termination call reasons (broken out by Inquiries, PCP Change, Opt Out/Plan Change).

5) Affected Participants in Service Coordination

a) Submit the total number of Participants in Service Coordination affected by the termination.
b) Submit the criteria to the Department that the CHC-MCO will utilize for continuity of care for Participants affected by the termination.
c) Submit an outreach plan and outreach script to the Department for prior approval if outbound calls are to be made to inform Participants in care management about the termination.

6) Participants Affected by Home Care Agency Termination:

a) Submit the total number of Participants in the home care agency affected by the termination.
b) Submit the criteria to the Department that the CHC-MCO will utilize for continuity of care for Participants affected by the termination.
c) Submit an outreach plan and outreach script to the Department for prior approval if outbound calls are to be made to inform Participants about the termination.

7) Participants Affected by Nursing Facility Termination

a) Submit the total number of Participants affected by the termination.
b) Submit the criteria to the Department that the CHC-MCO will utilize for continuity of care for Participants affected by the termination.
c) Submit an outreach plan and outreach script to the Department for prior approval if outbound calls are to be made to inform Participants in care management about the termination.

8) Enrollment Services

Submit final, approved Participant notices to the Department on CHC-MCO letterhead.

9) News Releases

Any news releases related to the termination must be submitted to the Department for prior approval.

10) Website Update

Indicate when the CHC-MCO's web-based Provider directories will be updated, and what, if any, additional information will be posted to the CHC-MCO website.

EXHIBIT W

EXTERNAL QUALITY REVIEW

External Quality Review (EQR) is a requirement under Title XIX of the Social Security Act, Section 1932(c)(2), for states to obtain an independent, external review body to perform an annual review of the quality of services furnished under state contracts with Managed Care Organizations, including the evaluation of quality outcomes, timeliness and access to services. The requirements for EQR were further outlined in 42 C.F.R. Parts 433 and 438, External Quality Review of Medicaid Managed Care Organizations. EQR refers to the analysis and evaluation of aggregated information on timeliness, access, and quality of healthcare services furnished to Participants. "Quality," as it pertains to EQR, means the degree to which a CHC-MCO maintains or improves the health outcomes of its Participants through its structural and operational characteristics and through the provision of services. The results of the EQR are made available, upon request, to specified groups and to interested stakeholders. This is one of many tools that facilitate achieving continuous quality improvement in the delivery of care and services, healthcare outcomes, and timeliness of care and services, access to services, quality and utilization management systems, and program oversight. The Department will use the EQR process for its early implementation process. The CHC-MCO must comply with all information requests from the External Quality Review Organization (EQRO). The Department requires as part of the EQR process that the CHC-MCOs:

A. Actively participate in planning and developing the measures to be utilized with the Department and the EQRO. The Medical Assistance Advisory Committee will be given an opportunity to provide input into the measures to be utilized.

B. Accurately, completely and within the required timeframe identify eligible Participants to the EQRO.

C. Correctly identify and report the numerator and denominator for each measure.

D. Actively encourage and require Providers, including subcontractors, to provide complete and accurate Provider medical records within the timeframe specified by the EQRO.

E. Demonstrate how the results of the EQR are incorporated into the Plan's overall Quality Improvement Plan and demonstrate progressive improvements during the term of the contract.

F. Improve Encounter Data in an effort to decrease the need for extensive Provider medical record reviews.

G. Provide information to the EQRO as requested to fulfill the requirements of the mandatory and optional activities required in 42 C.F.R. Parts 433 and 438.

H. Ensure that data, clinical records and workspace located at the CHC-MCO's work

site are available to the independent review team and to the Department, upon request.

I. Participate in Performance Improvement Projects whose target areas are dictated by the Department to address key quality areas of focus for improvements. The CHC-MCO will comply with the PIP timelines as prescribed by the EQRO.

1. The CHC-MCO shall perform at least two (2) PIPs, one (1) clinical and one (1) non-clinical. Clinical PIPs include projects focusing on prevention and care of acute and chronic conditions, high-volume services, high-risk services, and continuity and coordination of care and services; non-clinical PIPs include projects focusing on availability, accessibility, and cultural competency of services, interpersonal aspects of care and services, and appeals, grievances, and other complaints.
2. The CHC-MCO shall follow CMS protocols for PIPs and document all steps outlined in the CMS protocols for PIPs
3. The CHC-MCO shall identify benchmarks and set achievable performance goals for each of its PIPs. The CHC-MCO shall identify and implement intervention and improvement strategies for achieving the performance goal set for each PIP and promoting sustained improvements.
4. The CHC-MCO shall report on PIPs as required in the Reporting Requirements For Performance Improvement Project topics that are conducted in the assigned Zone of the State. The CHC-MCO shall submit one Performance Improvement Project Summary Report that includes Zone-specific data and information, including *improvement strategies* as required by CMS.
5. After three (3) years, the CHC-MCO shall, using evaluation criteria established by the Department, determine if one or all of the PIPs should be continued.

EXHIBIT W(1)

CRITICAL INCIDENT REPORTING AND MANAGEMENT AND

PROVIDER PREVENTABLE CONDITIONS/PREVENTABLE SERIOUS ADVERSE EVENTS REPORTING

All CHC-MCO staff and staff of providers in their networks are mandatory reporters under both the Adult Protective Services Act (APS) and the Older Adult Protective Services Act (OAPSA). Reporting requirements can be found at:

- APS- http://www.dhs.pa.gov/citizens/reportabuse/dhsadultprotectiveservices/
- OAPSA- http://www.aging.pa.gov/organization/advocacy-and-protection/Pages/Protective-Services.aspx

CHC-MCOs must train or educate its Network Providers and ensure they comply with the reporting requirements established in the OAPSA and APS. In addition, CHC-MCOs must ensure that Network Providers comply with the following critical incident and adverse event reporting requirements outlined in this Exhibit.

Critical Incident Reporting to the Department

A. Network Providers and Subcontractors must report critical events or incidents to the CHC-MCOs.

B. Using the Department's Enterprise Incident Management System (EIM), the CHC-MCOs must investigate critical events or incidents reported by Network Providers and Subcontractors and report the outcomes of these investigations. CHC-MCOs must require all information entered in EIM to be written in English. To report the outcome the Department has established an Operations Report for critical incidents (OPS 30: CHC Waiver Assurance Performance Measures – Health & Welfare). This reporting requirement is in addition to any other reporting requirements that may exist under the law.

C. CHC-MCO must establish a process to receive and manage critical incident reports that:

1. Safeguards the health and welfare of the participant involved in a critical incident, including seeking emergency medical services if needed.
2. Determines if an incident is reportable based on the definition of a critical incident.
3. Requires the CHC-MCO staff person or Network Provider to submit a critical incident report in EIM within forty-eight (48) hours of discovery of the incident, excluding weekends and holidays. The forty-eight (48) hour clock begins at the time that the incident was discovered. If the incident was discovered on a weekend or holiday the clock would start at 12:00 a.m. on the first business following the discovery of the incident.
4. Ensures all required fields are completed in EIM.

5. Requires the CHC-MCO to notify the Participant involved in the incident and the Participant's designated representative (unless the representative is suspected to be involved in the incident) within twenty-four (24) hours that a critical incident report was filed.
6. Requires CHC-MCO staff and Network Providers to report critical incidents even if the Participants involved choose not to report.
7. Respects the right of a Participant involved in a critical incident to: not report the incident; decline further interventions; refuse involvement in a critical incident investigation; and have an advocate present during any investigation resulting from a critical incident report.
8. Provides the number and percentage of substantiated cases of abuse, neglect and exploitation where potential issues related to health and welfare were addressed.

D. The following are critical incidents:

1. Death (other than by natural causes);
2. Serious injury that results in emergency room visits, hospitalizations, or death;
3. Hospitalization except in certain cases, such as hospital stays that were planned in advance;
4. Provider or staff misconduct, including deliberate, willful, unlawful, or dishonest activities;
5. Abuse, which includes the infliction of injury, unreasonable confinement, intimidation, punishment, mental anguish, or sexual abuse of a participant. Types of abuse include, but are not necessarily limited to:
6. Physical abuse, defined as a physical act by an individual that may cause physical injury to a participant;
7. Psychological abuse, defined as an act, other than verbal, that may inflict emotional harm, invoke fear, or humiliate, intimidate, degrade or demean a participant;
8. Sexual abuse, defined as an act or attempted act, such as rape, incest, sexual molestation, sexual exploitation, or sexual harassment and/or inappropriate or unwanted touching of a participant; and
9. Verbal abuse, defined as using words to threaten, coerce, intimidate, degrade, demean, harass, or humiliate a participant;
10. Neglect, which includes the failure to provide a participant the reasonable care that he/she requires, including, but not limited to, food, clothing, shelter, medical care, personal hygiene, and protection from harm. Seclusion, which is the involuntary confinement of an individual alone in a room or an area from which the individual is physically prevented from having contact with others or leaving, is a form of neglect;
11. Exploitation, which includes the act of depriving, defrauding, or otherwise obtaining the personal property from a participant in an unjust, or cruel manner, against one's will, or without one's consent, or knowledge for the benefit of self or others;
12. Restraint, which includes any physical, chemical or mechanical intervention that is used to control acute, episodic behavior that restricts the movement or

function of the individual or a portion of the individual's body. Use of restraints and seclusion are both restrictive interventions, which are actions or procedures that limit an individual's movement, a person's access to other individuals, locations or activities, or restricts participant rights;

13. Service interruption, which includes any event that results in the participant's health and/or safety being at risk because of their inability to receive services. This includes involuntary termination by the provider agency, and failure of the participant's back-up plan. If these events occur, the provider agency must have a plan for temporary stabilization; and
14. Medication errors that result in hospitalization, an emergency room visit or other medical intervention.

For the purposes of Critical Incident reporting an emergency room visit is defined as the use of a hospital emergency room. This includes situations that are clearly emergencies, such as a serious injury, life-threatening medical conditions, medication errors, as well as those when an individual is directed to an emergency room in lieu of a visit to the PCP or as the result of a visit to the PCP. The use of an emergency room by an individual, in place of the physician's office, is not reportable.

A serious injury is defined as an injury that:
1) causes a person severe pain; or
2) significantly impairs a person's physical or mental functioning, either temporarily or permanently.

Critical Incident Investigation and Management

The CHC-MCO must ensure that the investigation of critical incidents begins within twenty-four (24) hours after the CHC-MCO discovers the incident.

The CHC-MCO must conclude critical incident investigations and provide the results of their investigations in EIM within thirty (30) calendar days of discovery of the incident. If the CHC-MCO is unable to conclude an investigation within thirty (30) days, the CHC-MCO must document the need for an extension and the reasons for the delay in EIM.

For any participant with more than three critical incidents within a 12-month period, the CHC-MCO must perform an analysis and take action as necessary to prevent or mitigate further incidents. The CHC-MCO must commence the analysis and implement the actions to address potential issues related to the health and welfare of the Participant within the 30-day investigation period. If additional time is needed to investigate and to implement any necessary actions to address potential issues related to the health and welfare of the Participant, the CHC-MCO must document an extension in EIM.

For critical incidents reportable under APS and OAPSA, including those involving suspected abuse, neglect, exploitation or abandonment, the CHC-MCO is responsible to report the incident to APS or OAPSA but not to investigate. CHC-MCO staff and service coordinators are required to provide information to and cooperate with APS and OAPSA staff who are conducting the investigation. In addition, the CHC-MCO shall fully cooperate with APS and OAPSA staff in the coordination of any services provided by the CHC-MCO.

Upon being notified by APS and OAPSA staff that a case has been closed, or upon being notified by OLTL, the CHC-MCO will resume full responsibility for subsequent critical incident reporting and investigation for that Participant.

As part of its quality management plan, the CHC-MCO shall have a means to identify Participants who may be at risk of abuse or neglect and take steps to minimize those risks while balancing the right of the Participant to live in his or her community or place of choice.

The Department retains the right to review any incident reports or internal documentation, to conduct its own investigations and to require further corrective actions by the CHC-MCO.

Critical Incident Reporting Requirements for Providers

Providers must report in accordance with applicable requirements.

The CHC-MCO must require providers to cooperate with its investigation of critical incidents. The CHC-MCO must include critical incidents training in its annual training plan and quarterly updates to demonstrate all applicable CHC-MCO staff, Network Providers and their staff and contractors have received the training.

Provider Preventable Conditions/Preventable Serious Adverse Events (PSAE)

The CHC-MCO must require all Network Providers to identify provider preventable conditions as defined in 42 C.F.R. § 447.26 and may not pay for services related to provider preventable conditions unless the condition existed prior to the initiation of treatment for the patient. The CHC-MCO must submit all identified Provider Preventable Conditions in a form or frequency as required by the Department.

The CHC-MCO is prohibited from making payment to a provider for provider preventable conditions that meet the following criteria:

a. Is identified in the State Plan;
b. Has been found by the State, based upon a review of medical literature by qualified professionals, to be reasonably preventable through the application of procedures supported by the evidence-based guidelines;
c. Has a negative consequence for the Participant;
d. Is auditable;
e. Includes, at a minimum, wrong surgical or other invasive procedure performed on a patient; surgical or other invasive procedure performed on the wrong body part; surgical or other invasive procedure performed on the wrong patient.

The CHC-MCO must develop and disseminate policies and procedures that prohibit payments for inpatient services related to treating provider preventable conditions.

The Department will recoup any funds expended by the CH-MCO for payments related to inpatient services for provider preventable conditions.

Please refer to the Department's website for additional information regarding PSAE
http://www.dpw.state.pa.us/cs/groups/webcontent/documents/document/c_101648.pdf

EXHIBIT W(2)

HEALTHCARE EFFECTIVENESS DATA AND INFORMATION SET (HEDIS®)

AND

CONSUMER ASSESSMENT OF HEALTHCARE PROVIDERS AND SYSTEMS (CAHPS®)

Annually, the CHC-MCO must complete all HEDIS measures designated by NCQA as relevant to Medicaid. The HEDIS measure results must be reported separately for each Zone in which the CHC-MCO operates. The CHC-MCO must contract with an NCQA-certified HEDIS auditor to validate the processes of the CHC-MCO in accordance with NCQA requirements. Audited HEDIS results must be submitted to the Department, NCQA and the Department's EQRO annually by June 15th of each calendar year.

The CHC-MCO must utilize the Hybrid methodology (i.e., gathered from administrative and medical record data) as the data collection method for any Medicaid HEDIS measure containing Hybrid Specifications as identified by NCQA. If, in the event the CHC-MCO fails to pass the medical record review for any given standard and NCQA *mandates* that administrative data must be submitted instead of hybrid, the administrative data may be used.

The CHC-MCO must submit to the Department by June 15th of each calendar year a detailed explanation for any Medicaid HEDIS measure marked as "Not Reported."

HEDIS is a set of standardized performance measures designed to reliably compare health plan performance. HEDIS performance measures are divided into the following domains of care:

- Effectiveness of care
- Access/availability of care
- Experience of care
- Utilization and Risk Adjusted Utilization
- Health plan descriptive information
- Measures Reported Using Electronic Clinical Data Systems

The Department requires that the CHC-MCOs:

A. Must produce rates for all Medicaid reporting measures unless otherwise specified by the Department.

B. Must follow NCQA specifications as outlined in the HEDIS Technical Specifications, clearly identifying the numerator and denominator for each measure.

C. Must have all HEDIS results validated by an NCQA-licensed vendor. The Department currently contracts with an NCQA-licensed entity to validate the MCOs' HEDIS results used in public reporting. The MCO may utilize these validation results for other purposes such as pursuit of accreditation. The Department may at some future date relinquish the direct contracting of NCQA validation activities.

D. Must assist with the HEDIS validation process by the Department's NCQA licensed contractor.

E. Must demonstrate how HEDIS results are incorporated into the CHC-MCO's overall Quality Improvement Plan.

F. Must submit validated HEDIS results annually on June 15th unless otherwise specified by the Department.

G. Must provide Participant level data on select measures and must oversample select measures, as defined by the Department and the EQRO.

Consumer Assessment of Healthcare Providers and Systems (CAHPS)

The CHC-MCO must conduct any CAHPS survey required by the Department. CAHPS surveys are standardized instruments that assess various aspects of patient experience with care. CHC requires that both the Adult CAHPS and HCBS CAHPS surveys be conducted for Participants. Specific requirements are listed below for both surveys.

CAHPS Health Plan Survey (Adult CAHPS)

The Adult CAHPS is a subset of HEDIS reporting required by the Department. The CHC-MCO must conduct the Adult CAHPS using the most current CAHPS version specified by NCQA. Survey results must be reported to the Department both electronically and hardcopy in an Excel file in the format determined by the Department. The survey results must be reported separately for each Zone in which the CHC-MCO operates. Validated survey results must be submitted to the Department, NCQA and the Department's EQRO annually by June 15th of each calendar year unless otherwise specified by the Department.

The CHC-MCO must enter into an Agreement with a vendor that is certified by NCQA to perform CAHPS surveys. The CHC-MCO's vendor must perform the CAHPS Adult survey using the most current CAHPS version specified by NCQA.

The CHC-MCO must submit annually the Relative Resource Use (RRU) data to the

Department within ten (10) business days of receipt from NCQA. The CHC-MCO must submit both the Regional and National RRU results.

CAHPS are a set of standardized surveys that assess patient satisfaction with the experience of care. The Adult CAHPS survey is a subset of HEDIS reporting required by the Department. For HEDIS, MCOs must contract with an NCQA-certified vendor to administer the survey according to the HEDIS survey protocol that is designed to produce standardized results. The survey is based on a randomly selected sample of Participants from the CHC-MCO and summarizes satisfaction with the experience of care through ratings and composites. For the Department's purposes, the sample and response rate must be sufficient to ensure a margin of error for each question to be less than 5% for the CHC-MCO's enrolled population at a 95% confidence level. It is recommended that the CHC-MCOs work with their certified CAHPS vendors to determine an adequate sample size to meet the 5% margin of error at a 95% confidence level (CAHPS recommends a minimum of 300 completed responses).

The HEDIS protocol for administering CAHPS surveys consists of a mail protocol followed by telephone administration to those not responding by mail. CHC-MCOs must contract with a certified vendor to administer the Adult CAHPS survey. The CHC-MCO must generate a sample frame for each survey sample and arrange for an NCQA-certified auditor to verify the integrity of the sample frame before the certified vendor draws the sample and administers the survey. The CHC-MCOs are also required to have the certified vendor submit Participant-level data files to NCQA for calculation of HEDIS CAHPS survey results. The Department requires that the CHC-MCOs:

A. Must conduct the Adult CAHPS survey using the current version of CAHPS.

B. Must include all Medicaid core questions in the survey.

C. Must add all state specific modifications, which may include unique specifications or content as directed by the Department to the Adult CAHPS survey.

D. Must add the following supplemental questions to the Adult CAHPS survey:

1. In the last 6 months, did you get care from a dentist's office or dental clinic?
2. In the last 6 months, how many times did you go to a dentist's office or dental clinic for care for yourself?
3. We want to know your rating of all your dental care from all dentists and other dental providers in the last 6 months. Using any number from 0 to 10, where 0 is the worst dental care possible and 10 is the best dental care possible, what number would you use to rate your dental care?

E. Must add the following supplemental question from the Supplemental Items for the Adult Questionnaires to the Adult CAHPS survey:

1. In the last 6 months, how often was it hard to find a personal doctor who speaks your language?
2. In the last 6 months, how often was it hard to find a personal doctor who

knows your culture?

3. In the last 6 months, how often did your personal doctor consider your cultural needs, including race, ethnicity or background, when providing care?
4. In the last 6 months, if you utilized an interpreter or language services to help speak with your doctors or other healthcare providers, how would you rate your experience (with 0 being the worst possible experience, and 10 being the best possible experience)?

F. Must forward Adult CAHPS data to the Department both electronically and hardcopy in an Excel file in the format determined by the Department.

G. Must submit validated Adult CAHPS results annually on June 15th unless otherwise specified by the Department.

The Department annually releases an Ops Memo that contains detailed information regarding the submission of HEDIS and Adult CAHPS, and may include additional Pa-specific questions.

Home and Community-based Services CAHPS Survey (HCBS CAHPS)

CHC-MCOs must contract with a vendor to administer the HCBS CAHPS survey. The CHC-MCO's vendor must conduct the HCBS CAHPS Survey using the most current version of the survey instrument provided by CMS. Each CHC-MCO's vendor will administer the survey using the mode determined by the Department, which can be in-person or via telephone. Survey results must be reported to the Department both electronically and hardcopy in an Excel file in the format determined by the Department. The survey results must be reported separately for each Zone in which the CHC-MCO operates. Validated survey results must be submitted to the Department, and the Department's EQRO annually each calendar year unless otherwise specified by the Department.

CAHPS are a set of standardized surveys that assess Participant satisfaction with the experience of care. CHC-MCOs must contract with a vendor to administer the survey according to CMS survey protocol that is designed to produce standardized results. The survey is based on a randomly selected sample of Participants from the CHC-MCO and summarizes satisfaction with the experience of care through ratings and composites. The Department also requires that the CHC-MCOs:

A. Provide to the Department the name of the selected survey vendor and a copy of the contract with the selected survey vendor.

B. Ensure that the selected survey vendor uses computer assisted interviewing software, has sufficient personnel to conduct recruitment of Participants as well as availability to schedule interviews to achieve required number of surveys considered complete due to the respondent providing a substantive response for at least 50% of the questions that all respondents are eligible to answer, not including the "About You" section.

C. Ensure that the selected survey vendor develops and submits a comprehensive Quality Assurance Plan (QAP) for survey administration that details its implementation of and compliance with all required HCBS CAHPS Survey protocols and provide the Department with a copy of the selected survey vendor's QAP.

D. Provide the selected survey vendor with a complete file of its HCBS population for use in selecting the statistically random sample as specified by the Department. If a minimum effective sample size is not specified by the Department, the selected vendor must select a statistically valid random sample based on a 95% Confidence Level, ± 5% Confidence Interval, and a 50% Distribution. Insure that the selected survey vendor stratifies the sample to assure equal race/ethnicity representation of the CHC waiver population and stratifies by region to assure geographic representation of the CHC waiver population.

E. Must send a pre-notification letter to CHC Participants seven business days before the initial recruitment call after the letter has been reviewed and approved by the Department.

F. Meet the following requirements if the selected survey vendor administers the survey to Participants by telephone and/or the Participant declines to take the survey:

- The CHC-MCO's vendor must ask the Participant "*Would you have preferred to take this survey in person? In that case, an interviewer would have come to where you live or another location you agreed on in advance."*

- In the event the Participants decline to take the survey, the CHC-MCO's vendor must summarize in the plan-specific HCBS CAHPS Survey results the reasons why the Participants declined to take the survey.

G. Ensure that the selected survey vendor obtains and records consent by Participants or their legal guardians, as well as consent by Participants when a legal guardian or proxy will be surveyed on their behalf. Consent can be verbal for telephone and written for in-person interviews.

H. Ensure that the selected survey vendor has a process in place to report suspected participant abuse, neglect and/or exploitation to both the CHC-MCO and to the Department.

I. Must conduct the HCBS CAHPS survey using the current version of CAHPS.

J. Must include all HCBS core questions in the survey.

K. Must include all HCBS supplemental employment questions in the survey.

L. Must add all supplemental state specific questions as directed by the Department to the HCBS CAHPS survey.

M. Must add the following supplemental dental care questions to the HCBS CAHPS survey. The Department reserves the right to modify these questions as necessary:

1. In the last 6 months, did you get care from a dentist's office or dental clinic?
2. In the last 6 months, how many times did you go to a dentist's office or dental clinic for care for yourself?
3. We want to know your rating of all your dental care from all dentists and other dental providers in the last 6 months. Using any number from 0 to 10, where 0 is the worst dental care possible and 10 is the best dental care possible, what number would you use to rate your dental care?

N. Must forward HCBS CAHPS data to the Department electronically in an Excel format including an executive summary in the format determined by the Department.

O. Must have selected survey vendor submit a First Twenty-Five Completed HCBS CAHPS Survey data file annually per the due date and in the format determined by the Department.

P. Must have selected survey vendor submit a weekly Survey Administration Status report during the course of administering the survey beginning by the second week of survey administration in the format determined by the Department.

Q. Must provide a validated disposition report using disposition categories defined by the American Association for Public Opinion Research (AAPOR) or developed by the selected survey vendor. This final disposition for all sampled cases indicates the final outcome in terms of whether the participant responded to the survey and, if not, why they did not respond. The disposition report must be submitted annually on November 15 unless otherwise specified by the Department.

R. Must submit validated HCBS CAHPS results annually on November 15th unless otherwise specified by the Department.

S. Provide Limited English Proficiency and Text Telephone services in support of the HCBS CAHPS Survey if requested by the survey participant.

The Department reserves the right to review the subsequent years' results and determine if an in-person interview will be required. The Department will notify the CHC-MCOs in advance of any change in the requirements.

The Department annually releases an Ops Memo that contains detailed information regarding the submission of HCBS CAHPS.

EXHIBIT X

ENCOUNTER DATA SUBMISSION REQUIREMENTS AND DAMAGES APPLICATIONS

The submission of timely, complete, and accurate Encounter Data is critical to the Department's ability to establish and maintain cost-effective and quality managed care programs.
Consequently, the requirements for submission and metrics for measuring the value of the data for achieving these goals are crucial.

- **CERTIFICATION REQUIREMENTS**

  The CHC-MCO must be certified through the Department's MMIS prior to the submission of live encounter data. The certification process is detailed on the Pennsylvania HealthChoices Extranet.

- **SUBMISSION REQUIREMENTS**

  - Timeliness:

    With the exception of NCPDP Encounters, all CHC-MCO approved Encounters and specified CHC-MCO denied Encounters must be approved in the Department's MMIS by the last day of the third month following the month of initial CHC-MCO adjudication. NCPDP Encounters must be submitted and approved in the Department's MMIS within thirty (30) days following the CHC-MCO adjudication.

    - Metric:

      During the six (6) months following the month of the initial MMIS adjudication, Encounters will be analyzed for timely submission.

      - Failure to achieve the Department's MMIS approved status for 98% of all CHC-MCO approved and specified CHC-MCO denied Encounters by the last day of the third month following initial CHC-MCO adjudication may result in damages.
      - Any Encounter Data corrected or initially submitted after the last day of the third month following initial CHC-MCO adjudication may be subject to damages.

  - Accuracy and Completeness:

    Accuracy and completeness are based on consistency between Encounter Data submitted to the Department's MMIS and information for the same service maintained by the CHC-MCO in their Claims and service history databases.

- Metric:

  Accuracy and completeness will be determined through a series of analyses of CHC-MCO Claims history data and Encounters received and processed through the Department's MMIS. The analysis will be conducted in accordance with triennial audit requirements found in Exhibit O of this Agreement.

- **PENALTY PROVISION**

  - Timeliness:

    Failure to comply with timeliness requirements may result in a sanction of up to $10,000 for each program month.

  - Completeness and Accuracy:

    Errors in accuracy or completeness identified by the Department in an annual or semi-annual analysis may result in sanctions as follows. Multiple errors in accuracy or completeness in one sample record count as one error.

Percentage of the sample that includes an error	Sanction
Less than 1.0 percent	None
1.0 – 1.4 percent	$4,000
1.5 – 2.0 percent	$10,000
2.1 - 3.0 percent	$16,000
3.1 – 4.0 percent	$22,000
4.1 – 5.0 percent	$28000
5.1 – 6.0 percent	$34,000
6.1 – 7.0 percent	$40,000
7.1 – 8.0 percent	$46,000
8.1 – 9.0 percent	$52,000
9.1 – 10.0 percent	$58,000
10.1 percent and higher	$100,000

Rev. 08-11-09

EXHIBIT Y

GUIDELINES FOR SANCTIONS REGARDING FRAUD, WASTE AND ABUSE

The Department recognizes its responsibility to administer the Community HealthChoices (CHC) Program and ensure that the public funds which pay for this program are properly spent.

To maintain the integrity of the CHC Program and to ensure that CHC-MCOs comply with pertinent provisions and related state and federal policies, including rules and regulations involving Fraud, Waste and Abuse issues, the Department will impose sanctions on the CHC-MCOs as deemed appropriate where there is evidence of violations involving Fraud, Waste and Abuse issues in the CHC Program. To that end, program compliance and improvement assessments, including financial assessments payable to BPI, will be applied by BPI for the CHC-MCO's identified program integrity compliance deficiencies. Note that the Department also retains discretion to impose additional remedies available under applicable law and regulations.

FRAUD, WASTE AND ABUSE ISSUES WHICH MAY RESULT IN SANCTIONS

The Department may impose sanctions, for non-compliance with Fraud, Waste and Abuse requirements which include, but are not limited to, the following:

A. Failure to implement, develop, monitor, continue and/or maintain the required compliance plan and policies and procedures directly related to the detection, prevention, investigation, referral or sanction of Fraud, Waste and Abuse by providers, caregivers, members or employees.

B. Failure to cooperate with reviews by oversight agencies or their designees, including the Department, Pennsylvania Office of Attorney General Medicaid Fraud Control Unit, Office of Inspector General of the U.S. DHHS, and other state or federal agencies and auditors under contract to CMS or the Department 42 CFR §438.3(h).

C. Failure to adhere to applicable state and federal laws and regulations.

D. Failure to adhere to the terms of the CHC- Agreement, and the relevant Exhibits which relate to Fraud, Waste and Abuse issues.

E. If a CHC-MCO fails to provide the relevant operating agency, upon its written request, encounter data, claims data and information, payment methodology, policies and/or other data required to document the services and items delivered by or through the CHC-MCO to Participants 42 CFR §438.604.

F. CHC MCO engaging in actions that indicate a pattern of wrongful denial of payment for a health-care benefit, service or item that the organization is required to provide under its agreement.

G. If a CHC-MCO or associate fails to furnish services or to provide Participants a health benefit, service or item that the organization is required to provide under its Agreement 42 CFR § 438.700(b)(1).

H. CHC-MCO engaging in actions that indicate a pattern of wrongful delay of at least for 45 days or a longer period specified in the Agreement (not to exceed 60 days) in making payment for a health-care benefit, service or item that the organization is required to provide under its Agreement.

I. Discriminating against Participants or prospective Participants on any basis including without limitation, age, gender, ethnic origin or health status 42 CFR §438.3(d)(3- 4)

J. The CHC-MCO must conduct a preliminary investigation and may consult with other state agencies or law enforcement to determine credible allegations of fraud for which an investigation is pending under the Medicaid program against an individual, a provider, or other entity (42 CFR §455.23(a)). Allegations are to be considered credible when there is indicia of reliability and the State Medicaid agency has reviewed all allegations, facts and evidence carefully and acts judiciously on a case by case basis (42 CFR §455.2).

K. CHC-MCO failure to pay overpayments to DHS as identified through network provider audits, reviews, investigations conducted by BPI or its designee and other state and federal agencies.

RANGE OF SANCTIONS

The Department may impose any of the sanctions indicated in Section VIII.I. of the Agreement including, but not limited to, the following:

Preclusion or exclusion of the CHC-MCO, its officers, managing employees or other individuals with direct or indirect ownership or control interest in accordance with 42 U.S.C. §1320a-7, 42 C.F.R. Parts 1001 and 1002; 62 P.S. §1407 and 55 Pa. Code §§1101.75 and 1101.77.

These sanctions may, but need not be, progressive. The Department's intends to maintain an effective, reasonable and consistent sanctioning process as deemed necessary to protect the integrity of the CHC- Program.

EXHIBIT Z

PERSON-CENTERED SERVICE PLANNING

Federal and state regulations (42 CFR § 441.301, 55 Pa. Code §§ 52.25 and 52.26) require that Person-Centered Planning be used in Medicaid LTSS programs. Person-Centered Planning is a process directed by the CHC LTSS Participant. The process involves a PCPT actively coordinated by the LTSS Participant's Service Coordinator. The PCSP must be developed by the Service Coordinator, the Participant, the Participant's representative, and the Participant's PCPT. The process assists the Participant to articulate a plan for the future and helps determine the supports and services that the Participant needs to achieve identified outcomes.

Note: The information in this exhibit is to be used in conjunction with, and does not replace, the requirements in the CHC 1915(c) HCBS waiver.

Guidelines for Person-Centered Service Planning

i. The CHC-MCO must deliver LTSS in a person-centered way:

   a. LTSS must be furnished under a written service plan, based on a person-centered approach that identifies and addresses an LTSS Participant's needs, goals, and preferences while incorporating existing resources and supports as identified by the Participant.

   b. Service plans must be:

      1. Approved by the CHC-MCO no more than thirty (30) calendar days from the date the Assessment or Reassessment is completed.

PCSP Procedures Overview

i. General

   a. The PCSP must be adequate and appropriate according to needs identified by the Assessment.
   b. If a legal guardian has been appointed for the Participant, the guardian must be an integral part of the PCPT. The Participant's legal guardian

has the right to actively participate on the Participant's behalf in the planning process and to file an appeal or grievance on behalf of the Participant.

c. If the Participant uses an alternative means of communication or if the Participant's primary language is not English, the process must utilize the Participant's primary means of communication or an interpreter.
d. The Participant's cultural preferences must be acknowledged and reflected in the planning process.
e. The CHC-MCO must provide the necessary level of support to ensure that the individual directs the PCPT process to the maximum extent possible and is enabled to make informed choices and decisions.
f. The Department may review, question, and request revisions to LTSS Participants' PCSPs. The CHC-MCO must provide the Department with monthly aggregate reports on PCSP changes in a format specified by the Department.
g. CHC-MCOs must annually submit and obtain Department approval of their Service Coordination staffing, caseloads, the required frequency of in-person contact with Participants, and how Service Coordinators share and receive real-time information about Participants and Participant encounters.

ii. Participant Education

a. The Service Coordinator must educate the Participant on the following:

1. Strategies for resolving conflict or disagreement within the PCPT process, including clear conflict-of-interest guidelines for all members of the Person-Centered Planning Team.
2. Informed choice regarding the services and supports they receive and from whom.
3. Informed choice regarding their right to select their Service Coordinator and to change Service Coordinators at any time.

4. A method for the Participant to request updates to the PCSP as needed.
5. Participant self-directed services.
6. The Complaint, Grievance and Fair Hearing Appeals Processes.
7. How to report abuse, neglect, and exploitation. The Service Coordinator must obtain a signature verifying that the Participant or their representative fully understand the process.

b. The Service Coordinator provides Participants and their representative, if any, with a Participant handbook within 5 days of enrollment. The handbook is intended to provide Participants with a basis for self-advocacy safeguards. The Service Coordinator educates the Participant and/or their representative on the following:

1. Participant rights and responsibilities;
2. Participant choice;
3. the role of the Service Coordinator;
4. the role of the PCPT;
5. how to connect to other community resources;
6. abuse, neglect and exploitation;
7. fraud and abuse; and
8. Participant self-directed services.

iii. Content of the PCSP for Participants Receiving LTSS in the Community

a. The holistic PCSP at minimum must include the following:

1. A Care Management Plan to identify and address how the Participant's physical, cognitive, and behavioral healthcare needs will be care managed. See Section V.G.1 of the CHC Agreement for the required components of PCSP Care Management Plans.

2. An LTSS Service Plan to identify and address how LTSS needs will be met and how services will be provided in accordance with the PCSP. The requirements for the LTSS Service Plan are in Section V.G.2 of the CHC Agreement. In addition to the requirements listed in the CHC Agreement, the CHC-MCO must also include the following in the PCSP and PCSP process:

    A. Individualized and emergency back-up plans to ensure the health and safety of Participants.

        i. Service Coordinators must review the PCSP quarterly to validate that the strategies and back-up plans are working and are current.
        ii. Service Coordinators must update back-up plans as necessary, or if the back-up has failed at any point.

3. The PCSP must document the following:

    A. The Participant's eligibility and CHC/MA ID number;
    B. The names of individuals who participated in the PCSP process;
    C. The Participant's household composition (i.e., does the individual live alone, with a sibling or other relative, or friend?);
    D. The Participant's emergency contacts;
    E. The Service Coordinator must describe contact with the Participant, family members, and providers in the case management notes of the PCSP.
    F. The Service Coordinator's quarterly review of the Participant's back-up plan, including updates to the back-up plan if necessary;
    G. The Participant's completed Assessment, including the Diagnosis, Medications, Allergies, and Medical Contacts;
    H. Any CHC services that reflect unmet needs identified in the Assessment;

I. The Participant's strengths and capabilities;
J. That the Participant was offered a choice of network providers;
K. The review of rights and responsibilities with the Participant;
L. The Participant's delivery preferences for all services;
M. Any barriers, risks, and mitigation strategies;
N. The assignment of responsibilities to implement and monitor the PCSP;
O. A list of the Participant's preferences for employment, education, and community engagement, as well as an overview of the discussion the Service Coordinator had with the Participant on these issues;
P. When a participant uses informal supports, the CHC-MCO must discuss with and document in the PCSP each informal support's availability, willingness, and ability to provide the needed HCBS and the participants' acceptance of assistance from that informal support. The PCSP also must identify each informal support, and, with respect to each informal support, the day(s) and number of hours per day informal supports is provided, as well as the specific type and scope of services provided.
Q. If the Participant does not have informal support, include reasons why informal support is not available;
R. The type, scope, amount, duration, and frequency of services needed by the Participant;
S. Justification for all services;
T. If a service definition requires a physician prescription, documentation that the Service Coordinator obtained the prescription prior to adding the service to the PCSP; and
U. If the Participant refuses to have a need addressed, when the Participant refused to have the need addressed and why the Participant chose for the need to remain unaddressed.

iv. Content of the PCSP for Participants Receiving LTSS in Nursing Facilities

1. For nursing facility residents, nursing facilities are responsible to develop care plans and provide services consistent with state licensing requirements and federal conditions of participation. The Department of Health will continue to enforce state licensing requirements and act as the State Survey Agency for federal survey and certification purposes.

2. The CHC-MCO Service Coordinator will review a Participant's nursing facility care plan as part of coordination of care and provide input into the plan. The CHC-MCO Service Coordinator will work with the nursing facility staff to determine the services that the Participant needs and the roles of who should be providing the services in the PCSP process. The CHC-MCO Service Coordinator will be responsible for the coordination of Medicare benefits, Veterans benefits, behavioral health services, and other health coverage insurers and supports in conjunction with the nursing facility. A separate PCSP does not have to be created as long as the NF care plan includes all appropriate services, goals for transitioning to the community (if desired by the Participant), and how Medicare benefits, Veterans benefits, behavioral health services, and other health coverage will be coordinated.

v. PCSP Process

1. The Service Coordinator describes and explains the concept of person-centered service planning to the Participant and/or his or her representative.
2. Prior to a PCPT meeting, the Service Coordinator works with the Participant and/or his or her representative to coordinate attendees and meeting dates, times and locations. The Participant chooses who to invite and when and where meetings will take place.
3. The Service Coordinator provides information to the Participant and to his or her representative, if any, in advance of the planning meeting so that the Participant can make informed choices about their services and service delivery in order to effectively develop a PCSP.

4. The Service Coordinator, along with the PCPT, utilizes the assessments, documentation obtained from direct services and discussions with the Participant to secure information about the Participant's needs, including health care needs, preferences, goals, health status, and available, willing and able informal supports to develop the PCSP. This information is captured by the Service Coordinator and then documented in the Participant's record.
5. Service Coordinators ensure that the PCSP includes sufficient and appropriate services to maintain health, safety and welfare, and, for CHC Waiver Participants, provides the support that an individual needs or is likely to need in the community to avoid institutionalization. Service unit calculations must be accurate and appropriate. Each Participant need must be addressed unless the Participant chooses for a need not to be addressed.
6. The Service Coordinator reviews, in conjunction with the Participant, the Participant's services to ensure the services are adequate to meet the desired outcomes. Revisions are discussed with the Participant and incorporated into the PCSP. All service plan meetings and discussions with the Participant are documented in the Participant's record.
7. Annually, the Service Coordinator provides the Participant with the choice of receiving community services in the CHC Waiver, LIFE Program (if age 55 or older), nursing facility services, or no LTSS services. Completed forms detailing this must be maintained in the Participant's file.
8. Participants are also given the choice of willing and qualified Providers within the network at each Reassessment and at any time during the year when a Participant requests a change of services. The Service Coordinator must document the Participant's choice of provider as part of the Participant's PCSP. As noted above, the Service Coordinator must also document that the Participant was offered a choice of network providers.

9. The Service Coordinator provides Participants and/or his or her representative with information on services and supports available to LTSS Participants and the processes for selecting qualified Providers of services.
10. For Participants receiving home and community-based services, the Service Coordinator must provide information regarding opportunities for Participant-Directed Services and responsibilities for directing those services. The Service Coordinator must document these discussions in the Participant's record and record why the Participant declined this model when a reason is provided.
11. The Service Coordinator gathers information on an ongoing basis to ensure the PCSP reflects the Participant's current needs. The Service Coordinator discusses potential revisions to the PCSP with the Participant and individuals important to the Participant. All changes to existing PCSPs must be documented in the Participant's record.
12. The Service Coordinator must obtain the electronic or written signatures of the Participant, Participant's representative and any others involved in the planning process, indicating they participated in the process, they approve and understand the services outlined in the PCSP, and that services are adequate and appropriate to the Participant's needs. The PCSP is not considered complete until all of the required signatures are received. The finalized PCSP must include the type, scope, amount, duration and frequency of the services authorized by the PCSP. If a Participant refuses to sign their PCSP, not because they do not agree with the plan, but because they simply refuse to sign it at that time and there is no representative to sign on their behalf, the PCSP should not be deemed invalid due to lacking the signature. For instances where this occurs the Service Coordinator should document the refusal of the Participant to sign the document and note verbal consent of the PCSP by the Participant. The Service Coordinator should attempt to obtain the Participant's signature during their next interaction. A Participant may also sign indicating disapproval of the plan if the Participant disagrees

with the PCSP. When this occurs, the Service Coordinator must provide the Participant with a denial notice within two (2) business days that includes his or her right to file a grievance, and assist the Participant through the process as appropriate. Every Participant must be given a copy or mailed a copy of his or her PCSP within two (2) business days of when initial completion or subsequent revisions are finalized. A copy of the signed PCSP is given to the Participant as well as all members of the PCPT who the Participant consents to receiving the PCSP or portions of the PCSP.

13. If the CHC-MCO makes the decision to deny in whole or in part, reduce, suspend or terminate a service or item in the Participant's PCSP, the CHC-MCO must use the templates specified by the Department to issue a written denial notice which meets the following criteria:

    A. Written at a 6th grade reading level;
    B. Written in an individualized manner;
    C. Specifically references the service or item that is being reduced or denied;
    D. Includes specific references to approved medical necessity guidelines, rules, or protocols on which the decision is based.

14. Section V.B.2e of the CHC Agreement contains a limited number of exceptions to the notice requirement. One exception is the receipt of a clear written statement signed by a Participant that he or she no longer wishes to receive the requested service or gives information that requires termination or reduction of services and indicates that he or she understands that termination will be the result of supplying that information. If this occurs the CHC-MCO must still offer the Participant appeal rights. The CHC-MCO may not consider a Participant's signature on the PCSP in itself to be a "clear written statement" as described in V.B.2e.

15. If the Participant grieves the CHC-MCOs authorized PCSP, the Service Coordinator must provide the final, approved PCSP to the Participant at the conclusion of the grievance process.
16. Once the PCSP is authorized by the CHC-MCO, the Service Coordinator communicates the service plan content to the Participant and to the Participant's appropriate service provider or providers to ensure that service delivery matches the approved PCSP. The CHC-MCO must approve the PCSP prior to the provision of services.
17. The Service Coordinator initiates a Reassessment at least annually (at least once every 365 days) and when either there is a significant change in the Participant's situation or condition, a trigger event occurs, or the Participant requests Reassessment. CHC-MCOs may conduct a Reassessment prior to the one-year mark of the last Assessment for Participants who are transitioning to them from another CHC-MCO.
18. The CHC-MCO must complete the PCSP in a format approved by the CHC Agreement and enter the PCSP in the CHC-MCO's designated information system.

EXHIBIT AA

MANAGED CARE DEFINITIONS FOR PARTICIPANT COMMUNICATIONS

The 2016 CMS "Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability" final rule established a requirement (42 CFR § 438.10(c)(4)(i)) that mandated that all states which contract with MCOs for delivery of Medicaid services must develop standardized definitions for a set of managed care related terms to be utilized by MCOs in communications with Participants. The state developed definitions were required to be written at no higher than a sixth-grade reading level and are to be utilized by CHC-MCOs for communications with Participants such as newsletters, informational pamphlets, Participant handbooks, etc.

When using any of the terms below in communications to Participants, CHC-MCOs must utilize the terms with the same intent as defined by the state.

Managed Care Definitions

1) **Appeal-** To file a Complaint, Grievance, or request a Fair Hearing.
2) **Complaint**- When a Participant tells a CHC-MCO that he or she is unhappy with the CHC-MCO or his or her provider or does not agree with a decision by the CHC-MCO.
3) **Co-Payment-** A co-payment is the amount a Participant pays for some covered services. It is usually only a small amount.
4) **Durable Medical Equipment**- A medical item or device that can be used in a Participant's home or in any setting where normal life activities occur and is generally not used unless a person has an illness or injury.
5) **Emergency Medical Condition**- An injury or illness that is so severe that a reasonable person with no medical training would believe that there is an immediate risk to a person's life or long-term health.
6) **Emergency Medical Transportation**- Transportation by an ambulance for an emergency medical condition.
7) **Emergency Room Care**- Services needed to treat or evaluate an emergency medical condition in an emergency room.
8) **Emergency Services**- Services needed to treat or evaluate an emergency medical condition.
9) **Excluded Services**- Term should not be used. CHC-MCO should use "Services That Are Not Covered" instead.
10) **Grievance**- When a Participant tells a CHC-MCO that he or she disagrees with a CHC-MCO's decision to deny, decrease, or approve a service or item different than the service or item the Participant requested because it is not medically necessary.

11) **Habilitation Services and Devices**- Term should not be used by CHC-MCO. CHC-MCO should define specific service.
12) **Health Insurance**- A type of insurance coverage that pays for certain health care services. (If used by CHC-MCO, should be used to refer only to private insurance.)
13) **Home Health Care**- Home health care is care provided in a Participant's home and includes skilled nursing services; help with activities of daily living such as bathing, dressing, and eating; and physical, speech, and occupational therapy.
14) **Hospice Services**- Home and inpatient care that provides treatment for terminally ill Participants to manage pain and physical symptoms and provide supportive care to Participants and their families.
15) **Hospitalization-** Care in a hospital that requires admission as an inpatient.
16) **Hospital Outpatient Care**- Care provided by a hospital or hospital-based clinic that does not require admission to the hospital.
17) **Medically Necessary**- A service, item, or medicine that does one of the following:
    - Will, or is reasonably expected to, prevent an illness, condition, or disability;
    - Will, or is reasonably expected to, reduce or improve the physical, mental, or developmental effects of an illness, condition, injury or disability;
    - Will help a Participant get or keep the ability to perform daily tasks, taking into consideration both the Participant's abilities and the abilities of someone of the same age.
    - Will help a CHC Participant receiving long-term services and supports (LTSS) to take part in community living, meet the Participant's goals, and live and work in the setting of the Participant's choice.
18) **Network**- Contracted providers, facilities, and suppliers that provide covered services to CHC-MCO Participants.
19) **Non-Participating Provider**- When referring to a provider that is not in the network, CHC-MCOs should use the term "Out-of-Network Provider."
20) **Physician Services**- Health care services provided or directed by a licensed medical physician (M.D. – Medical Doctor or D.O. – Doctor of Osteopathic Medicine).
21) **Plan**- A health care organization that provides or pays for the cost of services or supplies.
22) **Preauthorization or Prior Authorization**- Approval of a service or item before a Participant receives the service or item.
23) **Participating Provider**- When referring to a provider that is in the network, CHC-MCOs should use "Network Provider."
24) **Premium**- The amount a Participant pays for health care coverage.
25) **Prescription Drug Coverage**- A benefit that pays for prescribed drugs or medications.
26) **Prescription Drugs**- Drugs or medications that require a prescription for coverage.

27) **Primary Care Physician**- A physician (M.D. – Medical Doctor or D.O. – Doctor of Osteopathic Medicine) who directly provides or coordinates a range of health care services for a patient.
28) **Primary Care Provider**- A doctor, doctors' group, or certified registered nurse practitioner who provides and works with a Participant's other health care providers to make sure the Participant gets the health care services the Participant needs.
29) **Provider**- An individual or entity that delivers health care services or supplies.
30) **Rehabilitative Services and Devices**- Term should not be used by CHC-MCO. CHC-MCO should define specific service.
31) **Skilled Nursing Care**- Services provided by a licensed nurse.
32) **Specialist**- A doctor, a doctor's group, or a certified registered nurse practitioner who focuses his or her practice on treating one disease or medical condition or a specific part of the body.
33) **Urgent Care**- Care for an illness, injury, or condition which if not treated within 24 hours, could rapidly become a crisis or an emergency medical condition.
34) **Network Provider**- A provider, facility, or supplier that has a contract with an CHC-MCO to provide services to Participants.
35) **Out-of-Network Provider**- A provider that does not have a contract with an CHC-MCO to provide services to Participants.

EXHIBIT BB

CHC Waiver Assurance Performance Measure Requirements and Sanctions

The submission of timely, complete, and accurate Operations Reports is critical to the Department's oversight of the CHC program. The CHC 1915(c) Waiver requires the Department to have systems in place to measure and improve its performance in meeting certain waiver assurances. There are fifteen (15) CHC Waiver Assurance Performance Measures ("WPM") : two (2) for Administrative Authority; one (1) for Qualified Providers; five (5) for Person-Centered Service Plans ("PCSP"); and, seven (7) for Health & Welfare.

SUBMISSION REQUIREMENTS

CHC-MCOs must report WPM data on the following forms and by the due dates specified in the Operations Reporting Requirements Submission Schedule (add link):

a. OPS 004 (Compliant and Grievance Detail)
b. OPS 011 (Provider Education)
c. OPS 029 (CHC PCSP Waiver Assurance Performance Measures)
d. OPS 030 (CHC Health & Welfare Waiver Assurance Performance Measures).
e. OPS 038 (Financial Management Services)

- Metric 1:

During the reporting quarter, the total number of timely submissions in the reporting quarter is divided by the total number of required submissions in the reporting quarter. CHC-MCO zone level performance will be combined and measured at the plan level (e.g., four submissions of a report x 5 zones result in 20 total submissions for the applicable report). 86% of all required reports must be submitted by the established due date.

Failure to achieve the CMS required level of 86% may result in imposition of sanctions as provided under Sanctions for Metric 1.

- Metric 2:

CHC-MCO compliance will be measured based on the WPM for each identified OPS report. During the reporting quarter, the total number of WPM meeting the 86% required level of performance is divided by the total number of WPM measured in the reporting quarter. CHC-MCO zone level performance will be combined and measured at the plan level (e.g., fifteen WPMs x 5 zones result in 75 total WPM measured for the reporting period)

- Failure to achieve the CMS required level of 86% may result in the imposition of sanctions as provided under Sanctions for Metric 2.

- **SANCTIONS**

  - Metric 1: Timeliness

    Failure to comply with timeliness requirements may result in a sanction of up to $10,000 for each program month.

  - Metric 2: CHC-MCO Performance Compliance

    Failure to meet the CMS required level of performance for a WPM may result in sanctions as follows. (e.g. if 4 WPMs have an 85% compliance, the CHC-MCO may be sanctioned $4,000 x 4 WPMs = $16,000)

WPM Performance Compliance	Sanction
86% or more	None
85.0% to 85.9%	$4,000
84.0% to 84.9%	$10,000
83.0% to 83.9%	$16,000
82.0% to 82.9%	$22,000
81.0% to 81.9%	$28,000
80.0% to 80.9%	$34,000
79.0% to 79.9%	$40,000
78.0% to 78.9%	$46,000
77.0% to 77.9%	$52,000
76.0% to 76.9%	$58,000
75% or less	$100,000

Exhibit CC

Financial Management Services (FMS)

All HCBS LTSS participants have the option to make decisions about and self-direct their own waiver services as identified in Section E-1.g of the CHC Waiver and Section V.A.16 of the CHC Agreement. Participants in the CHC Waiver may choose to hire and manage staff using Employer Authority or manage an individual budget using Budget Authority. In addition, Participants may choose a combination of service models to meet their individual needs.

Financial Management Services (FMS) are provided to participants across the Commonwealth by qualified Vendor Fiscal/Employer Agent(s) (F/EA). The CHC-MCOs are responsible for FMS functions and must process, file, and pay all applicable state and federal taxes on behalf of participants and their direct service workers. The CHC-MCOs must operate as an F/EA or subcontract this function.

The CHC-MCOs must submit in writing for prior approval by the Department any subcontracts to perform part or all of the FMS administrative services described herein, together with documentation that the proposed FMS subcontractor meets all requirements herein, before commencing the provision of FMS with any subcontractor. The Department must pre-approve the proposed FMS subcontractor in writing. The Department reserves the right to reject any subcontractor who does not meet these requirements. Whether the CHC-MCO provides the FMS administrative services directly or through an approved subcontractor, the entity which provides those services (hereinafter the “FMS Entity”) must provide all the services and meet all the requirements below.

A. General Requirements

Conflict Free Requirements

The FMS Entity must be free of any conflict of interest with any existing or future waiver and program providers. To ensure an objective, unbiased provision of functions, the FMS Entity and any subcontractors must be free of real or perceived conflicts of interest.

1. The FMS Entity and its subcontractors may not be a part of or affiliated with and must remain independent from any provider of HCBS. Neither the governing body of the FMS Entity nor individual members of the governing body may be affiliated with any provider of HCBS. The FMS Entity or its subcontractors may not be affiliated with or a subsidiary of any existing provider of HCBS.

No personnel assigned to the FMS Entity may work for any provider of HCBS. Personnel assigned to the FMS Entity may receive direct care services or supports from such provider as long as the services are purchased at fair rates (either private pay, through an HCBS program, or through another third-party program).

FMS Entity Obligations

An FMS Entity enrolls Participants in FMS and applies for and receives approval from the IRS to act as an agent on behalf of the Participant. As the Participant's agent, the FMS Entity processes timesheets, makes payments, and manages all required tax withholdings, including Federal Insurance Contributions Act (FICA) taxes, for personal assistance workers employed by Participants under each self-directed model. If choosing to subcontract this administrative service, the CHC-MCO must jointly collaborate with all other contracted CHC-MCOs to contract with a single statewide FMS Entity under the requirements described below, and each CHC-MCO must establish agreements and cooperate with this statewide entity in order that necessary FMS services are provided to participants. The FMS Entity must enroll in PA Medicaid and sign an MA provider agreement.

The FMS Entity must maintain an online portal to allow both Participants and those involved in their service delivery access to documents, time entry, utilization and budget information, access to pay stubs and tax documents, lists of employees, and the ability to communicate with the FMS Entity.

The CHC-MCO must provide sufficient funds to the FMS Entity so that payroll is satisfied on a timely basis. The amount, time period and other terms for those funds shall be set forth in policies established by the CHC-MCO and approved by the Department. The CHC-MCOs must notify OLTL as soon as possible when made aware that a payroll for all DCWs on a particular payroll schedule will be or has been missed for any reason.

The CHC-MCO must verify that before a direct care worker provides services, the direct care worker received a pre-service orientation provided through a training vendor organization who meets the requirements outlined in this agreement and under contract with the FMS Entity. The CHC-MCO must ensure each direct care worker obtains a Unique ID number from the DHS Unique ID registry and provide it to the FMS Entity prior to providing services.

Qualifications

The FMS Entity must have:

1. Demonstrated financial health. The CHC-MCO must ensure that a reserve of at least six (6) weeks of payroll is maintained and readily available to avoid a negative impact to operations of the organization;
2. At least five years of experience successfully managing and paying a distributed group of individuals and operate a current program(s) serving participant-directed participants in at least one other state;
3. Demonstrated experience providing FMS services to a self-directed services model;
4. A minimum of 10,000 individuals who are paid by the vendor in a current program or as of one year (365 days) before the start of the provision of this function. This count may be at the parent company or a partner or subcontracted organization level;

5. A transition methodology including industry standard project management tools (e.g. Project Management Institute standards tools for documenting and managing projects);
6. A current Comprehensive Policies and Procedures Manual for managing distributed DCWs;
7. Policies and procedures for data management standards reflecting data integrity and data governance practices;
8. A call center staffed by qualified representatives;
9. Demonstrated experience and arm's length references demonstrating collaboration with relevant stakeholders in participant-directed services, including the disability community, senior groups, and DCW organizations;
10. Ability to track and provide, upon request by the Department, accurate workforce data, including demographics, wages, benefits, DCW turnover, family caregivers, comprehensive list with contact information of active DCWs in the participant-directed program, participation and completion of orientation and/or training, average timeline for enrollment, and other workforce data and analysis as requested.

Training and Orientation

The CHC-MCO or FMS Entity is responsible for ensuring Participants obtain enrollment and informational materials. In addition, the CHC-MCO or FMS Entity is responsible for ensuring orientation is provided to the Participant or common law employer prior to employing their direct care worker. Orientation and training materials must be submitted to the Department for review and approval prior to implementation and must include the following at minimum:

- Review of the information and forms contained in both the Employer and Direct Care Worker enrollment packets and how they should be completed
- The role and responsibilities of the common law employer;
- The role and responsibilities of the FMS Entity;
- The process for receipt and processing timesheets and employee payroll checks;
- The process for resolving issues and complaints; and
- The process for reviewing workplace safety issues, managing workplace injuries, and workers compensation.

Providing Direct Care Worker Pre-Service Orientation Training

Pre-Service Orientation

The CHC-MCO or FMS Entity must:

1. Verify that all newly hired DCWs have completed an in-person, pre-service orientation. In the limited situations where in-person, pre-service orientation is not

possible due to geographical limitations or a health pandemic, the CHC-MCO or FMS Entity will verify that the newly hired DCW has completed pre-service orientation by a DHS approved alternative means, including real time, instructor-led virtual orientation.

2. Notify DCWs of this pre-service orientation requirement and how they may enroll and complete this pre-service orientation.

3. Provide standardized core training that includes the following required hours and elements which shall be offered as 8 hours of training within the first 4 months of hire.

- First Aid & CPR
- Home Health & Safety
- Universal Precautions

4. Maintain documentation to verify a DCW's completion of this pre-service orientation along with the Qualified DCW Employment Packet. This pre-service orientation and documentation must be completed before a DCW is given clearance to provide services.

5. Receive prior approval by OLTL of the content of DCW pre-service orientation. Pre-service orientation must, at a minimum, cover the following topics: a basic understanding of the functions and requirements of the participant-directed programs; the role and responsibility of the common law employer as the employer to direct, supervise, train, and select the DCWAs; operational procedures and paperwork; roles and responsibilities in independent living system; workplace safety; transparency and fraud; eligibility for public benefits and DCW support organization; electronic visit verification; and worker rights and responsibilities. The content of the pre-service orientation shall be consistent across the Commonwealth as well as consistent with information provided through SCEs, and other elements of the participant-directed program.

6. The CHC-MCO or FMS Entity must ensure that the pre-service orientation is provided by an OLTL approved statewide entity. The CHC-MCO or FMS Entity may use a subcontractor to satisfy the pre-service orientation experience requirements. The selected entity must have at least 2 years of experience in providing training and in-person orientation for participant-directed DCWs in Pennsylvania and home caregivers such as DCWs, in the development and implementation of relevant participant-directed orientation curriculum, and the demonstrated experience working in participant directed orientation programs that orient at least 5,000 DCWs per year. Any orientation subcontractor must be pre-approved by OLTL and have current statewide capacity in Pennsylvania to implement a consistent, timely pre-service orientation program, including in-person training sites in at least 30 locations across the Commonwealth, a call center specifically designated to handle DCW registration, the capacity to do proactive outreach to DCWs via text, phone, and mail, and trainers to ensure opportunities for all DCWs to attend a local, pre-service orientation within 14 days of initial employment application.

7. Pay the DCW an hourly wage not to exceed the maximum DCW hourly wage rate (as defined by the PA Medicaid Fee Schedule or other criteria as specified and

directed by OLTL) and not less than prevailing minimum wage rules in the applicable region in which the DCW is to provide services for all time spent in DCW pre-service orientation. The CHC-MCO or FMS Entity shall include the payment for the hours of this pre-service orientation in the first paycheck after a DCW has been cleared to provide services.

Training

To make available optional training for active DCWs, the CHC-MCO or FMS Entity must:

Contract with a training vendor to offer and provide foundational skills training that include the following required hours and elements which may be offered as 24 hours of training.

- ADLs & IADLs
- Cultural Competency
- Communication
- Medication
- Body Mechanics
- Early Intervention

In the event a DCW chooses this optional training, the DCW must be paid for completing this training. DCWs may take this training more than once, but are only required to be paid for the initial training.

Processing and Distributing Payroll, Related Taxes and Insurances for Qualified DCWs The CHC-MCO or FMS Entity must process requests for voluntary deductions from the wages paid to DCWs for the convenience of those employees as permitted and authorized by Section 3 of the Wage Payment and Collection Law (43 P.S. § 260.3) and its implementing regulations, provided that the third party receiving the deductions is a not-for-profit organization exempt from taxes under Section 501(c) of the Internal Revenue Code in good standing. The CHC-MCO will ensure:

A. That the cost of processing such requests for voluntary deductions and transmittal of those deductions to the third party be borne by the third party, with the proviso that said costs shall be limited to the actual and reasonable costs of modifying the existing payroll system to permit these periodic deductions.
B. That an accurate payroll deduction mechanism is in place to deduct the applicable payments each pay period and transmit the payments to the third party.
C. That the amount deducted is printed on the DCWs payroll form.
D. That any authorization for voluntary deductions from the wages paid to DCWs shall terminate and such deductions shall cease upon the happening of any of the following events:
    a. Termination of the DCWs employment.
    b. Written notice by the third party that the DCWs authorization has been cancelled; or
    c. When the third-party states that it will no longer accept payment from the DCW.

E. That a record keeping system in place which maintains an accurate list of those DCWs who have submitted signed authorizations for the voluntary deductions and transmittal of those deductions to the third party.

Oversight and Monitoring Responsibilities

The CHC-MCO will ensure that the contract deliverables are met, and Participants are in receipt of FMS in accordance with their PCSP. The CHC-MCOs will monitor the performance of FMS administrative activities, as well as adherence to contract conditions and waiver requirements. These requirements include, but are not limited to, Participant satisfaction, timeliness of processing employer and employee paperwork, timeliness of and accuracy of payments to workers, accuracy of information provided to Participants and workers by the FMS Entity, timeliness and accuracy of tax fillings on behalf of the Participant, timeliness of executed agreements between the FMS Entity and the workers or other vendors and timeliness of criminal background checks and child abuse clearances as needed.

If the CHC-MCO or its subcontractor is not in compliance with contractual or waiver provisions, the CHC-MCO will take the necessary steps to address any issues of non-compliance, including the completion of remediation and/or Quality Improvement Plans (QIPs).

In addition to the process described above, the CHC-MCOs will monitor performance as described in the Reporting Requirements section below. CHC-MCOs will also conduct on-site monitoring more frequently if utilization or problem identification reports indicate additional review is necessary. CHC-MCOs will also be required to report any issues with the FMS Entity's performance to OLTL.

The CHC-MCO or its subcontractor will conduct a Common Law Employer Satisfaction Survey using the survey tool approved by the Department. The survey must be conducted 60 days after enrolling a new common law employer and annually. Survey data must be collected and analyzed by the CHC-MCO or its subcontractor, and a report must be prepared and submitted to OLTL based upon specifications determined by the Department.

Lastly, through an established claims oversight process, the CHC-MCO will monitor claims submitted by the FMS Entity to the CHC-MCO and ensure the payments to the vendor for both administrative fees and services are in accordance with all applicable regulations and requirements. The CHC-MCOs must also ensure that all EVV requirements outlined by the Department are followed. The CHC-MCOs are responsible for monitoring compliance with requirements outlined in corresponding EVV bulletins.

Performance Standards

The following standards must be adhered to:

1. Department-approved Common Law Employer (CLE) enrollment packets must be mailed within three (3) business days of referral. (Minimum Acceptable: Department approved CLE Enrollment packet mailed within five (5) business days of referral.)

2. Complete the processing of CLE enrollment paperwork within seven (7) business days of receipt of correctly completed-documents. (Minimum Acceptable: Seven (7) business days unless acceptable documentation for a delay is provided.)

3. Collect and process completed documents and forms for enrollment of DCWs, Vendors, Small Unlicensed Providers and Independent Contractors within seven (7) business days of receipt of correctly completed and file with the appropriate federal, state, and local government agencies. (Minimum Acceptable: Seven (7) business days (unless acceptable documentation for a delay is provided). This minimum standard assumes that only the State Police background check is required and that the DCW has no record. ChildLine and FBI Clearance require longer dissemination times by the agency.)

4. Conduct face to face meetings as requested by new Participants to orient them to the program and to assist in completion of any necessary paperwork. (Minimum Acceptable: The requested visit must occur on the date scheduled with the Participant.)

5. Level of customer satisfaction based on Employer Satisfaction Surveys. (Minimum Acceptable: 95% satisfaction rate from active Participants.)

If the standards are not met, the Department will notify the CHC-MCO of the specific deficiencies, request a CAP, and follow-up on the plan to ensure compliance. The CAP must be submitted to the Department within 15 business days. The Department will review and accept or reject the CAP within 30 business days. The Department will monitor the interventions to ensure the CAP was completed and successful in resolving the issue in accordance with the timeframes established for corrective action in the CAP. If the CAP was not successful in correcting the identified issue, technical assistance will be provided by the Department.

Reporting Requirements

The CHC-MCOs will be required to submit monthly and annual reports to the Department utilizing the OPS 38 template which covers activities performed and issues encountered during the reporting period and reflect progress in meeting all contractual obligations. Required reporting elements are as directed by the Department. The CHC-MCOs must coordinate with the selected entity to ensure all required reporting elements are transmitted to the CHC-MCOs in a timely manner to meet the Department's reporting deadlines.

OLTL staff will review this information and intercede, when necessary, with corrective actions to ensure compliance. Meetings will be held as needed between the CHC-

MCOs and the Department to discuss any issues and for the Department to provide any necessary technical assistance it feels is needed.

Direct Care Worker Referral and Matching System

The CHC-MCO or FMS entity must develop a secure statewide web-based DCW referral and matching system to match Participants utilizing Participant-Directed services with potential individual direct care workers. The intent of the referral and matching service is to create additional opportunities for direct care workers and to strengthen support for individuals who choose participant direction as the preferred model of service delivery. The CHC-MCO must jointly collaborate with all other contracted CHC-MCOs to contract with a single statewide vendor under the requirements described below, and each CHC-MCO must establish agreements and cooperate with this statewide entity.

The referral and matching portal shall manage worker and Participant information, match DCWs' qualifications with Participants' needs, and provide participants with lists of potential workers for them to interview. The portal must be directly usable by DCWs with specific functionality for creating profiles and searching for jobs with CHC Participants. The portal must be usable by Participants or their representative with specific functionality for posting jobs and searching from providers near them with availability.

The portal vendor should have at least three years of experience successfully operating a technology-driven referral system in a participant-directed Medicaid funded home care program.

Minimum portal requirements include the following:

1. Data Collection:
    a. During the first year of implementation, which is one year from the go live date of the portal, the portal shall collect either the FMS entity's ID for the DCW or last four digits of the DCWs social security number, or birth date to validate the DCW's status as an enrolled provider or at minimum has completed the required background checks. The portal should be open to DCWs who are currently working, and workers who have had background checks within the past year (365 days) who are either currently enrolled or in the process of getting enrolled.
    b. The portal shall allow common law employers and DCWs to view relevant certifications, credentials, and completed training when possible.
    c. The portal shall also verify the Participant is enrolled in CHC.
    d. The portal needs to have functionality to address consent to share data among DCWs and Participants.
    e. Information management and privacy: Users can upload and enter data while keeping personal contact info (email, phone number and address private) from other users until they are ready to share it. Primary users can manage personal information, such as their availability, preferences, and updated contact information. Users choose when to share their personal

contact information and the system does not force a reveal of this information.

2. Training: The web-based system should have in-app training and other training materials in addition to options for train-the-trainer for local training organizations that can do on the ground support for Participants.

3. System auto-generated reminders: The web-based system must support engagement by enabling auto-generated reminders such as personal information updates, mandated training requirements, certifications, and worker credentials.

4. Geographic search results: The web-based system should present geographically based results that include travel time by car and public transport while not revealing exact addresses.

5. Equity & Accessibility: The system must conform to Web Content Accessibility Guidelines 2.0 (WCAG 2.0) Level AA or similar framework regarding sensory characteristics, such as color, sound, and accommodations for individuals experiencing low vision to read content on websites via screen readers and high-contrast text. The system should be available in more than one language and be capable of adding additional languages. To facilitate choice and promote dignity and independence, workers and consumers should be able self-select categories related to their gender identities.

EXHIBIT DD(1)

CHC-MCO PAY FOR PERFORMANCE

This Exhibit DD(1) defines a potential payment obligation by the Department to the CHC-MCO for long-term services and support measures as defined below. This Exhibit is effective only if the CHC-MCO operates a statewide Community HealthChoices program under this Agreement in CY 2024. If the CHC-MCO does not operate a statewide CHC program under this Agreement in CY 2024, the Department has no payment obligation under this Exhibit. In cases where a CHC-MCO fails to successfully implement a corrective action plan from the previous year related to an associated Quality Performance Measure below in Section I, the CHC-MCO will not be eligible to receive an incentive payment for that measure.

This Exhibit does not supplant Exhibits that provide for any incentive payments directly impacting NFs.

I. Quality Performance Measures

For 2024, the Department selected National Committee for Quality Assurance (NCQA) and Pennsylvania Performance Measures (PAPMs) impacting nursing home transition, long-term services and supports, overall health plan satisfaction, Participant self-direction, competitive integrated employment, and participant satisfaction as quality measures using established statewide specific goals. The Department chose these indicators based on an analysis of past data indicating the need for improvement across the CHC Program as well as the potential to improve services and support for CHC participants receiving CHC services. The quality measures include:

1. Comprehensive Assessments (CAU)
2. Care Plans (CPU)
3. Reassessments and Care Planning after Inpatient Discharge (RAC)
4. Sharing Care Plans with PCP (SCP)
5. CAHPS Health Plan Survey- Overall Satisfaction with Health Plan (Aligned/Medicaid only population)
6. CAHPS Home and Community Based Services (HCBS) Survey- Person Centered Service Plan (PCSP) included all things important to you
7. Nursing Home Transition
8. Participant Self-Direction Enrollment by Zone

9. Participants in Competitive Integrated Employment

NOTE: The CHC-MCO P4P measures may be subject to change due to NCQA specifications or PAPM requirements.

The CHC-MCO P4P Program incentivizes Benchmark Performance and Incremental Improvement Performance. The incentive dollars will be distributed equally between the Benchmark and Incremental Improvement results as described in Section II.

A. Benchmark Performance*:* The Department will award a Benchmark Performance payout amount for each measure that meets the statewide goal that will be defined below in Table 1. The Department will distribute the payouts according to the following criteria:100% payout will occur if the CHC-MCO meets or exceeds the established goal defined below for each measure. Note: The Department has the right to change current CY 2024 goals based on CY 2023 performance. This will be done in consultation with the CHC-MCOs. Each of the seven measures will be considered equally for a benchmark payment. Calendar year (CY) 2024 measurement results will be used to calculate results.

Table 1

Basis	Baseline Year	Measurement Year	Description	Statewide Goal
HEDIS	CY 2023	CY 2024	Comprehensive Assessment and Update (CAU)	
HEDIS	CY 2023	CY 2024	Comprehensive Care Plan Update (CPU)	
HEDIS	CY 2023	CY 2024	Reassessment and Care Plan Update after Inpatient Discharge (RAC)	
HEDIS	CY 2023	CY 2024	Shared Care Plan with Primary Care	

			Practitioner (SCP)	
CAHPS HP	CY 2023	CY 2024	Overall Satisfaction with Health Plan (Aligned SNP/Medicaid only population)	
HCBS CAHPS	CY 2023	CY 2024	PCSP included all things important to you	
Ops 32 Report	CY 2023	CY 2024	Number of Participants who, as defined on Ops 32, were successfully transitioned from the NF to the community and remained there for at least six months	
Encounter Data	CY 2023	CY 2024	Participant-Directed Services (including PAS, Agency with Choice, and Services My Way) by MCO by Zone, weight by HCBS in each zone	
Ops 22 Report	CY 2023	CY 2024	Supported Employment Benchmark for Competitive Integrated Employment - MCO Ratio Based on HCBS	

			population age group 21-64	

B. Incremental Improvement Performance*:* The Department will award an Incremental Improvement Performance payout amount for each measure in Table 1 that will range from 0% up to and including 100% of the measure's value. Incremental performance improvements are measured comparing rates from HEDIS® 2024 (CY 2023) to HEDIS® 2025 (CY 2024) and PAPM 2024 (CY 2023) to PAPM 2025 (CY 2024). Each of the nine measures will be considered equally for an incremental payment.

The percent payout for each measure will be determined by the following sliding scale:

- ≥ 3 Percentage Point Improvement: 100 percent of the measure value.
- ≥ 2 and < 3 Percentage Point Improvement: 85 percent of the measure value.
- ≥ 1 and < 2 Percentage Point Improvement: 75 percent of the measure value.
- ≥ 0.5 and < 1 Percentage Point Improvement: 50 percent of the measure value.
- < 0.5 Percentage Point Improvement: no payout.

II. Payment for CHC-MCO Pay for Performance

The Maximum Program Payout amount will be proportionally split between the CHC-MCOs based on membership as of December 1, 2024. Each CHC-MCO's maximal allocation will then be split with 50% of the funds allocated to benchmark performance and 50% to incremental improvement. Within the benchmark allocation, each of the nine measures will be eligible for equal payment based on achieving the statewide goal. Within the incremental improvement allocation, each of the nine measures will be eligible for equal payment based on the sliding scale results for each measure.

The Department will inform the CHC-MCO of the Maximum Program Payout amount by November 30, 2025.

Per 42 C.F.R. 438.6(b)(2)(ii) –(iii), this incentive arrangement does not automatically renew and is made available to both public and private CHC-MCOs under the same terms of performance.

NOTE: The Department may change the payout methodology based on reporting restrictions due to a natural disaster, pandemic or other unforeseen events. The payout methodology will be shared with the CHC-MCOs prior to finalizing.

If the CHC-MCO has a payment obligation to the Department pursuant to this Exhibit DD(1), the Department will reduce a subsequent payment to the CHC-MCO by this amount.

EXHIBIT DD(2)

NURSING FACILITY QUALITY INCENTIVE PROGRAM

This Exhibit DD(2) defines a potential payment obligation by the Department to the CHC-MCO for a Nursing Facility Quality Incentive Program to evaluate Nursing Facilities (NFs) that participate in the Medical Assistance Program and to develop a valued-based incentive arrangement. This Exhibit is effective only if the CHC-MCO operates a statewide Community HealthChoices program under this Agreement in CY 2024. If the CHC-MCO does not operate a statewide CHC program under this Agreement in 2024 the Department has no payment obligation under this Exhibit.

I. Quality Performance Measures

For 2024, the Department selected Centers for Medicare and Medicaid Services (CMS) Compare quality metrics impacting clinical care using the Minimum Data Set (MDS) system and utilization using Medicare Part A data. The Department chose these indicators based on national and state analysis of past data indicating the need for improvements across the NFs and to improve quality of care for a broad base of the CHC population. The NF quality metrics include:

1. Percentage of short-stay residents who were re-hospitalized after a NF admission (Claims)
2. Percentage of long-stay residents with pressure ulcers (MDS)
3. Percentage of long-stay residents experiencing one or more falls with major injury (MDS)
4. Percentage of long-stay residents assessed and appropriately given the seasonal influenza vaccine (MDS)
5. Percentage of long-stay residents assessed and appropriately given the pneumococcal vaccine (MDS)
6. Percentage of long-stay residents who received an antipsychotic medication (MDS)

The above quality metrics must be used in any NF VBP arrangements for calendar year 2024.

NOTE: The CHC-MCO NF quality metrics may be subject to change due to NQF specifications, CMS requirements, or the Pennsylvania Department of Health requirements.

The CHC-MCO NF Quality Incentive Program rewards NFs based on achieving statewide benchmark goals and incremental improvement for these quality measures. The Department will establish CY 2024 statewide benchmark goals for measures 1-6 above. NFs will be rewarded for incremental improvement from the CY 2023 (base year) to CY 2024 results for measures 1-6 above. CHC adjusted payments will be made to NFs as described in Section ll below.

A. Benchmark Performance*:* The Department will establish CY 2024 statewide benchmark goals for measures 1-6 above. The Department will award a benchmark performance payout amount for each metric in Section I. NFs will be rewarded one point for obtaining the statewide 50th percentile and one point for obtaining the next quartile of improvement for the quality and utilization metrics. NFs can receive up to 14 points for benchmark performance. These points will be used to calculate a CHC adjusted incentive payment described in Section ll.

B. Incremental Improvement Performance*:* The Department will award an incremental improvement payment for measures 1-6 above. NFs will be rewarded for incremental improvement from CY 2023 (base year) to CY 2024. For each measure, NFs can earn from 0 to 2 points based on the sliding scale below. NFs can earn a maximal incremental improvement score of 12 points.

Sliding Scale:

- 2 points for ≥ 2.0 Percentage Point Improvement
- 1 point for ≥ 1 and < 2.0 Percentage Point Improvement
- 0.5 point for ≥ 0.5 and < 1 Percentage Point Improvement
- 0 points for < 0.5 Percentage Point Improvement

II. Payment for CHC-MCO Pay for Performance

The Department will direct the CHC-MCO to make Nursing Facility Incentive Program CHC adjusted payments based on performance measures defined in Section I for CY 2024 benchmark performance and incremental improvement from CY 2023 (base year) to CY 2024. NFs must participate fully in Medical Assistance Programs to be eligible for this incentive program. The NFs are eligible to earn up to 12 points for benchmark performance and 12 points for incremental performance with a maximum of 24 incentive points as described above in IA and IB. The Department will distribute CHC adjusted payments based on each NF's total incentive points and CHC MA occupancy. The Department will determine a maximum potential dollar amount for each incentive point. Payouts will be based on multiplying each NF's total number of points by the dollar amount per incentive point as adjusted for each facility's CHC MA occupancy. The Department will direct the CHC-MCO to make payments to assigned NFs.

The Department will inform the CHC-MCO of the Maximum Program Payout amount by November 30, 2025.

Per 42 C.F.R. 438.6(b)(2)(ii) –(iii), this incentive arrangement does not automatically renew and is made available to both county and non-public nursing facilities under the same terms of performance.

NOTE: The Department may change the payout methodology based on reporting restrictions due to a natural disaster, pandemic or other unforeseen events. The payout methodology will be shared with the CHC-MCOs prior to finalizing.

III. Value-Based Arrangements

The CHC MCOs will use the six quality measures listed above in Section I to develop value-based arrangements with nursing facilities in 2024 to help achieve the 25% VBP goal described in section VII.E.16.b.ii, Value-Based Purchasing. The CHC MCOs may use additional quality and utilization metrics to develop value-based arrangements with nursing facilities.

Exhibit EE

OPIOID USE DISORDER CENTERS OF EXCELLENCE

A. The CHC-MCO must develop an adequate network of physical health Opioid Use Disorder Centers of Excellence (OUD-COE) enrolled in the MA Program as Provider Specialty Type 232 – Opioid Center of Excellence according to the terms of Exhibit T of this Agreement.

B. The CHC-MCO must coordinate with a Participant's BH-MCO and any OUD-COE providing services to the Participant in accordance with Section V.D.2 of this Agreement to ensure that the Participant's care is coordinated and not duplicated.

C. The following services, when provided as clinically appropriate and included or reflected in the individual Participant's care plan, constitute community-based care management services. COE care management services may be provided via telemedicine in accordance with Medical Assistance Bulletin 99-21-06: Guidelines for the Delivery of Physical Health Services via Telemedicine.

1. Screening and Assessment

    a. Assessments to identify a Participant's needs related to Social Determinants of Health, administered in home and community-based settings whenever practicable.

    b. Level of Care Assessments, which may be completed either by the OUD-COE or through a referral. If a level of care assessment results in a recommendation of MAT, the OUD-COE must provide education related to MAT.

    c. Screenings for clinical needs that require referrals or treatment, including screenings for risk of suicide.

2. Care Planning

    a. Development of integrated, individualized care plans that include, at a minimum:

        1. A Participant's treatment and non-treatment needs

        2. The Participant's preferred method of care management, such as in-person meetings, phone calls, or through a secure messaging application

        3. The identities of the members of the Participant's community-based care management team, as well as the members of the Participant's individual support system

b. Care coordination with a Participant's primary care provider, mental health service provider, drug & alcohol treatment provider, pain management provider, obstetrician or gynecologist, and CHC-MCO, as applicable

3. Referrals

   a. Facilitating referrals to necessary and appropriate clinical services according to the Participant's care plan, including:

      1. Primary Care, including screening for and treatment of positive screens for: HIV, Hepatitis A (screening only); Hepatitis B; Hepatitis C; and Tuberculosis

      2. Perinatal Care and Family Planning Services

      3. Mental Health Services

      4. Forms of medication approved for use in MAT not provided at the OUD-COE Provider's enrolled service location(s)

      5. MAT for pregnant women, if the OUD-COE Provider does not provide MAT to pregnant women

      6. Drug and Alcohol Outpatient Services

      7. Pain Management

   b. Facilitating referrals to any ASAM Level of Care that is clinically appropriate according to a Level of Care Assessment

   c. Facilitating referrals to necessary and appropriate non-clinical services according to the results of the Participant's needs identified through a Social Determinants of Health screening

4. Monitoring

   a. Individualized follow-up with Participants and monitoring of Participants' progress per the Participant's care plan, including referrals for clinical and non-clinical services

   b. Continued and periodic re-assessment of a Participant's Social Determinants of Health needs

   c. Performing Urine Drug Screenings at least monthly

5. Making and receiving warm hand-offs. In the event of a warm hand-off from an overdose event, the OUD-COE must provide education related to overdose risk and naloxone.

D. To determine whether OUD-COE care management services are appropriate for a Participant, the CHC-MCO, in coordination with the OUD-COE, shall utilize the inclusion and exclusion criteria established in the OUD-COE Fidelity Checklist. The Department will make the OUD-COE Fidelity Checklist available to the CHC-MCO upon request.

Exhibit FF

Requirements for Non-Commonwealth Hosted Applications/Services

The purpose of this Attachment is to define requirements for business or technology solutions and services procured by the Commonwealth that are hosted within the Licensor's or its subcontractor's managed infrastructure.

A. Hosting Requirements

1. The Licensor or its subcontractor shall supply all hosting equipment (hardware and software) required for the cloud services and performance of the software and services set forth in the Quote and Statement of Work.

2. The Licensor shall provide secure access to applicable levels of users via the internet.

3. The Licensor shall use commercially reasonable resources and efforts to maintain adequate internet connection bandwidth and server capacity.

4. The Licensor or its subcontractors shall maintain all components of the hosted solution with commercially reasonable support and replace as necessary to maintain compliance.

5. The Licensor shall monitor, prevent and deter unauthorized system access. The Licensor shall use all commercially reasonable methods to confirm suspected breaches. In the event of any impermissible disclosure unauthorized loss or destruction of Confidential Information, the receiving Party must immediately notify the disclosing Party and take all reasonable steps to mitigate any potential harm or further disclosure of such Confidential Information. In addition, pertaining to the unauthorized access, use, release, or disclosure of data, the Licensor shall comply with state and federal data breach notification statutes and regulations, and shall report security incidents to the Commonwealth within **twenty-four (24) hours** of when the Licensor has reasonable confirmation of such unauthorized access, use, release, or disclosure of data.

6. The Licensor or the Licensor's subcontractor shall allow the Commonwealth or its delegate, at times chosen by the Commonwealth, and with at least **ten (10) business days'** notice, to review the hosted system's data center locations and security architecture.

7. The Licensor's employees or subcontractors, who are directly responsible for day-to-day monitoring and maintenance of the hosted system, shall have industry standard certifications applicable to the environment and system architecture used.

The Licensor or the Licensor's subcontractor shall locate servers in a climate- controlled environment. The Licensor or the Licensor's contractor shall house all servers and equipment in an operational environment that meets industry standards including climate control, fire and security hazard detection, electrical needs, and physical security.

8. The Licensor shall examine applicable system and error logs daily to minimize and predict system problems and initiate appropriate action.

9. The Licensor shall completely test and apply patches for all third-party software products in the server environment before release.

10. The Licensor shall provide all Commonwealth data to the Commonwealth, upon request, in a form acceptable to the Commonwealth, at no cost to the Commonwealth.

B. System and Organization Controls (SOC) Reporting Requirements

1. Subject to this section and unless otherwise agreed to in writing by the Commonwealth, the Licensor shall, and shall require its subcontractors to, engage, on an annual basis, a CPA certified third-party auditing firm to conduct the following, as applicable:

   (i) Reserved

   (ii) a SOC 2 Type II report with respect to controls used by the Licensor relevant to internal and external procedures and systems that access, process, host or contain Commonwealth Data designated as Class "C" Classified Records or Closed Records, as defined in ITP-SEC019, or in compliance with mandates by federal or state audit requirements and/or policy.

   The Licensor shall receive and review their subcontractor's relevant SOC reports, and the Licensor shall provide the Commonwealth with a Letter of Attestation that includes an analysis of their subcontractor's SOC report.

2. Unless otherwise agreed to in writing by the Commonwealth, the Licensor's SOC Report(s) shall be provided upon contract execution and annually thereafter. While it is preferable that SOC Reports coincide with Pennsylvania's fiscal year (July 1 through June 30), SOC Reports, at the very least, must cover at least **6 consecutive months** of Pennsylvania's fiscal year.

3. SOC 2 Type II reports shall address the following:

   (i) Security of Information and Systems;

(ii) Availability of Information and Systems;
(iii) Processing Integrity;
(iv) Confidentiality; and
(v) Privacy.
(vi) Reserved

4. At the request of the Commonwealth, the Licensor shall, and shall require its subcontractors, as applicable, complete a SOC for Cybersecurity audit, or another risk management framework as may be approved by the Commonwealth in its sole discretion, in the event:

(i) repeated non-conformities are identified in any SOC report required by subsection 1; or

(ii) if the Licensor's business model changes (such as a merger, acquisition, or change sub-contractors, etc.).

The SOC for Cybersecurity report shall detail the controls used by the Licensor or its subcontractor setting forth the description and effectiveness of the Licensor's or subcontractor's cybersecurity risk management program and the policies, processes and controls enacted to achieve each cybersecurity objective.

The Licensor shall provide to the Commonwealth a report of the SOC for Cybersecurity audit findings within **60 days** of its completion.

5. The Commonwealth may specify other or additional standards, certifications or audits it requires under any Purchase Orders or within an ITP.

6. The Licensor shall adhere to Statement on Standards for Attestation Engagements (SSAE) 18 audit standards. The Licensor acknowledges that the SSAE guidance may be updated during the Term of this Contract, and the Licensor shall comply with such updates which shall be reflected in the next annual report.

7. In the event an audit reveals any non-conformity to SSAE standards, the Licensor shall provide the Commonwealth, within **45 days** of the issuance of the SOC report, a documented corrective action plan that addresses each non-conformity that is identified within the SOC report, including any subcontractor's SOC report. The corrective action plan shall provide, in detail:

(i) clear responsibilities of the personnel designated to resolve the non-conformity;
(ii) the remedial action to be taken by the Licensor or its subcontractor(s);
(iii) the dates when each remedial action is to be implemented; and
(iv) a summary of potential risks or impacts to the Commonwealth that are associated with the non-conformity(ies).

8. The Commonwealth may in its sole discretion agree, in writing, to accept alternative security report in lieu of a SOC report.

C. Security Requirements

1. The Licensor shall conduct a third-party independent security/vulnerability assessment at its own expense on an annual basis.

2. The Licensor shall comply with the Commonwealth's directions/resolutions to remediate the results of the security/vulnerability assessment to align with the standards of the Commonwealth.

3. The Licensor shall use industry best practices to protect access to the system with a firewall and firewall rules to prevent access by non-authorized users and block all improper and unauthorized access attempts.

4. The Licensor shall use industry best practices to provide applicable system intrusion detection and prevention in order to detect intrusions in a timely manner.

5. The Licensor shall use industry best practices to provide applicable malware and virus protection or compensating controls on all servers and network components.

7.1

6. The Licensor shall limit access to Commonwealth-specific systems, data and services and provide access only to those staff, located within CONUS (any of the Continental United States and Hawaii) that must have access to provide services proposed. If Licensor staff located outside of the United States require access to the Commonwealth's data for any purpose, such as **but not limited to** system administration and support services, investigation, or debugging, these provisions shall apply to any offshore support provided by the Licensor and any subcontractors:

7.2

i. No offshore support shall be permitted from any countries that are identified as state sponsors of terrorism by the US Department of State, which shall be monitored by the purchasing Agency to ensure compliance through the life of the Agreement, Contract, or Purchase Order;
ii. Access by offshore vendor resources shall be limited to solely that which is required to perform the Services, including support services;
iii. Offshore vendor resources who are providing the services shall be trained in the proper handling of Commonwealth Data;
    a. Any vendor offshore resources that are dedicated to the Commonwealth shall be required to undergo Commonwealth Security Awareness Training provided by the Commonwealth and the vendor shall provide monthly compliance report.
    b. Vendor attests that offshore vendor resources shall comply with Management Directive 205.34 and Management Directive 245.18 and

that the Vendor has trained the offshore resources in the proper handling of Commonwealth Data.

iv. Offshore vendor resources that are providing the services shall be obligated to handle Commonwealth Data in ways at least as restrictive as the requirements outlined in the Agreement;

v. Offshore vendor resources that are providing the services and require access must be uniquely identified (e.g., by a unique User ID);

vi. Offshore vendor resources that are providing the services shall access Commonwealth systems, data, or services in a manner that meets or exceeds the minimum requirements set forth in Commonwealth ITPs;

vii. The date, time (including time zone), resource name, source IP, and nature of the access (i.e., read-only or modify) shall be recorded in a log file which is maintained and preserved according to applicable data protection law(s) and industry best practice standards;

viii. Any offshore vendor resource access must be granted by an authorized Commonwealth resource and shall only be granted on least required privilege or need-to-know basis prior to any offshore vendor resource obtaining access and shall only be granted to offshore vendor resource that must have access to provide and/or support the services;

ix. The vendor shall agree explicitly in the agreement that with respect to any services provided by any offshore vendor resources, the vendor shall be obligated to comply with the terms and conditions of the Agreement, Contract or Purchase Order, as though the offshore vendor resources were located within the United States and that the vendor shall assume all obligations and risks associated with the use of offshore vendor resources as if those resources were located within the United States;

x. The purchasing agency shall ensure that background check requirements apply to all offshore vendor resources assigned to perform services under the Agreement, Contract or Purchase Order.

a. The vendor shall identify each offshore vendor resource that will perform services under the Agreement, Contract or Purchase Order and shall perform the following background checks on each individual offshore vendor resource providing services:

i. Criminal Records Database check (country where the offshore vendor resource is located);

ii. Civil Litigation Database check (country where the offshore vendor resource is located);

iii. Credit and Reputational Risk Database Check (country where the offshore vendor resource is located);

iv. Compliance Authorities (global check);

v. Regulatory Authorities (global check);

vi. Serious and Organized Crimes (global check); and

vii. Web and media searches (global check).

b. On an annual basis, the vendor shall provide written confirmation that the above required background checks have been completed and that the background checks did not identify any criminal record that includes a felony or misdemeanor (or equivalent) involving terroristic behavior, violence, use of a lethal weapon, or breach of trust/fiduciary

responsibility or which raises concerns about building, system or personal security or is otherwise job-related. This written confirmation must be provided prior to the subject offshore vendor resource being provided access to Commonwealth data or systems. The vendor shall not assign any offshore vendor resource that fails to pass the background checks required in this section to any Commonwealth services and shall remove any access privileges already given to the offshore vendor resource unless the Commonwealth consents to the access, in writing, prior to the access.

xi. No recording, streaming, monitoring, or photographic devices enter, are accessible, or utilized in the workspace where work under the Agreement, Contract or Purchase Order is performed while located outside of the United States.

7. The Licensor shall provide the services, using security technologies and techniques in accordance with industry best practices and the Commonwealth's ITPs set forth in Attachment 1, including those relating to the prevention and detection of intrusions, and any other inappropriate use or access of systems and networks.

D. Data Protection

1. The Licensor shall only host, store or backup Commonwealth Data in physical locations within CONUS.

2. The Licensor shall use industry best practices to update and patch all applicable systems and third-party software security configurations to reduce security risk.

3. The Licensor shall protect their operational systems with applicable anti-virus, host intrusion protection, incident response monitoring and reporting, network firewalls, application firewalls, and employ system and application patch management to protect its network and customer data from unauthorized disclosure.

4. The Licensor shall be solely responsible for applicable data storage required.

5. The Licensor shall encrypt all Commonwealth data in transit and at rest. The Licensor shall comply with ITP-SEC031, and ITP-SEC019, encryption policies and minimum standards or stronger.

6. The Licensor shall take all commercially viable and applicable measures to protect the data availability including, but not limited to, real-time replication, traditional backup, and/or georedundant storage of Commonwealth data in accordance with industry best practices and encryption techniques.

7. The Licensor shall have appropriate controls in place to protect critical or sensitive data and shall employ stringent policies, procedures, to protect that

data particularly in instances where such critical or sensitive data may be stored on a Licensor-controlled or Licensor-owned electronic device.

8. The Licensor shall utilize a secured backup solution to prevent loss of data. Stored backups must be kept in an all-hazards protective storage environment at the primary location and any additional locations where the data is being maintained. All back up data and media shall be encrypted.

E. Adherence to Policy

1. The Licensor support and problem resolution solution shall provide a means to classify problems as to criticality and impact and with appropriate resolution procedures and escalation process for classification of each problem.

2. The Licensor shall abide by the applicable Commonwealth's Information Technology Policies (ITPs), a list of the most relevant being attached hereto as Attachment 1.

3. The Licensor shall comply with all pertinent federal and state privacy regulations.

F. Closeout

When the purchase order's or other procurement document's term expires or terminates, and a new purchase order or other procurement document has not been issued by a Commonwealth Agency within **60 days** of expiration or termination, or at any other time at the written request of the Commonwealth, the Licensor must promptly return to the Commonwealth all Commonwealth's data (and all copies of this information) that is in the Licensor's possession or control. The Commonwealth's data shall be returned in a format agreed to by the Commonwealth.

Upon confirmation that Commonwealth data is in possession or control of the Commonwealth, the Licensor shall ensure all residual user account(s) are promptly deleted or reset in the solution. The Licensor shall notify the Commonwealth within **10 business days** that all user account(s) have been deleted or reset.

ATTACHMENT 1

Information Technology Policies (ITPs) for Outsourced/Licensor(s)-hosted Solutions

ITP Number - Name	Policy Link
ITP_ACC001 - Accessibility Policy	https://www.oa.pa.gov/Policies/Documents/itp_acc001.pdf
ITP_APP030 - Active Directory Architecture	https://www.oa.pa.gov/Policies/Documents/itp_app030.pdf
ITP_BUS007 - Enterprise Service Catalog	https://www.oa.pa.gov/Policies/Documents/itp_bus007.pdf
ITP_BUS010 - Business Process Management Policy	https://www.oa.pa.gov/Policies/Documents/itp_bus010.pdf
ITP_BUS012 -Artificial Intelligence General Policy	httpss://www.oa.pa.gov/Policies/Documents/itp_bus012.pdf
ITP_INF000 - Enterprise Data and Information Management Policy	https://www.oa.pa.gov/Policies/Documents/itp_inf000.pdf
ITP_INF001 - Database Management Systems	https://www.oa.pa.gov/Policies/Documents/itp_inf001.pdf
ITP_INF006 - Commonwealth County Code Standard	https://www.oa.pa.gov/Policies/Documents/itp_inf006.pdf
ITP_INF009 - e-Discovery Technology Standard	https://www.oa.pa.gov/Policies/Documents/itp_inf009.pdf
ITP_INF010 - Business Intelligence Policy	https://www.oa.pa.gov/Policies/Documents/itp_inf010.pdf
ITP_INF011 - Reporting Policy	https://www.oa.pa.gov/Policies/Documents/itp_inf011.pdf
ITP_INF012 - Dashboard Policy	https://www.oa.pa.gov/Policies/Documents/itp_inf012.pdf
ITP_INFRM001 - The Life Cycle of Records: General Policy Statement	https://www.oa.pa.gov/Policies/Documents/itp_infrm001.pdf
ITP_INFRM004 - Management of Web Records	https://www.oa.pa.gov/Policies/Documents/itp_infrm004.pdf
ITP_INFRM005 - System Design Review of Electronic Systems	https://www.oa.pa.gov/Policies/Documents/itp_infrm005.pdf
ITP_INFRM006 - Electronic Document Management Systems	https://www.oa.pa.gov/Policies/Documents/itp_infrm006.pdf
ITP_INT_B_1 - Electronic Commerce Formats and Standards	https://www.oa.pa.gov/Policies/Documents/itp_int_b_1.pdf
ITP_INT_B_2 - Electronic Commerce Interface Guidelines	https://www.oa.pa.gov/Policies/Documents/itp_int_b_2.pdf
ITP_INT006 - Business Engine Rules	https://www.oa.pa.gov/Policies/Documents/itp_int006.pdf
ITP_NET004 - Internet Protocol Address Standards	https://www.oa.pa.gov/Policies/Documents/itp_net004.pdf
ITP_NET005 - Commonwealth External and Internal Domain Name Services (DNS)	

	https://www.oa.pa.gov/Policies/Documents/itp_net005.pdf
ITP_PRV001 - Commonwealth of Pennsylvania Electronic Information Privacy Policy	https://www.oa.pa.gov/Policies/Documents/itp_prv001.pdf
ITP_SEC000 - Information Security Policy	https://www.oa.pa.gov/Policies/Documents/itp_sec000.pdf
ITP_SEC001 - Enterprise Host Security Software Policy	httpss://www.oa.pa.gov/Policies/Documents/itp_sec001.pdf
ITP_SEC002 - Internet Accessible Proxy Servers and Services	https://www.oa.pa.gov/Policies/Documents/itp_sec002.pdf
ITP_SEC003 - Enterprise Security Auditing and Monitoring	https://www.oa.pa.gov/Policies/Documents/itp_sec003.pdf
ITP_SEC004 - Enterprise Web Application Firewall	https://www.oa.pa.gov/Policies/Documents/itp_sec004.pdf
ITP_SEC006 - Commonwealth of Pennsylvania Electronic Signature Policy	https://www.oa.pa.gov/Policies/Documents/itp_sec006.pdf
ITP_SEC007 - Minimum Standards for IDs, Passwords and Multi-Factor Authentication	https://www.oa.pa.gov/Policies/Documents/itp_sec007.pdf
ITP_SEC008 - Enterprise E-mail Encryption	https://www.oa.pa.gov/Policies/Documents/itp_sec008.pdf
ITP_SEC009 - Minimum Contractor Background Checks Policy	https://www.oa.pa.gov/Policies/Documents/itp_sec009.pdf
ITP_SEC010 - Virtual Private Network Standards	https://www.oa.pa.gov/Policies/Documents/itp_sec010.pdf

ITP Number - Name	Policy Link
ITP_SEC011 - Enterprise Policy and Software Standards for Agency Firewalls	https://www.oa.pa.gov/Policies/Documents/itp_sec011.pdf
ITP_SEC012 - System Logon Banner and Screensaver Requirements	httpss://www.oa.pa.gov/Policies/Documents/itp_sec012.pdf
ITP_SEC015 - Data Cleansing	https://www.oa.pa.gov/Policies/Documents/itp_sec015.pdf
ITP_SEC016 - Information Security Officer Policy	httpss://www.oa.pa.gov/Policies/Documents/itp_sec016.pdf
ITP_SEC017 - Copa Policy for Credit Card Use for e-Government	https://www.oa.pa.gov/Policies/Documents/itp_sec017.pdf
ITP_SEC019 - Policy and Procedures for Protecting Commonwealth Electronic Data	https://www.oa.pa.gov/Policies/Documents/itp_sec019.pdf
ITP_SEC021 - Security Information and Event Management Policy	https://www.oa.pa.gov/Policies/Documents/itp_sec021.pdf
ITP_SEC023 - Information Technology Security Assessment and Testing Policy	https://www.oa.pa.gov/Policies/Documents/itp_sec023.pdf
ITP_SEC024 - IT Security Incident Reporting Policy	https://www.oa.pa.gov/Policies/Documents/itp_sec024.pdf
ITP_SEC025 - Proper Use and Disclosure of Personally Identifiable Information (PII)	https://www.oa.pa.gov/Policies/Documents/itp_sec025.pdf
ITP_SEC029 - Physical Security Policy for IT Resources	https://www.oa.pa.gov/Policies/Documents/itp_sec029.pdf
ITP_SEC031 - Encryption Standards	https://www.oa.pa.gov/Policies/Documents/itp_sec031.pdf
ITP_SEC032 - Enterprise Data Loss Prevention (DLP) Compliance Standards	https://www.oa.pa.gov/Policies/Documents/itp_sec032.pdf
ITP_SEC034- Enterprise Firewall Rule Set	https://www.oa.pa.gov/Policies/Documents/itp_sec034.pdf
ITP_SEC035 - Mobile Device Security Policy	httpss://www.oa.pa.gov/Policies/Documents/itp_sec035.pdf
ITP_SEC038 - Commonwealth Data Center Privileged User IAM Policy	https://www.oa.pa.gov/Policies/Documents/itp_sec038.pdf
ITP-SEC039 - Keystone Login and Identity Proofing	https://www.oa.pa.gov/Policies/Documents/itp-sec039.pdf
ITP_SEC040 - Commonwealth Cloud Computing Services Requirements	https://www.oa.pa.gov/Policies/Documents/itp_sec040.pdf
ITP SFT000 - Software Development Life Cycle (SDLC) Policy	https://www.oa.pa.gov/Policies/Documents/itp_sft000.pdf
ITP_SFT001 - Software Licensing	https://www.oa.pa.gov/Policies/Documents/itp_sft001.pdf

ITP_SFT002 - Commonwealth of PA Website Standards	https://www.oa.pa.gov/Policies/Documents/itp_sft002.pdf
ITP_SFT003 - Geospatial Enterprise Service Architecture	https://www.oa.pa.gov/Policies/Documents/itp_sft003.pdf
ITP_SFT004 - Geospatial Information Systems (GIS)	https://www.oa.pa.gov/Policies/Documents/itp_sft004.pdf
ITP_SFT005 - Managed File Transfer (MFT)	https://www.oa.pa.gov/Policies/Documents/itp_sft005.pdf
ITP_SFT007 - Office Productivity Policy	https://www.oa.pa.gov/Policies/Documents/itp_sft007.pdf
ITP SFT008 - Enterprise Resource Planning (ERP) Management	https://www.oa.pa.gov/Policies/Documents/itp_sft008.pdf
ITP SFT009 - Application Development	https://www.oa.pa.gov/Policies/Documents/itp_sft009.pdf
ITP_SYM003 - Off-Site Storage for Commonwealth Agencies	https://www.oa.pa.gov/Policies/Documents/itp_sym003.pdf
ITP_SYM004 - Policy for Establishing Alternate Processing Sites for Commonwealth Agencies	https://www.oa.pa.gov/Policies/Documents/itp_sym004.pdf
ITP_SYM006 - Commonwealth IT Resources Patching Policy	https://www.oa.pa.gov/Policies/Documents/itp_sym006.pdf
ITP_SYM008 - Server Virtualization Policy	https://www.oa.pa.gov/Policies/Documents/itp_sym008.pdf
ITP_SYM010 - Enterprise Services Maintenance Scheduling	https://www.oa.pa.gov/Policies/Documents/itp_sym010.pdf

Cloud Services Requirements

Offeror/Contractors proposing solutions that include cloud services must respond to the questions included in this document. The purpose of this document is to gain the necessary information from the Offeror/Contractor to fully understand and evaluate the cloud service being proposed.

Offeror/Contractor shall describe if any part of the proposed cloud service is provided by another third party or subcontractor. The ability of each subcontractor to meet these Cloud Services Requirements must be incorporated into this document. Offeror/Contractor may add a separate attachment or denote responses as "Offeror/Contractor" or "Name of Subcontractor".

If using links in Offeror/Contractor Response column, please provide specific reference point that addresses the question.

REQ #	Category	Question	Offeror/Contractor Response
1	General	Offeror/Contractor shall provide an overview of the proposed cloud service. Please list the solution components, hosting environments, as well as the service organization and subservice organizations operating all aspects that are a part of the overall proposed solution. • Solution Component(s) – SKU/Product Titles and/or Resources utilized by solution provider • Solution Environment(s) – Which public cloud provider, which private cloud stack, and/or who's datacenter for traditional hosting of components. • Solution Operator(s) – Organizational name of the Service Organization and any Subservice Organizations actively supporting the proposed solution.	
2	General	Offeror/Contractor shall describe if the proposed cloud service is a dedicated single tenant or shared (multi-tenant) cloud solution. If multi-tenant, Offeror/Contractor shall describe the security controls to isolate the tenants.	
3	General	Offeror/Contractor shall describe Service Level Agreements (SLAs) included with the proposed	

		Cloud Service that identify both the services required and the expected level of service including, but not limited to, the following: • Availability • Performance • Disaster Recovery expectations (RTO/RPO) • Pandemic Recovery expectations • Location of the data Primary/Secondary (if applicable?) • Access to the data • Portability of the data (ability to move data to a different hosting provider) • Metrics used to measure the service, e.g. service level objectives	
4	General	Offeror/Contractor shall describe controls for record retention and data destruction of data past retention period in accordance with ITP-SEC019 Policy and Procedures for Protecting Commonwealth Data and ITP-SEC015 Data Cleansing Policy. Offeror/Contractor shall describe how they will confirm that the data has been destroyed. Commonwealth preference is certified letter(s) of confirmation at end of contract and quarterly for aged data.	
5	General	Offeror/Contractor shall, upon contract expiration or at any other time at the written request of the Commonwealth, return to the Commonwealth all of its data (and all copies of this information) in a format agreed to by the Commonwealth. Offeror/Contractor shall provide method of export of Commonwealth data during the contract term.	
6	General	Offeror/Contractor shall provide current FedRamp Status (ready, in process, authorized, not yet applied) and level (Low, Moderate, or High). If FedRamp status is "authorized," Offeror/Contractor shall provide details for the following: • Service Model	

		• Deployment Model • Impact Level • Independent Assessor • Authorization Date • Service Description • Agencies using this service	
7	General	Offeror/Contractor shall indicate if the following NIST guidelines are adhered to: • NIST SP 800-53 Assessing Security and Privacy Controls in FIS organizations • NIST SP 800-63 Digital Identity Guidelines • NIST SP 800-92 Guide to Computer Security Log Management • NIST SP 800-144 Guideline on Security and Privacy in Public Cloud Computing • NIST SP 800-145 NIST Definition of Cloud Computing and Deployment Models • NIST SP 800-146 NIST Cloud Computing Synopsis and Recommendations Please also indicate if other NIST guidelines apply to the proposed cloud service.	
8	Regulatory Compliance Verification	Offeror/Contractor shall indicate if the proposed cloud service is subject to any of the following laws: • CJIS and CHRIA for criminal history data • HIPAA for health-related data • IRS Pub 1075 and SSA for federal protected data • PCI-DSS for financial data Offeror/Contractor shall provide certifications or letters of attestation for any deemed applicable to the proposed cloud service.	
9	Access to Commonwealth specific systems, data, and	Offeror/Contractor shall limit access to Commonwealth-specific systems, data and services and provide access only to those staff,	

	services (ITP-SEC040 CSR-L3)	located within CONUS, that must have access to provide services proposed. Offeror/Contractor shall describe their support model including after-hours support. Offeror/Contractor shall indicate if any support mechanism or staff are located outside of CONUS and describe in detail the offshore access required to provide services proposed. a) If OCONUS, Offeror/Contractor shall indicate if logging is enabled to capture the date, time, named user, and nature of the offshore access (i.e., read-only or modify) and whether such logs are maintained and preserved according to applicable data protection law(s) and industry best practice standards. b) If OCONUS support is required, Offeror/Contractor shall indicate whether offshore staff are direct employees or are subcontracted staff. c) If OCONUS, Offeror/Contractor shall indicate whether offshore staff have direct access to Commonwealth data or if the Commonwealth must grant access? If Commonwealth must grant access, please provide request and approval process flow. d) Please describe any additional protections in place with respect to Commonwealth data that vendors employees and/or subcontractors would have access to while OCONUS.	
10	Data Hosting (ITP-SEC040 CSR-L4)	Offeror/Contractor shall only host, store, or backup Commonwealth Data in physical locations within CONUS. • Offeror/Contractor shall describe which data centers are intended for use with the proposed cloud service. • Offeror/Contractor shall provide a description of the physical security measures in place within the proposed data centers. Describe both the physical	

		data center access as well as server room and physical host access. Offeror/Contractor shall completely test and apply patches for all third-party software products before release. • Offeror/Contractor shall describe how often the infrastructure, hardware, and software are upgraded, hardened, and patched and what notifications are provided to the customer.	
11	System and Organization Controls (SOC) Reporting (ITP-SEC040 CSR-L5)	Offeror/Contractor shall provide relevant SOC reports, which have been performed by an independent CPA-certified auditor, for the proposed cloud service. Reports should be submitted to the Contract Manager. Link to OPD_SEC040B SOC Reporting Procedures SOC 1 TYPE II Report is required under the following conditions: • The service organization is hosting financial information that could affect or have a material impact on a Commonwealth agency's financial statements and/or reporting. • Compliance mandate for federal or state audit requirements and/or policy. • A third-party provides financial service(s) (such as, but not limited to, payroll processing, accounts receivable, payable, or collection service). SOC 2 TYPE II Report is required under the following conditions: • The service organization is hosting, **handling, or processing Class "C"** Classified Records or Closed Records as defined in ITP-SEC019 • Compliance mandated with federal or state audit requirements and/or policy.	
12	Accessibility Standards (ITP-SEC040 CSR-A1)	Offeror/Contractor shall comply with the Accessibility Standards in Section 6 of ITP-ACC001 for all provided	

		products and services. • Offeror/Contractor shall submit a completed VPAT using the most current version of the VPAT template for the proposed cloud service(s). o The VPAT template should be filled out in its entirety and include testing methodology, conformance level, and remarks for any partially supported or non-supported level. o If VPAT(s) are submitted, using an older version of the template, Offeror/Contractor should provide an explanation, as to why the most current version is not being used.	
13	System Monitoring Audit Logging (ITP-SEC040 CSR-S1)	Commonwealth policy requirements: • Audit logging must be enabled and accessible to the Commonwealth (Information Security Office or designee) • Verbose logging is required • Vendor must have ability to correlate events, create security alerts, and based on severity of event (critical, severe, high-level) send incident notifications to Commonwealth Information Security Officers (ISOs). • Maintain reports online for a minimum of 90 days and archive for a minimum of 1 year. If the Commonwealth requires longer retention periods, the longer retention requirement takes precedence and should be documented in the SOW. a) Offeror/Contractor shall review and evaluate the system monitoring and audit logging requirements listed in ITP-SEC040 Section 5.2 and describe which apply and how they are being addressed as part of the proposed cloud service. Offeror/Contractor shall also indicate if any additional monitoring and logging is included.	

		b) Offeror/Contractor shall describe which system monitoring and audit logs are available to the customer and indicate how they are made available to the Commonwealth Information Security Officers (ISOs). Please indicate if authorized direct access, available only upon request, or other. c) Offeror/Contractor shall provide an example of the logs to show what level of detail is available. d) Offeror/Contractor shall describe if any dashboards and/or analytics are in place for Commonwealth ISO use. e) Offeror/Contractor shall provide examples of monthly reporting. f) Offeror/Contractor shall provide examples of annual reporting. g) Offeror/Contractor shall define their continuous monitoring strategy, including measures, metrics and control assessments including frequencies. h) Offeror/Contractor shall provide examples of log review, contingency plan testing, incident response plan testing and vulnerability scans i) Offeror/Contractor shall describe responses to assessment findings, threshold alerts, decisions to either mitigate, transfer, or accept risks related to identified vulnerabilities j) Offeror/Contractor shall describe method of access for all of the above.	
14	Data Segmentation Boundary Protection (ITP-SEC040 CSR-S2)	Offeror/Contractor shall provide a network/architecture diagram showing what security and technical controls are performing the network segmentation within the cloud service offering. • If solution spans more than one hosting environment (such as	

		integration to Commonwealth managed environments, or across multiple hosting providers), provide details on what solution components and data are deployed in which environment. • Include border gateway, perimeter and/or network firewall, web application firewall, VPN tunnels, security zone access as applicable to the solution. • Describe data encryption methods at rest and in transit across environments. • Include the direction of connectivity (specify whether initiated inbound, outbound, or both) and specifications for API calls, protocols, etc. • Estimated Transaction size, and frequency to be identified for each connection. Offeror/Contractor shall describe how data segregation (physically or logically) of Commonwealth data from non-Commonwealth data is guaranteed. Offeror/Contractor shall maintain the diagram throughout the contract term and provide updates if changes occur.	
15	Exploit and Malware Protection (ITP-SEC040 CSR-S3)	Offeror/Contractor shall provide and manage security controls. These are required to identify attacks, identify changes to files, protect against malware, protect user web services, Data Loss Prevention (DLP) and provide for forensic analysis. Offeror/Contractor shall describe which of these security controls are included in the proposed cloud service and how these additional controls would generate a notification to the Commonwealth. Please indicate if any are not used and also if any are used that are not listed below. o File Monitoring controls	

		o Antivirus controls o Cloud Aware IDS/IPS o DLP controls o Forensic controls o Advanced Persistent Threat (APT) controls	
16	Encryption (ITP-SEC040 CSR-S4)	Commonwealth policy requires the vendor to comply with SEC031, and SEC019 encryption policies and minimum standards with the proposed cloud service. Encryption technical controls are required to protect data in transit and data at rest. Link to SEC031 Encryption Standards Data in Transit Link to SEC019 Protection of Commonwealth Data Offeror/Contractor shall describe what encryption protocols are used to secure data in transit, file uploads or transfers. Offeror/Contractor shall describe what encryption technology is used for data at rest. Describe how those encryption keys are managed. Offeror/Contractor shall describe what encryption technology is used for data backup and recovery. Describe how those encryption keys are managed. If databases are used, describe what level of encryption is applied.	
17	Identity and Access Management (ITP-SEC040 CSR-S5)	Offeror/Contractor must provide technical controls for authenticating users, provisioning and deprovisioning users, identity interaction and nonrepudiation needs for admins, internet users, and internal users. Offeror/Contractor must describe reporting and audit mechanism for new staff, access changes, and deprovisioning of Offeror/Contractor staff. Offeror/Contractor must support use of Commonwealth Authentication services and Commonwealth Multi-Factor Authentication services.	

		If cloud service is accessed by Commonwealth employees, Offeror/Contractor shall indicate if they can support Microsoft Azure Active Directory (AAD) or integration with ADFS. If cloud service is accessed by citizens or business partners, Offeror/Contractor shall indicate if they can support use of Keystone Login. If Offeror/Contractor cannot support use of Commonwealth authentication methods, Offeror/Contractor shall describe the technical controls used for authenticating users, multifactor services, provisioning and deprovisioning users, identity interaction and nonrepudiation needs for admins, internet user, internal users, etc.	
18	Vulnerability Assessment (ITP-SEC040 CSR-S6)	Offeror/Contractor shall conduct third-party independent security/vulnerability assessments on an annual basis. Offeror/Contractor shall describe its vulnerability assessment practices for the proposed cloud service and indicate how the following requirements will be addressed: a) Offeror/Contractor shall ensure cloud hosted application(s) are securely coded, vetted, and scanned. b) Offeror/Contractor shall conduct quarterly vulnerability assessments, or sooner if due to compliance regulations or other requirements, or upon a major change to the solution. *c)* Offeror/Contractor shall conduct a vulnerability assessment on an annual basis during the term of the contract and shall provide a copy of the results to the Commonwealth. *(Refer to ITP-SEC021 and ITP-SEC023 for guidance)* d) Offeror/Contractor shall be able to identify and validate vulnerabilities required for remediation and provide a mitigation plan and timeline to the Commonwealth. e) Offeror/Contractor shall ensure patching is up to date.	

19	Data Protection Recovery (ITP-SEC040 CSR-S7)	Offeror/Contractor shall provide a business continuity plan that addresses the following (indicate N/A if not applicable to the proposed cloud service and/or if customer responsibility): o Data / Database Recovery o Application Recovery o Operating System Recovery o Infrastructure Recovery Offeror/Contractor shall describe its capability to do a complete restoration in the event of a disaster. Offeror/Contractor shall describe what tests are performed as part of its disaster recovery plan. Offeror/Contractor shall describe its capability to provide services during a pandemic event.	
20	Compliance (ITP-SEC040 CSR-S8)	Offeror/Contractor shall describe its capability to meet compliance requirements if the proposed cloud service is subject to any regulations. At minimum, all offerings shall meet Commonwealth ITP requirements and NIST Moderate Level security controls specified in the Federal Information Processing Standards (FIPS) and Special Publications (SPs). NIST control enhancements shall also apply unless specified otherwise. The agency reserves the right to upgrade the NIST control level. The agency also reserves the right to mandate additional regulations or standards such as HIPAA, PCI, IRS, CMs/ARS, etc.	
21	Security Incident Handling (ITP-SEC040 CSR-S9)	Offeror/Contractor shall agree to monitor, prevent, and deter unauthorized system access as per the requirements outlined below and per the Requirement for Non-Commonwealth Hosted Applications/Services. Offeror/Contractor shall provide a copy of its customer facing Incident Response Plan (IRP). IRP should include incident handling practices, severity classification levels, customer	

		notification and escalation processes, expected timeframes from time of impact to resolution, etc. • The Commonwealth will provide escalation contacts and resource account to be used for notification purposes.	
22	Inventory (ITP-SEC040 CSR-S10)	Offeror/Contractor shall describe how it maintains a complete, accurate, and up-to-date asset inventory of all resources involved in the proposed cloud service. Offeror/Contractor shall provide a detailed asset inventory list, including country of origin, that will be used for the proposed cloud service offering. The Commonwealth reserves the right to prohibit use of certain hardware based on risk. Include manufacturer, model numbers, processors, disk drives, database hardware, data center networking components (routers, switches, etc.), security devices (firewalls, etc.), load balancers, and any other hardware relevant to the delivery of the service. Offeror/Contractor shall provide notice to the Commonwealth for any changes to the asset inventory used to support the cloud service being provided to the Commonwealth that would impact regulatory compliance (refer to REQ#5 Regulatory Compliance Verification)	
23	Capacity (ITP-SEC040 CSR-I4)	Offeror or contractor shall provide capacity data associated with their offering. If metrics were provided by the agency, values should be based on those metrics. If exact numbers are not available, Offeror shall provide the following details: • Typical values for organizations of similar size and type (note any known deviations in the expected PA implementation). • Values for individual transactions and connections (ex: Each connection of type X consumes approximately 200	

		Kbps, or each transaction is approximately 5KB). • For each of the above, provide details indicating whether such connections/transactions are batch processes (and expected/recommended intervals and run times) or not.	
24	Data Backup and Recovery (Hosting Terms)	Offeror/Contractor shall take all necessary measures to protect the data including, but not limited to, the backup of the servers on a daily and weekly basis in accordance with industry best practices and encryption techniques in accordance with Commonwealth retention requirements. Offeror/Contractor shall describe its backup and archival process including but not limited to the following: • What is the length of time backups are available? • Do you perform test restores? • What archival backup/restore/versioning is part of the agreement and what actions require any additional service fees? • Explain any shadowing or redundancy you have across multiple datacenters or repositories and if those data repositories are within the US and controlled by the vendor. • Is storage of backup media offsite provided? If so, for how long? • Location of backups and key management and storage for any backup encryption keys.	

Community HealthChoices RFA

Released Tuesday, January 30, 2024

Background

The CHC Program serves individuals who are dually eligible for Medicare and Medicaid and people with physical disabilities who receive home and community-based waiver services or nursing facility care.

CHC is the sole Medicare Advantage (MA) program option for fully dual eligible beneficiaries and most nursing facility clinically eligible (NFCE) individuals who reside in the five zones. The regional CHC zones are as follows:

- ***Southwest zone:*** Allegheny, Armstrong, Beaver, Bedford, Blair, Butler, Cambria, Fayette, Green, Indiana, Lawrence, Somerset, Washington, and Westmoreland counties.
- ***Southeast zone:*** Bucks, Chester, Delaware, Montgomery, and Philadelphia Counties.
- ***Remaining zones*** and respective counties, including:
    - ***Lehigh/Capital zone***: Adams, Berks, Cumberland, Dauphin, Fulton, Franklin, Huntingdon, Lancaster, Lebanon, Lehigh, Northampton, Perry, and York.
    - ***Northeast zone:*** Bradford, Carbon, Centre, Clinton, Columbia, Juniata, Lackawanna, Luzerne, Lycoming, Mifflin, Monroe, Montour, Northumberland, Pike, Schuylkill, Snyder, Sullivan, Susquehanna, Tioga, Union, Wayne, and Wyoming.
    - ***Northwest zone:*** Cameron, Clarion, Clearfield, Crawford, Elk, Erie, Forest, Jefferson, McKean, Mercer, Potter, Venango, and Warren.

Current Market

The CHC incumbents are AmeriHealth Caritas (Keystone First), Centene (PA Health and Wellness), and University of Pittsburgh Medical Center (UPMC), serving 411,034 CHC members as of October 2023.

Pennsylvania Community HealthChoices Enrollment by Plan, October 2023

Plan	Enrollment	% Market Share
AmeriHealth Caritas	179,896	43.8%
Centene	88,180	21.5%
UPMC	142,958	34.8%
Total	**411,034**	

Source: Pennsylvania Department of Human Services

DHS published a historical data summary here: Community HealthChoices Historical Data.

Rate Methodology Historical Data Observations:

- **Reduction in utilization** caused by COVID-19 and utilization management by MCOs, resulting in downward pressure on capitation rates for 2023.
- The Nursing Facility change in ratios will require more staff in nursing facilities. Rate adjustments to increase funding to support Nursing Facilities factored.

- **CY 2023 Rate changes resulted in $1.9 Billion impact** - $8M of that for AWC, $368.7M for PAS rate increases, and $1.574 for Nursing Facilities' access to care and staff ratio adjustments.
- **Rate adjustments assume that AWC will result in less than 1% of agency cases transitioning to AWC, but 50% of consumer-directed cases transitioning (assumes people who value choice will continue to). These assumptions resulted in upward pressure for PAS costs in this program.**

Evaluation

For an applicant to be considered eligible:

- 75% of raw technical points available in technical submittal
- Financial information must demonstrate financial capacity to fulfill the good faith performance of the agreement.

For each zone, DHS must select for negotiations the applicants with the highest overall score.

The final technical scores will be determined by giving the maximum number of technical points available to the application with the highest raw technical score. The remaining applications will be rated by applying the formula located at RFP Scoring Formula.

Financial information will not be scored as part of the technical submittal. It will be reviewed only to determine an applicant's financial responsibility.

SDB and VBE participation submittals will not be scored, however, if an applicant fails to satisfy the SDB or VBE requirements described. DHS will reject the application.

DHS will not score the CPP submittal. Once an applicant has been selected for negotiations, DHS will review the CPP submittal.

PHA Focus Areas of Draft Agreement:

1. Promotion and support of FMS, including Agency With Choice
2. Development of a Registry for participant-directed DCWs
3. Care Plan assessment timelines expanded
4. RN requirement for bedbound patients
5. Direct Care Worker Coordinator role for MCOs
6. Increase in use of VBP Arrangements

RFA & Draft CHC Agreement

Link to solicitation
Link to RFP

General RFA Terms

- **Applications Due: March 15, 2024** *This 45 day timeline is shorter than anticipated (60 days).*
- **Implementation Date: January 1, 2025** *(subject to change)*
- The department anticipates awarding agreements to **three to five CHC-MCOs in each of the five CHC zones**.
- Full risk, capitated agreement.
- The **contract term is five years** and will have three one-year renewal options.
- Does not require a cost submittal. Rates are negotiated annually with DHS providing draft structure for year one to begin negotiations.
- Includes small diverse business (SDB) or veteran business enterprise (VBE) goals of 11 percent and three percent, respectively. Applicants must include separate SDB and VBE submittals for each zone in their application.
- **Protest Timeline:** Protests must be received by 4:00 p.m. on the seventh day following the date the Applicant knew or should have known of the facts giving rise to the protest; however, **no protest may be filed more than seven days after award.**
- The Applicant must **disclose any current or recent CAPs** or sanctions.
- **Readiness Review:** Prior to an Agreement, the Department must determine that the CHC-MCO successfully completed the Department's six-month Readiness Review for each CHC zone.
- **Performance Standards:** The Commonwealth developed a set of minimum Key Performance Standards; There are fifteen (15) CHC Waiver Assurance Performance Measures ("WPM"): two (2) for Administrative Authority; one (1) for Qualified Providers; five (5) for Person-Centered Service Plans ("PCSP"); and seven (7) for Health & Welfare. MCOs must meet 86% compliance with timely submission of data reporting for these areas.
- DHS provided itself flexibility within the RFA to implement **a pay-for-performance incentive to MCOs**. Under this policy, DHS could make incentives available to MCOs that help participants successfully complete the financial eligibility redetermination process with their local County Assistance Offices (CAOs).
- **CPP: Contractor Partnership Program**: The CPP was created by the Department to address workforce needs by connecting beneficiaries of Temporary Assistance for Needy Families ("TANF") to jobs. CPP requires entities who are awarded a contract or agreement with DHS to establish a hiring target that supports TANF beneficiaries in obtaining employment with the contractor, grantee, or subcontractors for jobs within their organizations.

FMS

- Participant direction must be offered first to participants who are eligible for HCBS (consistent with current agreement language). NEW language now requires the reason they are not picking self-directed services to be documented by the MCOs.
- Multiple references to SC responsibility to provide education on participant-direction.
- **FMS Standard of 95% customer satisfaction rate from active participants** based on Employer Satisfaction Surveys.
- Notably, page 47 notes that **"upon federal approval", Agency With Choice may be a FMS option.** Still refers to AWC provider as a single entity. Minimal additional information shared regarding Agency With Choice and the FMS addendum does not address Agency With Choice requirements at all.

- **New Direct Care Worker Referral and Matching System (Registry):** The CHC-MCO must jointly collaborate with all other contracted CHC-MCOs to contract with a single statewide vendor under the requirements described below, and each CHC-MCO must establish agreements and cooperate with this statewide entity. The vendor should be able to demonstrate it has successfully matched at least 35% of the direct care workers utilizing the system.
- The vendor should be able to demonstrate it has successfully matched at least 35% of the direct care workers utilizing the system.
- Adds new pre-service training for participant directed direct care workers (8 hours of training within first four months of hire):
    - First Aid & CPR
    - Home Health & Safety
    - Universal Precautions

Care Plan and Continuity of Care

- **Continuity of Care:** New language requires services remain as authorized until an assessment is completed when a participant transfers MCOs – former language had this at 60 days, new language removes 60 days, potentially shortening the timeframe to a reassessment. This could shorten the timeframe for reductions.
- New Language to **allow MCOs to complete assessment** sooner than one year if Participant transfers MCOs.
- As part of the Assessment process when a Participant is bedbound, CHC-MCOs must document the need for quarterly in person visits at a minimum, by an RN, LPN, or certified home health aide to assess wounds and catheters. The assessor must also gain an understanding of how the Participant gets repositioned and offer any necessary feedback or education to DCWs to ensure the Participants health and safety.
- **New Service Plan Requirements:**
    - Participant preferences for how often they would like to engage with their Service Coordinator (Participants must not be steered toward minimal quarterly contacts).
    - Participant communication preferences including how they would like to be identified, addressed and preferred method of communication.
    - Participant identified goals.
    - Health-related education needs and a plan to ensure understanding of health needs and treatment plan.
- New requirement to include **afterhours SC contact information** in PCSP that is shared with providers at the request of the Participant.
- **New response time for SCs:** Service Coordinators must respond to Participant outreach within two (2) business days, or sooner when an imminent risk to a participant's health and safety is involved.
- **Care Plan Detail Sharing:** If requested, the MCO must share minimum necessary service plan information with providers, consistent with HIPAA rules and regulations. If sufficient justification is demonstrated by a provider, that information may include the following:
    - Total number of authorized units per week (i.e., amount)
    - Service provision dates (i.e., service begin and end dates)
    - Preferred schedule (i.e., duration and frequency)
    - List of tasks detailing participant needs (i.e., ADLs/IADLs)
    - Service coordinator's name, phone, and email address

- Off-hours service coordination contact number
- Special conditions and instructions
- Unique circumstances (e.g., allergies, smoking, pets, children under 18 years of age, etc.)

- **Start of Services Requirement:** When new services are authorized or services are increased via inclusion on a Participant's PCSP, **the new service or increased service level must commence within seven (7) business days of the approval, unless the Participant requests a longer timeframe for the services to start.**
- **Case Loads for Supports Coordinators:** The maximum caseload ratio for Service Coordinators serving HCBS Participants is 1:60 (this is a decrease from current 1:70). The maximum caseload ratio for Service Coordinators serving Participants in nursing facilities is 1:225 (decrease from current 1:250).
- **Translation Services:** The CHC-MCO must require Network Providers to offer interpretation services and prohibit Network Providers from requiring that a Participant's family member be used for interpretation.
- The CHC-MCO must evaluate and mail a decision for each home/vehicle modification, pest eradication, or assistive technology request within sixty (60) business days of the date of request.

Fraud, Waste and Abuse

- **Fraud Waste and Abuse Reporting:** The CHC-MCO must inform all Network Providers of the Pennsylvania MA Provider Self Audit Protocol which allows Providers to voluntarily disclose overpayments or improper payments of MA funds. This includes, but is not limited to, inclusion in the Provider handbook. The CHC-MCO must provide written documentation that this action has been completed. The protocol is available on the Department's website at https://www.dhs.pa.gov/about/Fraud-And-Abuse/Pages/MA-ProviderSelf-Audit-Protocol.aspx4
- **Fraud Waste and Abuse** policies and procedures must contain:
  - An active method for verifying directly with Participants whether services billed by providers were received, as required by 42 CFR § 438.608(a)(5). Active verification requires the CHC-MCO to directly engage with consumers and develop a process to track both methods of verification and the results of verification attempts.
  - A process to recover overpayments or otherwise sanction Providers as required by 42 CFR §§438.608(a)(5) and 438.608(d)(1)(i-iv). iv. Provisions for payment suspension to a network provider for which the State determines that there is a credible allegation of fraud as required in 42 CFR §§455.23 and 438.608(a)(8)
  - The CHC-MCO must submit to the Department quarterly and annual statistical reports which relate to its Fraud, Waste and Abuse detection and sanctioning activities regarding Providers.
- **EVV:** Neither CHC-MCOs nor Providers can limit the locations for EVV as long as the locations are allowable by the program. EVV does not change the method and location for service delivery.

Value Based Payment Arrangements

- **VBP:** The MCO must enter into VBP Payment Arrangements with Providers that incorporate approved VBP Payment Strategies. The approved VBP Payment Strategies are tiered as:
  - Low risk (performance-based contracting)

    - Medium risk (shared savings, shared risk, bundled payments)
    - High risk (global payments)
- The **CHC-MCO must achieve the following percentages through VBP arrangements**:
    - Calendar year 2024 –twenty five percent (25%) of LTSS payments through a value-based payment arrangement (up from 7.5% in current agreement). A minimum of ten **percent (10%) of the total LTSS spend needs to be in Medium or High Financial Risk categories.**

Miscellaneous

- **PAS Rate:** The Department requires CHC-MCOs to pay for Personal Assistance Services at no less than the HCBS MA fee schedule rate.
- **Participant Advisory Committee:** The CHC-MCO must establish and maintain a PAC for each zone in which it operates. The PAC must include Participants, Network Providers, and direct care worker representatives to advise on the experiences and needs of Participants. Participants must comprise 50% of the PAC, must be reimbursed for their travel and should represent home care a facility care. Meetings must be at least quarterly.
- The CHC-MCO's **Provider Disputes and Provider Appeals policies and procedures** must include, at a minimum:
    - Informal and formal processes for settlement of Provider Disputes.
    - Acceptance and usage of this Agreement's definition of Provider Appeals and Provider Disputes.
    - Time frames for submission and resolution of Provider Disputes and Provider Appeals.
    - Processes to provide equitability for all Providers.
    - Establishment of a CHC-MCO Committee to process formal Provider Appeals, which must provide: – At least one-fourth (1/4th) of the membership of the Committee must be composed of Providers/peers. – Committee members who have the authority, training, and expertise to address and resolve Provider Dispute/Provider Appeal issues. – Access to data necessary to assist Committee members in making decisions. – Documentation of meetings and decisions of the Committee
- **Innovation:** The CHC-MCO must promote innovation in the CHC service delivery system, including innovation pursued by the CHC-MCO on its own initiative, as well as collaborative efforts with the Department, CMS, and local partners. Initial required target areas include:
    - Workforce innovation that improves the recruitment, retention, and skills of direct care workers, which may include but are not limited to direct or enhanced payment and other incentives to Providers, Participant-Directed employers, and direct care workers for education, training, and other initiatives designed to enable direct care workers to become a more functional member of the PCPT. Such initiatives may include but not be limited to:
        - Labor/management partnerships or employee/employer partnerships
        - Training programs that exceed DOH and DHS requirements for direct-care worker qualifications, including programs to address complex needs of Participants.
        - Pre-service orientation
        - Promotion of direct-care worker organizations and associations
        - Professional support, certifications, and career-ladder opportunities
        - Care team integration that engages front-line workers

        - Marketing for education and increased awareness of Participant-directed service options
- The Department added language in more than one area indicating their right to impose remediation for any CHC-MCO non-compliance with the CHC program requirements contained in this agreement.
- MCO Roles required for program oversight include a new role **of Direct Care Worker Workforce Development Coordinator** who oversees DCW recruitment and retention.
- Executive Order 2023-08 - Bolstering Service Delivery Through a Digital Experience Strategy calls for the enablement of an online service delivery system that would provide a **universal entryway to all Commonwealth programs, services, and resources** organized by users' needs and life experiences. More information about the Executive Order is available at the following. Applicants shall acknowledge and conform to the following six design principles and requirements when proposing solutions to applications.

This summary is being provided by the Pennsylvania Homecare Association with the intention of summarizing key language and terms that may impact providers from the recently released DRAFT CHC Agreement between the MCOs and the DHS. It is not meant to summarize all areas of the RFA and may not be all inclusive. Providers are encouraged to directly review the Draft Agreement online and any subsequent releases finalizing this document.

Changes to the OBRA Waiver Effective 1/1/25 (Amendment)

KEY – **Bold** = Recommended additions
Strikethrough = Recommended removal

#	Waiver Section	Current Approved Language	Recommended Revised Language	Reason for the Change
1.	Main Module: Additional Needed Information	N/A	**TELESERVICES** **Teleservices are the delivery of direct services using remote technology. The following direct services may be rendered via teleservices:** **• Cognitive Rehabilitation Therapy Services** **• Counseling Services** **Participants must have an informed choice to receive direct services in-person or via teleservices. Teleservices may only occur when the Individual Service Planning team determines that using remote technology is the most appropriate service delivery method to meet the participant's needs (including health and safety needs) and goals. This determination must be based on consideration of all of the following:** **• Service delivery complies with the requirements in the service definition, OLTL policies, and regulations.** **• Teleservices must be provided by means that allow for live two-way communication with the participant, no recording of the interaction shall be captured. Live video or audio transmission is only allowable to persons designated by the participant and designated staff employed by the provider responsible for direct service delivery. Providers can call participants over the phone as an incidental component of teleservices to check-in with participants as allowed in the service definition or in emergency circumstances when all other criteria are met. Monitoring of devices is not allowable under teleservices.** **• The provider has explained to the participant and everyone else residing in the home the impact that teleservices will have on their privacy.** o **The use of live video communication devices in bathrooms is strictly prohibited as part of teleservices.**	Adding Teleservice delivery to the waiver.

			o It is allowable for staff to provide live audio prompts needed by the participant in bathrooms and bedrooms as part of teleservices. The participant must be alerted prior to the activation of any audio communication device unless the participant turns on the audio communication device themselves. **o Live real time video communication between the participant and a staff person as part of teleservices may only occur in a participant's bedroom when all of the following are met:** **- The participant has chosen to receive teleservices in their bedroom due to a medical condition which makes it difficult or impossible for them to leave their bedroom to receive services in another room in the house or the participant would like privacy from others in the home (family, housemates, etc.) during the receipt of services;** **- The participant turns the video communication device on and off themselves or requests assistance in turning the video communication device on and off;** **- The participant does not share a bedroom with others; and** **- Service delivery via video communication will not be performed as part of any activity during which privacy would generally be expected (while a participant is in a state of undress, during sexual activities, etc.).** **o All live real time audio and video communication devices used to render teleservices in any part of the home or community must include indicators that let the participant know that the equipment is on and operating in audio or video mode.** **• How teleservices will support community integration.** **• How teleservices will promote improved health and welfare.** **• The request to use teleservices was initiated by a request from the participant and/or the family/representative when appropriate, and not the provider.** **• How the participant's need for in-person support during service provision will be met.** **• The provider, in conjunction with the Individual Service Planning team, has developed a back-up plan that will be implemented should there be a problem with the technology.**	

			The provider is responsible for ensuring that any technology used to render teleservices are HIPAA compliant and that the delivery of teleservices has been reviewed and accepted by the HIPAA compliance officer. The provider is also responsible for providing initial and ongoing training and support to the participant, and anyone designated by the participant, regarding the operation of the technology used during teleservices, including turning it on and off at-will.	
2.	Appendix C-1/C-3 Service Specifications Benefits Counseling	Benefits Counseling is a service designed to inform, and answer questions from, a participant about competitive integrated employment and how and whether it will result in increased economic self-sufficiency and/or net financial benefit through the use of various work incentives. This service provides an accurate, individualized assessment. The service provides information to the individual regarding the full array of available work incentives for essential benefit programs including SSI, SSDI, Medicaid, Medicare, housing subsidies, SNAP, etc. The service also will provide information and education to the participant regarding income reporting requirements for public benefit programs, including the Social Security Administration.	Benefits Counseling is a service designed to inform **participants** and answer **their** questions ~~from, a participant about~~ **regarding if working in** competitive integrated employment **(CIE) while using various work incentives** ~~and how and whether it~~ will result in increased economic self-sufficiency and/or net financial benefit ~~through the use of various work incentives~~. This service provides an accurate, individualized **financial and benefit** assessment **for participants interested in gaining and/or maintaining CIE**. **Additionally,** ~~The~~ **this** service provides information ~~to the individual~~ regarding ~~the full array of~~ **all** available work incentives for essential benefit programs including SSI, SSDI, Medicaid, Medicare, housing subsidies, SNAP, etc. The service also ~~will~~ provide**s** information ~~and education~~ to **educate** the participant regarding income reporting requirements for public benefit programs, including the Social Security Administration **(SSA)**.	Modify language for better readability.
3.	Appendix C-1/C-3 Service Specifications Benefits Counseling Provider Specifications	- A Certified Work Incentives Counselor certification that is accepted by the Social Security Administration for its Work Incentives Planning and Assistance program.	- A Certified Work Incentives Counselor **(CWIC)** certification that is accepted by the Social Security Administration for its Work Incentives Planning and Assistance program. **- A Work Incentives Professional Certification (WIP-C) that is accepted by the Social Security Administration (SSA) to provide benefits counseling services.**	Add WIP-C certification for providers of Benefits Counseling to expand the pool of individuals who may provide the service.
4.	Appendix C-1/C-3 Service Specifications	N/A	**CRT teleservices may be provided in accordance with the requirement in the Additional Needed Information Section of the Main Module.**	Adding Teleservice to Cognitive Rehabilitation Therapy Services.

	Cognitive Rehabilitation Services			
5.	Appendix C-1/C-3 Service Specifications Counseling Services	N/A	**Counseling teleservices may be provided in accordance with the requirement in the Additional Needed Information Section of the Main Module.**	Adding Teleservice to Counseling Services.
6.	Appendix C-1/C-3 Service Definition Employment Skills Development	Handicapped employment, as defined in Title 55, Chapter 2390, may not be funded through the waiver. Waiver funding is not available for the provision of Employment Skills Development (e.g., sheltered work performed in a facility) where participants are supervised in producing goods or performing services under contract to third parties.	Handicapped employment, as defined in Title 55, Chapter 2390, may not be funded through the waiver. Waiver funding is not available for the provision of Employment Skills Development (e.g., sheltered work performed in a facility) where participants are supervised in producing goods or performing services under contract to third parties **at subminimum wage and are not community integrated**.	Add text to emphasize that sheltered workshop employment is not funded through the waiver.
7.	Appendix C-1/C-3 Service Specifications Home Adaptations	Adaptations to a household are limited to the following: … Home Adaptations may only be funded through the waiver when the services are not covered by another responsible third-party, such as Medicare or private insurance. Supports Coordinators must assure that coverage of services provided under a responsible third-party continues until the plan limitations have been reached or a determination of non-coverage has been established prior to this service's inclusion in the service plan. … Home adaptations must be obtained at the lowest cost. Building a new room is excluded. Specialized Medical Equipment and Supplies is excluded.	Adaptations to a household are limited to the following **only when not covered by the MA State Plan**: … **The MA State Plan will cover home accessibility durable medical equipment, including but not limited to, wheelchair lifts, stair glides, ceiling lifts, and metal accessibility ramps, which are medically necessary to enter and exit the home or to support activities of daily living and meets the definition of 42 CFR Section 440.70(b)(3)(I-ii), along with installation of the equipment or appliance. Other home adaptations in this service specification are not covered in the State Plan.** Home Adaptations may only be funded through the waiver when the services are not covered by another responsible third-party, such as Medicare or private insurance. ~~Supports~~ **Service** Coordinators must assure that coverage of services provided under a responsible third-party continues until the plan limitations have been reached or a determination of non-coverage has been established prior to this service's inclusion in the service plan. …	Add language to better differentiate between Home Adaptations in the waiver and Home Accessibility Durable Medical Equipment covered by the State Plan. Aligned OBRA Home Adaptations service definition with Community HealthChoices (CHC) Home Adaptations service definition.

		… Rented property must meet the following: • there is a reasonable expectation that the participant will continue to live in the home; • written permission is secured from the property owner for the adaptation; • the landlord will not increase the rent because of the adaptation; • there is no expectation that waiver funds will be used to return the home to its original state. Except as permitted in accordance with requirements contained in Department guidance, policy and regulations, this service may not be provided on the same day and at the same time as services that contain elements integral to the delivery of this service. This service may not be included on the same service plan as Residential Habilitation**.**	**Depending on the complexity of the home adaptation, the independent evaluation by an occupational therapist or a physical therapist may be supplemented with an assessment by individuals holding the following certifications: Certified Environmental Access Consultant (C.E.A.C), Certified Living in Place Professional (CLIPP) or Executive Certificate in Home Modifications. Assessors with these certifications must have at least two years of experience assessing home adaptations for older adults or individuals with disabilities.** … Home adaptations must be obtained **in the least expensive, most cost-effective manner. Adaptations will not be approved if the home is in foreclosure, delinquent tax status, is not structurally sound, or the adaptation presents a safety concern based on applicable state and local building codes. Rent-to-purchase vertical lifts and stair glides may be rented provided the rental cost does not exceed the purchase price. When long-term use by the participant is expected or when the rental is anticipated to exceed the cost of purchase, the equipment will be purchased for the participant or a permanent home adaptation will be considered** ~~at the lowest cost~~. Building a new room **that adds to the total square footage of the home is excluded, except as noted below** ~~is excluded~~. Specialized Medical Equipment and Supplies is excluded. … ~~Rented property adaptions~~ **Adaptations at rental properties** must meet the following: • there is a reasonable expectation that the participant will continue to live in the home; • written permission is secured from the property owner for the adaptation;	

			• the landlord will not increase the rent because of the adaptation; • there is no expectation that waiver funds will be used to return the home to its original state. Except as permitted in accordance with requirements contained in Department guidance, policy and regulations, this service may not be provided on the same day and at the same time as services that contain elements integral to the delivery of this service. This service may not be **provided to participants receiving Residential Habilitation or residing in Assisted Living Residences, Domiciliary Care Homes or other provider owned and operated settings** ~~included on the same service plan as Residential Habilitation~~**.**	
8.	Appendix C-1/C-3 Service Specifications Personal Emergency Response System (PERS)	PERS is an electronic device which enables waiver participants to secure help in an emergency. The individual may also wear a portable "help" button to allow for mobility. The system is connected to the person's phone and programmed to signal a response center once a "help" button is activated. The response center is staffed by trained professionals, as specified. The PERS vendor must provide 24 hour staffing, by trained operators of the emergency response center, 365 days a year. ... Installation is covered one time per residential site. Stand-alone smoke detectors will not be billed under PERS. PERS covers the actual cost of the service and does not include any additional administrative costs.	**A Personal Emergency Response System (PERS)** is an electronic device **that transmits a signal to a central monitoring center to summon assistance in the event of an emergency.** ~~which enables waiver participants to secure help in an emergency~~. ~~The individual may also wear a portable "help" button to allow for mobility. The system is connected to the person's phone and programmed to signal a response center once a "help" button is activated. The response center is staffed by trained professionals, as specified. The PERS vendor must provide 24 hour staffing, by trained operators of the emergency response center, 365 days a year.~~ **The necessary components of a system are:** **1. An in-home medical communications transceiver.** **2. A remote, portable activator.** **3. A central monitoring center with backup systems which is staffed at all times.** **4. Current data files at the central monitoring station contain response protocols and personal, medical, and emergency information for each participant.** **A portable locator system is an electronic device that transmits a signal to a monitoring device. The system allows a participant to access assistance in the event of an emergency and allows law enforcement or the monitoring system provider to locate a participant who is unable to request help or to activate a system independently. A portable locator**	Aligned OBRA PERS service definition with CHC PERS service definition for consistency.

			system can be obtained as PERS only if the participant is unable to access assistance in an emergency situation due to the participant's age or disability. The required components of the portable locator system are: **1. A portable communications transceiver or transmitter to be worn or carried by the participant.** **2. Monitoring by the provider at a central location with response protocols and personal, medical, and emergency information for each participant as applicable.** ... **A unit of service is a one-time installation fee or a monthly monitoring fee. Maintenance and repair of PERS rental equipment is the responsibility of the provider. In addition, provider staff are responsible for training participants regarding the use of the system.** **PERS equipment shall include a variety of remote or other specialty activation devices from which the individual can choose in accordance with their specific needs. All PERS equipment shall have an internal battery that provides at least twenty-four hours of power without recharging and sends notification to the emergency response center when the battery's level is low. Equipment includes, but is not limited to:** **• Wearable waterproof activation devices; and** **• Devices that offer:** **– Voice-to-voice communication capability,** **– Visual indication of an alarm that may be appropriate if the consumer is hearing impaired, or** **– Audible indication of an alarm that may be appropriate if the consumer is visually impaired.** **PERS does not include the following:** **• Equipment such as a boundary alarm, a medication dispenser, a medication reminder, or any other equipment or home medical equipment or supplies, regardless of whether such equipment is connected to the PERS equipment.**	

			• **Stand-alone smoke or carbon monoxide detectors.** • **Remote Telecare monitoring services, i.e., Health Status Measuring and Monitoring and Activity and Sensor Monitoring.** • **Monthly telephone charges associated with the participant's phone service.** **When previously approved equipment has been damaged as a result of misuse, abuse or negligence, the Service Coordinator will make the determination around the cost-effectiveness of repairing and/or replacing damaged equipment or providing the participant with additional supports.** ... **The cost of training participants is included in the charges for installation or the monthly monitoring fee. The maximum units per calendar year shall be one initial installation fee and 12 months of monthly monitoring service. The provider may not charge any additional costs over and above the installation and monthly monitoring fees.** ~~Installation is covered one time per residential site.~~ ~~Stand-alone smoke detectors will not be billed under PERS.~~ ~~PERS covers the actual cost of the service and does not include any additional administrative costs.~~	
9.	Appendix C-1/C-3 Service Specifications PERS Provider Specifications		• **Organization must have capacity to provide 24-hour coverage by trained professionals, 365 days/year.**	All providers of PERS must have this capacity. This is not a new requirement but changes to the service description above necessitate this addition.

10.	Appendix C-1/C-3 Service Specifications Structured Day Habilitation	In addition to the general standards listed above, Individual Support Staff must: • Be at least 18 years of age • Have a high school diploma or GED and have a minimum of five (5) years' experience working with people with disabilities, or…	In addition to the general standards listed above, Individual Support Staff must: • Be at least 18 years of age • Have a high school diploma or GED and have a minimum of ~~five (5)~~ **two (2)** years' experience working with people with disabilities, or…	Change years of experience to 2 years to increase the pool of eligible workers to address workforce shortages.
11.	Appendix C-2-a	Criminal history clearances are obtained from the Pennsylvania State Police within 30 work days from the date that the employee/provider initiates services to the participant. . The Pennsylvania State Police access the Pennsylvania Crime Information Center (PCIC) and the National Crime Information Center (NCIC) for this information; results are typically available within 1-2 business days. A Federal Bureau of Investigation (FBI) federal criminal history record is required for applicants who have resided in Pennsylvania for less than two years.	**All applicants are required to obtain a report of criminal history from the Pennsylvania State Police (PSP)** ~~Criminal history clearances are obtained from the Pennsylvania State Police~~ within 30 work days from the date that the employee/provider initiates services to the participant. The Pennsylvania State Police access the Pennsylvania Crime Information Center (PCIC) and the National Crime Information Center (NCIC) for this information; results are typically available within 1-2 business days. **For applicants who have resided in Pennsylvania for less than two years, a fingerprint-based** Federal Bureau of Investigation (FBI) federal criminal history record is **also** required. ~~for applicants who have resided in Pennsylvania for less than two years.~~	Clarification of what clearances are needed.
12.	Appendix C-2-b	Clearances are required for all direct care workers and service providers, including service coordinators and contractors, providing services in homes where children reside. A child is defined as an individual under 18 years of age. The following three certifications must be obtained prior to providing services in homes where children reside: • Report of criminal history from the Pennsylvania State Police (PSP); • Fingerprint-based federal criminal history submitted through the Pennsylvania State Police or its authorized agent (FBI); and	Clearances are required for all direct care workers and service providers, including service coordinators and contractors, providing services in homes where children ~~reside~~ **are present**. A child is defined as an individual under 18 years of age. The following three certifications must be obtained prior to providing services in homes where children ~~reside~~ **are present**: • Report of criminal history from the Pennsylvania State Police (PSP); • Fingerprint-based federal criminal history submitted through the Pennsylvania State Police or its authorized agent (FBI); and • Child Abuse History Certification from the Department of Human Services (Child Abuse). …	Clarification of when child abuse clearances are needed for direct care workers.

		• Child Abuse History Certification from the Department of Human Services (Child Abuse). … For those workers required to have clearances (see above), written results are required prior to the employee/provider initiating services in the participant's home. Workers who are employed by waiver participants who have children residing in their homes must have child abuse clearances completed prior to hire so that participants can make an informed decision on whether to employ a worker who has been named as a perpetrator of founded or indicated child abuse.	For those workers required to have clearances (see above), written results are required prior to the employee/provider initiating services in the participant's home. Workers who are employed by waiver participants who have children ~~residing~~ **present** in their homes must have child abuse clearances completed prior to hire so that participants can make an informed decision on whether to employ a worker who has been named as a perpetrator of founded or indicated child abuse.	
13.	Appendix D-1-d	How responsibilities are assigned for implementing the plan:	How responsibilities are assigned for implementing the plan: … **If the provider develops a treatment or service plan for the participant, it must be incorporated into the overall ISP.** **Any modification of a participant's rights in a setting, under § 441.301(c)(4)(vi)(A) through (D), must be supported by a specific assessed need and justified in the ISP. The following requirements must be documented in the ISP:** **• Identify a specific and individualized assessed need.** **• Document the positive interventions and supports used prior to any modifications to the person-centered service plan.** **• Document less intrusive methods of meeting the need that have been tried but did not work.** **• Include a clear description of the condition that is directly proportionate to the specific assessed need.** **• Include regular collection and review of data to measure the ongoing effectiveness of the modification.** **• Include established time limits for periodic reviews to determine if the modification is still necessary or can be terminated.** **• Include the informed consent of the individual.**	Add language to reinforce that if a participant's rights in a setting need to be modified due to an assessed need it must be documented in the ISP and if a provider creates a treatment or service plan, that plan must be incorporated into the ISP. These items are in response to feedback from CMS during the HCB Settings Final Rule Heightened Scrutiny onsite visits.

			• Include an assurance that interventions and supports will cause no harm to the individual.	
14.	Appendix F-1: Opportunity to Request a Fair Hearing	If the participant files an appeal (written or oral) within 10 calendar days of the mailing date of the written notification from the Service Coordinator, the appealed Waiver service(s) are required to continue until a decision is rendered after the appeal hearing (55 Pa. Code § 275.4(a)(3)(v)(C)(I)). As noted above, the continuation language is included in the written notice that is sent to the participant by the Service Coordinator. The postmark of a mailed appeal will be used to determine if the 10 day requirement was met by the participant.	If the participant files an appeal (written or oral) within **15** ~~10~~ calendar days of the mailing date of the written notification from the Service Coordinator, the appealed Waiver service(s) are required to continue until a decision is rendered after the appeal hearing (55 Pa. Code § 275.4(a)(3)(v)(C)(I)). As noted above, the continuation language is included in the written notice that is sent to the participant by the Service Coordinator. The postmark of a mailed appeal will be used to determine if the **15** ~~10~~ day requirement was met by the participant.	Update the time frame to file appeals.
15.	Appendix F-3-c	Individuals calling the OLTL Participant HelpLine with a complaint/grievance are logged into the Enterprise Information System (EIM), a web-based database, and the information is then referred to the appropriate Bureau for resolution.	**When an individual calls** ~~Individuals calling~~ the OLTL Participant HelpLine with a complaint/grievance, **the calls are logged (complaints by the Case Management Unit and grievances into the Enterprise Information System (EIM), a web-based database)** ~~are logged into the Enterprise Information System (EIM), a web-based database,~~ and the information is then referred to the appropriate Bureau for resolution.	To be more specific how complaint/grievances are logged.
16.	Appendix G-1-b	The Office of Long-Term Living has initiated a comprehensive incident reporting and management process. Critical events are referred to as critical incidents and defined as an event that jeopardizes the participant's health and welfare. Two OLTL offices are involved in the oversight of the Incident Management process – the Bureau of Quality and Provider Management (BQPM) and the Bureau of Participant Operations (BPO).	The Office of Long-Term Living has initiated a comprehensive incident reporting and management process. Critical events are referred to as critical incidents and defined as an event that jeopardizes the participant's health and welfare. Two OLTL offices are involved in the oversight of the Incident Management process – **The Bureau of Quality Assurance and Program Analytics and the Bureau of Coordinated and Integrated Services (BCIS).** ~~the Bureau of Quality and Provider Management (BQPM) and the Bureau of Participant Operations (BPO).~~	Bureau names updated.
17.	Appendix G-1-b	Required reporters must report critical incidents within 48 hours of their occurrence or discovery. OLTL has initiated a mandatory electronic reporting system for reporting all critical incidents. The electronic reporting system, referred to as EIM, allows Service Coordinators and Direct Service providers to submit critical incidents through a web-based application where they are accessed by Service Coordinators, the CHC-MCOs and OLTL staff.	Required reporters must report critical incidents within 48 hours of their ~~occurrence or~~ discovery. OLTL has initiated a mandatory electronic reporting system for reporting all critical incidents. The electronic reporting system, referred to as EIM, allows Service Coordinators and ~~Direct Service~~ providers to submit critical incidents through a web-based application where they are accessed by Service Coordinators, the CHC-MCOs and OLTL staff.	Clarify that critical incidents must be reported with 48 hours of discovery.

18.	Appendix G-1-b	Incidents reported through the OLTL Participant HelpLine are entered into EIM by OLTL staff and the incidents are handled the same way as those reported directly through the web-based application. The following information is collected for each reported incident, regardless of how it is received: reporter information, participant demographics, OLTL program information, event type/details and description of the incident.	Incidents **are** reported **in** ~~through the OLTL Participant HelpLine are entered into~~ EIM by OLTL staff and the incidents are handled the same way as those reported directly through the web-based application. The following information is collected for each reported incident, regardless of how it is received: reporter information, participant demographics, OLTL program information, event type/details and description of the incident.	Clarification on how incidents are reported. Update Bureau name.
19.	Appendix G-1-d	The Service Coordinator is responsible for conducting an investigation of incidents The Service Coordination Entity has two (2) days to provide initial information to OLTL in cases involving sexual abuse, serious injury, serious bodily injury or suspicious death, and 30 days from the initial report to provide all the information regarding the incident to OLTL.	The Service Coordinator is responsible for conducting an investigation of incidents The Service Coordination Entity **must provide initial report to OLTL of any incidents** ~~has two (2) days to provide initial information to OLTL in cases~~ involving sexual abuse, serious injury, serious bodily injury or suspicious death **within 48 hours of discovery.** ~~and 30 days from the initial report to provide all the information regarding the incident to OLTL.~~ **All information regarding the incident must be provided to OLTL within 30 days of the discovery of the incident.**	Clarification on timeframes of reporting incidents.
20.	Appendix G-1-d	• Provide a report to OLTL within 30 business days of the occurrence. When unable to conclude initial investigation within 30 days, request an extension from OLTL through EIM.	• Provide a report to OLTL within 30 ~~business~~ **calendar** days of the occurrence. When unable to conclude initial investigation within 30 days, request an extension from OLTL through EIM.	Clarification on timeframes of reporting incidents.
21.	Appendix G-2-a	Once a complaint has been filed it is recorded by OLTL staff in a central database and appropriate actions are taken, including notification of the local law enforcement agency.	~~Once a complaint has been filed it is recorded by OLTL staff in a central database~~ **Complaints regarding use of restraints are reported through EIM** and **then** appropriate actions are taken, including notification of the local law enforcement agency.	Clarification on how use of restraint complaints are reported.
22.	Appendix G-2-b	Once a complaint has been filed, it is recorded by OLTL staff in a central database and appropriate actions are taken, including notification of the local law enforcement agency.	~~Once a complaint has been filed, it is recorded by OLTL staff in a central database~~ **Complaints are reported through EIM** and appropriate actions are taken, including notification of the local law enforcement agency.	Clarification on filing complaints on restrictive interventions.
23.	Appendix G-2-c	Once a complaint has been filed, it is recorded by OLTL staff in a central database and appropriate actions are	~~Once a complaint has been filed, it is recorded by OLTL staff in a central database~~ **Complaints are reported through EIM** and appropriate actions are taken, including notification of the local law enforcement agency.	Clarification on filing complaints for use of seclusion.

		taken, including notification of the local law enforcement agency.		
24.	Appendix G-3-b-ii	Providers are required to immediately report medication errors to the participant, the participant's designated party, when applicable, and the prescriber. Medication errors that require medical intervention, i.e. hospitalization or emergency room visits, must be reported to OLTL via EIM within 24 hours of occurrence or discovery as outlined in Appendix G-1-b.	Providers are required to immediately report medication errors to the participant, the participant's designated party, when applicable, and the prescriber. Medication errors that require medical intervention, i.e. hospitalization or emergency room visits, must be reported to OLTL via EIM within **48**~~24~~ hours of ~~occurrence or~~ discovery as outlined in Appendix G-1-b.	Updated reporting timeframes.
25.	Appendix G-3-c-ii	Medication Administration by Unlicensed Residential Habilitation Providers: Unlicensed Residential Habilitation providers are required to follow- OLTL's "Medication Management Policy for Unlicensed Providers Bulletin", which clarifies when a participant is expected to self-administer, receive assistance with medication administration, and the training required for provider staff to administer medication. … Medication Administration Training (b) For the purposes of this bulletin, an OLTL-approved medications administration course refers to the Department of Human Services Office of Developmental Program's training program. Information on this training program is found by calling 1-800-438-1958 or by going to: http://www.dhs.state.pa.us/provider/training/medicationadministration/index.htm	Medication Administration by Unlicensed Residential Habilitation Providers: ~~Unlicensed Residential Habilitation providers are required to follow- OLTL's "Medication Management Policy for Unlicensed Providers Bulletin", which clarifies when a participant is expected to self-administer, receive assistance with medication administration, and the training required for provider staff to administer medication.~~ … (b) ~~For the purposes of this bulletin,~~ **A**n OLTL-approved medications administration course refers to the Department of Human Services Office of Developmental Program's training program. Information on this training program is found by calling ~~1-800-438-1958~~ **717-221-1630** or by going to: ~~http://www.dhs.state.pa.us/provider/training/medicationadministration/index.htm~~ **https://medadmin.myodp.org/**	The bulletin is already incorporated into the waiver. Update contact information for the Medication Administration training.
26.	Appendix G-3-c-iii	Medication errors that require medical intervention, i.e. hospitalization or emergency room visits, must be reported to OLTL via EIM within 24 hours of occurrence or discovery as specified in OLTL Critical Incident Management Bulletin.	Medication errors that require medical intervention, i.e. hospitalization or emergency room visits, must be reported to OLTL via EIM within **48** ~~24~~ hours of ~~occurrence or~~ discovery as specified in OLTL Critical Incident Management Bulletin.	Update reporting timeframes.
27.	Appendix H-2	H.2 Use of a Patient Experience of Care/Quality of Life Survey	H.2 Use of a Patient Experience of Care/Quality of Life Survey	OLTL added the HCBS CAHPS Survey.

		a. Specify whether the state has deployed a patient experience of care or quality of life survey for its HCBS population in the last 12 months (Select one): ○ No • Yes (Complete item H.2b) b. Specify the type of survey tool the state uses: o HCBS CAHPS Survey; o NCI Survey; o NCI AD Survey; • Other (Please provide a description of the survey tool used): The Participant Review Tool (PRT) was designed by Office of Long-Term Living (OLTL) and Service Coordinators (SC) to elicit information from the participant in order to help the SC determine whether the participant needs additional, different and/or varied services, including additional community activities. The PRT is administered by the SC; which was intended to assist the SC Entity to identify signs of actual or potential abuse, neglect, and exploitation and determine the next steps they need to take in order to protect the health and welfare of the participant.	a. Specify whether the state has deployed a patient experience of care or quality of life survey for its HCBS population in the last 12 months (Select one): ○ No • Yes (Complete item H.2b) b. Specify the type of survey tool the state uses: **• HCBS CAHPS Survey**; o NCI Survey; o NCI AD Survey; • Other (Please provide a description of the survey tool used): The Participant Review Tool (PRT) was designed by Office of Long-Term Living (OLTL) and Service Coordinators (SC) to elicit information from the participant in order to help the SC determine whether the participant needs additional, different and/or varied services, including additional community activities. The PRT is administered by the SC; which was intended to assist the SC Entity to identify signs of actual or potential abuse, neglect, and exploitation and determine the next steps they need to take in order to protect the health and welfare of the participant.	

Changes to the CHC Waiver Effective January 1, 2025 (Renewal)

KEY – **Bold** = Recommended additions
Strikethrough = Recommended removal

#	Waiver Section	Current Approved Language	Recommended Revised Language	Reason for the Change
1.	Main Module: Additional Needed Information	N/A	**TELESERVICES** **Teleservices are the delivery of direct services using remote technology. The following direct services may be rendered via teleservices:** **• Cognitive Rehabilitation Therapy Services** **• Counseling Services** **Participants must have an informed choice to receive direct services in-person or via teleservices. Teleservices may only occur when the Person-Centered Planning team determines that using remote technology is the most appropriate service delivery method to meet the participant's needs (including health and safety needs) and goals. This determination must be based on consideration of all of the following:** **• Service delivery complies with the requirements in the service definition, OLTL policies, and regulations.** **• Teleservices must be provided by means that allow for live two-way communication with the participant, no recording of the interaction shall be captured. Live video or audio transmission is only allowable to persons designated by the participant and designated staff**	Adding Teleservice delivery to the waiver.

#	Waiver Section	Current Approved Language	Recommended Revised Language	Reason for the Change
			employed by the provider responsible for direct service delivery. Providers can call participants over the phone as an incidental component of teleservices to check-in with participants as allowed in the service definition or in emergency circumstances when all other criteria are met. Monitoring of devices is not allowable under teleservices. • **The provider has explained to the participant and everyone else residing in the home the impact that teleservices will have on their privacy.** o **The use of live video communication devices in bathrooms is strictly prohibited as part of teleservices.** o **It is allowable for staff to provide live audio prompts needed by the participant in bathrooms and bedrooms as part of teleservices. The participant must be alerted prior to the activation of any audio communication device unless the participant turns on the audio communication device themselves.** o **Live real time video communication between the participant and a staff person as part of teleservices may only occur in a participant's bedroom**	

#	Waiver Section	Current Approved Language	Recommended Revised Language	Reason for the Change
			when all of the following are met: **- The participant has chosen to receive teleservices in their bedroom due to a medical condition which makes it difficult or impossible for them to leave their bedroom to receive services in another room in the house or the participant would like privacy from others in the home (family, housemates, etc.) during the receipt of services;** **- The participant turns the video communication device on and off themselves or requests assistance in turning the video communication device on and off;** **- The participant does not share a bedroom with others; and** **- Service delivery via video communication will not be performed as part of any activity during which privacy would generally be expected (while a participant is in a state of undress, during sexual activities, etc.).**	

#	Waiver Section	Current Approved Language	Recommended Revised Language	Reason for the Change
			○ All live real time audio and video communication devices used to render teleservices in any part of the home or community must include indicators that let the participant know that the equipment is on and operating in audio or video mode. • How teleservices will support community integration. • How teleservices will promote improved health and welfare. • The request to use teleservices was initiated by a request from the participant and/or the family/representative when appropriate, and not the provider. • How the participant's need for in-person support during service provision will be met. • The provider, in conjunction with the Person Center Planning team, has developed a back-up plan that will be implemented should there be a problem with the technology. The provider is responsible for ensuring that any technology used to render teleservices are HIPAA compliant and that the delivery of teleservices has been reviewed and accepted by the HIPAA compliance officer. The provider is also responsible for providing initial and ongoing training and support to the	

#	Waiver Section	Current Approved Language	Recommended Revised Language	Reason for the Change
			participant, and anyone designated by the participant, regarding the operation of the technology used during teleservices, including turning it on and off at-will.	
2.	Appendix C-1/C-3 Service Specifications Benefits Counseling	Benefits Counseling is a service designed to inform, and answer questions from, a participant about competitive integrated employment and how and whether it will result in increased economic self-sufficiency and/or net financial benefit through the use of various work incentives. This service provides an accurate, individualized assessment. The service provides information to the individual regarding the full array of available work incentives for essential benefit programs including SSI, SSDI, Medicaid, Medicare, housing subsidies, SNAP, etc. The service also will provide information and education to the participant regarding income reporting requirements for public benefit programs, including the Social Security Administration.	Benefits Counseling is a service designed to inform **participants** and answer **their** questions ~~from, a participant about~~ **regarding if working in** competitive integrated employment **(CIE) while using various work incentives** ~~and how and whether it~~ will result in increased economic self-sufficiency and/or net financial benefit ~~through the use of various work incentives~~. This service provides an accurate, individualized **financial and benefit** assessment **for participants interested in gaining and/or maintaining CIE. Additionally,** ~~The~~ **this** service provides information ~~to the individual~~ regarding ~~the full array of~~ **all** available work incentives for essential benefit programs including SSI, SSDI, Medicaid, Medicare, housing subsidies, SNAP, etc. The service also ~~will~~ provide**s** information ~~and education~~ to **educate** the participant regarding income reporting requirements for public benefit programs, including the Social Security Administration **(SSA)**.	Modify language for better readability.
3.	Appendix C-1/C-3 Service Specifications Benefits Counseling Provider Specifications	- A Certified Work Incentives Counselor certification that is accepted by the Social Security Administration for its Work Incentives Planning and Assistance program.	- A Certified Work Incentives Counselor **(CWIC)** certification that is accepted by the Social Security Administration for its Work Incentives Planning and Assistance program.	Add WIP-C certification for providers of Benefits Counseling to expand the pool of individuals who may provide the service.

#	Waiver Section	Current Approved Language	Recommended Revised Language	Reason for the Change
			- A Work Incentives Professional Certification (WIP-C) that is accepted by the Social Security Administration (SSA) to provide benefits counseling services.	
4.	Appendix C-1/C-3 Service Specifications Chore Services	N/A	**Chore Services consist of heavy household chores which are necessary to maintain the functional use of the home or provide a clean, sanitary and safe environment. This service may be authorized only when an unclean and cluttered living space impedes service delivery or increases the probability of injury from environmental hazards, such as falls or burns.** **Covered Chore Services are limited to the following:** **Washing floors, windows and walls;** **Moving or removing large household furnishings and heavy appliances in order to provide safe access and egress for the participant, the direct service worker and/or emergency personnel. This may include addressing items that are stored outside of the home on porches or in front of doorways;** **Securing household fixtures and items, including tacking down loose rugs and flooring, in order to or prevent falls or injuries; and**	Adding Chore Services to the waiver.

#	Waiver Section	Current Approved Language	Recommended Revised Language	Reason for the Change
			Seasonal installation and removal of window air conditioners. **For individuals with hoarding disorders, this service is intended to be utilized in conjunction with behavioral health services. The participant must be actively engaged in behavioral health services or attend a behavioral health consultation before the following services can be provided. The following additional services may be provided when a hoarding disorder is present:** **Cleaning attics, basements or common living space to remove fire hazards as determined necessary by the Service Coordinator;** **Dumpster rental and refuse disposal;** **Sorting, packing and/or removal of the participant's belongings; and** **Remediation and disposal of hazardous waste.**	
5.	Appendix C-1/C-3 Service Specifications Cognitive Rehabilitation Therapy Services	N/A	**CRT teleservices may be provided in accordance with the requirement in the Additional Needed Information Section of the Main Module.**	Adding Teleservice to Cognitive Rehabilitation Therapy Services.
6.	Appendix C-1/C-3 Service Specifications	N/A	**Counseling teleservices may be provided in accordance with the requirement in**	Adding Teleservice to Counseling Services.

#	Waiver Section	Current Approved Language	Recommended Revised Language	Reason for the Change
	Counseling Services		**the Additional Needed Information Section of the Main Module.**	
7.	Appendix C-1/C-3 Service Definitions Employment skills Development	Handicapped employment, as defined in Title 55, Chapter 2390, may not be funded through the waiver. Waiver funding is not available for the provision of Employment Skills Development (e.g., sheltered work performed in a facility) where participants are supervised in producing goods or performing services under contract to third parties.	Handicapped employment, as defined in Title 55, Chapter 2390, may not be funded through the waiver. Waiver funding is not available for the provision of Employment Skills Development (e.g., sheltered work performed in a facility) where participants are supervised in producing goods or performing services under contract to third parties **at subminimum wage and are not community integrated**.	Add text to emphasize that sheltered workshop employment is not funded through the waiver.
8.	Appendix C-1/C-3 Service Specifications Home Adaptations	Adaptations to a household are limited to the following: • Ramps from street, sidewalk or house • Installation of specialized electric and plumbing systems that are necessary to accommodate the medical equipment and supplies necessary for the health, welfare and safety of the participant • Vertical lifts only when vertical lifts and installation are not covered under the MA State Plan … • Stair gliders and stair lifts only when stair gliders, stair lifts and installation are not covered under the MA State Plan. A stair lift is a chair or platform that travels on a rail, installed to follow the slope and direction of a staircase, which allows a user to ride up and down stairs safely	Adaptations to a household are limited to the following **only when not covered by the MA State Plan**: • Ramps from street, sidewalk or house • Installation of specialized electric and plumbing systems that are necessary to accommodate the medical equipment and supplies necessary for the health, welfare and safety of the participant • Vertical lifts ~~only when vertical lifts and installation are not covered under the MA State Plan~~ … • Stair gliders and stair lifts ~~only when stair gliders, stair lifts and installation are not covered under the MA State Plan~~. A stair lift is a chair or platform that travels on a rail, installed to follow the slope and direction of a staircase, which allows a user to ride up and down stairs safely	Add language to better differentiate between Home Adaptations in the waiver and Home Accessibility Durable Medical Equipment covered by the State Plan.

#	Waiver Section	Current Approved Language	Recommended Revised Language	Reason for the Change
9.	Appendix C-1/C-3 Service Specifications Home Adaptations	Wheelchair lifts, stair glides, ceiling lifts, and metal accessibility ramps are covered by the State Plan, along with installation of the equipment or appliance. Other home adaptations in this service specification are not covered in the State Plan.	~~Wheelchair lifts, stair glides, ceiling lifts, and metal accessibility ramps are covered by the State Plan~~ **The MA State Plan will cover home accessibility durable medical equipment, including but not limited to, wheelchair lifts, stair glides, ceiling lifts, and metal accessibility ramps, which are medically necessary to enter and exit the home or to support activities of daily living and meets the definition of 42 CFR Section 440.70(b)(3)(I-ii), along with installation of the equipment or appliance. Other home adaptations in this service specification are not covered in the State Plan.**	Add language to better differentiate between Home Adaptations in the waiver and Home Accessibility Durable Medical Equipment covered by the State Plan.
10.	Appendix C-1/C-3 Service Specifications Structured Day Habilitation	In addition to the general standards listed above, Individual Support Staff must: • Be at least 18 years of age • Have a high school diploma or GED and have a minimum of five (5) years' experience working with people with disabilities, or…	In addition to the general standards listed above, Individual Support Staff must: • Be at least 18 years of age • Have a high school diploma or GED and have a minimum of ~~five (5)~~ **two (2)** years' experience working with people with disabilities, or…	Change years of experience to 2 years to increase the pool of eligible workers to address workforce shortages.
11.	Appendix C-1/C-3 Service Specifications Telecare	Participants can only receive TeleCare services when they meet eligibility criteria specified in the state's published TeleCare Services policy guidance, and the services are not covered under Medicare or other third party resources.	Participants can only receive TeleCare services when ~~they meet eligibility criteria specified in the state's published TeleCare Services policy guidance, and~~ the services are not covered under Medicare or other third party resources.	Telecare Services policy guidance is no longer applicable to this service.

#	Waiver Section	Current Approved Language	Recommended Revised Language	Reason for the Change
12.	Appendix C-1/C-3 Telecare Provider Specifications for Service Under Durable Medical Equipment and Supply Company, Home Health Agency, Hospital, and Pharmacy.	Meet provider requirements as specified in the TeleCare Services Directive	~~Meet provider requirements as specified in the TeleCare Services Directive~~	Telecare Services Directive is no longer applicable to this service.
13.	Appendix C-2-a	Criminal history clearances are obtained from the Pennsylvania State Police which access the Pennsylvania Crime Information Center (PCIC) and the National Crime Information Center (NCIC) for this information. The results are typically available within 1-2 business days. A Federal Bureau of Investigation (FBI) federal criminal history record is required for applicants who have resided in Pennsylvania for less than two years.	**All applicants are required to obtain a report of criminal history from the Pennsylvania State Police (PSP)** ~~Criminal history clearances are obtained from the Pennsylvania State Police~~ which access the Pennsylvania Crime Information Center (PCIC) and the National Crime Information Center (NCIC). ~~for this information.~~ The results are typically available within 1-2 business days. **For applicants who have resided in Pennsylvania for less than two years,** a **fingerprint-based** Federal Bureau of Investigation (FBI) federal criminal history record is **also** required. ~~for applicants who have resided in Pennsylvania for less than two years~~.	Clarification on clearances that are required.
14.	Appendix C-2-b	Clearances are required for all direct care workers and service providers, including Service Coordinators and contractors, providing services in homes where children reside. A child is defined as an individual under 18 years of age. The following three certifications must be obtained prior to providing services in homes where children reside: • Report of criminal history from the Pennsylvania State Police (PSP);	Clearances are required for all direct care workers and service providers, including Service Coordinators and contractors, providing services in homes where children ~~reside~~ **are present**. A child is defined as an individual under 18 years of age.	Clarification of when child abuse clearances are required for direct care workers.

#	Waiver Section	Current Approved Language	Recommended Revised Language	Reason for the Change
		• Fingerprint-based federal criminal history submitted through the Pennsylvania State Police or its authorized agent (FBI); and • Child Abuse History Certification from the Department of Human Services (Child Abuse). The option to provisionally hire a person for employment described in 55 Pa. Code Ch. 52.20 does not apply to the clearances required prior to providing services in homes where children reside. ... For those workers required to have clearances (see above), written results are required prior to the employee/provider initiating services in the participant's home. Direct care workers who are employed by waiver participants who have children residing in their homes must have child abuse clearances completed prior to hire so that participants can make an informed decision on whether to employ a worker who has been named as a perpetrator of founded or indicated child abuse.	The following three certifications must be obtained prior to providing services in homes where children ~~reside~~ **are present**: • Report of criminal history from the Pennsylvania State Police (PSP); • Fingerprint-based federal criminal history submitted through the Pennsylvania State Police or its authorized agent (FBI); and • Child Abuse History Certification from the Department of Human Services (Child Abuse). The option to provisionally hire a person for employment described in 55 Pa. Code Ch. 52.20 does not apply to the clearances required prior to providing services in homes where children ~~reside~~ **are present**. ... For those workers required to have clearances (see above), written results are required prior to the employee/provider initiating services in the participant's home. Direct care workers who are employed by waiver participants who have children ~~residing~~ **present** in their homes must have child abuse clearances completed prior to hire so that participants can make an informed decision on whether to employ a worker who has been named as a perpetrator of founded or indicated child abuse.	
15.	Appendix D-1-b, D-2-b	Service Coordination agencies may provide the following vendor services under an Organized Health Care Delivery	~~Service Coordination agencies may provide the following vendor services~~	OHCDS was permitted in CHC until the end of the

#	Waiver Section	Current Approved Language	Recommended Revised Language	Reason for the Change
		System (OHCDS) only during the 180-day continuity of care period for each implementation phase: • Assistive Technology; • Community Transition Services; • Home Delivered Meals; • Home Modifications; • Non-Medical Transportation; • Personal Emergency Response System (PERS); and/or • Vehicle Modifications. Participants are not required to receive these vendor services subcontracted through an OHCDS. Participants are able to either select any qualified provider that has contracted with the OHCDS or select any other qualified provider that is part of the CHC-MCO's provider network. The Service Coordination provider cannot require a participant to use their OHCDS as a condition to receive service coordination services from their agency.	~~under an Organized Health Care Delivery System (OHCDS) only during the 180-day continuity of care period for each implementation phase:~~ ~~• Assistive Technology;~~ ~~• Community Transition Services;~~ ~~• Home Delivered Meals;~~ ~~• Home Modifications;~~ ~~• Non-Medical Transportation;~~ ~~• Personal Emergency Response System (PERS); and/or~~ ~~• Vehicle Modifications.~~ ~~Participants are not required to receive these vendor services subcontracted through an OHCDS. Participants are able to either select any qualified provider that has contracted with the OHCDS or select any other qualified provider that is part of the CHC-MCO's provider network. The Service Coordination provider cannot require a participant to use their OHCDS as a condition to receive service coordination services from their agency.~~	180-day continuity of care period after the last implementation date. This provision expired June 30, 2020.
16.	Appendix D-1-d	PCSPs must be completed no later than 30 days from the date the comprehensive needs assessment or reassessment is completed.	PCSPs must be ~~completed~~ **developed and implemented** no later than ~~30~~ **15** days from the date the comprehensive needs assessment or reassessment is completed.	Reducing the timeframe of PCSP implementation to create a timelier process.
17.	Appendix D-1-d	e. How responsibilities are assigned for implementing the plan:	e. How responsibilities are assigned for implementing the plan: …. **If the provider develops a treatment or service plan for the participant, it must be incorporated into the overall PCSP.**	Add language to reinforce that if a participant's rights in a setting need to be modified due to an assessed need it must be documented in the PCSP and if a provider creates a treatment or service plan, that plan must

#	Waiver Section	Current Approved Language	Recommended Revised Language	Reason for the Change
			Any modification of a participant's rights in a setting, under § 441.301(c)(4)(vi)(A) through (D), must be supported by a specific assessed need and justified in the person-centered service plan. The following requirements must be documented in the PCSP: **• Identify a specific and individualized assessed need.** **• Document the positive interventions and supports used prior to any modifications to the person-centered service plan.** **• Document less intrusive methods of meeting the need that have been tried but did not work.** **• Include a clear description of the condition that is directly proportionate to the specific assessed need.** **• Include regular collection and review of data to measure the ongoing effectiveness of the modification.** **• Include established time limits for periodic reviews to determine if the modification is still necessary or can be terminated.** **• Include the informed consent of the individual.** **• Include an assurance that interventions and supports will cause no harm to the individual.**	be incorporated into the PCSP. These items are in response to feedback from CMS during the HCB Settings Final Rule Heightened Scrutiny onsite visits.
18.	Appendix D-1-d, D-2-a	In addition, CHC service coordinators are responsible to use the standardized participant review tool designed by OLTL to capture information on Participants' health, welfare, and service needs in all HCBS settings. The tool also captures information on provider owned and operated residential settings to assist in assessing compliance with the Centers for Medicare and Medicaid Services HCBS regulation found in 42	In addition, CHC service coordinators are responsible to ~~use the standardized participant review tool designed by OLTL to~~ capture information on Participants' health, welfare, and service needs in all HCBS settings. The ~~tool also captures~~ **SC must also capture** information on provider owned and operated residential	Remove this paragraph because service coordinators no longer use the participant review tool – they use the InterRAI and the Person-Centered Planning process.

#	Waiver Section	Current Approved Language	Recommended Revised Language	Reason for the Change
		CFR § 441.301. The overall goal of the tool is to assist SCs in their role of improving the experience of care for participants.	settings to assist in assessing compliance with the Centers for Medicare and Medicaid Services HCBS regulation found in 42 CFR § 441.301. The overall goal of the tool is to assist SCs in their role of improving the experience of care for participants.	
19.	Appendix F-3-c	Individuals calling the OLTL Participant HelpLine with a complaint/grievance are logged into the Enterprise Information System (EIM), a web-based database, and the information is then referred to the appropriate Bureau for resolution.	**When an individual calls** ~~Individuals calling~~ the OLTL Participant HelpLine with a complaint/grievance, **the calls are logged (complaints by the Case Management Unit and grievances into the Enterprise Information System (EIM), a web-based database)** ~~are logged into the Enterprise Information System (EIM), a web-based database,~~ and the information is then referred to the appropriate Bureau for resolution.	To be more specific how complaint/grievances are logged.
20.	Appendix G-1-b	Required reporters must report critical incidents within 48 hours of their occurrence or discovery. OLTL has initiated a mandatory electronic reporting system for reporting all critical incidents. The electronic reporting system, referred to as EIM, allows Direct Service providers to submit critical incidents through a web-based application where they are accessed by Service Coordinators, the CHC-MCOs and OLTL staff.	Required reporters must report critical incidents within 48 hours of their ~~occurrence or~~ discovery. OLTL has initiated a mandatory electronic reporting system for reporting all critical incidents. The electronic reporting system, referred to as EIM, allows ~~Direct Service~~ providers to submit critical incidents through a web-based application where they are accessed by Service Coordinators, the CHC-MCOs and OLTL staff.	Clarify that critical incidents must be reported with 48 hours of discovery.
21.	Appendix G-1-d	OLTL is responsible for reviewing and investigating all allegations of abuse, neglect, or exploitation that identify the CHC-MCO and/or their staff as the alleged perpetrator. OLTL retains the right to review any incident reports, conduct its own investigations and require further corrective actions by the CHC-MCO.	**The Protective Services agency is responsible for reviewing all allegations of abuse, neglect, or exploitation. If the CHC-MCO and/or their staff is identified as the alleged perpetrator, OLTL is responsible for ensuring the incident report is handled appropriately and is reviewed and approved for closure by**	Specify which entity is responsible for reviewing allegations.

#	Waiver Section	Current Approved Language	Recommended Revised Language	Reason for the Change
			OLTL staff. ~~OLTL is responsible for reviewing and investigating all allegations of abuse, neglect, or exploitation that identify the CHC-MCO and/or their staff as the alleged perpetrator.~~ OLTL retains the right to review any incident reports, conduct its own investigations and require further corrective actions by the CHC-MCO.	
22.	Appendix G-1-d	The Service Coordinator has two (2) days to enter initial information into EIM in cases involving sexual abuse, serious injury, serious bodily injury or suspicious death, and thirty (30) days from the initial report to enter all the information regarding the incident into EIM	The Service Coordinator has **48 hours** ~~two (2) days~~ to enter initial information **regarding critical incidents** into EIM ~~in cases involving sexual abuse, serious injury, serious bodily injury or suspicious death~~, and **30 days from discovery of the incident to investigate it and close the incident report in EIM.** ~~thirty (30) days from the initial report to enter all the information regarding the incident into EIM~~	Adjust timeframes for critical incident investigations.
23.	Appendix G-1-d	Investigations that are performed by the CHC-MCOs include, but are not limited to:	Investigations that are performed by the CHC-MCOs **must be initiated within 24 hours of having knowledge of the incident. Investigations** include, but are not limited to:	Timeframe clarification.
24.	Appendix G-1-d	CHC-MCOs are required to: • Take necessary actions to ensure the health and welfare of the participant. … • Provide a report to OLTL within thirty (30) business days of the occurrence. When the CHC-MCO is unable to conclude initial investigation within thirty (30) days, request an extension from OLTL through EIM. In cases investigated involving protective services, the CHC-MCO Service Coordinator works with the protective service	CHC-MCOs are required to: • **Initiate investigation within 24 hours of having knowledge of the incident.** … • **Submit** ~~Provide~~ a report to OLTL within thirty (30) **calendar** ~~business~~ days of the occurrence. When the CHC-MCO is unable to conclude initial investigation within thirty (30)	Timeframe clarification.

#	Waiver Section	Current Approved Language	Recommended Revised Language	Reason for the Change
		worker to ensure the health and welfare of the participant. This may involve revisions to the service plan as necessary, to meet the participant's needs and to mitigate recurrence of the incident.	days, request an extension from OLTL through EIM. In cases investigated ~~involving~~ **by the** protective services **agency,** the CHC-MCO Service Coordinator works with the protective service worker to ensure the health and welfare of the participant. This may involve revisions to the service plan as necessary, to meet the participant's needs and to mitigate recurrence of the incident.	
25.	Appendix G-1-d	The timeframes for conducting an investigation and completing an investigation. The investigation of all critical incidents must be completed within thirty (30) days of receiving the incident report. If the timeframe is not met, the details regarding the delay will be documented in EIM. The MCO will monitor any investigative process that is taking beyond the allotted time for completion.	The timeframes for conducting an investigation and completing an investigation. **Investigations must be initiated within 24 hours of the incident being reported.** ~~The~~ **I**~~i~~nvestigation**s** of all critical incidents must be completed within thirty (30) days of receiving the incident report. If the timeframe is not met, the details regarding the delay will be documented in EIM. The MCO will monitor any investigative process that is taking beyond the allotted time for completion.	Timeframe clarification.
26.	Appendix G-1-e	Additional agencies have responsibilities for oversight on reports of abuse. The Department of Aging is responsible for administering protective services for the over 60 population; the Department of Human Services' Adult Protective Services Office handles protective services for the 18-60 disability population	Additional agencies have responsibilities for oversight on reports of abuse. The Department of Aging is responsible for administering protective services for the ~~over~~ 60 **and older** population; the Department of Human Services' Adult Protective Services Office handles protective services for the 18-**59**~~60~~ disability population	Age clarification.
27.	Appendix G-3-c-ii	Medication Administration by Unlicensed Residential Habilitation Providers:	Medication Administration by Unlicensed Residential Habilitation Providers:	The bulletin is already incorporated into the waiver.

#	Waiver Section	Current Approved Language	Recommended Revised Language	Reason for the Change
		Unlicensed Residential Habilitation providers are required to follow- OLTL's "Medication Management Policy for Unlicensed Providers Bulletin", which clarifies when a participant is expected to self-administer, receive assistance with medication administration, and the training required for provider staff to administer medication. … Medication Administration Training (b) The OLTL-approved medications administration course refers to the Department of Human Services Office of Developmental Program's training program. Information on this training program is found by calling 1-800-438-1958 or by going to: https://medsadmin.tiu11.org/cms/	~~Unlicensed Residential Habilitation providers are required to follow- OLTL's "Medication Management Policy for Unlicensed Providers Bulletin", which clarifies when a participant is expected to self-administer, receive assistance with medication administration, and the training required for provider staff to administer medication.~~ … Medication Administration Training (b) The OLTL-approved medications administration course refers to the Department of Human Services Office of Developmental Program's training program. Information on this training program is found by calling ~~1-800-438-1958~~ **717-221-1630** or by going to: ~~https://medsadmin.tiu11.org/cms/~~ **https://medadmin.myodp.org/**	Update contact information for the Medication Administration training.
28.	Appendix H-1-a-i System Improvements	CHC-MCOs are also required to annually administer the HCBS CAHPS Survey to gather feedback on HCBS participants' experience receiving long-term services and supports. CHC-MCOs will administer the most current version of the instruments and report survey results to DHS/OLTL as required under the CHC agreement. This includes using the Supplemental Employment Module specifically designed to be used alongside the HCBS CAHPS Survey tool as well as Pennsylvania specific questions designated by OLTL that relate to service plan, transportation, housing, and preventative health care. In 2018, each individual CHC-MCO will survey a random sample that generates a targeted number of complete surveys. Starting in 2019, the CHC-MCO will select a statistically valid random sample based on a 95% Confidence Level, ± 5% Confidence Interval, and a 50% Distribution, proportioned by region.	CHC-MCOs are also required to annually administer the **Consumer Assessment of Healthcare Providers and Systems (CAHPS)**~~HCBS CAHPS~~ Survey to gather feedback on HCBS participants' experience receiving long-term services and supports. CHC-MCOs will administer the most current version of the instruments and report survey results to DHS/OLTL as required under the CHC agreement. This includes using the Supplemental Employment Module specifically designed to be used alongside theCAHPS Survey tool as well as Pennsylvania specific questions designated by OLTL that relate to **person-**	Update quality strategy to current practice.

#	Waiver Section	Current Approved Language	Recommended Revised Language	Reason for the Change
		… OLTL has designed an approach in oversight and monitoring of the CHC program. This includes a comprehensive statewide Medical Assistance Quality Strategy for Pennsylvania, which outlines a number of key components on how OLTL will ensure quality assurance that will help identify system improvements for CHC to include: readiness review, early implementation and ongoing monitoring. … • Performance measures using indicators established by the Center for Medicare and Medicaid Service (CMS) and various national organizations: o Healthcare Effectiveness Data and Information Set (HEDIS) o CMS Medicaid Adult Core Measures … In order to prioritize quality management issues, BQAPA has assigned each of the five waiver assurances to a quality management (QM) liaison to review various quality reports through tracking and trending and determine possible causes of aberrant data or compliance issues. Quality data is gathered for performance measures from numerous sources, including OLTL discovery and remediation activities, on-site monitoring by the OLTL, as well as internal OLTL activities/reporting. This information is aggregated for tracking and trending. The QM liaison makes initial recommendations and prioritizes issues for problem-solving or corrective measures. The QM liaison reviews and responds to aggregated, analyzed discovery and remediation information collected on each of the assurances, and makes initial recommendations and prioritizes issues for problem-solving or corrective measures. In addition to trending and analyzing, this structure allows BQAPA to review for possible internal OLTL systemic changes and to identify possible program training or technical assistance needs.	**centered** service plan, transportation, housing, **dental, supplemental nutrition assistance program, survey assistance and mental health.** ~~and preventative health care. In 2018, each individual CHC-MCO will survey a random sample that generates a targeted number of complete surveys. Starting in 2019, the CHC-MCO will select a statistically valid random sample based on a 95% Confidence Level, ± 5% Confidence Interval, and a 50% Distribution, proportioned by region.~~ … OLTL has designed an approach in oversight and monitoring of the CHC program. This includes a comprehensive statewide Medical Assistance **and Children's Health Insurance Program Managed Care** Quality Strategy for Pennsylvania, which outlines a number of key components on how OLTL will ensure quality assurance that will help identify system improvements for CHC to include: readiness review, early implementation and ongoing monitoring. … • Performance measures using indicators established by the Center for Medicare and Medicaid Service (CMS) and various national organizations: o Healthcare Effectiveness Data and Information Set (HEDIS) ~~o CMS Medicaid Adult Core Measures~~	

#	Waiver Section	Current Approved Language	Recommended Revised Language	Reason for the Change
		BQAPA internally reviews the assessments made by the QM liaison. For those issues that are considered critical by the QM liaison, an expedited process of review is implemented by working closely with other OLTL bureaus. The QMU summarizes the list of priorities and recommendations in a monthly report to present at the monthly QM2 meetings, which are attended by key personnel from all OLTL bureaus. The comments from the quality meetings are considered and included in a revised report for discussion with the MCOs during weekly update meetings. OLTL Bureau Directors will collectively submit final recommendations as to any action needed for system improvements to the Deputy Secretary of OLTL. The implemented system improvements return to the quality cycle through monitoring and remediation.	… ~~In order to prioritize quality management issues, BQAPA has assigned each of the five waiver assurances to a quality management (QM) liaison to review various quality reports through tracking and trending and determine possible causes of aberrant data or compliance issues. Quality data is gathered for performance measures from numerous sources, including OLTL discovery and remediation activities, on-site monitoring by the OLTL, as well as internal OLTL activities/reporting. This information is aggregated for tracking and trending. The QM liaison makes initial recommendations and prioritizes issues for problem-solving or corrective measures. The QM liaison reviews and responds to aggregated, analyzed discovery and remediation information collected on each of the assurances, and makes initial recommendations and prioritizes issues for problem-solving or corrective measures. In addition to trending and analyzing, this structure allows BQAPA to review for possible internal OLTL systemic changes and to identify possible program training or technical assistance needs.~~ ~~BQAPA internally reviews the assessments made by the QM liaison. For those issues that are considered critical by the QM liaison, an expedited process of review is implemented by working closely with other OLTL bureaus. The QMU summarizes the list of priorities and~~	

#	Waiver Section	Current Approved Language	Recommended Revised Language	Reason for the Change
			~~recommendations in a monthly report to present at the monthly QM2 meetings, which are attended by key personnel from all OLTL bureaus. The comments from the quality meetings are considered and included in a revised report for discussion with the MCOs during weekly update meetings. OLTL Bureau Directors will collectively submit final recommendations as to any action needed for system improvements to the Deputy Secretary of OLTL. The implemented system improvements return to the quality cycle through monitoring and remediation.~~ **To prioritize quality management issues, BQAPA works with consultants and Subject Matter Experts (SMEs) on the waiver assurances and performance measures. The SMEs review various quality reports, tracking and trending possible causes of irregular data or compliance issues. Performance measure data is gathered from various sources, including OLTL discovery and remediation activities, on-site monitoring by OLTL, as well as internal OLTL activities/reporting. The SMEs prioritize issues for problem-solving and/or identify corrective measures. This process allows BQAPA along with consultants and SMEs to identify possible program training or technical**	

#	Waiver Section	Current Approved Language	Recommended Revised Language	Reason for the Change
			assistance needs, recognize trending, and identify internal systematic changes. **BQAPA, along with consultants, reviews the assessments made by the SMEs. When issues are identified, the SMEs ensure the CHC-MCOs develop remediation efforts, and quality improvement projects, as necessary. Issues are discussed with the individual CHC-MCOs at weekly and monthly contract meetings.**	
29.	Appendix H-1-b-i System Design Changes	CHC will be implemented starting in January 2018. OLTL plans to meet regularly with CHC-MCOs to discuss operations issues and to apprise the CHC-MCOs of administrative changes and updates that may have an impact on service delivery. In addition, our intent will be to mirror the existing HealthChoices program and implement a Quarterly Quality Review Meeting (QQRM)to ensure that there are devoted meetings with each individual MCO – to discuss key quality indicators, best practices and areas for improvements. The basis of these meetings will be an open, creative, collaborative dialogue with OLTL and the CHC-MCOs with an emphasis on quality outcomes.	~~CHC will be implemented starting in January 2018.~~ OLTL ~~plans to meet regularly~~ **meets** with CHC-MCOs to discuss operations issues and to apprise the CHC-MCOs of administrative changes and updates that may have an impact on service delivery. ~~In addition, our intent will be to mirror the existing HealthChoices program and implement~~ **OLTL hosts** a Quarterly Quality Review Meeting (QQRM)to ensure that there are devoted meetings with **the** ~~each individual~~ **CHC-**MCO**s** – to discuss key quality indicators, best practices and areas for improvements. The basis of these meetings will be an open, creative, collaborative dialogue with OLTL and the CHC-MCOs with an emphasis on quality outcomes.	Update quality strategy to current practice.
30.	Appendix H-1-b-ii System Design Changes	The OLTL Division of Quality Assurance meets formally with the SMEs for all EBR performance measures every six months to review the data and remediation efforts. Trends are identified and strategies established to improve the quality of waiver services. Informal discussions are also held throughout the year	~~The OLTL Division of Quality Assurance meets formally with the SMEs for all EBR performance measures every six months to review the data and remediation efforts.~~ **The OLTL Division of Quality**	Update quality strategy to current practice.

#	Waiver Section	Current Approved Language	Recommended Revised Language	Reason for the Change
		to discuss data trends, quality improvement projects, corrective action plans and remediation efforts.	**Assurance works with consultants and the waiver performance measure Subject Matter Experts (SMEs) for the CHC Waiver Evidentiary Based Report (EBR) throughout the year to review the data and remediation efforts.** Trends are identified and strategies established to improve the quality of waiver services. Informal discussions are also held throughout the year to discuss data trends, quality improvement projects, corrective action plans and remediation efforts.	
31.	Appendix I-3-g-ii	a. Service Coordination agencies may provide those services outlined in Appendix D-1-b and D-2-b through an OHCDS only during the 180-day continuity of care period for each implementation phase. Such requests are reviewed and approved by OLTL and the CHC-MCO prior to any service provided through the OHCDS arrangement. This arrangement is expected to end no later than June 30, 2020. b. Providers who are not affiliated with an OHCDS must enroll in the Pennsylvania Medical Assistance program and seek inclusion in the CHC-MCO's provider network. c. As described in Appendix D-1-b and D-2-b, individuals are fully informed of their right to choose from any qualified provider that is part of the CHC-MCO's provider network, and are not required to utilize the OHCDS arrangement. As noted above, providers who are not affiliated with an OHCDS must enroll in the Pennsylvania Medical Assistance program and seek inclusion in the CHC-MCO's provider network. d. Through provider/SC oversight and monitoring, as well as through information garnered through service plan and encounter data, the CHC-MCOs monitor services provided through an OHCDS to ensure that the OHCDS has contracted only with providers meeting established qualifications. e. Through these oversight mechanisms, OLTL will also ensure that the arrangements meet State and Federal requirements. f. The full amount of service dollars is passed through for the provision of service.	~~a. Service Coordination agencies may provide those services outlined in Appendix D-1-b and D-2-b through an OHCDS only during the 180-day continuity of care period for each implementation phase. Such requests are reviewed and approved by OLTL and the CHC-MCO prior to any service provided through the OHCDS arrangement. This arrangement is expected to end no later than June 30, 2020.~~ ~~b. Providers who are not affiliated with an OHCDS must enroll in the Pennsylvania Medical Assistance program and seek inclusion in the CHC-MCO's provider network.~~ ~~c. As described in Appendix D-1-b and D-2-b, individuals are fully informed of their right to choose from any qualified provider that is part of the CHC-MCO's provider network, and are not required to utilize the OHCDS arrangement. As noted above, providers who are not affiliated with an OHCDS must enroll in the Pennsylvania Medical Assistance~~	OHCDS was permitted in CHC until the end of the 180-day continuity of care period after the last implementation date. This provision expired June 30, 2020.

#	Waiver Section	Current Approved Language	Recommended Revised Language	Reason for the Change
		g. The State assures financial accountability when an OHCDS arrangement is used by monitoring individual service plans and claims paid to the OHCDS entities through the provider and SC monitoring processes performed by the CHC-MCOs. The state ensures that the payment to the OHCDS does not result in excessive payments through the established process of paying only the cost of the service or good provided.	~~program and seek inclusion in the CHC-MCO's provider network.~~ ~~d. Through provider/SC oversight and monitoring, as well as through information garnered through service plan and encounter data, the CHC-MCOs monitor services provided through an OHCDS to ensure that the OHCDS has contracted only with providers meeting established qualifications.~~ ~~e. Through these oversight mechanisms, OLTL will also ensure that the arrangements meet State and Federal requirements.~~ ~~f. The full amount of service dollars is passed through for the provision of service.~~ ~~g. The State assures financial accountability when an OHCDS arrangement is used by monitoring individual service plans and claims paid to the OHCDS entities through the provider and SC monitoring processes performed by the CHC-MCOs. The state ensures that the payment to the OHCDS does not result in excessive payments through the established process of paying only the cost of the service or good provided.~~	

PENNSYLVANIA HOMECARE ASSOCIATION

July 14, 2024

Juliet Marsala, Deputy Secretary
Office of Long-Term Living
555 Walnut Street, 6th Floor
Harrisburg, PA 17101

Dear Deputy Secretary Marsala:

The Pennsylvania Homecare Association (PHA) is a non-profit trade association representing more than 700 home health, home care (personal care), and hospice providers across the state of Pennsylvania. The association's mission is to support the provider community in the effort to bring care home. Home is the most preferred and cost-effective setting for care as we age. We appreciate this opportunity to provide feedback and commentary on the recently released Waiver Amendment for OBRA and Waiver Renewal for Community HealthChoices. Our hope is to be a thought partner and collaborator to the Department in our shared goal to bring care home.

Appendix C-2-B: Clearances for workers and providers when providing services in homes where children reside

While we wholeheartedly support measures to protect vulnerable populations, including children, we believe that expanding the requirements as indicated would have significant unintended consequences for our industry. The current proposal expands applicability from a when a child "resides" in a home to when a child is "present" in a home.

Clarification of "Presence" vs. "Residence" of a Child

We believe it is essential to better define the distinction between having a child "present" in a home versus a child "residing" in a home within the context of child abuse clearance requirements. The current ambiguity in these definitions can lead to inconsistent application of the rules and unnecessary burdens on homecare providers.

A child "present" in a home implies a temporary and possibly infrequent situation, such as visiting grandchildren or neighborhood children who may ring the client's doorbell and come in for a glass of water while a caregiver happens to be in the home. In contrast, a child "residing" in a home indicates a more permanent and consistent living arrangement, such as children who live in the home full-time with the recipient.

Without clear definitions, providers are likely to obtain child abuse clearances in situations where it is not practically necessary. This could result in a significant increase in the number of

clearances needed, causing delays in processing times and additional costs for providers without a corresponding increase in child safety.

Delays in Hiring and Its Impact on Access to Care

One of the primary concerns is a delay in the hiring process. Currently, obtaining child abuse clearances and FBI fingerprints is a multi-step process that can take weeks to complete. Consider the following challenges to this process:

1. Fingerprinting locations in rural areas can be upwards of 20 miles from a Direct Care Worker and result in expenditures on gas and travel to get there.
2. Many fingerprinting sites have multi-week wait times for appointment availability.
3. Fingerprint results are often sent to the home of the worker resulting in an exchange of information with the provider that further delays hiring and starts of care, especially for populations where availability of technology is limited.
4. Expanding these requirements to include all homecare providers serving a home where a child is present would exponentially increase the volume of clearance requests, thereby straining the existing system and causing further delays.
5. Child abuse clearance do not allow for provisional hiring, resulting in delays for hiring and delayed access to care for individuals where a child may be present in the home.

The homecare industry is already experiencing a workforce shortage, and any additional delays in the hiring process would exacerbate this issue. Delays in hiring not only impact our ability to provide timely care but also place additional stress on existing staff, who must cover for the vacancies. This could potentially compromise the quality of care provided to our clients, many of whom are elderly or have disabilities and rely on consistent and dependable support.

Additional Costs for Providers

Expanding the requirements for child abuse clearances would also result in significant additional costs for homecare providers. The fees associated with obtaining these clearances, along with the administrative burden of managing the clearance process, would place a financial strain on many providers, particularly smaller agencies operating on tight budgets. If this language persists, providers could be facing the below background checking costs for the majority of their workforce, a significant strain on resources and finances in an industry with a higher than average turnover rate:

1.	Criminal Background Check (e-patch):	$22
2.	Child Abuse Clearance:	$13
3.	FBI Fingerprint – Office of Children and Youth:	$25.25
4.	FBI Fingerprint – Department of Aging:	$25.25
5.	TB Testing	$50 (estimated)
6.	Medicaid Fraud Checks (annual cost for monthly)	$20 (estimated Clearing House Expense)
		$95.50

Furthermore, the cumulative costs of compliance, including the need for additional administrative staff to handle the increased volume of clearances, would divert resources away from direct client care. This could lead to higher service costs for consumers or force some providers to reduce the range or quality of services offered.

Recommendations

We recommend considering alternative approaches to achieve the goal of protecting vulnerable populations without imposing undue burdens on providers. These could include:

1. **Define "Present" for Clear Applicability:**

   A child is considered "present in the home" if there is a significant likelihood that a child would be physically on the premises for:

   - Regular visits that are common, predetermined, or known to occur by the participant and/or a representative
   - Occasional stays such as weekends, holidays, or school vacations where the child spends time on premises
   - A child resides in the home

2. **Require Determination in Person Centered Support Plan**

   To ensure consistency of applicability across all providers and models of care, we recommend that the presence of children in the home be determined and documented during the PCSP development. This would ensure clear applicability and a regular review (at minimum annual) to ensure that the topic is revisited regularly to reflect changes in the recipient's home environment. Providers would then consistently use the PCSP to indicate if clearances are required for that participant.

3. **Streamlined Processing**: Investing in technology and resources to streamline the clearance process, thereby reducing the time and administrative burden associated with obtaining clearances. This would include easier enrollments online (with clear indicators for type of FBI fingerprint) AND investing in additional IDEMIA locations, with an emphasis on rural locations.

4. **Financial Support**: If the language proceeds, we recommend:

   1. Funding background checks directly to providers AND/OR
   2. Including the cost of required background checks in rate setting methodologies, specifically in the current study being conducted by Mercer on behalf of the Office of Long-Term Living.

Appendix C-1/C-3: Service Specifications Chore Services

We would like to commend the recent addition of chore services as a benefit for recipients of the waiver. This thoughtful enhancement reflects a deep understanding of the diverse needs of those we serve. Chore services are crucial for maintaining a safe and healthy living environment, especially for individuals who struggle with home environments that are a health risk to themselves or their support staff due to physical, cognitive or financial limitations.

Provider Network Adequacy

However, we caution that this service may be challenging to utilize due to the lack of an Organized Health Care Delivery Service (OHCDS) option in the waiver. Commercial cleaning organizations are not accustomed to the administrative requirements of becoming and maintaining Medicaid Provider status. Furthermore, their cost structure is such that jobs are typically individually quoted to account for the size and severity of the project. Fee schedules, revalidations, Medicaid fraud checks for all staff, OLTL training for all staff and other administrative obstacles may create barriers to provider network adequacy for this critical service.

Recommendation

We recommend that OLTL create specific requirements for approval as a Chore Service provider so that current Medicaid Providers can consider adding this service to their current offerings. We feel that this approach would yield improved provider network adequacy and continuity of care for participants

Appendix D-1-d: Service Plan Development Process

We would like to commend the effort to drive efficiency in the development and delivery of the Person Centered Service Plan. Access to care is an important foundation of quality services, positive patient outcomes, and prevention of more costly care interventions.

Supports Coordination/Case Management Adequacy

Supports Coordinators and Case Managers play an important role in the development a Person Centered Service Plans and their distribution to the provider network. However, PHA and its members have frequently seen delays due to turnover in these critical positions, as well as high case loads that makes management of these tasks challenging.

Recommendation

The PHA recommends that the Department initiate a task force to identify the top challenges facing Supports Coordinators and Case Managers today in Pennsylvania so that this task force can compile recommendations on how to support this critical function better in the future. This may include consideration of caseloads, purpose of the role, reimbursement for the position, and technology/infrastructure needs to drive more efficient processes that can scale with our aging population.

Also, please keep in mind that while PCSPs may be completed in a shorter time frame, the above referenced expansion of the child abuse clearance language could result in significant delays to starting care, despite the shorter timeframe of PCSP completion.

Appendix H-1-a-i System Improvements

PHA supports the use and administration of the Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey. We recommend that survey results be transparent and shared with all provider communities on an ongoing basis, with the ability for individual providers to capture their organization specific results, if possible. We also would welcome the opportunity to discuss consumer survey opportunities administered by the association, or in collaboration with the association, that can support feedback in writing, via phone, or via text message.

Participant Direction

The CHC waiver renewal makes no changes to the descriptions and policies of participant-directed services. However, we note the significant increase in projected participants within the program. Such a dramatic increase would require policy and programmatic changes. PHA requests Department transparency and the opportunity for input in any programmatic changes influencing these projections.

Support for All Models of Care

The Pennsylvania Homecare Association advocates for choice in all aspects of participant care. Participants should have a right to a robust provider network, as well as a right to choose the model of care that they would like to receive their services through. However, the association has concerns that recent efforts to promote participant-direction conflict with the intended differences in how each model of care is administered and it thus threatens the foundation on which each model was built. If a model of care does not experience an increase in participant utilization, programmatic changes should consider addressing specific concerns within the existing model rather than to create an environment that disadvantages another model of care to rectify utilization in the other. In doing so, the Department could inadvertently and indirectly threaten choice.

PHA supports all efforts to improve quality within participant direction and the agency models of care and would appreciate the opportunity to further collaborate on how all models of care can be properly supported to drive choice, quality and utilization.

Workforce Development

PHA is disappointed that these changes to the Waiver do not address workforce development needs within the Commonwealth. Specifically, we would like to see the following considered for inclusion in the Waiver language:

1. Immediate rate increases for Personal Assistance Services, Respite Services and Nursing services to support the attraction of qualified staff and to meet the growing needs of this participant population.
2. Reimbursement rate study/reviews that occur regularly, but no less than every three years. Studies should encompass a robust market analysis across all regions

and industries, taking into account inflationary pressures. Rate considerations should align to state policy goals, such as promoting community-based care over institutional care, improving patient outcomes, and improvements in quality. Higher reimbursement rates not only elevate the pay for our critical Direct Care Workforce, but it support professionalism of the industry and advancement in participant quality of care and participant protections.

3. Grant opportunities for organizations, such as PHA, to pilot workforce job quality enhancements

The Pennsylvania Homecare Association and its provider organizations appreciate the opportunity for comment on these important Waiver changes. We would be honored to collaborate on any initiatives discussed herein in the coming month. Please do not hesitate to call on us for support.

Sincerely,

Mia Haney, CEO
Pennsylvania Homecare Association
MHaney@pahomcare.org

pennsylvania
DEPARTMENT OF HUMAN SERVICES

The Office of Long-Term Living Data Dashboard

Data for June 2024

Reported in July 2024

Table of Contents:

Acronym Guide:

- AHC—Amerihealth Caritas
- CHC—Community HealthChoices
- D-SNP—Dual Special Needs Plan
- FFS—Fee-for-Service
- HCBS—Home and Community-Based Services
- KF—Keystone First
- LC—Lehigh/Capital
- LIFE— Living Independence for the Elderly
- LTC—Long-Term Care
- LTSS—Long-Term Services and Supports
- MCO—Managed Care Organization
- NE—Northeast
- NFI—Nursing Facility Ineligible
- NW—Northwest
- OBRA—Omnibus Budget Reconciliation Act
- PAS—Personal Assistance Services
- PHW—PA Health & Wellness
- SE—Southeast
- SW—Southwest
- UPMC—University of Pittsburgh Medical Center

Contact Info:

Questions regarding this data brief can be directed to:

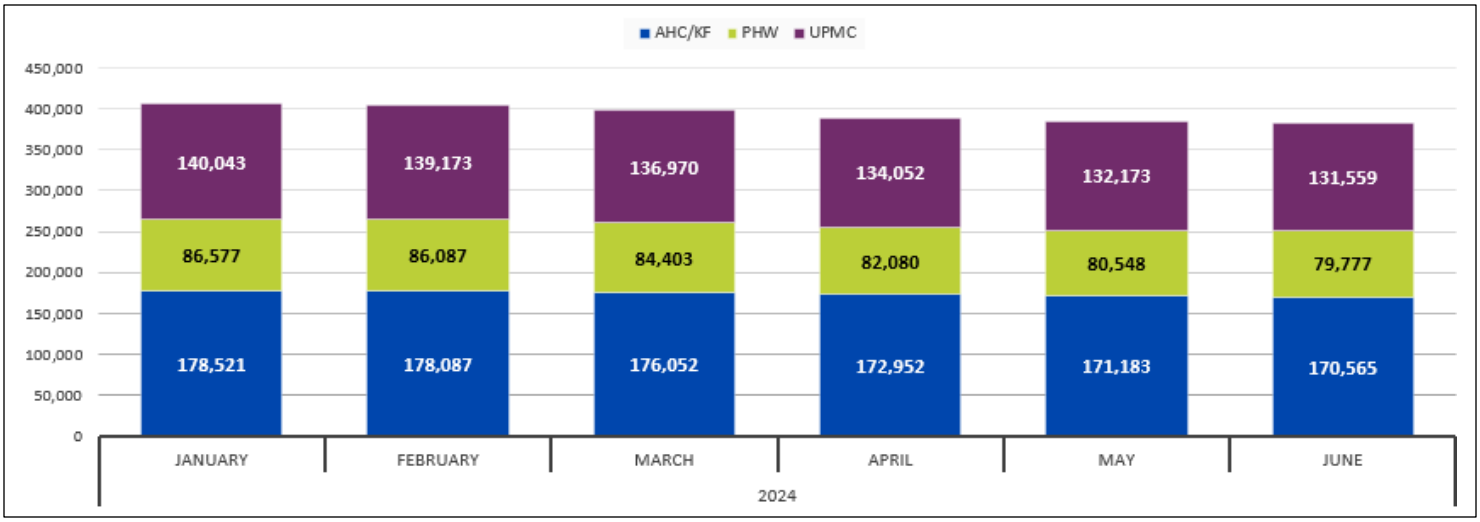
The Office of Long-Term Living
Abigail Coleman
Director, Division of Program Analytics
abcoleman@pa.gov

pennsylvania
DEPARTMENT OF HUMAN SERVICES

Total CHC Enrollment ↓	Total CHC HCBS Enrollment ↑	Total CHC LTC Enrollment ↑
381,901	132,561	42,057

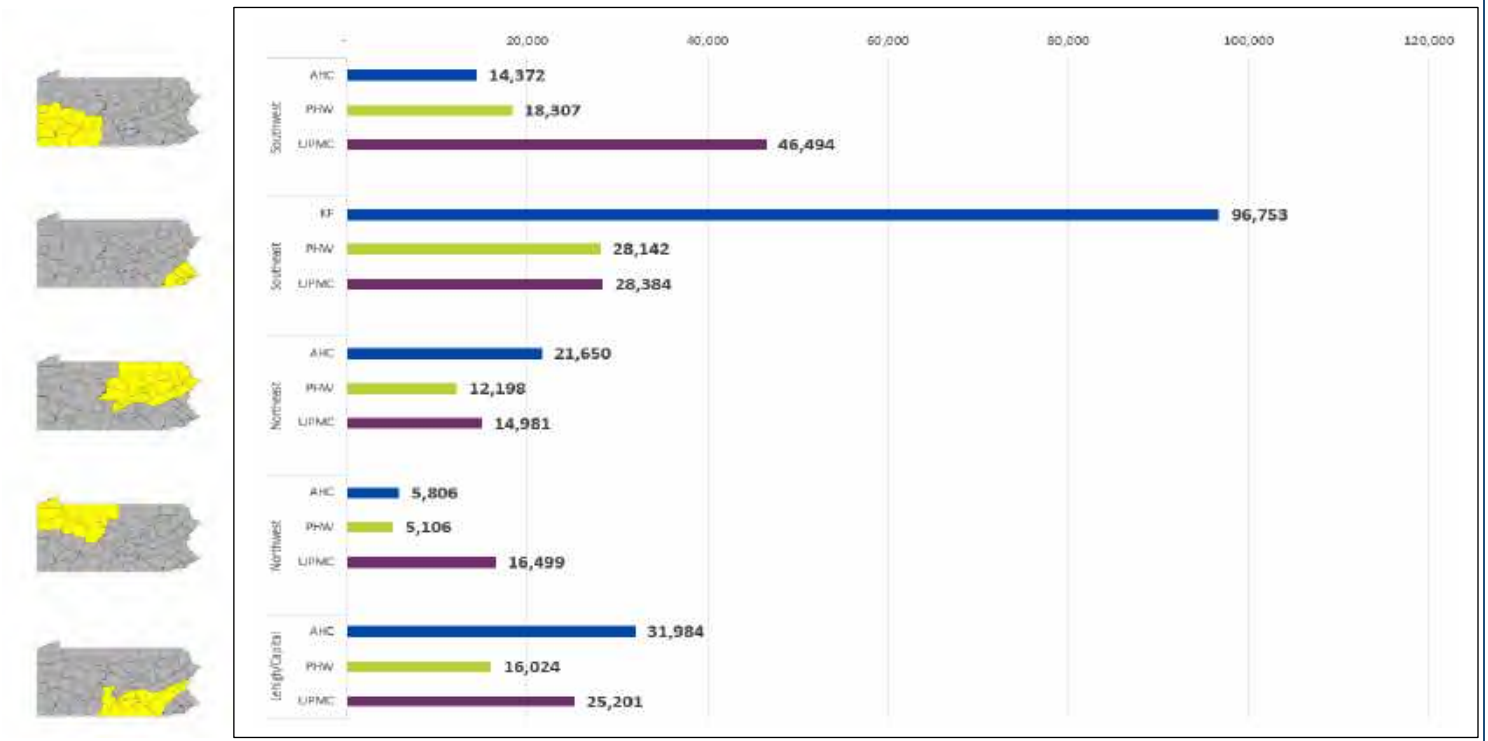
CHC Statewide Enrollments Trends by MCO

Data Period: June 2024



Total CHC enrollment as of June 2024 is 381,901 down from 383,904 in May 2024. Waiver growth continues an upward trend. The nursing facility enrollments saw an increase this month.

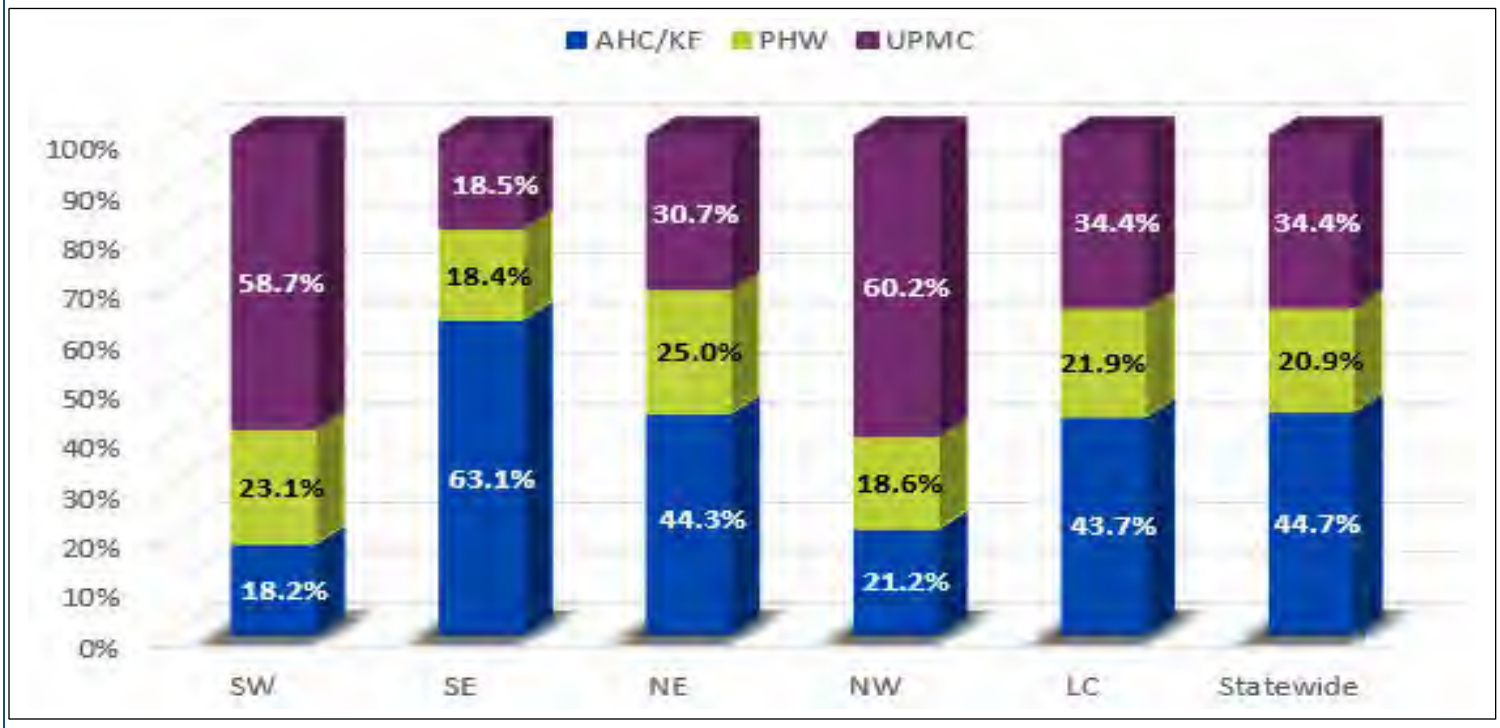
CHC Monthly Enrollment by Zone and MCO



Data period: June 2024

CHC Market Share Chart

Data Period: June 2024



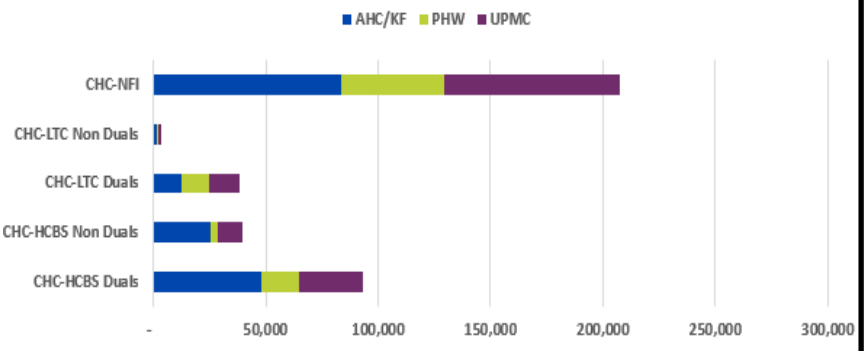
Due to rounding percentages may not sum to 100%

The graphic below reflects the changes from May's market share by MCO to June's market share by MCO. **All fluctuations are 0.5% or less.**

CHC May to June Market Share Changes

	AHC/KF	PHW	UPMC
SW	↔	↓	↑
SE	↔	↓	↔
NE	↓	↔	↔
NW	↔	↓	↑
LC	↑	↓	↔
State	↑	↓	↔

CHC Market Share by Population Group



	CHC-HCBS Duals	CHC-HCBS Non Duals	CHC-LTC Duals	CHC-LTC Non Duals	CHC-NFI
AHC/KF	48,019	25,459	12,398	1,358	83,331
PHW	16,921	3,512	12,508	1,066	45,770
UPMC	28,302	10,348	13,485	1,242	78,182
Statewide	93,242	39,319	38,391	3,666	207,283

The NFI population continues to account for the majority of the population at 54.3%, this was a decrease since May. The percentage of HCBS participants increased from 34.3% to 34.7%. The LTC population increased from 10.9% to 11.0%.

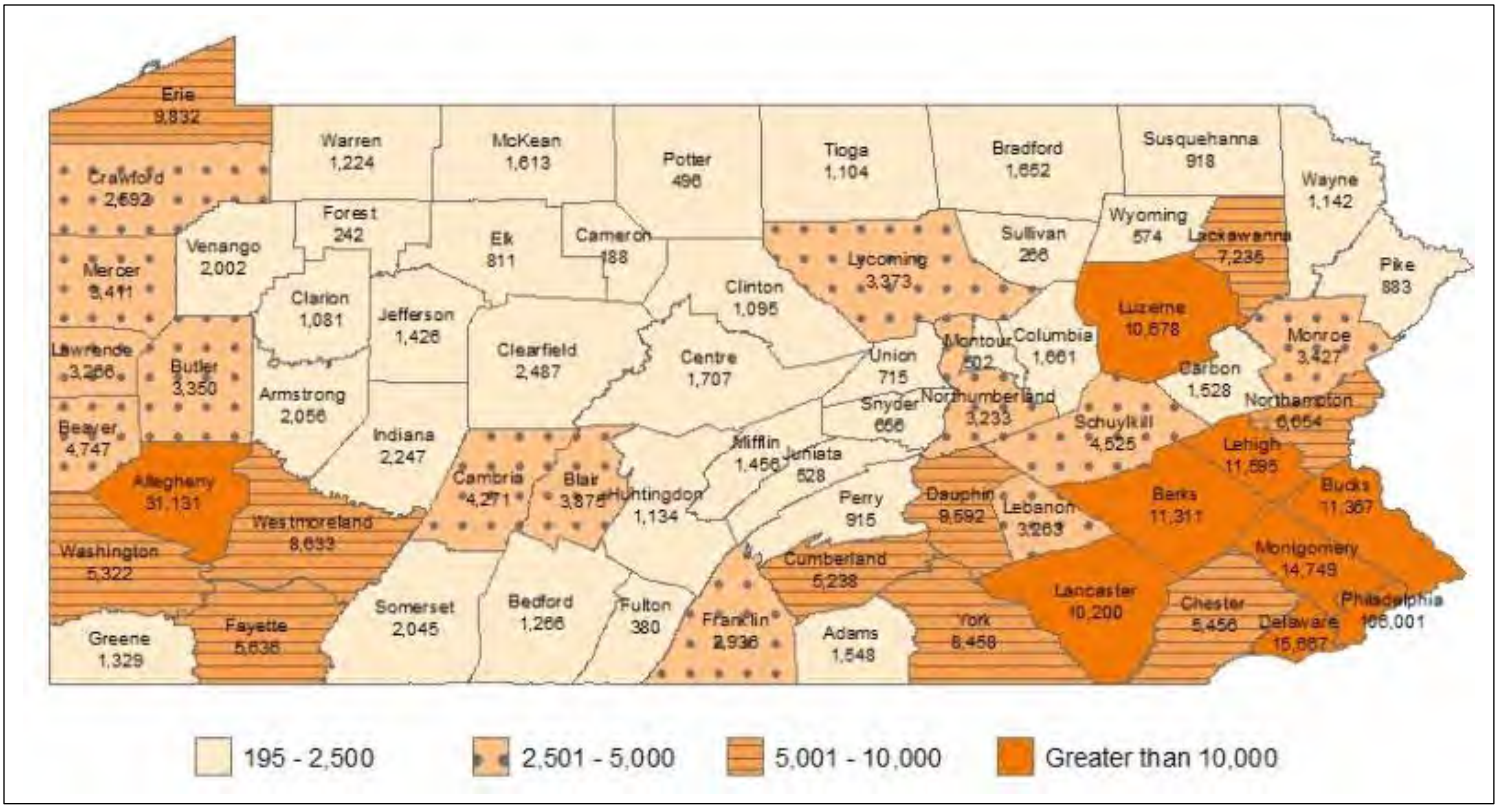
Due to rounding percentages may not sum to 100%

Data Period: June 2024

CHC Enrollments by County[1,2]

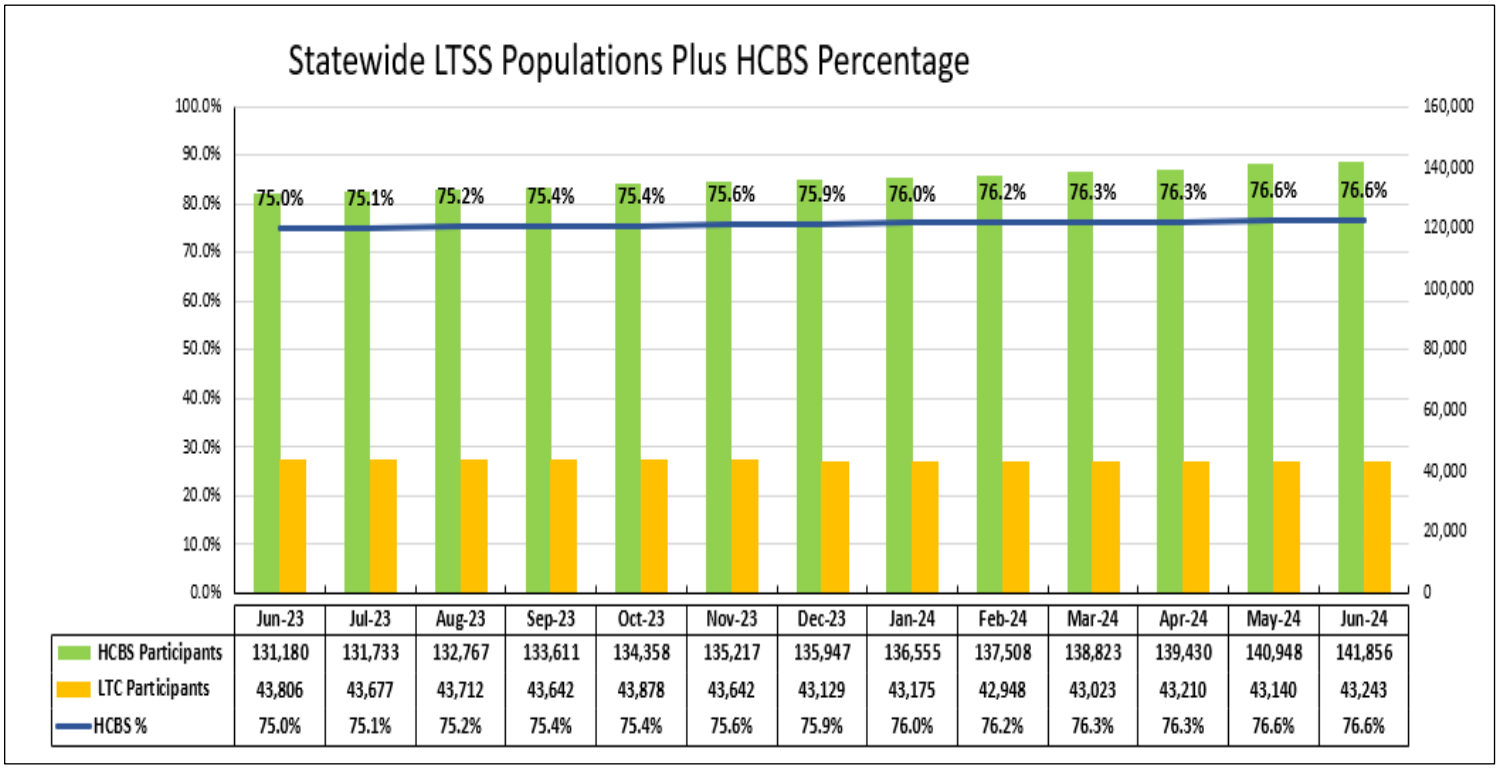
Data Period: June 2024

pennsylvania
DEPARTMENT OF HUMAN SERVICES



1. If a participant is in a nursing facility and has a home outside of the nursing facility, the participant is counted in the county of the nursing facility
2. Further breakouts can be found in Appendix A: CHC Enrollment Breakouts

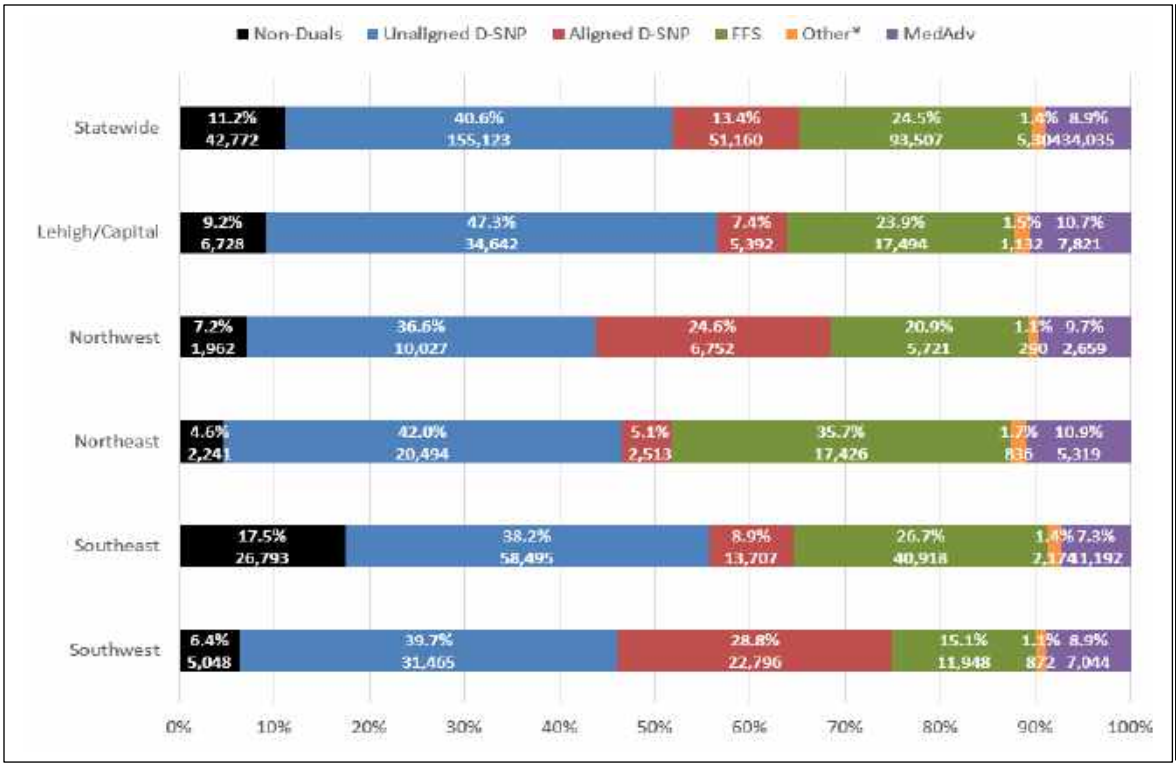
Statewide LTSS Populations Plus HCBS Percentage



	Jun-23	Jul-23	Aug-23	Sep-23	Oct-23	Nov-23	Dec-23	Jan-24	Feb-24	Mar-24	Apr-24	May-24	Jun-24
HCBS Participants	131,180	131,733	132,767	133,611	134,358	135,217	135,947	136,555	137,508	138,823	139,430	140,948	141,856
LTC Participants	43,806	43,677	43,712	43,642	43,878	43,642	43,129	43,175	42,948	43,023	43,210	43,140	43,243
HCBS %	75.0%	75.1%	75.2%	75.4%	75.4%	75.6%	75.9%	76.0%	76.2%	76.3%	76.3%	76.6%	76.6%

Data Period: June 2024

Medicare Type for All CHC Participants by Region**

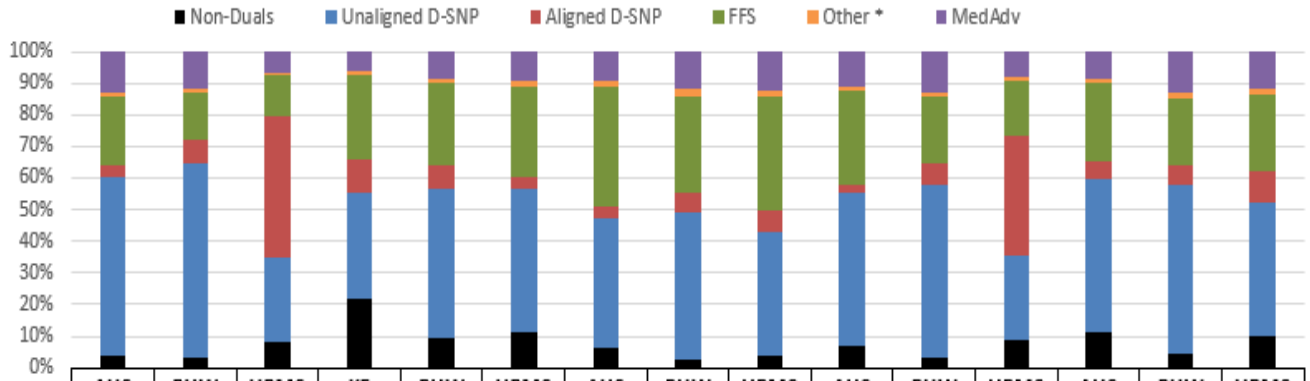


In June, the statewide percentage of non-duals increased from 11.1% to 11.2%. The percentage of participants in aligned D-SNPs increased from 13.2% to 13.4%, and the percentage of participants in unaligned D-SNPs increased from 40.3% to 40.6%. The percentage of participants in FFS Medicare decreased from 24.8% to 24.5%. Other Medicare Advantage decreased from 9.1% to 8.9%.

** Includes records where Medicare Eligibility or Medicare Type couldn't be confirmed* ***Due to rounding percentages may not sum to 100%*

Data Period: June 2024

Medicare Type by CHC Zone and Plan

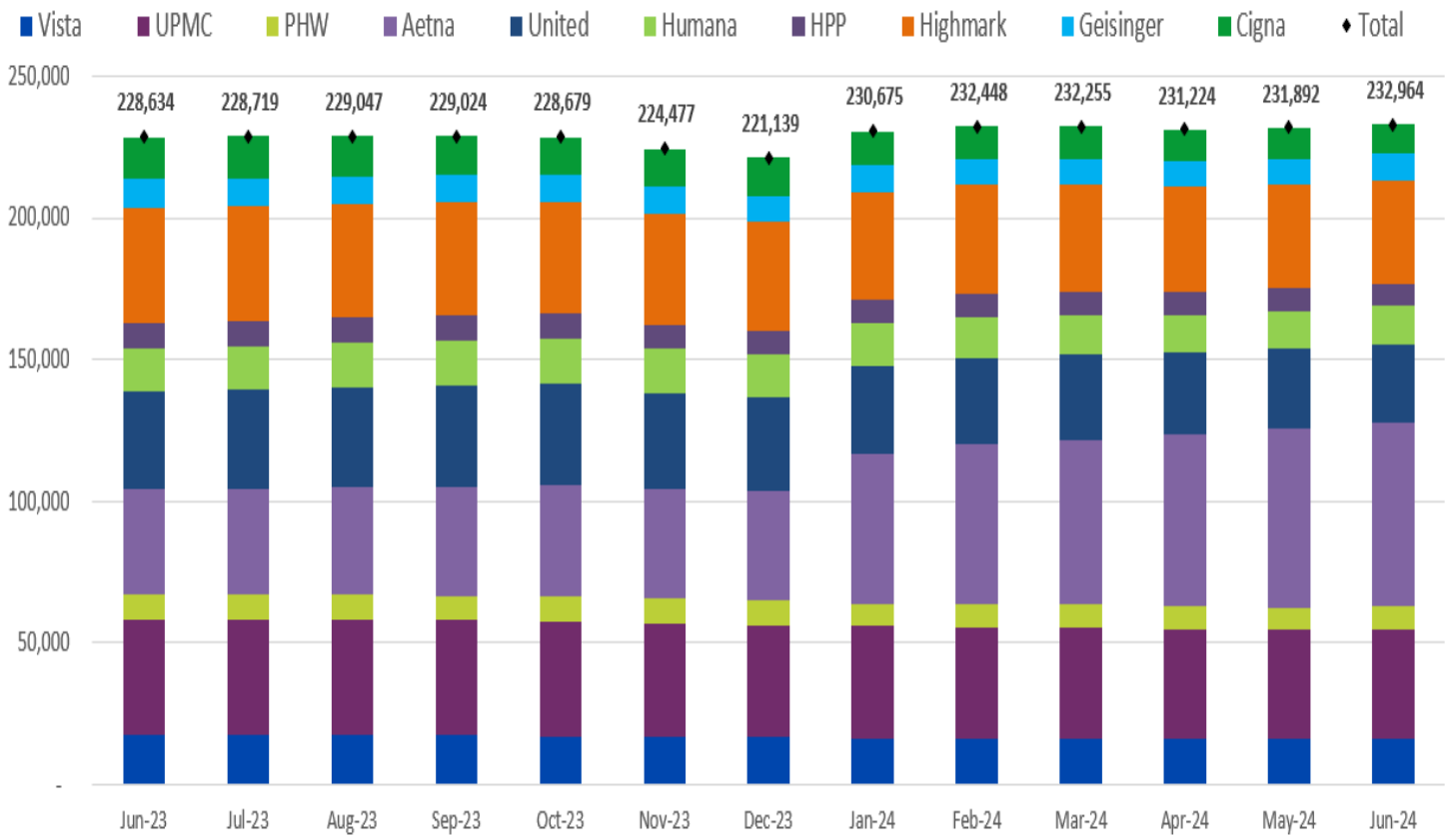


	Southwest			Southeast			Northeast			Northwest			Lehigh/Capital		
	AHC	PHW	UPMC	KF	PHW	UPMC	AHC	PHW	UPMC	AHC	PHW	UPMC	AHC	PHW	UPMC
MedAdv	1,857	2,157	3,030	6,117	2,356	2,719	2,010	1,458	1,851	640	654	1,365	2,746	2,049	3,026
Other *	189	213	470	1,340	437	397	346	253	237	72	65	153	413	314	405
FFS	3,094	2,768	6,086	25,386	7,311	8,221	8,281	3,734	5,411	1,732	1,075	2,914	8,029	3,392	6,073
Aligned D-SNP	602	1,356	20,838	10,660	2,094	953	719	787	1,007	133	374	6,245	1,795	1,050	2,547
Unaligned D-SNP	8,072	11,184	12,209	32,420	13,217	12,858	8,942	5,634	5,918	2,839	2,777	4,411	15,439	8,517	10,686
Non-Duals	558	629	3,861	20,830	2,727	3,236	1,352	332	557	390	161	1,411	3,562	702	2,464

Data Period: June 2024

pennsylvania
DEPARTMENT OF HUMAN SERVICES

D-SNP Enrollments by Plan



Plan	Jun-23	Jul-23	Aug-23	Sep-23	Oct-23	Nov-23	Dec-23	Jan-24	Feb-24	Mar-24	Apr-24	May-24	Jun-24
Cigna	14,950	14,616	14,265	13,808	13,534	13,433	13,201	11,953	11,568	11,385	11,008	10,786	10,425
Geisinger	10,082	9,933	9,861	9,791	9,679	9,562	9,407	9,499	9,398	9,332	9,185	9,212	9,233
Highmark	40,876	40,450	40,139	39,752	39,474	39,016	38,370	38,367	38,250	37,925	37,215	36,747	36,359
HPP	9,070	8,954	8,892	8,748	8,649	8,595	8,512	8,219	8,200	8,133	7,963	7,871	7,782
Humana	14,866	15,229	15,510	15,928	16,108	15,669	15,281	14,741	14,267	13,892	13,472	13,517	13,608
United	34,736	35,041	35,347	35,742	35,808	34,119	33,077	31,568	30,812	30,173	28,824	28,183	27,578
Aetna	36,712	37,332	38,010	38,659	39,315	38,717	38,592	52,435	56,356	57,989	60,968	63,224	65,372
PHW	9,197	9,069	8,952	8,847	8,756	8,630	8,475	8,208	8,106	8,161	7,941	7,919	8,004
UPMC	40,842	40,680	40,665	40,521	40,358	39,868	39,470	39,583	39,500	39,289	38,763	38,602	38,516
Vista	17,303	17,415	17,406	17,228	16,998	16,868	16,754	16,102	15,991	15,976	15,885	15,831	16,087
Total	228,634	228,719	229,047	229,024	228,679	224,477	221,139	230,675	232,448	232,255	231,224	231,892	232,964
% Change**	0.4%	0.0%	0.1%	0.0%	-0.2%	-1.8%	-1.5%	4.3%	0.8%	-0.1%	-0.4%	0.3%	0.5%

**Nov and Dec data may be excluding participants who changed Medicare MCO during open enrollment, due to IT system rules.*

*** Percent Change from Previous Month.*

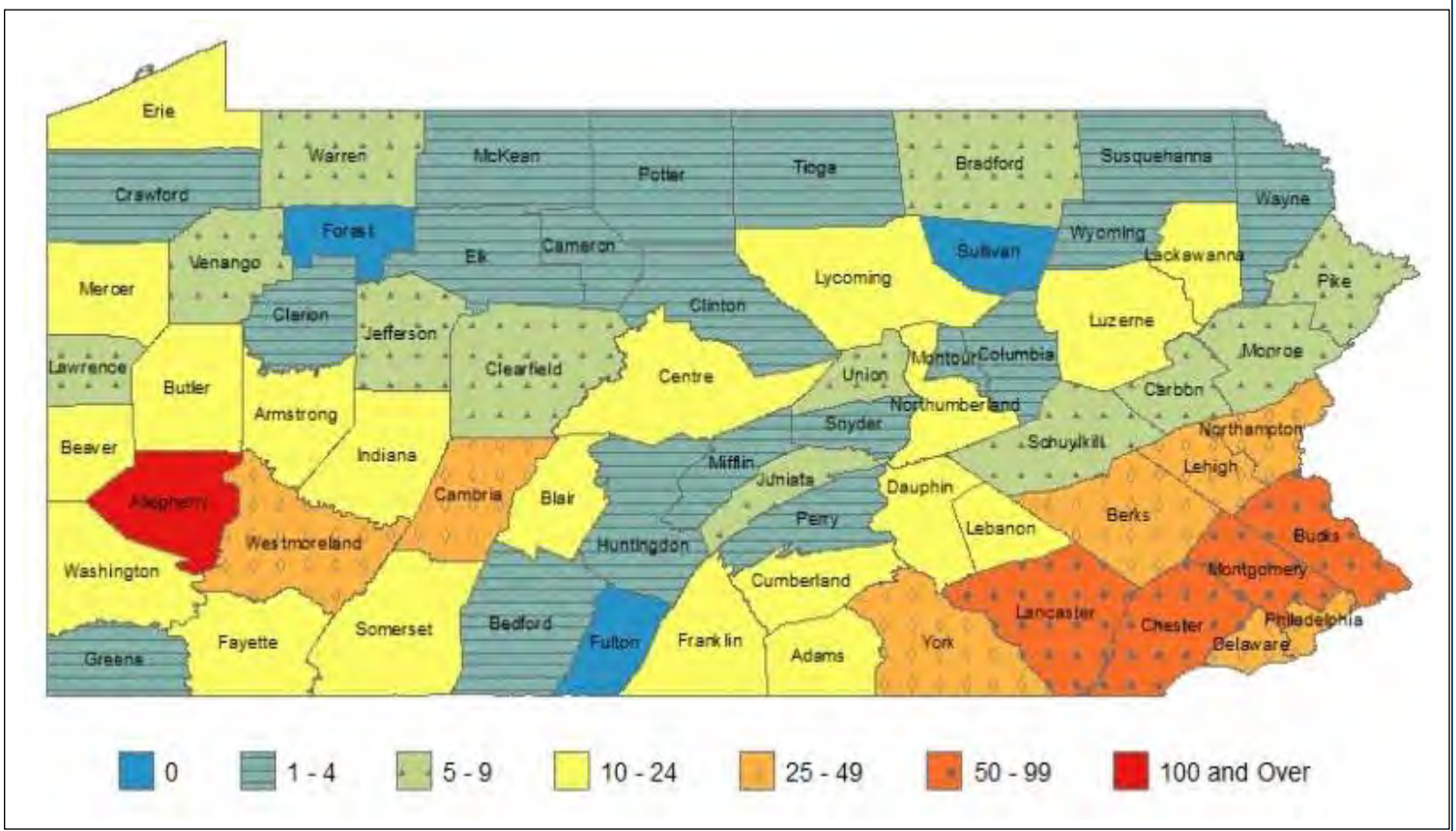
Data Period: June 2024

DID YOU KNOW?

In June 2024, there were 8,018 participants in CHC who chose to direct their own PAS services and 461 participants in OLTL's FFS programs.

	Lehigh/Capital	Northeast	Northwest	Southeast	Southwest	Grand Total
AmeriHealth Caritas	672	512	162	N/A	309	1,655
Keystone First	N/A	N/A	N/A	1,612	N/A	1,612
PA Health & Wellness	279	211	172	470	412	1,544
UPMC	432	272	619	371	1,513	3,207
Grand Total	1,383	995	953	2,453	2,234	8,018

Number of Personal Care Homes and Assisted Living Facilities by County

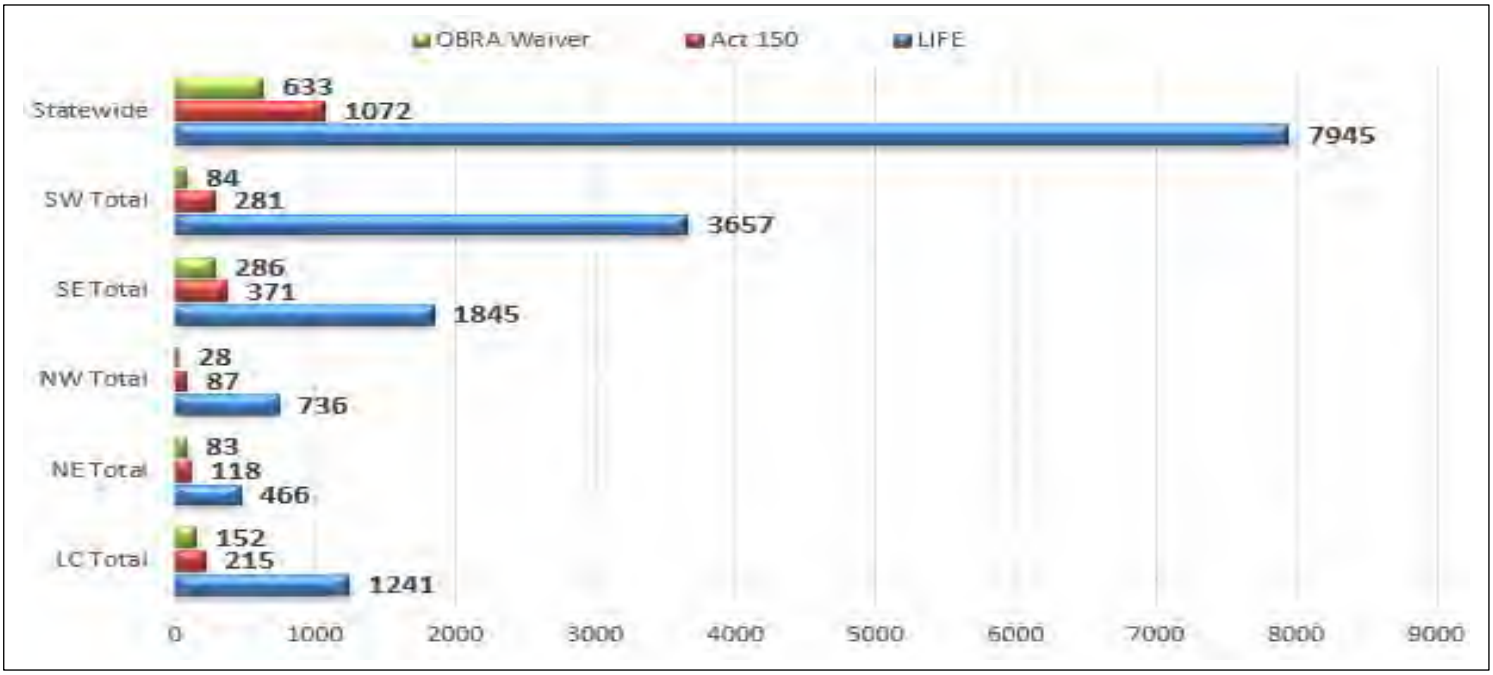


Data Period: June 2024

pennsylvania
DEPARTMENT OF HUMAN SERVICES

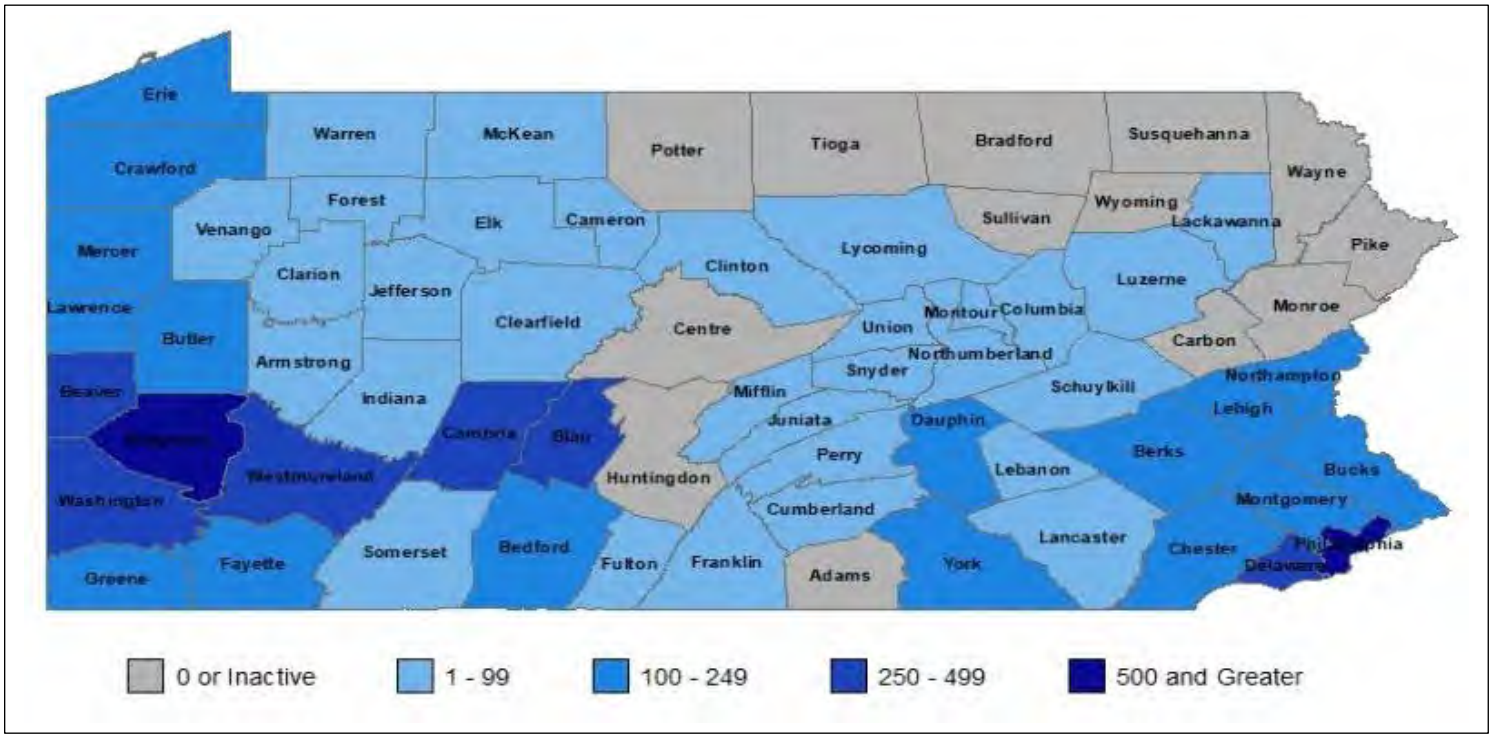
Other OLTL Program Enrollment

Total OBRA Enrollment ↓	Total Act 150 Enrollment ↑	Total LIFE Enrollment ↓
633	1,072	7,945



Data Period: June 2024

LIFE Enrollments by County



Data Period: June 2024

pennsylvania
DEPARTMENT OF HUMAN SERVICES

Appendix A.I: CHC Enrollments by County and Population Group

Data Period: June 2024

County	CHC-HCBS	CHC-LTC	CHC-NFI	Grand Total
Adams	214	338	996	1,548
Allegheny	8,704	2,798	19,629	31,131
Armstrong	348	207	1,501	2,056
Beaver	1,338	593	2,816	4,747
Bedford	128	109	1,029	1,266
Berks	3,373	1,303	6,635	11,311
Blair	466	561	2,848	3,875
Bradford	254	225	1,173	1,652
Bucks	4,262	1,898	5,207	11,367
Butler	485	634	2,231	3,350
Cambria	645	392	3,234	4,271
Cameron	45	19	124	188
Carbon	292	223	1,013	1,528
Centre	298	295	1,114	1,707
Chester	1,388	935	3,133	5,456
Clarion	156	140	785	1,081
Clearfield	319	268	1,900	2,487
Clinton	180	143	772	1,095
Columbia	343	297	1,021	1,661
Crawford	465	311	1,816	2,592
Cumberland	1,963	1,025	2,250	5,238
Dauphin	4,534	735	4,323	9,592
Delaware	7,165	1,833	6,669	15,667
Elk	147	103	561	811
Erie	3,687	1,022	5,123	9,832
Fayette	1,074	436	4,126	5,636
Forest	49	86	107	242
Franklin	508	409	2,019	2,936
Fulton	64	41	275	380
Greene	254	142	933	1,329
Huntingdon	204	161	769	1,134
Indiana	271	247	1,729	2,247
Jefferson	225	186	1,015	1,426
Juniata	68	133	327	528
Grand Total	**43,916**	**18,248**	**89,203**	**151,367**

County	CHC-HCBS	CHC-LTC	CHC-NFI	Grand Total
Lackawanna	1,398	1,051	4,786	7,235
Lancaster	2,271	1,689	6,240	10,200
Lawrence	880	457	1,929	3,266
Lebanon	911	454	1,898	3,263
Lehigh	3,298	1,493	6,804	11,595
Luzerne	1,779	1,552	7,347	10,678
Lycoming	721	553	2,099	3,373
McKean	267	333	1,013	1,613
Mercer	561	437	2,413	3,411
Mifflin	245	195	1,016	1,456
Monroe	576	230	2,621	3,427
Montgomery	5,009	3,594	6,146	14,749
Montour	76	151	275	502
Northampton	1,708	924	4,022	6,654
Northumberland	532	603	2,098	3,233
Perry	182	130	603	915
Philadelphia	60,416	4,051	41,534	106,001
Pike	215	60	608	883
Potter	85	56	355	496
Schuylkill	881	1,005	2,639	4,525
Snyder	148	73	435	656
Somerset	171	328	1,546	2,045
Sullivan	24	137	105	266
Susquehanna	127	109	682	918
Tioga	156	122	826	1,104
Union	147	155	413	715
Venango	383	251	1,368	2,002
Warren	350	215	659	1,224
Washington	1,276	734	3,312	5,322
Wayne	153	177	812	1,142
Westmoreland	1,708	1,213	5,712	8,633
Wyoming	87	48	439	574
York	1,904	1,229	5,325	8,458
Grand Total	**88,645**	**23,809**	**118,080**	**230,534**

Appendix A.II: CHC Enrollments by County and Race

Data Period: June 2024

County	Asian/American Indian/Alaskan Native/Native Hawaiian/Pacific Islander	Black	Other-Race	White
Adams	14	63	146	1,325
Allegheny	2,029	11,030	1,642	16,430
Armstrong	**	28	**	1,994
Beaver	25	912	190	3,620
Bedford	**	**	22	1,223
Berks	220	900	5,114	5,077
Blair	24	158	87	3,606
Bradford	11	25	31	1,585
Bucks	1,386	1,048	1,400	7,533
Butler	40	99	118	3,093
Cambria	13	399	130	3,729
Cameron	**	**	0	184
Carbon	14	70	100	1,344
Centre	38	59	62	1,548
Chester	373	1,079	785	3,219
Clarion	**	**	16	1,046
Clearfield	12	29	32	2,414
Clinton	**	**	18	1,057
Columbia	20	33	80	1,528
Crawford	14	87	48	2,443
Cumberland	1,276	359	731	2,872
Dauphin	2,445	2,465	1,652	3,030
Delaware	1,496	7,395	1,313	5,463
Elk	**	**	**	792
Erie	615	1,565	724	6,928
Fayette	25	371	119	5,121
Forest	**	**	**	232
Franklin	145	188	349	2,254
Fulton	**	13	**	357
Greene	**	**	28	1,283
Huntingdon	**	40	**	1,073
Indiana	**	**	61	2,128
Jefferson	**	**	28	1,383
Juniata	**	**	29	490
Grand Total	**10,301**	**28,544**	**15,118**	**97,404**

Appendix A.II: CHC Enrollments by County and Race

Data Period: June 2024

County	Asian/American Indian/Alaskan Native/Native Hawaiian/Pacific Islander	Black	Other-Race	White
Lackawanna	514	436	870	5,415
Lancaster	760	885	2,801	5,754
Lawrence	18	353	99	2,796
Lebanon	217	103	916	2,027
Lehigh	424	1,008	2,067	8,096
Luzerne	154	749	1,945	7,830
Lycoming	16	455	110	2,792
McKean	**	**	19	1,573
Mercer	24	472	93	2,822
Mifflin	**	**	41	1,380
Monroe	119	505	743	2,060
Montgomery	2,319	3,762	1,890	6,778
Montour	**	**	21	464
Northampton	276	590	1,585	4,203
Northumberland	21	87	176	2,949
Perry	15	17	40	843
Philadelphia	9,735	59,742	18,385	18,139
Pike	26	58	130	669
Potter	**	**	**	486
Schuylkill	36	144	319	4,026
Snyder	**	12	**	627
Somerset	11	20	39	1,975
Sullivan	**	**	**	253
Susquehanna	**	**	14	892
Tioga	**	**	24	1,061
Union	**	**	39	643
Venango	12	38	42	1,910
Warren	**	**	24	1,187
Washington	128	508	203	4,483
Wayne	16	18	70	1,038
Westmoreland	152	623	271	7,587
Wyoming	**	**	14	551
York	391	1,136	1,724	5,207
Grand Total	**15,451**	**71,833**	**34,734**	**108,516**

Appendix A.III: CHC Enrollments by County and Ethnicity

Data Period: June 2024

County	Hispanic	Non-Hispanic
Adams	83	1,465
Allegheny	363	30,767
Armstrong	**	**
Beaver	47	4,700
Bedford	11	1,255
Berks	5,276	6,034
Blair	35	3,840
Bradford	**	**
Bucks	682	10,685
Butler	35	3,315
Cambria	67	4,204
Cameron	**	**
Carbon	94	1,434
Centre	21	1,686
Chester	526	4,929
Clarion	**	**
Clearfield	16	2,471
Clinton	**	**
Columbia	52	1,609
Crawford	19	2,573
Cumberland	215	5,023
Dauphin	1,180	8,412
Delaware	653	15,014
Elk	**	**
Erie	600	9,231
Fayette	20	5,616
Forest	**	**
Franklin	196	2,740
Fulton	**	**
Greene	**	**
Huntingdon	**	**
Indiana	21	2,226
Jefferson	**	**
Juniata	23	505
Grand Total	**10,282**	**141,081**

County	Hispanic	Non-Hispanic
Lackawanna	744	6,490
Lancaster	2,618	7,582
Lawrence	42	3,224
Lebanon	1,028	2,235
Lehigh	4,817	6,778
Luzerne	1,857	8,821
Lycoming	45	3,328
McKean	**	**
Mercer	21	3,390
Mifflin	26	1,430
Monroe	567	2,860
Montgomery	717	14,032
Montour	20	482
Northampton	1,820	4,834
Northumberland	184	3,049
Perry	18	897
Philadelphia	17,095	88,903
Pike	90	793
Potter	**	**
Schuylkill	305	4,220
Snyder	12	644
Somerset	11	2,033
Sullivan	**	**
Susquehanna	**	**
Tioga	**	**
Union	29	686
Venango	14	1,988
Warren	**	**
Washington	35	5,287
Wayne	37	1,105
Westmoreland	45	8,588
Wyoming	**	**
York	1,446	7,011
Grand Total	**33,687**	**196,841**

Linda Chamberlain, Division Chief
Division of Home Health
2525 N. 7th Street, Harrisburg PA 17110
ra-dhhomehealth@pa.gov

Vacant, Health Care Surveyor Supervisor for Jackson Center, Meadville, Greensburg, and Indiana	Diane Alexander, Health Care Surveyor Supervisor for Norristown, Chester, Scranton and Whitehall dialexande@pa.gov	Steffanie Abbattiscianni, Health Care Surveyor Supervisor for Harrisburg, Reading and Sunbury sabbattisc@pa.gov
Stephen Klinger, Health Care Nurse Surveyor stklinger@pa.gov Tanisha Folk, Health Care Nurse Surveyor tafolk@pa.gov Whitehall Field Office 3730 Lehigh Street, Suite 204 Whitehall, PA 18052		Vicki Wessner, Health Care Nurse Surveyor Northumberland County State Health Center 247 Pennsylvania Avenue Sunbury, PA 17801 vwessner@pa.gov
Vanessa Williams, Health Care Nurse Surveyor vaneswilli@pa.gov Allison Kim, Health Care Nurse Surveyor alkim@pa.gov Sandy Brittingham, Health Care Nurse Surveyor sbrittingh@pa.gov Ann Fluck, Health Care Nurse Surveyor afluck@pa.gov Donna Gares, Health Care Nurse Surveyor dgares@pa.gov Christine McKoy, Health Care Nurse Surveyor chrmckoy@pa.gov Jihye Lee, Health Care Nurse Surveyor jilee@pa.gov Amanda Patrick, Health Care Nurse Surveyor ampatrick@pa.gov Norristown Field Office 1937 New Hope Street Norristown, PA 19401		Sharon Selbi, Health Care Nurse Surveyor sselbi@pa.gov JoAnne Specht, Health Care Nurse Surveyor jospecht@pa.gov Viktoriya Higgins, Health Care Nurse Surveyor vihiggins@pa.gov 2525 N. 7th Street Harrisburg PA 17110 Marissa Eddy, Health Care Nurse Surveyor maeddy@pa.gov Deb Helbert, Health Care Nurse Surveyor dhelbert@pa.gov Southeast District Office 625 Cherry Street Room 442 Reading PA 19602
Sandra Kowalczyk-Wills, Health Care Nurse Surveyor Scranton State Office Building 100 Lackawanna Avenue, Room 111 Scranton, PA 18503 sakowalczy@pa.gov		Barbara Johns, HCS Butler State Health Center 100 Brugh Ave, Suite 201 Butler, PA 16001 bajohns@pa.gov
Walt Casher, Health Care Nurse Surveyor Crawford County State Health Center 847 North Main Street Meadville, PA 16335 wcasher@pa.gov		Jon Price, Health Care Nurse Surveyor 75th North 2nd Street Indiana, PA 15701 jonpric@pa.gov
Mandy Weaver Johnson, Health Care Nurse Surveyor mweaverjoh@pa.gov Christina Kistler-Bowman, Health Care Nurse Surveyor ckistlerbo@pa.gov Michael Rietscha, Health Care Nurse Surveyor mirietscha@pa.gov Southwest District Office 233 West Otterman Street Greensburg, PA 15601		Sheri Varion, Health Care Nurse Surveyor svarion@pa.gov Jeff Papay, Health Care Nurse Surveyor jepapay@pa.gov 19 McQuiston Drive Jackson Center, PA 16133

PENNSYLVANIA DEPARTMENT OF HEALTH

2022 – PAHAN – 661 – 9-30- UPD

UPDATE: Work Restrictions for Healthcare Personnel with Exposure to COVID-19

DATE:	9/30/2022
TO:	Health Alert Network
FROM:	Denise Johnson, Acting Secretary of Health
SUBJECT:	**UPDATE: Work Restrictions for Healthcare Personnel with Exposure to COVID-19**
DISTRIBUTION:	Statewide
LOCATION:	n/a
STREET ADDRESS:	n/a
COUNTY:	n/a
MUNICIPALITY:	n/a
ZIP CODE:	n/a

This transmission is a Health Update: provides updated information regarding an incident or situation; unlikely to require immediate action.

HOSPITALS: PLEASE SHARE WITH ALL MEDICAL, PEDIATRIC, NURSING AND LABORATORY STAFF IN YOUR HOSPITAL**; EMS COUNCILS:** PLEASE DISTRIBUTE AS APPROPRIATE; **FQHCs:** PLEASE DISTRIBUTE AS APPROPRIATE **LOCAL HEALTH JURISDICTIONS**: PLEASE DISTRIBUTE AS APPROPRIATE; **PROFESSIONAL ORGANIZATIONS:** PLEASE DISTRIBUTE TO YOUR MEMBERSHIP; **LONG-TERM CARE FACILITIES:** PLEASE SHARE WITH ALL MEDICAL, INFECTION CONTROL, AND NURSING STAFF

This guidance replaces PA-HAN-621 and includes changes made by CDC on September 23, 2022.

This guidance pertains only to the healthcare personnel and their need for work restriction. For guidance on isolation and quarantine in the community, please refer to PA-HAN-619 or its successor.

Major additions and edits in this version include:

- Revised work restriction guidance. In most circumstances, asymptomatic HCP with higher-risk exposures **do not** require work restriction. However, they should receive a series of three viral tests on day 1, day 3, and day 5 after the exposure (day 0). Additionally, they should wear well-fitting source control and monitor for signs and symptoms of COVID-19 for 10 days.
- Updated recommendations for testing frequency to detect potential for variants with shorter incubation periods and to address the risk for false negative antigen tests in people without symptoms.
- Removed contingency and crisis strategies about earlier return to work for HCP with higher-risk exposures.

If you have additional questions about this guidance, please contact DOH at 1-877-PA-HEALTH (1-877-724-3258) or your local health department.

This guidance replaces PA-HAN-621 and includes the following sections:

1. Background
2. Definition of a higher-risk exposure for HCP
    a. Community-related exposure
    b. Household exposure
    c. Exposure in the healthcare setting while at work
3. Return to work criteria for HCP who were exposed to individuals with confirmed COVID-19

1. BACKGROUND

Because of their often extensive and close contact with vulnerable individuals in healthcare settings, a conservative approach to managing HCP with higher-risk exposure is recommended to prevent transmission from potentially contagious HCP to patients and residents, other HCP, and visitors. Occupational health programs should have a low threshold for evaluating any potential symptoms of COVID-19 and testing HCP.

This guidance describes the process for contact tracing and application of testing and work restrictions (if applicable) that should occur when capacity exists to perform these activities without compromising other critical infection prevention and control functions. If a healthcare facility is not performing contact tracing, testing, and work restrictions (if applicable) as outlined in this guidance, they must be operating according to the facility's emergency management plan.

This guidance is based on currently available data about COVID-19. Occupational health programs should use clinical judgement as well as the principles outlined in this guidance to assign risk level and determine the need for work restrictions.

2. DEFINITION OF A HIGHER-RISK EXPOSURE FOR HCP

The term **higher-risk exposure** has been used by CDC and the Department of Health to outline when work restriction might occur for HCP following exposure to COVID-19. **A higher-risk exposure includes any exposure to COVID-19 that meets the criteria outlined below for community-related exposure, for household exposure, or for higher-risk exposure in the healthcare setting while at work.**

a. Community-related exposure

As outlined in the CDC guidance for community-related exposure to COVID-19, persons who have had close contact (within 6 feet for a total of 15 minutes or more) with an infectious person with COVID-19 are considered exposed. Other activities of shorter duration may also be considered close contact, like providing care for a sick person, hugging, or kissing them, sharing dishware or utensils, and having been coughed or sneezed upon by an infectious person.

Note that when an HCP is exposed to COVID-19 within a healthcare setting as a *patient or visitor*, the criteria for community-related exposure apply.

b. Household exposure

An infectious person living in the home with an HCP represents an exposure to that HCP except in the unusual situation that the HCP was not in the home at any point during the infectious period (for example, HCP had been away on vacation or staying elsewhere). In most cases, the shared environment represents a level of risk consistent with higher-risk exposure, even if two persons in the home are not in direct contact with each other (e.g., as reported sometimes by roommates who work different shifts).

For HCP who share a household with someone who has COVID-19, the HCP's testing and work restriction period (if applicable) start from the last time they were exposed to the person with COVID-19. If the person with COVID-19 cannot fully isolate and exposure is ongoing, the HCP should extend their testing and work restriction. In that case, the day the person with COVID-19 is released from isolation would be day 0 for exposure.

c. Exposure in the healthcare setting while at work

Higher-risk exposures in the healthcare setting generally involve exposure of HCP eyes, nose, or mouth to material potentially containing SARS-CoV-2, particularly if these HCP were present in the room for an aerosol-generating procedure. Other exposures classified as lower-risk, including having body contact with the patient (e.g., rolling the patient) without gown or gloves, may impart some risk for transmission, particularly if hand hygiene is not performed and HCP then touch their eyes, nose, or mouth.

When classifying potential exposures, specific factors associated with these exposures (e.g., quality of ventilation, use of PPE and source control) should be evaluated on a case-by-case basis. These factors might raise or lower the level of risk; interventions, including restriction from work, can be adjusted based on the estimated risk for transmission.

For the purposes of this guidance, higher-risk exposures are classified as HCP who had prolonged[1] close contact[2] with a patient, visitor, or HCP with confirmed SARS-CoV-2 infection[3] and:

- HCP was not wearing a respirator (or if wearing a facemask, the person with SARS-CoV-2 infection was not wearing a cloth mask or facemask);[4]
- HCP was not wearing eye protection if the person with SARS-CoV-2 infection was not wearing a cloth mask or facemask; or
- HCP was not wearing all recommended PPE (i.e., gown, gloves, eye protection, respirator) while present in the room for an aerosol-generating procedure.

3. RETURN TO WORK CRITERIA FOR HCP WHO WHERE EXPOSED TO INDIVIDUALS WITH CONFIRMED COVID-19

In most circumstances, asymptomatic HCP with higher-risk exposures do not require work restriction. Examples of when work restriction may be considered are described below.

Following a higher-risk exposure HCP should:

- Have a series of three viral tests for SARS-CoV-2 infection.
    - Testing is recommended immediately (but not earlier than 24 hours after the exposure) and, if negative, again 48 hours after the first negative test and, if negative, again 48 hours after the second negative test. This will typically be at day 1 (where day of exposure is day 0), day 3, and day 5.
    - Due to challenges in interpreting the result, testing is generally not recommended for asymptomatic people who have recovered from SARS-CoV-2 infection in the prior 30 days. Testing should be considered for those who have recovered in the prior 31-90 days; however, an antigen test instead of NAAT is recommended. This is because some people may remain NAAT positive but not be infectious during this period.
- Wear well-fitting source control for 10 days following the exposure.
- Monitor themselves for fever or symptoms consistent with COVID-19, and not report to work when ill or if testing positive for SARS-CoV-2 infection.
    - Any HCP who develop fever or symptoms consistent with COVID-19 should immediately self-isolate and contact their established point of contact (e.g., occupational health program) to arrange for medical evaluation and testing.
- Follow additional recommended infection prevention and control practices as outlined by facility policy.

In addition to testing, source control, and monitoring recommendations listed above, examples of when work restriction may be considered for asymptomatic HCP following a higher-risk exposure include:

- HCP is unable to be tested or wear source control as recommended for the 10 days following their exposure;
- HCP is moderately to severely immunocompromised;
- HCP cares for or works on a unit with patients who are moderately to severely immunocompromised;
- HCP works on a unit experiencing ongoing SARS-CoV-2 transmission that is not controlled with initial interventions.

If work restriction is recommended, HCP could return to work after either of the following time periods:

- HCP can return to work after day 7 following the exposure (day 0) if they do not develop symptoms and all viral testing (at least three tests as described above) for HCP following a higher-risk exposure is negative.
- If viral testing is not performed, HCP can return to work after day 10 following the exposure (day 0) if they do not develop symptoms.

HCP with travel or community exposures should consult their occupational health program for guidance on need for work restrictions. In general, HCP who have had prolonged close contact with someone with SARS-CoV-2 in the community (e.g., household contacts) should be managed as described for higher-risk occupational exposures above.

Footnotes:

1. For this guidance an exposure of 15 minutes or more is considered prolonged. This could refer to a single 15-minute exposure to one infected individual or several briefer exposures to one or more infected individuals adding up to at least 15 minutes during a 24-hour period. However, the presence of extenuating factors (e.g., exposure in a confined space, performance of aerosol-generating procedure) could warrant more aggressive actions even if the cumulative duration is less than 15 minutes. For example, **any duration** should be considered prolonged if the exposure occurred during performance of an aerosol generating procedure.
2. For this guidance it is defined as: a) being within 6 feet of a person with confirmed SARS-CoV-2 infection or b) having unprotected direct contact with infectious secretions or excretions of the person with confirmed SARS-CoV-2 infection. Distances of more than 6 feet might also be of concern, particularly when exposures occur over long periods of time in indoor areas with poor ventilation.
3. Determining the time period when the patient, visitor, or HCP with confirmed SARS-CoV-2 infection could have been infectious:
    a. For individuals with confirmed COVID-19 who developed symptoms, consider the exposure window to be 2 days before symptom onset through the time period when the individual meets criteria for discontinuation of Transmission-Based Precautions
    b. For individuals with confirmed SARS-CoV-2 infection who never developed symptoms, determining the infectious period can be challenging. In these situations, collecting information about when the asymptomatic individual with SARS-CoV-2 infection may have been exposed could help inform the period when they were infectious.
        i. If the date of exposure cannot be determined, although the infectious period could be longer, it is reasonable to use a starting point of 2 days prior to the positive test through the time period when the individual meets criteria for discontinuation of Transmission-Based Precautions for contact tracing.
4. While respirators confer a higher level of protection than facemasks and are recommended when caring for patients with SARS-CoV-2 infection, facemasks still confer some level of protection to HCP, which was factored into this risk assessment if the patient was also wearing a cloth mask or facemask

Definitions:

Cloth mask: Textile (cloth) covers that are intended primarily for source control in the community. **They are not personal protective equipment (PPE) appropriate for use by healthcare personnel.** Guidance on design, use, and maintenance of cloth masks is available.

Facemask: OSHA defines facemasks as “a surgical, medical procedure, dental, or isolation mask that is FDA-cleared, authorized by an FDA EUA, or offered or distributed as described in an FDA enforcement policy. Facemasks may also be referred to as ‘medical procedure masks’.” Facemasks should be used according to product labeling and local, state, and federal requirements. FDA-cleared surgical masks are designed to protect against splashes and sprays and are prioritized for use when such exposures are

anticipated, including surgical procedures. Other facemasks, such as some procedure masks, which are typically used for isolation purposes, may not provide protection against splashes and sprays.

Healthcare Personnel (HCP): HCP include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, physicians, technicians, therapists, phlebotomists, pharmacists, students and trainees, contractual staff not employed by the healthcare facility, and persons not directly involved in patient care, but who could be exposed to infectious agents that can be transmitted in the healthcare setting (e.g., clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, volunteer personnel). For this guidance, HCP does not include clinical laboratory personnel.

Immunocompromised: For the purposes of this guidance, moderate to severely immunocompromising conditions include, but might not be limited to, those defined in the CDC Interim Clinical Considerations for Use of COVID-19 Vaccines.

- Other factors, such as end-stage renal disease, may pose a much lower degree of immunocompromise and not clearly affect decisions about need for work restriction if the healthcare provider had close contact with someone with SARS-CoV-2 infection. However, people in this category should still consider continuing to practice physical distancing and use of source control while in a healthcare facility, even if they are up to date with vaccine as recommended by CDC.
- Ultimately, the degree of immunocompromise for the healthcare provider is determined by the treating provider, and preventive actions are tailored to each individual and situation.

Respirator: A respirator is a personal protective device that is worn on the face, covers at least the nose and mouth, and is used to reduce the wearer's risk of inhaling hazardous airborne particles (including dust particles and infectious agents), gases, or vapors. Respirators, including those intended for use in healthcare, are certified by the CDC/NIOSH.

If you have questions about this guidance, please contact DOH at 1-877-PA-HEALTH (1-877- 724-3258) or your local health department.

Categories of Health Alert messages:
Health Alert: conveys the highest level of importance; warrants immediate action or attention.
Health Advisory: provides important information for a specific incident or situation; may not require immediate action.
Health Update: provides updated information regarding an incident or situation; unlikely to require immediate action.

This information is current as of September 30, 2022 but may be modified in the future. We will continue to post updated information regarding the most common questions about this subject.

PENNSYLVANIA DEPARTMENT OF HEALTH
2022 – PAHAN – 662– 9-30-UPD
UPDATE: Return to Work for Healthcare Personnel with Confirmed or Suspected COVID-19

DATE:	9/30/2022
TO:	Health Alert Network
FROM:	Denise Johnson, Acting Secretary of Health
SUBJECT:	**UPDATE: Return to Work for Healthcare Personnel with Confirmed or Suspected COVID-19**
DISTRIBUTION:	Statewide
LOCATION:	n/a
STREET ADDRESS:	n/a
COUNTY:	n/a
MUNICIPALITY:	n/a
ZIP CODE:	n/a

This transmission is a "Health Update", provides updated information regarding an incident or situation; unlikely to require immediate action.

HOSPITALS: PLEASE SHARE WITH ALL MEDICAL, PEDIATRIC, NURSING AND LABORATORY STAFF IN YOUR HOSPITAL**; EMS COUNCILS:** PLEASE DISTRIBUTE AS APPROPRIATE; **FQHCs:** PLEASE DISTRIBUTE AS APPROPRIATE **LOCAL HEALTH JURISDICTIONS**: PLEASE DISTRIBUTE AS APPROPRIATE; **PROFESSIONAL ORGANIZATIONS:** PLEASE DISTRIBUTE TO YOUR MEMBERSHIP; **LONG-TERM CARE FACILITIES:** PLEASE SHARE WITH ALL MEDICAL, INFECTION CONTROL, AND NURSING STAFF IN YOUR FACILITY

This guidance replaces PA-HAN-622 and includes changes made by CDC on September 23, 2022. Major additions and edits in this version include:

Requirements for testing healthcare personnel (HCP) with symptoms of COVID-19 have been updated. In summary:

- If using NAAT (molecular), a single negative test is sufficient in most circumstances.
- If using an antigen test, a negative result should be confirmed by either a negative NAAT (molecular) or second negative antigen test taken 48 hours after the first negative test.

The section on Strategies to Mitigate Healthcare Personnel Staffing Shortages has been condensed, with the expectation that facilities will refer to the CDC guidance for additional details.

If you have additional questions about this guidance or would benefit from discussion to support infection prevention and control decisions in your facility, please contact DOH at **1-877-PA- HEALTH (1-877-724- 3258)** or your local health department.

The Pennsylvania Department of Health (DOH) is releasing the updated guidance for making decisions about return to work for healthcare personnel (HCP) with confirmed COVID-19, or who have suspected COVID-19 (e.g., developed symptoms of COVID-19 but did not get tested for COVID-19). These updates are consistent with those published by the CDC on September 23, 2022 and available for review at Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2

Infection or Exposure to SARS-CoV-2. This HAN *replaces* PA-HAN-622. If you have questions about this guidance, please contact DOH at **1-877-PA-HEALTH (1-877-724-3258)** or your local health department.

1. EVALUATING HEALTHCARE PERSONNEL WITH SYMPTOMS OF SARS-COV-2 INFECTION

HCP with even mild symptoms of COVID-19 should be prioritized for viral testing with approved nucleic acid or antigen detection assays regardless of vaccination status.

When testing a person with symptoms of COVID-19, negative results from at least one viral test indicate that the person most likely does not have an active SARS-CoV-2 infection at the time the sample was collected.

- If using NAAT (molecular), a single negative test is sufficient in most circumstances. If a higher level of clinical suspicion for SARS-CoV-2 infection exists, consider maintaining work restrictions and confirming with a second negative NAAT.
- If using an antigen test, a negative result should be confirmed by either a negative NAAT (molecular) or second negative antigen test taken 48 hours after the first negative test.

For HCP who were suspected of having COVID-19 but following evaluation another diagnosis is suspected or confirmed, return to work decisions should be based on their other suspected or confirmed diagnoses.

2. RETURN TO WORK CRITERIA FOR HCP WITH SARS-CoV-2 INFECTION

The following are criteria to determine when HCP with SARS-CoV-2 infection could return to work regardless of vaccination status (boosted, vaccinated, or unvaccinated) and are influenced by severity of symptoms and presence of immunocompromising conditions. After returning to work, HCP should self-monitor for symptoms and seek re-evaluation from occupational health if symptoms recur or worsen. If symptoms recur (e.g., rebound) these HCP should be restricted from work and follow recommended practices to prevent transmission to others (e.g., use of well-fitting source control) until they again meet the healthcare criteria below to return to work unless an alternative diagnosis is identified.

HCP with mild to moderate illness who are not moderately to severely immunocompromised:

- Can return to work if at least 7 days have passed *since symptoms first appeared* AND a negative antigen* or NAAT (molecular) is obtained within 48 hours prior to returning to work OR 10 days have passed if testing is not performed or the HCP tests positive at day 5-7; **and**
- At least 24 hours have passed *since last* fever without the use of fever-reducing medications; **and**
- Symptoms (e.g., cough, shortness of breath) have improved.

* If using an antigen test, HCP should have a negative test obtained on day 5 and again 48 hours later.

HCP who were asymptomatic throughout their infection and are not moderately to severely immunocompromised:

- Can return to work if at least 7 days have passed since the date of their first positive viral test AND a negative antigen* or NAAT (molecular) is obtained within 48 hours prior to returning to work OR 10 days have passed if testing is not performed or the HCP tests positive at day 5-7.

* If using an antigen test, HCP should have a negative test obtained on day 5 and again 48 hours later.

HCP with severe to critical illness and are ***not*** *moderately to severely immunocompromised:*

- Can return to work if at least 10 days and up to 20 days have passed *since symptoms first appeared;* **and**
- At least 24 hours have passed *since last fever* without the use of fever-reducing medications; **and**
- Symptoms (e.g., cough, shortness of breath) have improved.

For HCP with severe to critical illness, the test-based strategy as described for moderately to severely immunocompromised HCP below can be used to inform the duration of isolation.

The exact criteria that determine which HCP will shed replication-competent virus for longer periods are not known. Disease severity factors and the presence of immunocompromising conditions should be considered when determining the appropriate duration for specific HCP. For a summary of the literature, refer to Ending Isolation and Precautions for People with COVID-19: Interim Guidance.

HCP who are *moderately to severely immunocompromised* may produce replication-competent virus beyond 20 days after symptom onset or, for those who were asymptomatic throughout their infection, the date of their first positive viral test.

- Use of a test-based strategy and consultation with an infectious disease specialist or other expert **and** an occupational health specialist is recommended to determine when these HCP may return to work.
- Criteria for the test-based strategy are:
  - *HCP who are symptomatic:*
    - Resolution of fever without the use of fever-reducing medications; **and**
    - Improvement in symptoms (e.g., cough, shortness of breath); **and**
    - Results are negative from at least two consecutive respiratory specimens collected ≥ 48 hours apart (total of two negative specimens) tested using an antigen test or NAAT.
  - *HCP who are not symptomatic:*
    - Results are negative from at least two consecutive respiratory specimens collected ≥ 48 hours apart (total of two negative specimens) tested using an antigen test or NAAT.

3. RETURN TO WORK PRACTICES

After returning to work, HCP should:

- Wear a facemask for source control at all times while in the healthcare facility until all symptoms are completely resolved or at baseline. After this period, these HCP should revert to their facility policy regarding universal source control during the pandemic.
  - A facemask for source control does not replace the need to wear an N95 or equivalent or higher-level respirator (or other recommended PPE) when indicated, including when caring for patients with suspected or confirmed SARS-CoV-2 infection.
  - Self-monitor for symptoms and seek re-evaluation from occupational health if respiratory symptoms recur or worsen.

- Ensure that recovered HCP wear all indicated PPE according to facility policy. The immunity of recovered persons to COVID-19 infection is not known, and a lack of proper PPE could expose HCP to other communicable diseases.

4. STRATEGIES TO MITIGATE HEALTHCARE PERSONNEL STAFFING SHORTAGES

Maintaining appropriate staffing in healthcare facilities is essential to providing a safe work environment for HCP and safe patient care. If community transmission levels rise, staffing shortages could occur due to HCP illness or the need to care for family members at home. Healthcare facilities must be prepared for potential staffing shortages and have plans and processes in place to mitigate these shortages. These plans and processes include communicating with HCP about actions the facility is taking to address shortages, maintaining patient and HCP safety, and providing resources to assist HCP with anxiety and stress.

If there are no longer enough staff to provide safe patient care, facilities should consider implementing CDC's Strategies to Mitigate Healthcare Personnel Staffing Shortages. Facility policy should include details provided in the CDC guidance; a summary is provided in Table 1 below. Contingency capacity strategies, followed by crisis capacity strategies, augment conventional strategies and are meant to be considered and implemented sequentially (i.e., implementing contingency strategies before crisis strategies).

Table 1. Summary of Strategies for Mitigating Staffing Shortages for HCP with SARS-COV-2 Infection

Conventional	Contingency	Crisis
10 days OR 7 days with negative test†, if asymptomatic or mild to moderate illness (with improving symptoms)	5 days with/without negative test§, if asymptomatic or mild to moderate illness (with improving symptoms)	No work restrictions, with prioritization considerations (e.g., types of patients they care for)

†Negative test result from test collected within 48 hours of returning to work. For calculating the day of the test, consider day of symptom onset (or first positive test if asymptomatic) as day 0. Either a NAAT (molecular) or antigen test may be used. If using an antigen test, HCP should have a negative test obtained on day 5 and again 48 hours later.

§Healthcare facilities may choose to confirm resolution of infection with a negative NAAT (molecular) or a series of 2 negative antigen tests taken 48 hours apart.

DEFINITIONS

Facemask: OSHA defines facemasks as "a surgical, medical procedure, dental, or isolation mask that is FDA-cleared, authorized by an FDA EUA, or offered or distributed as described in an FDA enforcement policy. Facemasks may also be referred to as "medical procedure masks." Facemasks should be used according to product labeling and local, state, and federal requirements. FDA-cleared surgical masks are designed to protect against splashes and sprays and are prioritized for use when such exposures are anticipated, including surgical procedures. Other facemasks, such as some procedure masks, which are typically used for isolation purposes, may not provide protection against splashes and sprays.

Fever: For the purpose of this guidance, fever is defined as subjective fever (feeling feverish) or a measured temperature of 100.0°F (37.8°C) or higher. Note that fever may be intermittent or may not

be present in some people, such as those who are elderly, immunocompromised, or taking certain fever-reducing medications (e.g., nonsteroidal anti-inflammatory drugs [NSAIDS]).

Healthcare Personnel (HCP): HCP include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, physicians, technicians, therapists, phlebotomists, pharmacists, students and trainees, contractual staff not employed by the healthcare facility, and persons not directly involved in patient care, but who could be exposed to infectious agents that can be transmitted in the healthcare setting (e.g., clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, volunteer personnel). For this guidance, HCP does not include clinical laboratory personnel.

Immunocompromised
For the purposes of this guidance, moderate to severely immunocompromising conditions include, but might not be limited to, those defined in the CDC Interim Clinical Considerations for Use of COVID-19 Vaccines.

- Other factors, such as end-stage renal disease, may pose a much lower degree of immunocompromise and not clearly affect decisions about need for work restriction if the healthcare provider had close contact with someone with SARS-CoV-2 infection. However, people in this category should still consider continuing to practice physical distancing and use of source control while in a healthcare facility, even if they have received all COVID-19 vaccine doses, including booster dose, as recommended by CDC.
- Ultimately, the degree of immunocompromise for HCP is determined by the treating provider, and preventive actions are tailored to each individual and situation.

Respirator: A respirator is a personal protective device that is worn on the face, covers at least the nose and mouth, and is used to reduce the wearer's risk of inhaling hazardous airborne particles (including dust particles and infectious agents), gases, or vapors. Respirators, including those intended for use in healthcare, are certified by the CDC/NIOSH.

SARS-COV-2 ILLNESS SEVERITY CRITERIA (adapted from the NIH COVID-19 Treatment Guidelines):

Note: The studies used to inform this guidance did not clearly define "severe" or "critical" illness. This guidance has taken a conservative approach to define these categories. Although not developed to inform decisions about when HCP with SARS-CoV-2 infection may return to work, the definitions in the National Institutes of Health (NIH) COVID-19 Treatment Guidelines are one option for defining severity of illness categories. The highest level of illness severity experienced by the HCP at any point in their clinical course should be used when determining when they may return to work.

Mild Illness: Individuals who have any of the various signs and symptoms of COVID 19 (e.g., fever, cough, sore throat, malaise, headache, muscle pain) without shortness of breath, dyspnea, or abnormal chest imaging.

Moderate Illness: Individuals who have evidence of lower respiratory disease by clinical assessment or imaging and a saturation of oxygen (SpO2) ≥94% on room air at sea level.

Severe Illness: Individuals who have respiratory frequency >30 breaths per minute, SpO2 <94% on room air at sea level (or, for patients with chronic hypoxemia, a decrease from baseline of >3%), ratio of arterial partial pressure of oxygen to fraction of inspired oxygen (PaO2/FiO2) <300 mmHg, or lung infiltrates >50%.

Critical Illness: Individuals who have respiratory failure, septic shock, and/or multiple organ dysfunction.

Categories of Health Alert messages:
Health Alert: conveys the highest level of importance; warrants immediate action or attention.
Health Advisory: provides important information for a specific incident or situation; may not require immediate action.
Health Update: provides updated information regarding an incident or situation; unlikely to require immediate action.

This information is current as of September 30, 2022 but may be modified in the future. We will continue to post updated information regarding the most common questions about this subject.

BILLING CODE: 4510-27-P

DEPARTMENT OF LABOR

Wage and Hour Division

29 CFR Part 541

RIN 1235-AA39

Defining and Delimiting the Exemptions for Executive, Administrative, Professional, Outside Sales, and Computer Employees

AGENCY: Wage and Hour Division, Department of Labor.

ACTION: Final rule.

SUMMARY: The Department of Labor (Department) is updating and revising the regulations issued under the Fair Labor Standards Act implementing the exemptions from minimum wage and overtime pay requirements for executive, administrative, professional, outside sales, and computer employees. Significant revisions include increasing the standard salary level, increasing the highly compensated employee total annual compensation threshold, and adding to the regulations a mechanism that will allow for the timely and efficient updating of the salary and compensation thresholds, including an initial update on July 1, 2024, to reflect earnings growth. The Department is not finalizing in this rule its proposal to apply the standard salary level to the U.S. territories subject to the Federal minimum wage and to update the special salary levels for American Samoa and the motion picture industry.

DATES: The effective date for this final rule is July 1, 2024. Sections 541.600(a)(2) and 541.601(a)(2) are applicable beginning January 1, 2025.

Disclaimer: This final rule has been approved by the Office of Management and Budget's Office of Information and Regulatory Affairs and has been submitted to the Office of the Federal Register (OFR) for publication. It is currently pending placement on public inspection at the OFR and publication in the *Federal Register*. This version of the final rule may vary slightly from the published document if minor technical or formatting changes are made during the OFR review process. Only the version published in the *Federal Register* is the official version.

FOR FURTHER INFORMATION CONTACT: Daniel Navarrete, Acting Director, Division of Regulations, Legislation, and Interpretation, Wage and Hour Division, U.S. Department of Labor, Room S-3502, 200 Constitution Avenue, NW, Washington, DC 20210; telephone: (202) 693-0406 (this is not a toll-free number). Alternative formats are available upon request by calling 1-866-487-9243. If you are deaf, hard of hearing, or have a speech disability, please dial 7-1-1 to access telecommunications relay services.

Questions of interpretation or enforcement of the agency's existing regulations may be directed to the nearest Wage and Hour Division (WHD) district office. Locate the nearest office by calling the WHD's toll-free help line at (866) 4US–WAGE ((866) 487-9243) between 8 a.m. and 5 p.m. in your local time zone, or log onto WHD's website at https://www.dol.gov/agencies/whd/contact/local-offices for a nationwide listing of WHD district and area offices.

SUPPLEMENTARY INFORMATION

I. Executive Summary

The Fair Labor Standards Act (FLSA or Act) requires covered employers to pay employees a minimum wage and, for employees who work more than 40 hours in a week, overtime premium pay of at least 1.5 times the employee's regular rate of pay. Section 13(a)(1) of the FLSA, which was included in the original Act in 1938, exempts from the minimum wage and overtime pay requirements "any employee employed in a bona fide executive, administrative, or professional capacity[.]"[1] The exemption is commonly referred to as the "white-collar" or executive, administrative, or professional (EAP) exemption. The statute

[1] 29 U.S.C. 213(a)(1).

expressly gives the Secretary of Labor (Secretary) authority to define and delimit the terms of the exemption. Since 1940, the regulations implementing the EAP exemption have generally required that each of the following three tests must be met: (1) the employee must be paid a predetermined and fixed salary that is not subject to reduction because of variations in the quality or quantity of work performed (the salary basis test); (2) the amount of salary paid must meet a minimum specified amount (the salary level test); and (3) the employee's job duties must primarily involve executive, administrative, or professional duties as defined by the regulations (the duties test). The employer bears the burden of establishing the applicability of the exemption.[2] Job titles and job descriptions do not determine EAP exemption status, nor does merely paying an employee a salary.

Consistent with its broad authority under the Act, in this final rule the Department is setting compensation thresholds for the standard test and the highly compensated employee test that will work effectively with the respective duties tests to better identify who is employed in a bona fide EAP capacity for purposes of determining exemption status under the Act. Specifically, the Department is setting the standard salary level at the 35th percentile of weekly earnings of full-time salaried workers in the lowest-wage Census Region ($1,128 per week or $58,656 annually for a full-year worker)[3] and the highly compensated employee total annual

[2] *See, e.g.*, *Idaho Sheet Metal Works, Inc. v. Wirtz*, 383 U.S. 190, 209 (1966); *Walling v. Gen. Indus. Co.*, 330 U.S. 545, 547-48 (1947).

[3] In determining earnings percentiles in its part 541 rulemakings since 2004, the Department has consistently looked at nonhourly earnings for full-time workers from the Current Population Survey (CPS) Merged Outgoing Rotation Group (MORG) data collected by the U.S. Bureau of Labor Statistics (BLS). As explained in section VII.B.5.i, the Department considers data representing compensation paid to nonhourly workers to be an appropriate proxy for compensation paid to salaried workers, although for simplicity the Department uses the terms

compensation threshold at the annualized weekly earnings of the 85th percentile of full-time salaried workers nationally ($151,164). These compensation thresholds are firmly grounded in the authority that the FLSA grants to the Secretary to define and delimit the EAP exemption, a power the Secretary has exercised for 85 years.

The increase in the standard salary level to the 35th percentile of weekly earnings of full-time salaried workers in the lowest-wage Census Region better fulfills the Department's obligation under the statute to define and delimit who is employed in a bona fide EAP capacity. Upon reflection, the Department has determined that its rulemakings over the past 20 years, since the Department simplified the test for the EAP exemption in 2004 by replacing the historic two-test system for determining exemption status with the single standard test, have vacillated between two distinct approaches: One used in rules in 2004[4] and 2019,[5] that exempted lower-paid workers who historically had been entitled to overtime because they did not meet the more detailed duties requirements of the test that was in place from 1949 to 2004; and one used in a rule in 2016,[6] that restored overtime protection to lower-paid white-collar workers who performed significant amounts of nonexempt work but also removed from the exemption other lower-paid workers who historically were exempt because they met the prior more detailed

---

salaried and nonhourly interchangeably in this rule. The Department relied on CPS MORG data for calendar year 2022 to develop the NPRM, including to determine the proposed salary level. The Department is using the most recent full-year data available for this final rule, which is CPS MORG data for calendar year 2023. The new standard salary level of $1,128 per week is $12 to $30 less than the Department estimated in the NPRM. 88 FR 62152, 62152–53 n.3 (Sept. 8, 2023).

[4] 69 FR 22122 (April 23, 2004).

[5] 84 FR 51230 (Sept. 27, 2019).

[6] 81 FR 32391 (May 23, 2016).

duties test, an approach that received unfavorable treatment in litigation.[7] Having grappled with these different approaches to setting the standard salary level, this final rule retains the simplified standard test, the benefits of which were recognized in the Department's 2004, 2016, and 2019 rulemakings,[8] while, through a revised methodology, fully restoring the salary level's screening function and accounting for the switch from a two-test to a one-test system for defining the EAP exemption, and also separately updating the standard salary level to account for earnings growth since the 2019 rule.

The new standard salary level will, in combination with the standard duties test, better define and delimit which employees are employed in a bona fide EAP capacity. By setting a salary level above what the methodology used in 2004 and 2019 would produce using current data, the new standard salary level will ensure that, consistent with the Department's historical approach to the exemption, fewer lower-paid white-collar employees who perform significant amounts of nonexempt work are included in the exemption. At the same time, by setting the salary level below what the methodology used in 2016 would produce using current data, the new standard salary level will allow employers to continue to use the exemption for many lower-paid white-collar employees who were made exempt under the 2004 standard duties test. The combined result will be a more effective test for determining who is employed in a bona fide EAP capacity. The applicability date of the new standard salary level will be January 1, 2025. The Department is not finalizing its proposal to apply the standard salary level to the U.S.

[7] The Department never enforced the 2016 rule because it was invalidated by the U.S. District Court for the Eastern District of Texas. *See Nevada v. U.S. Department of Labor*, 275 F.Supp.3d 795 (E.D. Tex. 2017).
[8] *See* 84 FR 51243–45; 81 FR 32414, 32444–45; 69 FR 22126–28.

territories subject to the federal minimum wage and to update the special salary levels for American Samoa and the motion picture industry.[9]

The Department is also increasing the earnings threshold for the highly compensated employee (HCE) exemption, which was added to the regulations in 2004 and applies to certain highly compensated employees and combines a much higher annual compensation requirement with a minimal duties test. The HCE test's primary purpose is to serve as a streamlined alternative for very highly compensated employees because a very high level of compensation is a strong indicator of an employee's exempt status, thus eliminating the need for a detailed duties analysis.[10] The Department is increasing the HCE total annual compensation threshold to the annualized weekly earnings amount of the 85th percentile of full-time salaried workers nationally ($151,164). The new HCE threshold is high enough to reserve the test for those employees who are "at the very top of [the] economic ladder"[11] and will guard against the unintended exemption of workers who are not bona fide EAP employees, including those in high-income regions and industries. The applicability date of the new HCE total annual compensation threshold will be January 1, 2025.

In each of its part 541 rulemakings since 2004, the Department recognized the need to regularly update the earnings thresholds to ensure that they remain effective in helping

[9] The Department proposed in sections IV.B.1 and B.2 of the NPRM to apply the updated standard salary level to the four U.S. territories that are subject to the federal minimum wage—Puerto Rico, Guam, the U.S. Virgin Islands, and the Commonwealth of the Northern Mariana Islands (CNMI)—and to update the special salary levels for American Samoa and the motion picture industry in relation to the new standard salary level. The Department will address these aspects of its proposal in a future final rule.
[10] *See* 69 FR 22172–73.
[11] *Id.* at 22174.

differentiate between exempt and nonexempt employees. As the Department observed in these rulemakings, even a well-calibrated salary level that is not kept up to date becomes obsolete as wages for nonexempt workers increase over time.[12] Long intervals between rulemakings have resulted in eroded earnings thresholds based on outdated earnings data that were ill-equipped to help identify bona fide EAP employees.

To address this problem, in the 2004 and 2019 rules the Department expressed its commitment to regularly updating the salary levels.[13] In the 2016 rule, it included a regulatory provision to automatically update the salary levels.[14] Based on its long experience with updating the salary levels, the Department has determined that adopting a regulatory provision for updating the salary levels to reflect current earnings data, with an exception for pausing future updates under certain conditions, is the most viable and efficient way to ensure the EAP exemption earnings thresholds keep pace with changes in employee pay and thus remain effective in helping determine exemption status. This rule establishes a new updating mechanism. The initial update to the standard salary level and the HCE total annual compensation threshold will take place on July 1, 2024, and will use the methodologies in place at that time (*i.e.*, the 2019 rule methodologies), resulting in a $844 per week standard salary level and a $132,964 HCE total annual compensation threshold. Future updates to the standard salary level and HCE total annual compensation threshold with current earnings data will begin 3 years after the date of the initial update (July 1, 2027), and every 3 years thereafter, using the methodologies in place at the time of the updates. The Department anticipates that, by the time

[12] 84 FR 51250–51; 81 FR 32430; *see also* 69 FR 22164.
[13] 69 FR 22171; 84 FR 51251–52.
[14] 81 FR 32430.

the first triennial update under the updating mechanism occurs, assuming the Department has not engaged in further rulemaking, the new methodologies for the standard salary level and HCE total annual compensation requirement established by this final rule will have become effective and the triennial update will employ these new methodologies. The new updating mechanism will allow for the timely, predictable, and efficient updating of the earnings thresholds.

The Department estimates that in Year 1, approximately 1 million employees who earn at least $684 per week but less than $844 per week will be impacted by the initial update applying current wage data to the standard salary level methodology from the 2019 rule, and approximately 3 million employees who earn at least $844 per week but less than the new standard salary level of $1,128 per week will be impacted by the subsequent application of the new standard salary level. *See* Table 25. As explained in section V.B.4.ii, for 1.8 million of the affected employees (including the 1 million impacted by the initial update), this rule will restore overtime protections that they would have been entitled to under every rule prior to the 2019 rule. The Department also estimates that 292,900 employees who are currently exempt under the HCE test, but do not meet the standard test for exemption, will be affected by the proposed increase in the HCE total annual compensation level. Absent an employer increasing these employees' pay to at or above the new HCE level, the exemption status of these employees will turn on the standard duties test (which these employees do not meet) rather than the minimal duties test that applies to employees earning at or above the HCE threshold. The economic analysis quantifies the direct costs resulting from this rule: (1) regulatory familiarization costs; (2) adjustment costs; and (3) managerial costs. The Department estimates that total annualized direct employer costs over the first 10 years will be $803 million with a 7 percent discount rate.

This rule will also give employees higher earnings in the form of transfers of income from employers to employees. The Department estimates annualized transfers will be $1.5 billion, with a 7 percent discount rate.

II. Background

A. The FLSA

The FLSA generally requires covered employers to pay employees at least the federal minimum wage (currently $7.25 an hour) for all hours worked and overtime premium pay of at least one and one-half times the employee's regular rate of pay for all hours worked over 40 in a workweek.[15] However, section 13(a)(1) of the FLSA, codified at 29 U.S.C. 213(a)(1), provides an exemption from both minimum wage and overtime pay for "any employee employed in a bona fide executive, administrative, or professional capacity . . . or in the capacity of [an] outside salesman (as such terms are defined and delimited from time to time by regulations of the Secretary [of Labor], subject to the provisions of [the Administrative Procedure Act] . . .)." The FLSA does not define the terms "executive," "administrative," "professional," or "outside salesman," but rather directs the Secretary to define those terms through rulemaking. Pursuant to Congress's grant of rulemaking authority, since 1938 the Department has issued regulations at 29 CFR part 541 to define and delimit the scope of the section 13(a)(1) exemption.[16] Because Congress explicitly gave the Secretary authority to define and delimit the specific terms of the exemption, the regulations so issued have the binding effect of law.[17]

---

[15] *See* 29 U.S.C. 206(a), 207(a).
[16] *See Helix Energy Solutions Group, Inc. v. Hewitt*, 143 S.Ct. 677, 682 (2023) ("Under [section 13(a)(1)], the Secretary sets out a standard for determining when an employee is a 'bona fide executive.'").
[17] *See Batterton v. Francis*, 432 U.S. 416, 425 n.9 (1977).

The exemption for executive, administrative, or professional employees was included in the original FLSA legislation passed in 1938.[18] It was modeled after similar provisions contained in the earlier National Industrial Recovery Act of 1933 and state law precedents.[19] As the Department has explained in prior rules, the EAP exemption is premised on two policy considerations. First, the type of work exempt employees perform is difficult to standardize to any time frame and cannot be easily spread to other workers after 40 hours in a week, making enforcement of the overtime provisions difficult and generally precluding the potential job expansion intended by the FLSA's time-and-a-half overtime premium.[20] Second, exempt workers typically earn salaries well above the minimum wage and are presumed to enjoy other privileges to compensate them for their long hours of work. These include, for example, above-average fringe benefits and better opportunities for advancement, setting them apart from nonexempt workers entitled to overtime pay.[21]

Section 13(a)(1) exempts covered EAP employees from both the FLSA's minimum wage and overtime requirements. However, because of their long hours of work, its most significant impact is its exemption of these employees from the Act's overtime protections, as discussed in section VII.C.4. An employer may employ such exempt employees for any number of hours in the workweek without paying an overtime premium. Some state laws have stricter standards to be exempt from state minimum wage and overtime protections than those which exist under

[18] *See* Fair Labor Standards Act of 1938, Pub. L. 75-718, 13(a)(1), 52 Stat. 1060, 1067 (June 25, 1938).
[19] *See* National Industrial Recovery Act, Pub. L. 73-67, ch. 90, title II, 206(2), 48 Stat 195, 204-5 (June 16, 1933).
[20] *See* Report of the Minimum Wage Study Commission, Volume IV, pp. 236 and 240 (June 1981).
[21] *See id*.

federal law, such as higher salary levels or more stringent duties tests. The FLSA does not preempt any such stricter state standards.[22] If a state establishes a higher standard than the provisions of the FLSA, the higher standard applies in that state.

B. Regulatory History

The Department's part 541 regulations have consistently looked to the duties performed by the employee and the salary paid by the employer in determining whether an individual is employed in a bona fide executive, administrative, or professional capacity. Since 1940, the Department's implementing regulations have generally required each of the following three prongs to be satisfied for the exemption to apply: (1) the employee must be paid a predetermined and fixed salary that is not subject to reduction because of variations in the quality or quantity of work performed (the salary basis test); (2) the amount of salary paid must meet a minimum specified amount (the salary level test); and (3) the employee's job duties must primarily involve executive, administrative, or professional duties as defined by the regulations (the duties test).

1. The Part 541 Regulations from 1938 to 2004

The Department's part 541 regulations have always included earnings criteria. From the first Part 541 regulations, there has been "wide agreement" that the amount paid to an employee is "a valuable and easily applied index to the 'bona fide' character of the employment for which [the] exemption is claimed[.]"[23] Because EAP employees "are denied the protection of the [A]ct[,]" they are "assumed [to] enjoy compensatory privileges" which distinguish them from

[22] *See* 29 U.S.C. 218(a).

[23] "Executive, Administrative, Professional . . . Outside Salesman" Redefined, Wage and Hour Division, U.S. Department of Labor, Report and Recommendations of the Presiding Officer [Harold Stein] at Hearings Preliminary to Redefinition (Oct. 10, 1940) (Stein Report) at 19.

nonexempt employees, including substantially higher pay.[24] Additionally, the Department has long recognized that the salary level test is a useful criterion for helping identify bona fide EAP employees and provides a practical guide for employers and employees, thus tending to reduce litigation and ensure that nonexempt employees receive the overtime protection to which they are entitled.[25] These benefits accrue to employees and employers alike, which is why, despite disagreement over the appropriate magnitude of the part 541 earnings thresholds, an "overwhelming majority" of stakeholders have supported the retention of such thresholds in prior part 541 rulemakings.[26]

The Department issued the first version of the part 541 regulations in October 1938.[27] The Department's initial regulations included a $30 per week compensation requirement for executive and administrative employees. It also included a duties test that prohibited employers from claiming the EAP exemption for employees who performed "[a] substantial amount of work of the same nature as that performed by nonexempt employees of the employer."[28]

The Department issued the first update to its part 541 regulations in October 1940,[29] following extensive public hearings.[30] Among other changes, the 1940 update newly applied the

[24] *Id.*; *see* Report of the Minimum Wage Study Commission, Volume IV, p. 236 ("Higher base pay, greater fringe benefits, improved promotion potential and greater job security have traditionally been considered as normal compensatory benefits received by EAP employees, which set them apart from non-EAP employees.").
[25] *See* 84 FR 51237; *see also* Report and Recommendations on Proposed Revisions of Regulations, Part 541, by Harry Weiss, Presiding Officer, Wage and Hour and Public Contracts Divisions, U.S. Department of Labor (June 30, 1949) (Weiss Report) at 8.
[26] 84 FR 51235; *see also* Stein Report at 5, 19; Weiss Report at 9.
[27] 3 FR 2518 (Oct. 20, 1938).
[28] *Id.*
[29] 5 FR 4077 (Oct. 15, 1940).
[30] *See* Stein Report.

salary level requirement to professional employees; added the salary basis requirement to the tests for executive, administrative, and professional employees; and introduced a 20 percent cap on the amount of nonexempt work that executive and professional employees could perform each workweek, replacing language which prohibited the performance of a "substantial amount" of nonexempt work.[31]

The Department conducted further hearings on the part 541 regulations in 1947[32] and issued revised regulations in December 1949.[33] The 1949 rulemaking updated the salary levels set in 1940 and introduced a second, less stringent duties test for higher paid executive, administrative, and professional employees.[34] Thus, beginning in 1949, the part 541 regulations contained two tests for the EAP exemption. These tests became known as the "long" test and the "short" test. The long test paired a lower earnings threshold with a more rigorous duties test that generally limited the performance of nonexempt work to no more than 20 percent of an employee's hours worked in a workweek. The short test paired a higher salary level and a less rigorous duties test, with no specified limit on the performance of nonexempt work. From 1958 until 2004, the regulations in place generally set the long test salary level at a level designed to exclude from exemption approximately the lowest-paid 10 percent of salaried white-collar employees who performed EAP duties in lower-wage areas and industries and set the short test salary level significantly higher.[35] The salary and duties components of each test complemented

[31] 5 FR 4077.
[32] *See* Weiss Report.
[33] *See* 14 FR 7705 (Dec. 24, 1949).
[34] *Id*. at 7706.
[35] *See* Report and Recommendations on Proposed Revision of Regulations, Part 541, Under the Fair Labor Standards Act, by Harry S. Kantor, Assistant Administrator, Office of Regulations

each other, and the two tests worked in combination to determine whether an individual was employed in a bona fide EAP capacity. Lower-paid employees who met the long test salary level but did not meet the higher short test salary level were subject to the long duties test which ensured that these employees were employed in an EAP capacity by limiting the amount of time they could spend on nonexempt work. Employees who met the higher short test salary level were considered to be more likely to meet the requirements of the long duties test and thus were subject to a short-cut duties test for determining exemption status.

Additional changes to the regulations, including salary level updates, were made in 1954,[36] 1958,[37] 1961,[38] 1963,[39] 1967,[40] 1970,[41] 1973,[42] and 1975.[43] The Department revised the part 541 regulations twice in 1992 but did not update the salary thresholds at that time.[44] None of these updates changed the basic structure of the long and short tests.

The Department described the salary levels adopted in the 1975 rule as "interim rates," intended to "be in effect for an interim period pending the completion of a study [of worker

---

and Research, Wage and Hour and Public Contracts Divisions, U.S. Department of Labor (Mar. 3, 1958) (Kantor Report) at 6-7. Under the two-test system, the ratio of the short test salary level to the long test salary levels ranged from approximately 130 percent to 180 percent. *See* 81 FR 32403.

[36] 19 FR 4405 (July 17, 1954).

[37] 23 FR 8962 (Nov. 18, 1958).

[38] 26 FR 8635 (Sept. 15, 1961).

[39] 28 FR 9505 (Aug. 30, 1963).

[40] 32 FR 7823 (May 30, 1967).

[41] 35 FR 883 (Jan. 22, 1970).

[42] 38 FR 11390 (May 7, 1973).

[43] 40 FR 7091 (Feb. 19, 1975).

[44] The Department first created a limited exception from the salary basis test for public employees. 57 FR 37677 (Aug. 19, 1992). The Department also implemented a 1990 law requiring it to promulgate regulations permitting employees in certain computer-related occupations to qualify as exempt under section 13(a)(1) of the FLSA. 57 FR 46744 (Oct. 9, 1992); *see* Pub. L. 101-583, sec. 2, 104 Stat. 2871 (Nov. 15, 1990).

earnings] by the Bureau of Labor Statistics . . . in 1975."[45] However, those salary levels remained in effect until 2004. The utility of the salary levels in helping to define the EAP exemption decreased as wages rose during this period. In 1991, the federal minimum wage rose to $4.25 per hour,[46] which for a 40-hour workweek exceeded the lower long test salary level of $155 per week for executive and administrative employees and equaled the long test salary level of $170 per week for professional employees. In 1997, the federal minimum wage rose to $5.15 per hour,[47] which for a 40-hour workweek not only exceeded the long test salary levels, but also was close to the higher short test salary level of $250 per week.

2. Part 541 Regulations from 2004 to 2019

The Department published a final rule in April 2004 (the 2004 rule)[48] that updated the part 541 salary levels for the first time since 1975 and made several significant changes to the regulations. Most significantly, the Department eliminated the separate long and short tests and replaced them with a single standard test. The Department set the standard salary level at $455 per week, which was equivalent to the 20th percentile of weekly earnings of full-time salaried workers in the lowest-wage Census Region (the South) and in the retail industry nationally. The Department paired the new standard salary level test with a new standard duties test for executive, administrative, and professional employees, respectively, which was substantially equivalent to the short duties test used in the two-test system.[49]

[45] 40 FR 7091.
[46] *See* Pub. L. 101-157, sec. 2, 103 Stat. 938 (Nov. 17, 1989).
[47] *See* Pub. L. 104-188, sec. 2104(b), 110 Stat 1755 (Aug. 20, 1996).
[48] 69 FR 22122.
[49] *See id.* at 22192–93 (acknowledging "de minimis differences in the standard duties tests compared to the . . . short duties tests").

In the 2004 rule, the Department acknowledged that the switch to the single standard test for exemption was a significant change in the regulatory structure,[50] and noted that the shift to setting the salary level based on "the lowest 20 percent of salaried employees in the South, rather than the lowest 10 percent" of EAP employees was made, in part, "because of the proposed change from the 'short' and 'long' test structure[.]"[51] The Department asserted that elimination of the long duties test was warranted because "the relatively small number of employees currently earning from $155 to $250 per week, and thus tested for exemption under the 'long' duties test, will gain stronger protections under the increased minimum salary level which . . . guarantees overtime protection for all employees earning less than $455 per week[.]"[52] The Department acknowledged, however, that the new standard salary level was comparable to the lower long test salary level used in the two-test system (*i.e.*, if the Department's long test salary level methodology had been applied to contemporaneous data).[53] Thus, employees who would have been subject to the long duties test with its limit on the amount of time spent on nonexempt work if the two-test system had been updated were subject to the equivalent of the short duties test under the new standard test. For example, under the 2004 rule's standard test, an employee

[50] *See id.* at 22126–28.
[51] *Id.* at 22167.
[52] *Id.* at 22126.
[53] *Id.* at 22171. The Department last set the long and short test salary levels in 1975. Throughout this preamble, when the Department refers to the relationship of salary levels set in this rule and the 2004, 2016, and 2019 rules to equivalent long or short test salary levels, it is referring to salary levels based on contemporaneous (at the relevant point in time) data that, in the case of the long test salary level, would exclude the lowest-paid 10 percent of exempt EAP employees in low-wage industries and areas and, in the case of the short test salary level, would be 149 percent of a contemporaneous long test salary level. The short test salary ratio of 149 percent is the simple average of the 15 historical ratios of the short test salary level to the long test salary level. *See* 81 FR 32467 & n.149.

who earned just over the rule's standard salary threshold of $455 in weekly salary, and who met the standard duties test, was exempt even if they would not have met the previous long duties test because they spent more than 20 percent of their time performing nonexempt work. If the Department had instead retained the two-test system and updated the long test salary level to $455, that same employee would have been nonexempt because they would have been subject to the long test's more rigorous duties analysis due to their lower salary.

In the 2004 rule, the Department also created a new test for exemption for certain highly compensated employees.[54] The HCE test paired a minimal duties requirement—customarily and regularly performing at least one of the exempt duties or responsibilities of an EAP employee—with a high total annual compensation requirement of $100,000, a threshold that exceeded the annual earnings of approximately 93.7 percent of salaried workers nationwide.[55] The Department also ended the use of special salary levels for Puerto Rico and the U.S. Virgin Islands, as they had become subject to the federal minimum wage since the Department last updated the part 541 salary levels in 1975, and set a special salary level only for American Samoa, which remained not subject to the federal minimum wage.[56] The Department also expressed its intent "in the future to update the salary levels on a more regular basis, as it did prior to 1975."[57]

In May 2016, the Department issued a final rule (the 2016 rule) that retained the single-test system introduced in 2004 but increased the standard salary level and provided for regular updating. Specifically, the 2016 rule (1) increased the standard salary level from the 2004 salary

[54] 69 FR 22172.
[55] *See id.* at 22169 (Table 3).
[56] *Id.* at 22172.
[57] *Id*. at 22171.

level of $455 to $913 per week, the 40th percentile of weekly earnings of full-time salaried workers in the lowest-wage Census Region (the South);[58] (2) increased the HCE test total annual compensation amount from $100,000 to $134,004 per year;[59] (3) increased the special salary level for EAP workers in American Samoa;[60] (4) allowed employers, for the first time, to credit nondiscretionary bonuses, incentive payments, and commissions paid at least quarterly towards up to 10 percent of the standard salary level;[61] and (5) added a mechanism to automatically update the part 541 earnings thresholds every 3 years.[62] The Department did not change any of the standard duties test criteria in the 2016 rule,[63] opting instead to adopt a standard salary level set at the low end of the historical range of short test salary levels used in the pre-2004 two-test system.[64] The 2016 rule was scheduled to take effect on December 1, 2016.

On November 22, 2016, the U.S. District Court for the Eastern District of Texas issued an order preliminarily enjoining the Department from implementing and enforcing the 2016 rule.[65] On August 31, 2017, the district court granted summary judgment to the plaintiff challengers, holding that the 2016 rule's salary level exceeded the Department's authority and invalidating the rule.[66] On October 30, 2017, the Department of Justice appealed to the U.S. Court of Appeals for the Fifth Circuit, which subsequently granted the Department's motion to

[58] 81 FR 32404–05.
[59] *Id*. at 32428.
[60] *Id*. at 32422.
[61] *See id*. at 32425–26.
[62] *See id*. at 32430.
[63] *Id*. at 32444.
[64] In the 2016 rule, the Department estimated the historical range of short test salary levels as from $889 to $1,231 (based on contemporaneous earnings data). *Id.* at 32405.
[65] *See Nevada v. U.S. Department of Labor*, 218 F. Supp. 3d 520 (E.D. Tex. 2016).
[66] *See Nevada*, 275 F.Supp.3d 795.

hold that appeal in abeyance while the Department undertook further rulemaking. Following an NPRM published on March 22, 2019,[67] the Department published a final rule on September 27, 2019 (the 2019 rule),[68] which formally rescinded and replaced the 2016 rule.

The 2019 rule (1) raised the standard salary level from the 2004 salary level of $455 to $684 per week, the equivalent of the 20th percentile of weekly earnings of full-time salaried workers in the lowest-wage Census Region (the South) and/or in the retail industry nationally; (2) increased the HCE total annual compensation threshold from $100,000 to $107,432, the equivalent of the 80th percentile of annual earnings of full-time salaried workers nationwide; (3) allowed employers to credit nondiscretionary bonuses and incentive payments (including commissions) paid at least annually to satisfy up to 10 percent of the standard salary level; and (4) established special salary levels for all U.S. territories.[69] The 2019 rule did not make changes to the standard duties test.[70] While using the same methodology used in the 2004 rule to set the salary threshold, the Department did not assert that this methodology constituted the outer limit for defining and delimiting the salary threshold. Rather, the Department reasoned the 2004 methodology was well-established, reasonable, would minimize uncertainty and potential legal challenge, and would address the concerns of the district court that the 2016 rule over-emphasized the salary level.[71] The Department acknowledged that the new standard salary level

[67] *See* 84 FR 10900 (March 22, 2019).
[68] *See* 84 FR 51230.
[69] The Department established special salary levels of $455 per week for Puerto Rico, Guam, the U.S. Virgin Islands, and the CNMI (effectively continuing the 2004 salary level); it also maintained the 2004 rule's $380 per week special salary level for employees in American Samoa. *Id*. at 51246.
[70] *See id.* at 51241–43.
[71] *See id.* at 51242.

was, unlike the salary level set in the 2004 rule, below the long test salary level used in the pre-2004 two-test system.[72] As in its 2004 rule, the Department "reaffirm[ed] its intent to update the standard salary level and HCE total annual compensation threshold more regularly in the future using notice-and-comment rulemaking."[73] The 2019 rule took effect on January 1, 2020.[74]

C. Overview of Existing Regulatory Requirements

The part 541 regulations contain specific criteria that define each category of exemption provided for in section 13(a)(1) for bona fide executive, administrative, professional, and outside sales employees, as well as teachers and academic administrative personnel. The regulations also define exempt computer employees under sections 13(a)(1) and 13(a)(17). The employer bears the burden of establishing the applicability of any exemption.[75] Job titles and job descriptions do not determine exemption status, nor does merely paying an employee a salary rather than an hourly rate.

As previously indicated, to satisfy the EAP exemption, employees must meet certain tests regarding their job duties[76] and generally must be paid on a salary basis at least the amount

[72] *Id.* at 51244.
[73] *Id.* at 51251.
[74] A lawsuit challenging the 2019 rule was filed in August 2022. The district court upheld the rule and an appeal of that decision was pending at the time the Department issued this final rule. *See Mayfield v. U.S. Department of Labor*, 2023 WL 6168251 (W.D. Tex. Sept. 20, 2023), *appeal docketed*, No. 23-50724 (5th Cir. Oct. 11, 2023).
[75] *See, e.g., Idaho Sheet Metal Works*, 383 U.S. at 209; *Walling*, 330 U.S. at 547–48.
[76] For a description of the duties that are required to be performed under the EAP exemption, *see* §§ 541.100 (executive employees); 541.200 (administrative employees); 541.300, 541.303–.304 (teachers and professional employees); 541.400 (computer employees); 541.500 (outside sales employees).

specified in the regulations.[77] Some employees, such as doctors, lawyers, teachers, and outside sales employees, are not subject to salary tests.[78] Others, such as academic administrative personnel and computer employees, are subject to special, contingent earning thresholds.[79] The standard salary level for the EAP exemption is currently $684 per week (equivalent to $35,568 per year), and the total annual compensation level for highly compensated employees under the HCE test is currently $107,432.[80] A special salary level of $455 per week currently applies to employees in Puerto Rico, Guam, the U.S. Virgin Islands, and the CNMI;[81] a special salary level of $380 per week applies to employees in American Samoa;[82] and employers can pay a special weekly "base rate" of $1,043 per week to employees in the motion picture producing industry.[83] Nondiscretionary bonuses and incentive payments (including commissions) paid on an annual or more frequent basis may be used to satisfy up to 10 percent of the standard or special salary levels.[84]

Under the HCE test, employees who currently receive at least $107,432 in total annual compensation are exempt from the FLSA's overtime requirements if they customarily and regularly perform at least one of the exempt duties or responsibilities of an executive,

---

[77] Alternatively, administrative and professional employees may be paid on a fee basis for a single job regardless of the time required for its completion as long as the hourly rate for work performed (*i.e.*, the fee payment divided by the number of hours worked) would total at least the weekly amount specified in the regulation if the employee worked 40 hours. *See* § 541.605.
[78] *See* §§ 541.303(d); 541.304(d); 541.500(c); 541.600(e). Such employees are also not subject to a fee basis test.
[79] *See* § 541.600(c)–(d).
[80] *See* §§ 541.600(a); 541.601(a)(1).
[81] *See* §§ 541.100; 541.200; 541.300.
[82] *See* §§ 541.100; 541.200; 541.300.
[83] *See* § 541.709.
[84] § 541.602(a)(3).

administrative, or professional employee identified in the standard tests for exemption.[85] The HCE test applies only to employees whose primary duty includes performing office or non-manual work.[86] Employees considered exempt under the HCE test must currently receive at least the $684 per week standard salary portion of their pay on a salary or fee basis without regard to the payment of nondiscretionary bonuses and incentive payments.[87]

D. The Department's Proposal

On September 8, 2023, consistent with its statutory authority to define and delimit the EAP exemption, the Department published a Notice of Proposed Rulemaking (NPRM) to revise the part 541 regulations.[88] The Department proposed to increase the standard salary level to the 35th percentile of weekly earnings of full-time salaried workers in the lowest-wage Census Region (currently the South), equivalent to $1,059 per week based on earnings data used in the NPRM.[89] The Department also proposed to apply this updated standard salary level to the four U.S. territories that are subject to the federal minimum wage—Puerto Rico, Guam, the U.S. Virgin Islands, and the CNMI—and to update the special salary levels for American Samoa and the motion picture industry in relation to the new standard salary level.[90] The Department

[85] § 541.601.
[86] § 541.601(d).
[87] *See* § 541.601(b)(1); *see also* 84 FR 51249.
[88] *See* 88 FR 62152.
[89] The Department noted that the final rule would use the most recent earnings data available to set the standard salary level, which would change the dollar amount of the resulting threshold. *See* 88 FR 62152-53 n. 3.
[90] In this final rule the Department is not finalizing its proposal in section IV.B.1 and B.2 of the NPRM to apply the standard salary level to the U.S. territories subject to the federal minimum wage and to update the special salary levels for American Samoa and the motion picture industry. The Department will address these aspects of its proposal in a future final rule. While the Department is not finalizing its proposal, it is making nonsubstantive changes in provisions addressing the territories as a result of other changes in this final rule.

additionally proposed raising the HCE test's total annual compensation requirement to the annual equivalent of the 85th percentile of weekly earnings of full-time salaried workers nationally, equivalent to $143,988 per year based on earnings data used in the NPRM. Finally, the Department proposed a new mechanism to update the standard salary level and the HCE total annual compensation threshold every 3 years to ensure that they remain effective tests for exemption.

The public comment period for the NPRM concluded on November 7, 2023. The Department received approximately 33,300 comments in response to the NPRM during the 60-day comment period.[91] Comments came from a diverse array of stakeholders, including employees, employers, trade associations, small business owners, labor unions, advocacy groups, nonprofit organizations, law firms, academics, educational organizations and representatives, religious organizations, economists, members of Congress, state and local government officials, tribal representatives, and other interested members of the public. All timely received comments may be viewed on the https://www.regulations.gov website, docket ID WHD-2023-0001.

Commenter views on the merits of the NPRM varied widely. Some of the comments the Department received were general statements of support or opposition, while many others addressed the Department's proposal in considerable detail. As with previous part 541 rulemakings, a majority of the total comments came from comment campaigns using similar or identical template language. Such campaign comments expressed support or opposition to the proposed salary level, and sometimes addressed other issues including applying the salary level

[91] In regulations.gov, the number of comments received is listed as 33,310 and the number of posted comments is 26,280. This difference is because one commenter, WorkMoney, attached thousands of comments to their one submission.

to teachers,[92] and concerns from nonprofit agencies. However, the Department also received thousands of unique comments. Significant issues raised in the comments are discussed in this final rule. Comments germane to the need for this rulemaking are discussed in section III, comments about the NPRM's proposals are discussed in section V, and comments about the potential costs, benefits, and other impacts of this rulemaking are discussed in section VII. The Department has carefully considered the timely submitted comments about the Department's proposal.

The Department received a number of comments on topics that are beyond the scope of this rulemaking. A significant number of commenters (including a large comment campaign) urged the Department to newly apply the part 541 salary criteria to teachers. The Department did not solicit comment about the exemption criteria for teachers in the NPRM and, as many commenters on this issue recognized, addressing this issue would require a separate rulemaking. Other topics outside the scope of this rulemaking include, for example, a request that the Department extend the right to overtime pay to medical residents, create exemptions from the salary level test, allow employers to credit the value of board and lodging towards the salary level, clarify issues related to the fluctuating workweek method of calculating overtime pay, or create a "safe harbor" provision for restaurant franchisors. The Department is not addressing these issues in its final rule.

Several stakeholders such as Catholic Charities USA and the National Council of Nonprofits expressed concern about funding and reimbursement rates to meet potential new

[92] As noted above, teachers are among the employees for whom there is no salary level requirement under the part 541 regulations. *See* § 541.303(d).

overtime expenses. The Department appreciates the concerns conveyed in these comments and the challenges of adjusting public funding. As discussed in section V.B.4.iv, however, the Department's EAP regulations have never had special rules for nonprofit or charitable organizations and employees of these organizations are subject to the EAP exemption if they satisfy the same salary level, salary basis, and duties tests as other employees.

III. Need for Rulemaking

The goal of this rulemaking is to set effective earnings thresholds to help define and delimit the FLSA's EAP exemption. To achieve this goal, the Department is not only updating the single standard salary level to account for earnings growth since the 2019 rule, but also to build on the lessons learned in its most recent rulemakings to more effectively define and delimit employees employed in a bona fide EAP capacity. To this end, the Department is finalizing its proposed changes to the standard salary level and the HCE test's total annual compensation requirement methodologies. Additionally, to maintain the effectiveness of these tests, the Department is finalizing an updating mechanism that will update these earnings thresholds to reflect current wage data, initially on July 1, 2024 and every 3 years thereafter. The Department's response to commenter feedback on the specific proposals included in the NPRM is provided in section V. This section explains the need for the Department to update the part 541 earnings thresholds and addresses commenter feedback on whether the earnings thresholds established in the 2019 rule should be increased.

As the Department explained in the NPRM, there is a need for the Department to update the salary level to fully restore the salary level's screening function and to account for the shift to a one-test system in the 2004 rule, which broadened the exemption by placing the entire burden

of this shift on employees who historically were entitled to the FLSA's overtime protection because they performed substantial amounts of nonexempt work and earned between the long and short test salary levels, but became exempt because they passed the more lenient standard duties test. Since switching from a two-test to a one-test system for defining and delimiting the EAP exemption in 2004, the Department has followed different approaches to set the standard salary level. In 2004, the Department used a methodology that produced a salary level amount that was equivalent to the lower long test salary level under the two-test system.[93] This approach continued to perform the historical screening function of the long salary test—providing overtime protection to employees who earned less than the long test salary level. But it broadened the exemption to include employees earning between the long and short test salary levels who historically had not met the long duties test (and therefore were not considered bona fide EAP employees) and now became exempt if they met the less rigorous standard duties test.[94] The Department followed this same methodology to set the standard salary level in 2019, but applying the 2004 rule's methodology to contemporaneous data in 2019 resulted in a salary level that was lower than what would have been the equivalent of the long test salary level and thus did not fulfill the historical screening function for low-paid employees.[95] This broadened the EAP exemption even further by, for the first time, exempting a group of white-collar employees earning below the equivalent of the long test salary level.

[93] *See* 69 FR 22168–69.
[94] *Id.* at 22214.
[95] *See* 84 FR 51260 (Table 4) (showing that the salary level derived from the Department's long test methodology would have been $724 per week rather than the finalized $684 per week amount).

To address the concern that the 2004 rule did not provide overtime compensation for lower-salaried white-collar employees performing large amounts of nonexempt work, in 2016 the Department set the standard salary level using a methodology that produced a salary at the low end of the historical range of short test salary levels.[96] This approach restored overtime protection to lower-salaried white-collar employees who performed substantial amounts of nonexempt work, but it also made nonexempt some employees paid below the new salary level who performed only a limited amount of nonexempt work and would have been exempt under the long duties test.[97] In the challenge to the 2016 rule, the district court expressed concern that the 2016 rule conferred overtime eligibility based on salary level alone to a substantial number of employees who would otherwise be exempt.[98]

As explained in greater detail in section V.B, setting the standard salary level at the 35th percentile of weekly earnings of full-time salaried workers in the lowest-wage Census Region ($1,128 per week, $58,656 annually), which is below the midpoint between the long and short tests, will work effectively with the standard duties test to better define and delimit the EAP exemption, in part by more effectively accounting for the switch from a two-test to a one-test system, and will reasonably distribute the impact of the shift by ensuring overtime protection for some lower-salaried employees without excluding from exemption too many white-collar employees solely based on their salary level.[99] The new standard salary level will also account for earnings growth since the 2019 rule and fully restore the historical screening function of the

[96] 81 FR 32405.
[97] *See* 84 FR 10908; 84 FR 51242.
[98] *See Nevada*, 275 F.Supp.3d. at 806.
[99] *See* section V.A.3.

salary level test. At the same time, the duties test will continue to determine exemption status for a large majority of all salaried white-collar employees subject to the part 541 regulations.

As the Department has explained,[100] earnings thresholds in the part 541 regulations gradually lose their effectiveness as the salaries paid to nonexempt employees rise over time. These impacts grow in the absence of increases to the salary threshold that keep pace with wage growth. Moreover, the longer it takes for the Department to implement such increases, the larger the increases must be to restore earning thresholds to maintain their effectiveness. More than 4 years have passed since the 2019 final rule established the current earnings thresholds. In the intervening years, salaried workers in the U.S. economy have experienced a rapid growth in their nominal wages, such that the current $684 per week salary level now corresponds to approximately the 12th percentile of earnings of full-time salaried workers in the lowest-wage Census Region and retail nationally. The longer the Department waits to update these earnings thresholds, the less effective they become in helping define and delimit the EAP exemption. For example, applying the 2019 standard salary level methodology to current earnings data will result in a new threshold of $844 per week—a 23 percent ($160 per week) increase over the current $684 salary level. Earnings for full-time wage and salary workers nationally have increased even more rapidly, rising by 24 percent during this period.[101]

The Department is also increasing the HCE total annual compensation threshold to the annualized weekly earnings amount of the 85th percentile of full-time salaried workers

[100] *See, e.g.*, 84 FR 51250–51.

[101] Estimate based on the change in median usual weekly earnings of full-time wage and salary workers from Q3 2019 to Q4 2023. BLS, Median usual weekly earnings of full-time wage and salary workers by sex, quarterly averages, seasonally adjusted. https://www.bls.gov/news.release/wkyeng.t01.htm.

nationally ($151,164). Similar to the standard salary level, nominal wage growth among higher-wage workers has eroded the effectiveness of the HCE threshold; data shows that the $107,432 threshold now corresponds to the 70th percentile of annual earnings of full-time salaried workers nationwide. Reapplying the 2019 methodology (annualized weekly earnings of the 80th percentile of full-time salaried workers nationally) to current earnings data would result in a threshold of $132,964 per year—a 24 percent increase over the current threshold of $107,432. Increasing the HCE test's total annual compensation threshold equivalent to the 85th percentile of salaried worker earnings nationwide will result in an HCE threshold reserved for employees at the top of today's economic ladder and, unlike a lower threshold, not risk the unintended exemption of large numbers of employees in high-wage regions.

Finally, the Department is adopting a mechanism to regularly update the thresholds for earnings growth, which will ensure that the thresholds continue to work effectively to help identify EAP employees. As noted above, the history of the part 541 regulations shows multiple, significant gaps during which the salary levels were not updated and their effectiveness in helping to define the EAP exemption decreased as wages increased. While the Department has generally increased its part 541 earnings thresholds every 5 to 9 years in the 37 years between 1938 and 1975, more recent decades have included long periods without raising the salary level, resulting in significant erosion of the real value of the threshold levels followed by unpredictable increases. Routine updates of the earnings thresholds to reflect wage growth will bring certainty and stability to employers and employees alike.

The Department received many comments addressing the adequacy of the current salary and compensation thresholds set in the 2019 rule and the need for this rulemaking. Generally,

employees and affiliated commenters, including labor unions, worker advocacy groups, plaintiff-side law firms, and others, supported the rulemaking as an overdue effort to restore FLSA protections that have eroded in recent decades, though a number of commenters urged the Department to adopt higher threshold increases than those proposed in the NPRM. By contrast, most employers and affiliated stakeholders opposed the main aspects of the proposal, with many urging the Department to withdraw the NPRM altogether. Some employers supported the proposal, or stated that they would support, or not oppose, some change to the current thresholds.

Many commenters agreed with the Department's assessment that the current salary level is too low.[102] *See, e.g.*, Coalition of Gender Justice and Civil Rights Organizations; Coalition of State Attorneys General; Economic Policy Institute (EPI); Schuck Law LLC; Texas RioGrande Legal Aid; United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union (United Steelworkers). Several commenters asserted that the current standard salary level "fails to provide a true incentive for employers to balance the additional hours they ask of their workers with the costs of . . . overtime pay[,]" which they stated in turn undermines the FLSA's policy goals of providing "extra pay for extra work . . . [and] spreading employment." *See, e.g.*, Center for Law and Social Policy (CLASP); Caring Across Generations; Family Values @ Work; Jobs to Move America; North Carolina Justice Center; Workplace Justice Project. Opining that the standard salary level "has been increased too infrequently – and by too little[,]" Business for a Fair Minimum Wage asserted that the "current outdated overtime threshold is ripe for abuse and fosters unfair pay, worker burnout, poorer

[102] Commenter views on the adequacy of the current HCE threshold are addressed in section V.C.

health and safety, and increased employee turnover." American Federation of Labor and Congress of Industrial Organizations (AFL-CIO) asserted that the $684 per week salary level is "so low that it risks becoming irrelevant[.]"

Finally, some supportive commenters provided reasons why, in their opinion, this rulemaking is timely. A joint comment submitted by 10 Democratic members of the House of Representatives asserted that "[o]vertime standards are long overdue for a meaningful update." *See also* AFL-CIO (asserting that setting the salary level below the long test level in the 2019 rule "led to the faster irrelevance of the current level"). The Coalition of State AGs commented that "[r]egardless of whether [the $684 per week standard salary] level was appropriate in 2019, economic trends in the intervening years have rendered that level obsolete . . . [as] $684 in January 2020 has the same buying power as $816.90 in September 2023." Sanford Heisler Sharp LLP (Sanford Heisler Sharp) invoked "the explosion of remote work since 2020" as support for the rulemaking, asserting that the significant increase in telework since 2020 has meant that employers are "no longer constrained by the practical limitation of the worker leaving the workplace."

Many employer trade associations that were neutral or opposed to the NPRM's specific proposals for increasing the compensation levels expressed openness or support for a rulemaking to change the existing part 541 earnings thresholds. *See, e.g.*, Alliance for Chemical Distribution; Growmark Comment Campaign (GROWMARK); National Cotton Ginners Association; National Golf Course Owners Association. Reporting on the results of a survey taken of its members, Society for Human Resource Management (SHRM) stated that its members "support a reasonable increase to the rule's minimum salary threshold . . . as only 4% of the total number of

respondents indicated that they would not support any increase." Independent Sector remarked that "a healthy and equitable nonprofit workforce requires an increase in the salary threshold beyond $35,568." *See also* North Carolina Center for Nonprofits ("The Center recognizes that a higher salary level threshold would benefit people served by nonprofits and many nonprofit employees, and we encourage the Department to move forward with a final rule that increases the [current] salary level threshold[.]"). National Association of Convenience Stores commented that it "acknowledges that the minimum salary level should be revisited occasionally, and it support[s] USDOL's approach in 2019 of doing so approximately every four years[.]" *See also* Retail Industry Leaders Association (RILA) ("We recognize that the DOL committed itself in 2019 to engage in more regular reviews of the salary threshold level for the [EAP] exemptions and that the DOL now is following up on that commitment.").

Other employer stakeholders disputed the need for this rulemaking. Many of these commenters, including the American Bus Association, Americans for Prosperity Foundation, Construction Industry Round Table, and National Restaurant Association, asserted that increases to the part 541 earnings thresholds were unnecessary at this time because the last update took effect on January 1, 2020. A number of commenters stated that prior salary level updates have occurred less frequently. *See, e.g.,* National Association of Manufacturers (NAM) (never less than 5 years); National Demolition Association (on average every 9 to 10 years); National Association of Wholesale Distributors (NAW) (historically 7 to 9 years). National Retail Federation (NRF) commented that "[t]here has been no increase of the federal minimum wage since 2019, and therefore, there is no need to adjust the minimum salary threshold." NRF further asserted that there was no need to increase the part 541 earnings thresholds because "market

forces have already increased the compensation of lower-level exempt employees" since 2019, echoing the sentiment from several individual employers that markets should determine employee wages rather than government regulation. *See also, e.g.*, Casa Del Mar Beachfront Suites (opposing changes to the regulations and stating that the wages it pays "are based on free enterprise and competitive business plans"); Individual Small Business Commenter (asking the Department to "let the market take care of the situation"). Numerous commenters also asserted that the Department should refrain from amending the part 541 regulations at this time due to current conditions in specific industries or the broader economy. *See, e.g.*, Asian American Hotel Owners Association, Inc.; American Hotel and Lodging Association (AHLA); College and University Professional Association for Human Resources (CUPA-HR); Food Marketing Institute (FMI); Indiana Chamber of Commerce; National Association of Home Builders (NAHB).

Finally, a small number of commenters opposed this rulemaking on the grounds that the Department lacks the legal authority to use any salary criteria to define and delimit the EAP exemption. *See, e.g.*, America First Policy Institute (AFPI); National Federation of Independent Business (NFIB); Pacific Legal Foundation.[103] However, the overwhelming majority of commenters did not oppose the use of salary criteria in the part 541 regulations or address the Department's authority, and a number of employer representatives expressed general support for the use of earnings thresholds. *See, e.g.*, AHLA ("[M]oving to a duties-only test would undoubtedly result in a more rigid duties test . . . [and] likely result in excessive burdens on the hospitality industry, including new and onerous recordkeeping requirements and increased

[103] *See* discussion in section V.A.

litigation costs."); National Restaurant Association ("[S]alary levels save investigators and employers time by giving them a quick, short-hand test[.]"); Transportation Intermediaries Association ("Implementing a duties-only test without considering salary would be overly complex[.]"). This sentiment is consistent with stakeholder feedback provided in earlier part 541 rulemakings.[104]

Having reviewed the comments received, the Department remains of the view that the earnings criteria in the part 541 regulations must be increased and disagrees with commenters that urged the Department to withdraw its proposal. In addition to updating the salary level to account for wage growth since 2019, an update is needed in part because the current standard salary level is too low to fully perform its screening role, as it is now significantly below the contemporary equivalent of the historical long test salary level ($942 per week).[105] Moreover, as the Department explained in the NPRM, there is a need for the Department to update the salary level to account for the shift to a one-test system in the 2004 rule, which broadened the exemption by placing the entire burden of this shift on employees who historically were entitled to the FLSA's overtime protection because they performed substantial amounts of nonexempt work and earned between the long and short test salary levels, but are now exempt because they pass the more lenient standard duties test. This effect would continue to grow over time in the absence of an increase to the current $684 per week standard salary level.

The Department disagrees with the criticism from some commenters that this rulemaking is premature due to the relative recency of the 2019 rule. In that rule, the Department

[104] *See supra* note 23.
[105] *See* sections V.B. and VII.C.8.

"reaffirm[ed] its intent to update the standard salary level and HCE total annual compensation threshold more regularly in the future" than it has in the past, noting that "long periods without updates . . . diminish the usefulness of the salary level test and cause future increases to be larger and more challenging for businesses to absorb."[106] Notably, the Department initially proposed in the 2019 NPRM to codify a commitment to update the part 541 earnings thresholds on a quadrennial basis (*i.e.*, once every 4 years) through notice and comment rulemaking.[107] While that proposed commitment was not adopted in the 2019 final rule, the Department reaffirmed the importance of, and its commitment to, regular updates in its 2019 final rule. The Department's 2019 final rule in no way suggested that increases to the part 541 earnings thresholds should occur only after some longer period of time.

Relatedly, the fact that employee salaries have grown substantially since 2019 underscores the need for this rulemaking. Commenter assertions to the contrary, including that the federal minimum wage has not increased since the salary level was last updated, misunderstand the purpose of the part 541 earnings thresholds, which are intended to assist in the identification of EAP employees based on the wages employees presently receive.[108] To the extent that employers have already been providing raises to exempt EAP workers since January 1, 2020 (the effective date of the 2019 final rule), as some commenters contended, those increases should be appropriately reflected in the earnings thresholds to ensure their effectiveness.

---

[106] 84 FR 51251–52.
[107] 84 FR 10914–15.
[108] The Department "is not authorized to set wages or salaries for executive, administrative, and professional employees . . . [and] improving the conditions of such employees is not the objective of the [part 541] regulations." Weiss Report at 11.

The Department is sensitive to commenter concerns about the potential impact of this rulemaking on affected employers. However, as discussed in greater detail in the regulatory impact analysis in section VII, the costs of this rule, while significant, are a necessary byproduct of ensuring a salary level that works effectively with the duties tests both now and in the future.

IV. Effective Date

The Department proposed that all aspects of the proposed rule would become effective 60 days after publication of the final rule. This proposed effective date was consistent with the 60 days mandated for a "major rule" under the Congressional Review Act and exceeded the 30-day minimum required under the Administrative Procedure Act (APA).[109] The Department recognized that the 60-day proposed effective date was shorter than the effective dates for the 2004, 2016, and 2019 rules, which were between approximately 90 and 180 days. The Department stated that a 60-day effective date was appropriate, however, in part because employers and employees are familiar with the procedures in the current regulations from the 2019 rulemaking and changed economic circumstances have caused a strong need to update the standard salary level. The Department also sought comments on whether to apply different effective dates to different provisions of the proposed rule. The Department is finalizing an effective date of July 1, 2024. The change to the standard salary level methodology and the change to the HCE total annual compensation methodology will have a delayed applicability date of January 1, 2025.[110] Accordingly, the standard salary level and HCE total annual compensation requirement will increase at the initial update on the effective date July 1, 2024 (to

[109] *See* 5 U.S.C. 801(a)(3)(A); 5 U.S.C. 553(d).
[110] The January 1, 2025 applicability date is six months after the effective date of the rule.

$844 and $132,964, respectively), again on the applicability date for the new methodologies on January 1, 2025 (to $1,128 and $151,164, respectively), and then every 3 years after the initial update on July 1 (using the methodology in effect at the time of each update).

The Department specifically asked for comments on whether the effective date for the increase of the standard salary level should be 60 days after publication as proposed or instead if the increase should be made effective at a later date, such as 6 months or 1 year after publication of the final rule. If the effective date were longer than 60 days, the Department sought comments on "whether it should initially adjust the salary level to reflect recent wage growth (for example, making an initial adjustment for wage growth 60 days after publication of a final rule and having the final rule standard salary level be effective 6 months or a year after publication)."[111] Were it to follow such an approach, the Department sought comments on the methodology it should use for an initial update, specifically "whether to implement an initial update to the standard salary level, effective 60 days after publication of a final rule, that uses the current salary level methodology (the 20th percentile of weekly earnings of full-time nonhourly workers in the lowest-wage Census Region and retail nationally) and applies it to the most recent data available[.]"[112]

[111] 88 FR 62180.

[112] *Id.* Commenters generally did not address the Department's suggestion that a delay in the effective date for the proposed standard salary level increase be combined with an initial update to the existing salary level to reflect wage growth. An individual commenter acknowledged the Department's suggestion but "defer[ed] to the economists and statisticians to comment as to whether, if the effective date is later than 60 days, the Department should initially adjust the salary level to reflect recent wage growth, and if so, the methodology for doing so." *See also* Ho-Chunk, Inc., a subsidiary of the Winnebago Tribe of Nebraska.

The Department did not specifically request comment on delaying the effective date of the proposed HCE compensation threshold beyond 60 days or on making an initial update using current data and the existing HCE compensation methodology if it were to delay the effective date of the new total annual compensation threshold. The Department stated that it believed a 60-day effective date was appropriate for the proposed increase to the HCE compensation threshold because only a relatively small number of employees earning between the current and proposed HCE compensation thresholds would not meet the standard duties test and be affected by the proposed change. The Department sought comment on the proposed effective date for the HCE compensation threshold.

Lastly, the Department proposed that the first automatic update to the new compensation levels be effective 3 years after the proposed 60-day effective date. The Department sought comments on whether the date for the first automatic update should be adjusted if it were to make an initial adjustment to any of the compensation levels.

Many commenters that objected to the proposed rule also objected to the proposed 60-day effective date should the Department go forward with a final rule. Commenters addressed their comments to the single 60-day effective date and generally did not suggest different effective dates for different provisions. Several commenters suggested effective dates between 90 and 180 days, which the NPRM noted was the range for recent rules. *See, e.g.*, HR Policy Association (minimum of 90 days); International Foodservice Distributors Association (IFDA) (minimum of 90 days); American Society of Travel Advisors (ASTA) (90 to 180 days); RILA (at least 120 days); NAIS/NBOA (at least 120 days). Several commenters suggested a 180-day effective date. *See, e.g.*, AASA/AESA/ASBO; CUPA-HR; LeadingAge; NRF. The National

Council of Young Men's Christian Associations of the United States of America (YMCA) suggested an effective date of at least 6 to 9 months. The United States Chamber of Commerce (Chamber), National Association of Convenience Stores, and NAFCU suggested an effective date of 12 months. Commenters including the U.S. Small Business Administration Office of Advocacy (SBA Advocacy), National Automobile Dealers Association, and Partnership to Protect Workplace Opportunity (PPWO) suggested an effective date of 12 to 18 months. Commenters including Seyfarth Shaw LLP (Seyfarth Shaw) and Credit Union National Association (CUNA) suggested an effective date of 150 days to align with the proposed notice period for future update amounts. A number of commenters suggested tying the effective date to the beginning of the next calendar year (January 1, 2025). *See, e.g.*, Seyfarth Shaw; SHRM; RILA; YMCA. Some commenters suggested a longer time period between the publication and effective date of the final rule for specific industries or types of employers. *See*, e.g., Boy Scouts of America (requesting at least 12 months of lead time for nonprofit employers); Small Business Majority (180 days for small businesses with fewer than 50 employees). A few commenters linked the need for a longer effective date with what they asserted was uncertainty as to the final salary amount caused by the Department's projections in footnote 3 of the NPRM, with NRF asserting that "[t]he brevity of the implementation period is particularly problematic given the Department's . . . lack of clarity about the dollar value of the proposed threshold." *See also* HR Policy Association; RILA.

Several commenters suggested phasing in any increase in the salary level, often in addition to an initial extension of the proposed effective date. Commenters advocating for a phase-in suggested a range of steps or timeframes. *See, e.g.*, ASTA (not less than 3 years);

Chamber (3 years in even or incrementally larger steps); North Carolina Center for Nonprofits ("multiple years"); National Council of Nonprofits (two or more steps); PPWO (a period of years), Safe Journeys (6 years); Washington Farm Labor Association ("multi-year"); YMCA (proportional increases over 5 years).

Most commenters supporting the Department's proposal did not specifically address the effective date for the Department's proposed changes. Commenters including American Federation of Teachers (AFT), National Partnership for Women & Families (National Partnership), and National Women's Law Center (NWLC) urged the Department to finalize the rule "without delay." American Federation of State, County, and Municipal Employees (AFSCME) specifically supported the 60-day effective date as proposed. A number of commenters in the home and community-based health services sector, that were generally supportive of the Department's intent but expressed concerns with its proposal, advocated for a longer effective date. ANCOR suggested a 2-year delayed effective date followed by a 3-to-5-year phase-in of the new salary level. *See also* Advancing States (18-month to 2-year effective date); National Association of State Directors of Developmental Disabilities Services (NASDDDS) (18- to 24-month effective date for providers of services to individuals with intellectual and developmental disabilities); United Cerebral Palsy (phase-in or transition period for the Department to work with the Centers for Medicare and Medicaid Services and the Administration for Community Living to minimize impact on access to services). BrightSpring Health Services urged the Department to delay the effective date for 2 years and to consider an enforcement delay for the sector as it did in 2016.

As discussed below, the Department believes it is important to update the standard salary level in part to account for substantial earnings growth since the Department last updated the salary level in the 2019 rule. It has been more than 4 years since the Department updated the salary level, and economic conditions have changed significantly since then as evidenced by the salary increase that would result by applying current data to the 2019 salary level methodology ($844 per week, an increase of $160 per week over the existing salary level). These economic conditions have also impacted employees subject to the HCE exemption. Applying current data to the 2019 HCE compensation methodology would result in an annual compensation threshold of $132,964 (an increase of $25,551 over the existing compensation threshold).

At the same time, the Department is also mindful of the desire expressed by multiple commenters to extend the effective date of the new standard salary and annual compensation methodologies from the proposed 60-day period to 6-to-12 months (or more). A longer effective date for the new standard salary level and HCE compensation methodologies would provide employers with more time to make adjustments after they are informed of the exact levels of the thresholds set in this final rule.

After considering the comments, the Department has determined that the final rule will be effective on July 1, 2024, but the new standard salary level methodology and the new HCE total annual compensation methodology will not be applicable until January 1, 2025. The Department is setting the effective date on July 1, 2024 rather than a set number of days after publication in the Federal Register because it will further administrability for employers to have the effective date coincide with the first of a month and some employers' budget years also begin on that

date.[113] While the rule will be effective on July 1, 2024, the Department is extending by an additional 6 months the time for employers to comply with the new standard salary level methodology and the HCE total annual compensation methodology. Accordingly, the applicability date for § 541.600(a)(2), which sets out the new standard salary level of the 35th percentile of weekly earnings of full-time nonhourly workers in the lowest-wage Census Region, and § 541.601(a)(2), which sets out the new HCE total annual compensation level of the annualized earnings amount of the 85th percentile of full-time nonhourly workers nationally, will be January 1, 2025. The Department decided to delay application of the new HCE total annual compensation methodology so that the new methodologies for both the standard salary level and the HCE compensation level take effect at the same time. The delayed applicability date will allow employers 6 additional months beyond the proposed 60-day effective date in which to evaluate employees who will be affected by the new standard salary level methodology and the new HCE compensation level methodology and make any adjustments.

New § 541.607, Regular updates to amounts of salary and compensation required, will be applicable on the effective date July 1, 2024. Because the current standard salary and HCE annual compensation levels have not been updated in more than 4 years, and economic conditions have changed markedly during that time, the first update will occur on that same date (§ 541.607(a)). Subsequent updates will occur every 3 years after this date starting on July 1, 2027 (§ 541.607(b)). As discussed in section V.A, regular updating of the standard salary and HCE annual compensation levels to reflect current wage data is imperative to ensure that they continue to work effectively in combination with the duties tests in defining bona fide EAP

[113] Future updates will occur every three years on July 1.

employees. In light of the approximately 8-month delay in applicability of the new standard salary and HCE total compensation methodologies, the initial update will use the current methodologies from the 2019 rule, which result in a salary level of $844 per week and an HCE total annual compensation threshold of $132,964. Accordingly, the requirement that an exempt employee be compensated on a salary basis at a salary level of at least $844 per week, set forth in § 541.600(a)(1), and that an employee receive total annual compensation of at least $132,964 per year to qualify for the HCE exemption, set forth in § 541.601(a)(1), will apply on July 1, 2024. The Department believes that this date for the initial update is appropriate because it will use methodologies that employers are familiar with. Subsequent triennial updates will apply the most recent four quarters of data to the standard salary and HCE total annual compensation levels in effect at the time of the updates. The Department anticipates that at the time of the first triennial update, the salary and compensation methodologies that are in effect will be the methodologies described in §§ 541.600(a)(2) and 541.601(a)(2) of this final rule. The Department notes that the standard salary and HCE compensation levels need to be updated regularly based on up-to-date earnings data to ensure that they continue to function effectively regardless of the methodology used to set the levels.

Except for the specific provisions discussed in this section that will become applicable on January 1, 2025, all other provisions of this final rule will be applicable on the effective date on July 1, 2024.

V. Discussion of Final Regulatory Revisions

Consistent with its statutory duty to define and delimit the EAP exemption, the Department is making several changes to the earnings thresholds provided in the part 541

regulations. As explained in greater detail below, the Department is setting the standard salary level at the 35th percentile of weekly earnings of full-time salaried workers in the lowest-wage Census Region (currently the South). The Department additionally is raising the HCE test's total annual compensation requirement to the annualized equivalent of the 85th percentile of weekly earnings of full-time salaried workers nationally. Finally, the Department is adopting a new mechanism to update the standard salary level and the HCE total annual compensation threshold, initially on July 1, 2024 and every 3 years thereafter to ensure that they remain effective tests for exemption. The Department is not making substantive changes to any provisions related to the salary basis or job duties tests.

The primary changes to the existing regulations are in §§ 541.5, 541.600, 541.601, and newly added § 541.607. In addition, the Department is making conforming changes throughout part 541 to update references to the applicable salary level requirements.[114] The discussion below begins with the new updating provision (§ 541.607), which will make an initial update to the salary and compensation thresholds on July 1, 2024, followed by discussion of changes to the standard salary level methodology (§ 541.600(a)(2)) and HCE total annual compensation

[114] The Department is also revising §§ 541.100, 541.200, and 541.300 to reflect that an executive, administrative, or professional employee must be compensated on a salary or fee basis at not less than the level set forth in § 541.600 (rather than referencing a specific salary level amount). Similarly, it is revising § 541.204 and § 541.400 to reflect that an employee employed in a bona fide administrative capacity and a computer employee may qualify for the section 13(a)(1) exemption if they are compensated on a salary or fee basis at not less than the level set forth in § 541.600 (rather than referencing a specific salary level amount). The Department is also updating cross-references to § 541.600(a) in §§ 541.602 and 541.605 to reference § 541.600(a)-(c). Finally, the Department is revising § 541.604, which explains the circumstances under which an employer may provide an exempt employee with additional compensation without violating the salary basis requirement, and § 541.605, which sets forth the conditions under which an administrative or professional employee may be compensated on a fee basis, with examples that reflect the new standard salary level amount of $1,128 per week.

threshold methodology (§ 541.601(a)(2)), which will become applicable on January 1, 2025. As noted in these sections, the Department intends for the changes in this final rule to be severable. Severability is addressed more fully at the end of the discussion of final revisions with a discussion of the new severability provision (§ 541.5).

A. Updating the Standard Salary Level and Total Annual Compensation Threshold

As the Department stated in the NPRM, it has long recognized the need to regularly update the earnings thresholds to ensure that they remain useful in helping differentiate between exempt and nonexempt white-collar employees. In each of its part 541 rulemakings since 2004, the Department has observed that a salary level that is not kept up to date becomes obsolete as wages for nonexempt workers increase over time.[115] Long intervals between rulemakings have resulted in eroded earnings thresholds based on outdated earnings data that were ill-equipped to help identify bona fide executive, administrative, and professional employees. This problem was most clearly illustrated by the stagnant salary levels in the regulations from 1975 to 2004, during which period increases in the federal minimum wage meant that by 1991, earnings of a worker paid the federal minimum wage exceeded the long test salary level for a 40-hour workweek and came close to equaling the short test salary level.[116]

The Department proposed in the NPRM a mechanism to regularly update the earnings thresholds to maintain their effectiveness. In a new § 541.607(a)(1) and (b)(1), the Department proposed to update the standard salary level and the HCE total annual compensation requirement every 3 years to reflect current earnings data. The Department proposed in § 541.607(a)(2) and

[115] 84 FR 51250–51; 81 FR 32430; 69 FR 22164. *See also*, 88 FR 62176.
[116] *See* section II.B.1.

(b)(2) to make the triennial updates using the methodologies proposed to set the thresholds in the NPRM—*i.e.*, the 35th percentile of weekly earnings of full-time nonhourly workers in the lowest-wage Census Region (currently the South) for the standard salary level and the annualized weekly earnings of the 85th percentile of full-time nonhourly workers nationally for the HCE total annual compensation requirement.[117] The NPRM also outlined in proposed § 541.607(c) the manner in which the Department would publish advance notice of the updated thresholds and included a pause mechanism in proposed § 541.607(d) that could be triggered to delay a scheduled update under certain circumstances.

The Department proposed to make the first update under its proposed updating mechanism 3 years after the effective date of the final rule. The effective date of the final rule was in turn proposed to be 60 days after publication and to apply to all aspects of the proposed rule, including the proposed methodologies for the standard salary level and the HCE total annual compensation threshold. As discussed in section IV, the Department specifically sought comments on whether the effective date for the proposed change to the standard salary level methodology (to the 35th percentile of weekly earnings of full-time salaried workers in the lowest-wage Census Region) should be 60 days after publication as proposed or if the change should be made effective at some later date, such as 6 months or 1 year after publication of the

[117] Observing that the proposed special salary level for American Samoa and the base rate for the motion picture industry are set in relation to the standard salary level, the Department also proposed that those earnings thresholds reset at the time the standard salary level was updated. The Department is not finalizing its proposal to apply the standard salary level to the U.S. territories subject to the federal minimum wage and to update the special salary levels for American Samoa and the motion picture industry. *See supra* note 9. Therefore, the updating mechanism finalized in this rule will not apply to the special salary levels at this time.

final rule.[118] If the effective date were longer than 60 days, the Department sought comments on "whether it should initially adjust the salary level to reflect recent wage growth (for example, making an initial adjustment for wage growth 60 days after publication of a final rule and having the final rule standard salary level be effective 6 months or a year after publication)."[119] The Department also sought comments on what methodology to use for the initial update, were it to follow such an approach. In particular, the Department invited comments on "whether to implement an initial update to the standard salary level, effective 60 days after publication of a final rule, that uses the current salary level methodology (the 20th percentile of weekly earnings of full-time nonhourly workers in the lowest-wage Census Region and retail nationally) and applies it to the most recent data available ($822 per week based on current data)."[120]

The Department received numerous comments on its proposed updating mechanism. Many organizations representing employee interests as well as some employers generally supported the updating mechanism, while most organizations representing employer interests opposed it. Many of the commenters opposing the proposed updating mechanism asserted that the Department lacked the authority to institute such a mechanism. After considering the comments received, the Department is finalizing the updating mechanism, with some modifications as discussed below, to keep the salary and compensation thresholds up to date with current data and maintain their effectiveness.

The first update under new § 541.607 will occur on July 1, 2024. As discussed in section IV, the new standard salary level and HCE total annual compensation threshold methodologies

[118] 88 FR 62180
[119] *Id.*
[120] *Id.*

will not be applicable until January 1, 2025 (a total of approximately 8 months after publication of this final rule). Accordingly, § 541.607(a) establishes an initial update on July 1, 2024 to the standard salary level and the HCE total annual compensation threshold using the methodologies in place at that time (*i.e.*, the 2019 rule methodologies), which results in a $844 per week standard salary level and a $132,964 HCE total annual compensation threshold. Section 541.607(b) further establishes future updates to the standard salary level and HCE total annual compensation threshold with current earnings data beginning 3 years after the date of the initial update, and every 3 years thereafter, using the methodologies in place at the time of the updates. The Department anticipates that by the time the first triennial update under the updating mechanism occurs on July 1, 2027, assuming the Department has not engaged in further rulemaking, the new methodologies for the standard salary level and HCE total annual compensation requirement established by this final rule will be effective and the triennial update would employ these new methodologies. In response to commenter concerns, the Department is also adding clarifying language from the NPRM preamble to the final regulatory text of the delay provision.

1. The Department's Authority to Adopt a Salary Level Test

The updating mechanism in new § 541.607 will maintain the effectiveness of the salary and compensation thresholds set in §§ 541.600 and 541.601 by adjusting them regularly to reflect current economic data. At the outset, a small number of commenters contended the Department lacked authority under section 13(a)(1) to even include a salary level test in the regulations, advocating for the Department to withdraw this rulemaking. *See, e.g.*, AFPI; Job Creators Network Foundation; NFIB; Pacific Legal Foundation. These commenters asserted that

the express terms of section 13(a)(1) do not permit the Department to include any compensation-based requirements.

The Department maintains its longstanding position that the Secretary's express authority to "define[]" and "delimit[]" the terms of the EAP exemption includes the authority to use a salary level test as one criterion for identifying employees who are employed in a "bona fide executive, administrative, or professional capacity." The Department has used a salary level test since the first part 541 regulations in 1938. From the FLSA's earliest days, stakeholders have generally favored the use of a salary test,[121] and the Department's authority to use a salary test has been repeatedly upheld,[122] including recently in *Mayfield v. U.S. Dept. of Labor*.[123] Despite numerous amendments to the FLSA over the past 85 years, Congress has not restricted the Department's use of the salary level tests in the regulations. Significant regulatory changes involving the salary requirements since 1938 include adding a separate salary level for professional employees in 1940, adopting a two-test system with separate short and long test salary levels in 1949, and creating a single standard salary level test and establishing a new HCE

[121] *See* Stein Report at 5, 19. As discussed in section V.B.4.i, the vast majority of employer commenters in this rulemaking, whether favoring no increase or a smaller increase, presumed the salary level test's continued existence and utility, with some, such as the National Restaurant Association, expressly referencing their support for the 2019 rule's salary level increase. Many commenters acknowledged the salary level's longstanding function of screening obviously nonexempt employees from the exemption. *See* section V.B.4.ii. Other commenters that opposed the proposal nonetheless cited benefits of having a salary level test, including helping to ensure that the EAP exemption is not abused, *see, e.g.*, AASA/AESA/ASBO, Bellevue University, and "sav[ing] investigators and employers time by giving them a quick, short-hand test[.]" *See* National Restaurant Association.

[122] *See, e.g.*, *Wirtz v. Miss. Publishers Corp.*, 364 F.2d 603, 608 (5th Cir. 1966); *Fanelli v. U.S. Gypsum Co.*, 141 F.2d 216, 218 (2d Cir. 1944); *Walling v. Yeakley*, 140 F.2d 830, 832–33 (10th Cir. 1944).

[123] 2023 WL 6168251 (W.D. Tex. Sept. 20, 2023), *appeal docketed*, No. 23-50724 (5th Cir. Oct. 11, 2023).

exemption test in 2004. These changes were all made through regulations issued pursuant to the Secretary's authority to define and delimit the exemption. Despite having amended the FLSA numerous times over the years, Congress has not amended section 13(a)(1) to alter these regulatory compensation requirements.

The FLSA gives the Secretary power to "define[]" and "delimit[]" the terms "bona fide executive, administrative, or professional capacity" through regulation. Congress thus "provided that employees should be exempt who fell within certain general classifications"—those employed in a bona fide executive, administrative, or professional capacity—and authorized the Secretary "to define and delimit those classifications by reasonable and rational specific criteria." [124] Therefore, the Department "is responsible not only for determining which employees are entitled to the exemption, but also for drawing the line beyond which the exemption is not applicable." [125]

2. Initial Update to the Standard Salary Level and Total Annual Compensation Threshold to Reflect the Change in Earnings Since the 2019 Rule

The Department received many comments regarding its proposed regulatory mechanism for updating the standard salary level and the HCE total annual compensation requirement to maintain their effectiveness. While commenters disagreed on how and when the salary and total annual compensation thresholds should be updated, commenters generally did not dispute that the earnings thresholds need to be periodically updated to reflect current economic conditions.

---

[124] *Walling*, 140 F.2d at 831-32; *see Ellis v. J.R.'s Country Stores, Inc.,* 779 F.3d 1184, 1199 (10th Cir. 2015) (approvingly quoting *Walling*); *see also Auer v. Robins,* 519 U.S. 452, 456 (1997) ("The FLSA grants the Secretary broad authority to 'defin[e] and delimi[t]' the scope of the exemption for executive, administrative, and professional employees.").
[125] Stein Report at 2.

Many commenters that opposed the proposed updating mechanism nonetheless agreed that the thresholds in the regulations need to be periodically updated. *See, e.g.*, ASTA; FMI; SBA Advocacy; SHRM; TechServe Alliance; World Floor Covering Association (WFCA).

In the context of addressing the Department's proposed standard salary level methodology, several commenters generally expressed support for—or in opposing the salary level suggested in the alternative—an increase to the salary level using the 2019 methodology. *See, e.g.*, Bellevue University; Center for Workplace Compliance (CWC); RILA; YMCA. CWC noted that the 2019 methodology is well-established and already familiar to employees and employers, and Bellevue University similarly stated that this methodology "has been previously field-tested on the U.S. economy[.]" As noted in section IV, commenters generally did not address applying the 2019 methodology through the updating mechanism.

The Department remains convinced that effective salary and compensation thresholds must use up-to-date earnings data. This position is long-standing. When the Department updated its salary level tests in 1949, for example, it explained that the "relative ineffectiveness of these tests in recent years is the result of changed economic conditions rather than any inherent weakness in the tests[,]" and that the "increase in wage rates and salary levels gradually weakened the effectiveness of the present salary tests as a dividing line between exempt and nonexempt employees."[126] The principle that effective tests for exemption must use up-to-date earnings data remains as true today as it was 75 years ago.

The Department's need to update the standard salary level and HCE total annual compensation requirement for current data in this rulemaking is distinct from its decision to

[126] Weiss Report at 8.

establish new methodologies for setting those thresholds. The current salary and compensation levels have been in place for more than 4 years and need to be updated to reflect current wage data to maintain their effectiveness.[127] Since the Department's last rulemaking in 2019, there has been significant change in salaried worker earnings.[128] The $684 standard salary level is far below what constitutes the 20th percentile of weekly earnings of full-time salaried workers in the South and/or in the retail industry nationally using current data, which greatly undermines the utility of the threshold as a means of helping distinguish exempt from nonexempt employees. The same is true for the HCE total annual compensation threshold. Updating the existing thresholds to reflect current earnings data is consistent with the intent the Department has expressed repeatedly in its past part 541 rulemakings, including in the 2019 rule, to periodically update the thresholds.

For these reasons, the Department is revising final § 541.607(a) to provide for an initial update to the standard salary level and HCE total annual compensation requirement with current earnings data on July 1, 2024. Specifically, the standard salary level will be updated to the 20th percentile of weekly earnings of full-time salaried workers in the South and/or in the retail industry nationally using the most recent data, resulting in a standard salary level of $844 per week. The HCE total annual compensation threshold will be updated to the 80th percentile of full-time salaried worker earnings nationwide using the most recent data, resulting in an annual compensation threshold of $132,964. The Department believes that the July 1, 2024 effective date provides sufficient time for employers to adjust to this initial update because the

[127] The standard salary level and HCE total annual compensation threshold in the 2019 rule were set using pooled data for July 2016 to June 2019, adjusted to reflect 2018/2019. 84 FR 51250.
[128] *See* section VII.

methodology used for the initial update to the standard salary level has been used since 2004 and is familiar to the regulated community. The size of the initial increase to the standard salary level, which is $160 per week, is also less (in nominal terms) than the $229 per week change that resulted from the 2019 rule.[129]

The initial update on July 1, 2024 and the change in the standard salary level and HCE total annual compensation methodologies on January 1, 2025 will result in two increases in the compensation thresholds within a 12-month period. The Department recognizes that for some employers both changes to the compensation thresholds may occur in the same budget year. Because both the amount of the initial update and the subsequent increase to the thresholds are set forth in this final rule, some employers may choose to make a single adjustment at the first date that encompasses both the initial update and the impending change to the standard salary level and the HCE total annual compensation threshold.[130]

The Department intends for the initial update of the standard salary level and the HCE total annual compensation requirement, using current earnings data applied to the 2019 rule methodologies, to be severable from future triennial updates to the thresholds under § 541.607(b), as well as from the revision to the methodologies for the standard salary level and the HCE total annual compensation threshold discussed in section V.B and section V.C. In implementing the initial update, the Department intends to account for changes in earnings since

[129] Consistent with the 2019 rule, the Department used pooled data for the most recent 3 years (2021, 2022, 2023), adjusting them to reflect 2023, for the initial updates to both the standard salary level and HCE total annual compensation threshold. *See* 84 FR 51250.

[130] Although the Department's approach is not a phase-in, the effect of increasing the salary level twice in 8 months is, from a timing perspective, not altogether different from the request from some commenters to phase in the salary level in more than one step. *See, e.g.*, Argentum & ASHA; Associated General Contractors; SBA Advocacy.

the 2019 rule. In changing the methodology for the standard salary level, the Department further intends to fully restore the salary level's historic screening function and account for the shift in the 2004 rule from a two-test to a one-test system for defining and delimiting the EAP exemption.[131] Lastly, in changing the methodology for the HCE total annual compensation threshold, the Department intends to ensure the HCE threshold's role as a streamlined alternative for those employees most likely to meet the standard duties test by excluding all but those employees "at the very top of [the] economic ladder[.]"[132] These are independent objectives of this rulemaking and the provisions implementing them can each stand alone. Therefore, the Department intends for the initial update to remain in force even if the methodologies for the standard salary level and/or the HCE total annual compensation threshold established by this final rule are stayed or do not take effect. Similarly, the Department intends for the initial update to remain in effect even if future triennial updates under § 541.607(b) are stayed or do not take effect.

The initial update will take effect approximately 60 days after the publication of the final rule, immediately coming out of this notice and comment rulemaking. As such, the notice procedures set forth in § 541.607(b)(3) will not apply. As discussed below, future triennial updates will be preceded by advance publication of a notice of the updated salary level and HCE total annual compensation threshold in the Federal Register. For the initial update, this final rule provides notice of the updated salary and compensation levels.[133]

---

[131] *See* section V.B.
[132] *See* section V.C.
[133] The NPRM included updating the 2019 rule standard salary level and HCE annual compensation threshold using 2022 data as a regulatory alternative, stating that applying the

3. Future Triennial Updates to Keep the Standard Salary Level and Total Annual Compensation Threshold Up to Date

As the Department previously explained, the earnings thresholds are only an effective indicator of exempt status if they are kept up to date. Left unchanged, the thresholds become substantially less effective in helping identify exempt EAP employees as wages for workers increase over time. To that end, the Department proposed to triennially update the standard salary level and HCE total annual compensation threshold by applying the most recent earnings data to the methodologies set forth in proposed § 541.600(a)(1) and § 541.601(a)(1), while any change to the methodologies used to set the standard salary level and HCE annual compensation threshold would be effectuated through future rulemaking.

The Department received many comments on its proposed triennial updating mechanism for keeping the thresholds up to date in the future, which are addressed below. The comments were sharply divided on this aspect of the NPRM. After considering the comments received, the Department concludes that establishing a mechanism for resetting the standard salary level and HCE total annual compensation requirement based on current earnings data, and on a regular 3-year schedule, will ensure that the thresholds remain effective into the future and thus better serve to help define and delimit the EAP exemption.

i. The Department's Authority to Update the Standard Salary Level and Total Annual Compensation Threshold with Current Data in the Future

The Department received many comments regarding its authority to update the earnings thresholds through the proposed triennial updating mechanism. A majority of the commenters

---

methodologies would result in a standard salary level of $822 per week and a HCE annual compensation threshold of $125,268. *See* 88 FR 62218.

opposing the updating mechanism challenged the Department's authority to adopt such a provision. Most commenters that supported the updating mechanism did not specifically discuss the Department's authority to institute such a mechanism. As to commenters supporting the proposed triennial updating mechanism that addressed the issue, they supported the Department's authority.

Commenters favoring automatic updating, such as AFL-CIO and EPI, agreed with the Department that just as the Department has authority to set salary thresholds for the EAP exemption, it also has authority to provide for regular updates to ensure the thresholds do not erode over time. Some supportive commenters further emphasized that future updates would make no change to the standard (*i.e.*, methodology) by which the Department implements the FLSA, but rather merely ensure that the standard accounts for current economic conditions. *See, e.g.*, Administrative Law Professors; Democracy Forward Foundation; EPI. The Administrative Law Professors similarly asserted that automatic adjustments to the earnings thresholds fall within the Secretary's authority to define and delimit "what it means to function in a 'bona fide executive, administrative, or professional capacity[.]'" Observing that even a so-called "static" salary threshold expressed in "non-indexed dollar terms" is constantly changing as a matter of economic value, the Administrative Law Professors asserted that "if a non-indexed salary threshold is lawful, as nobody seriously questions, so too is a standard pegged to income percentile." The Administrative Law Professors observed "it is arguably more rational" for the Department to "proffer a regulation that expressly accounts for the inevitably dynamic nature of every salary threshold . . . rather than to permit arbitrarily fluid macroeconomic conditions to dictate the threshold's true economic worth."

On the other hand, many commenters opposing the proposed updating mechanism asserted that the Department lacks statutory authority to update the thresholds in this manner. Some of these commenters contended that since the FLSA does not expressly authorize the Department to index the earnings thresholds unlike, for example, the Social Security Act or the Patient Protection and Affordable Care Act, it follows that the FLSA does not authorize the Department to automatically update the thresholds.[134] *See, e.g.*, CUPA-HR; International Dairy Foods Association (IDFA); PPWO; RILA; Seyfarth Shaw. Several commenters pointed out that Congress did not provide for automatic updating of any of the earnings requirements under the FLSA, such as the minimum wage under section 6, the tip credit wage under section 3(m), or the hourly wage for exempt computer employees under section 13(a)(17). *See, e.g.*, AFPI; FMI. Commenters including National Restaurant Association and PPWO further asserted that Congress never amended the FLSA to grant the Department explicit authority to index the salary level despite knowing that the Department has updated the salary level on an irregular schedule.

As the Department stated in the NPRM, the Department's authority to update the salary level tests for the EAP exemption by regularly resetting them based on existing methodologies is

[134] In contrast, the Administrative Law Professors highlighted that "[a]utomatic updating is a common feature of regulations pegged to monetary values, even when the relevant authorizing statutes make no specific reference to indexing or automatic adjustment." Some of the examples cited by the Administrative Law Professors to illustrate this point include: 79 FR 63317 (2014) (establishing automatic inflationary adjustments to the minimum amount set by the regulation to define "adverse credit history"); 76 FR 23110 (2011) (establishing automatic adjustments to the amount of "Denied Boarding Compensation" airlines must pay affected passengers); 88 FR 35150 (2023) (adopting once-every-five year inflation adjustments to the revenue threshold for defining a "small business"); and *Amusement & Music Operators Ass'n v. Copyright Royalty Tribunal*, 676 F.2d 1144 (7th Cir. 1982), cert. denied, 103 S. Ct. 210 (1982) (upholding a rule promulgated by the Copyright Royalty Tribunal establishing a $50 compulsory royalty fee to be paid by jukebox operators, and which would be subject to future inflationary adjustments).

grounded in section 13(a)(1), which expressly gives the Secretary broad authority to define and delimit the scope of the exemption. Using this broad authority, the Department established the first salary level tests by regulation in 1938. Despite numerous amendments to the FLSA over the past 85 years, Congress has not restricted the Department's use of the salary level tests. As just discussed, significant changes involving the salary requirements made through regulations issued pursuant to the Secretary's authority to define and delimit the exemption include adding a separate salary level for professional employees in 1940, adopting the two-test system in 1949, and switching to the single standard test and adding the new HCE test in 2004. Despite having amended the FLSA numerous times over the years, Congress has not amended section 13(a)(1) to alter these regulatory salary requirements.

Unlike the statutes some of the commenters referenced explicitly providing for indexing, or the statutory FLSA wage rates—*i.e.*, the minimum wage under section 6, the tip credit wage under section 3(m), or the hourly wage for exempt computer employees under section 13(a)(17)—the part 541 earnings thresholds are established in the regulations. Therefore, it is not surprising that the FLSA contains no specific reference to the indexing or automatic adjustments of these thresholds. The Department agrees with the Administrative Law Professors and other commenters that stated that the Department has the authority to establish a mechanism to automatically adjust the earnings thresholds to ensure their continued effectiveness, using a process established through notice and comment rulemaking, just as it has the authority to initially set them. The Department believes the updating mechanism in this final rule fulfills its statutory obligation to define and delimit the EAP exemptions by preventing the thresholds from becoming obsolete and providing predictability and clarity for the regulated community.

Many of the commenters opposed to the updating mechanism also asserted that automatically updating the earnings thresholds would violate the APA's rulemaking requirements expressly incorporated by reference in section 13(a)(1). *See, e.g.*, AFPI; FMI; National Club Association; and Wage and Hour Defense Institute. These and other commenters claimed that the Department cannot lawfully update the salary level without engaging in notice and comment rulemaking for each update. *See, e.g.*, AASA/AESA/ASBO; Competitive Enterprise Institute; CWC; RILA. IFDA, for example, asserted that notice and comment rulemaking needs to precede each future update so that stakeholders have the opportunity to comment on and adequately prepare for any changes that will affect them. AHLA commented that the proposal to update the thresholds triennially without a preceding opportunity for comment is "drastic and troublesome" and that "notice and comment will help ensure that the knowledge, expertise, and vital input of interested stakeholders will be considered before moving forward with increases."

Relatedly, AFPI, NRF, and SBA Advocacy asserted that automatic updating would violate the directive under section 13(a)(1) that the Department define and delimit the EAP exemption "from time to time" by regulations. NRF, for example, noted that Congress asked the Department to revisit the EAP exemptions from time to time "expecting the Department to use its deep knowledge of the U.S. economy in general, and labor market in particular, to establish appropriate parameters for the exemptions" and contended that by implementing automatic updates the Department evades that decision-making process. AFPI similarly asserted that the "directive, 'from time to time,' does not allow the Department to set it and forget it."

The Department disagrees with the assertion that triennial updates using the compensation methodologies adopted in the regulations improperly bypass the APA's—and

section 13(a)(1) by reference—requirements for notice and comment rulemaking. The Department is adopting an updating mechanism in this rulemaking after publishing a notice of the proposed rule and providing opportunity for stakeholders to comment in accordance with the APA's notice and comment requirements. The Department has received and considered numerous comments on the proposed updating mechanism. Future updates under the triennial updating mechanism would simply reset the thresholds by applying current data to a standard already established by notice and comment regulation, providing clarity for the regulated community as to future changes in the thresholds. Therefore, the Department disagrees with commenters that claimed that notice and comment rulemaking must precede each future update made through the updating mechanism even where the methodology for setting the compensation levels and the mechanism for updating those levels would remain unchanged.[135] The updating mechanism will not alter the Department's ability to engage in future rulemaking to change the updating mechanism or any other aspect of the part 541 regulations at any point.

The Department also disagrees with commenters that claimed section 13(a)(1)'s "time to time" language precludes the Department from adopting an updating mechanism. The updating

[135] Some commenters, such as Independent Electrical Contractors, RILA, and U-Haul, further asserted that automatic updates improperly bypass the requirements of the Regulatory Flexibility Act ("RFA") and executive orders requiring the Department to undertake a detailed economic and cost analysis. The Department disagrees. Pursuant to the RFA, the Department has included in this final rule as well as in the NPRM detailed estimates for the future costs of updates under the updating mechanism. *See* section VII and VIII; 88 FR 62224. Similarly, as relevant here, Executive Order 13563 directs agencies to take certain steps when promulgating regulations, including using the "best available techniques to quantify anticipated present and future benefits and costs as accurately as possible" and adopting regulations "through a process that involves public participation." 76 FR 3821 (Jan. 18, 2011). The current rulemaking fully satisfies all aspects of Executive Order 13563. *See* section VII; 88 FR 62182. The RFA and Executive Order 13563 do not require notice and comment rulemaking to precede future triennial updates made through the updating mechanism established in this rulemaking.

mechanism would only ensure the standard salary level and total annual compensation threshold remain at the percentiles established through rulemaking. This does not preclude the Department from engaging in future rulemaking "from time to time" if it determines that there is a need to change the underlying methodologies for setting the standard salary level or HCE total annual compensation threshold, the updating mechanism, or any other substantive change to part 541, as the Department did, for instance, in 1940, 1949, 1958 1975, 2004, 2016, and 2019.

Many commenters opposing the updating mechanism referenced the Department's prior statements to further support their assertion that the Department lacks authority to implement automatic updating. In particular, commenters pointed to the Department's decision not to institute an automatic updating mechanism in the 2004 rule and its statement that "the Department finds nothing in the legislative or regulatory history that would support indexing or automatic increases." *See, e.g.*, NAM; NFIB; SBA Advocacy. Others, like PPWO, further asserted that automatic updates are contrary to the Department's statement in the 2004 rule that "[t]he salary levels should be adjusted when wage survey data and other policy concerns support such a change."

As stated in the NPRM, the Department's decision not to institute an automatic updating mechanism in the 2004 and 2019 rulemakings in no way suggests that it lacks the authority to do so. In its 2004 rule, the Department stated that it found nothing in the legislative or regulatory history that would support indexing or automatic increases.[136] As the Department elaborated in its 2016 rulemaking, there was likewise no such authority prohibiting automatic updating.[137] The

[136] 69 FR 22171.
[137] *See* 81 FR 32432–33 (noting that "instituting an automatic updating mechanism . . . is an appropriate modernization and within the Department's authority.").

2004 rule did not discuss the Department's statutory authority to promulgate an updating mechanism through notice and comment rulemaking or explore in detail whether automatic updates to the salary levels posed a viable solution to problems created by lapses between rulemakings. As the Department explained in the 2016 rule, the Department's reference in the 2004 rule to automatic updating simply reflected the Department's conclusion at that time that an inflation-based updating mechanism, such as one based on changes in the prices of consumer goods, that unduly impacts low-wage regions and industries, would be inappropriate. Such concerns are not implicated here, where the mechanism will update the salary level to keep it at the same percentile of earnings of full-time salaried workers. As for concerns that the salary level should be updated only when wage data warrants it, the updating mechanism does just that—as the earnings thresholds will change only to the extent earnings data in the relevant data sets have changed, whether upward or downward as conditions dictate.

Similarly, the Department declined to adopt automatic updating in the 2019 rule because it "believe[d] that it is important to preserve the Department's flexibility to adapt to different types of circumstances,"[138] and not because it lacked authority to do so. While the Department decided not to institute an updating mechanism in its 2019 rule, it never said that it lacked the statutory authority to do so. Upon further consideration, the Department concludes that the best way to ensure the standard salary level and HCE total compensation threshold remain up to date is a triennial updating mechanism that maintains the Department's flexibility to adapt to different circumstances and change course as necessary.

[138] 84 FR 51252.

ii. Rationale for Continuing to Update the Standard Salary Level and Total Annual Compensation Threshold with Current Data in the Future

The Department explained in the NPRM that its proposed updating mechanism would allow for regular and more predictable updates to the earnings thresholds, which would benefit both employers and employees and would better fulfill the Department's statutory duty to define and delimit the EAP exemption by preventing the erosion of those levels over time. The Department noted that its regulatory history, marked in many instances by lengthy gaps between rulemakings, underscored the difficulty with updating the earnings thresholds as quickly and regularly as necessary to keep pace with changing employee earnings and to maintain the full effectiveness of the thresholds. Through the proposed updating mechanism, the Department explained it would be able to timely and efficiently update the standard salary level and the HCE total annual compensation requirement by using the same methodologies as initially proposed and adopted through notice and comment rulemaking to set the thresholds. The Department noted that updating the thresholds in this manner would prevent the more drastic and unpredictable increases associated with less frequent updates and ensure that future salary level increases occur at a known interval and in more gradual increments. The Department received many comments on the rationale for implementing the proposed triennial updating mechanism.

Several organizations representing employee interests as well as a handful of employers agreed with the Department that an updating mechanism would ensure the thresholds keep pace with wages and retain their usefulness. *See, e.g.*, Coalition of Gender Justice and Civil Rights Organizations; National Partnership; National Education Association (NEA); National Employment Lawyers Association (NELA); National Employment Law Project (NELP); Uncommon Goods; W.S. Badger Company. Nichols Kaster, PLLP (Nichols Kaster) noted the

updating mechanism protects the thresholds from becoming outdated and irrelevant, although it believed that annual updates would better reflect the economy. NELA commented that "indexing represents the only simple and accurate" way to preserve the real value of the standard salary level and the HCE total compensation threshold through time, although they contended that the proposed methodologies should be higher earnings percentiles.

Many commenters supportive of the updating mechanism also asserted that regular updates would provide greater predictability for employers and employees alike. *See, e.g.*, AFL-CIO; Center for WorkLife Law at University of California Law and Partner Organizations (Family Caregiving Coalition); Justice at Work; NEA. Small Business Majority expressed support for the proposed updating mechanism noting that smaller, predictable increases that are known well in advance—as opposed to "large and sudden" increases—would allow small business owners to be better prepared for any staffing or compensation changes they need to make. Nineteen Democratic Senators commented that an updating mechanism is the most effective way to provide consistency and stability for both workers and businesses. *See also, e.g.*, EPI; Washington State Department of Labor and Industries. CLASP similarly noted the proposed updating provision would enable employers to know exactly what to expect and when to expect it.

In contrast, many organizations representing employer interests disagreed with the Department's rationale for the proposed updating mechanism. Several of these commenters criticized the Department for stating that the updating mechanism is a more "viable and efficient" means of updating the thresholds by asserting that the Department is trying to avoid its obligation to engage in notice and comment rulemaking simply because such rulemaking is

resource-intensive. *See, e.g.*, IDFA; National Restaurant Association; PPWO. The Chamber similarly commented that the Department's history of long gaps in rulemaking is not an adequate justification for adopting what it characterized as "a historically unprecedented change."

Commenters including AHLA, FMI, the National Beer Wholesalers Association, and Seyfarth Shaw, asserted automatic updating would lead to uncertainty that would pose administrative and compliance burdens on employers. Some commenters, such as HR Policy Association and PPWO, asserted the proposed mechanism would make it difficult to ascertain exactly what the threshold will be every 3 years. Other commenters, including CUPA-HR, FMI, IDFA, and SHRM, asserted triennial updates would have a significant financial impact on employers as they would need to account for the cost of salaries or potential overtime as well as the cost of conducting reclassification analysis and implementing the necessary changes every 3 years. Some nonprofit organizations and providers of home and community-based health services expressed concern that future updates would be difficult for the nonprofit sector because of their funding sources. *See, e.g.*, Allegheny Children's Initiative; ANCOR.

Some commenters opposing the updating mechanism claimed automatic updates would hinder the Department from considering economic circumstances when making updates. Ten Republican Senators asserted automatic updates "blind the administration to critical considerations about the state of the economy and the workforce, including the unemployment rate, inflation, job vacancies, or whether employers are in a position to adjust to the increases without shedding jobs." Some commenters, including Illinois College, ISSA, and the Society of Independent Gasoline Marketers of America, expressed concern that the proposed mechanism could lead to updates happening at a time of economic downturn or a recession and could further

exacerbate those economic conditions. Others expressed concern that the updating mechanism would hinder future rulemaking to change the earnings thresholds. *See, e.g.*, Chamber; National Association of Convenience Stores.

The Department continues to believe that the updating mechanism will ensure the earnings thresholds keep pace with changes in earnings and remain useful in the future in helping to delineate EAP employees from non-EAP employees. Whereas a fixed salary level threshold becomes less effective over time as the data used to set it grows outdated, a fixed methodology remains relevant if applied to contemporaneous data. The Department agrees with the commenters that stated that the updating mechanism's triennial updates would provide greater certainty and predictability for the regulated community. Unlike irregular updates to the earnings thresholds, which may result in drastic changes to the thresholds, regular updates on a pre-determined interval and using an established methodology will produce more predictable and incremental changes. For this reason, the Department disagrees with the assertion by some commenters that regular updates will lead to unpredictable adjustments and ongoing uncertainty. The Department also disagrees with commenters like HR Policy Association that claimed the proposed mechanism will make it difficult to ascertain what exactly the threshold will be every 3 years. Through the updating mechanism, the Department will reset the standard salary level and total annual compensation threshold using the most recent, publicly available, U.S. Bureau of Labor Statistics (BLS) data on earnings for salaried workers. Therefore, stakeholders will be able to track where the thresholds would fall on a quarterly basis by looking at the BLS data[139] and can estimate the changes in the thresholds even before the Department publishes the notice with

[139] *See* https://www.bls.gov/cps/research/nonhourly/earnings-nonhourly-workers.htm.

the adjusted thresholds in the Federal Register. The Department believes that, compared to the irregular updates of the past, stakeholders will be better positioned to anticipate and prepare for future updates under the updating mechanism.

Moreover, the Department does not agree with the assertion that routine updates would lead to undue increases at a time of economic downturn or recession. If anything, the Department's new updating mechanism will ensure that the thresholds match the earnings data as they exist at the time of the update, whether by increasing or decreasing the earnings thresholds as warranted by the data. As discussed below, the Department's decision to deviate from the 2016 rule by adopting a mechanism for pausing future updates further guards against such concerns. Similarly, nothing about the updating mechanism precludes the Department from revisiting the standard salary level and HCE total annual compensation methodologies in the future when conditions warrant. Having considered the comments received, the Department remains convinced that an updating mechanism providing for regular updates on a triennial basis is the best means of ensuring that the salary and compensation tests continue to provide an effective means, in tandem with the duties tests, to distinguish between EAP and non-EAP employees.

iii. Specific Features of the Updating Mechanism

The Department received many comments regarding the various aspects of the proposed updating mechanism, including the updating frequency, methodology, notice period, and pause mechanism. The Department proposed in § 541.607(a) and (b) to update the earnings thresholds every 3 years by using the same methodology used in the regulations to set the thresholds. Specifically, proposed § 541.607(a)(2) and (b)(2) stated that the methodologies for setting the

standard salary level and HCE annual compensation threshold in the NPRM would be used for future updates.

Many commenters that supported the proposed updating mechanism expressed a preference for more frequent updates. *See, e.g.*, Coalition of State AGs; Jobs to Move America; NEA; NELP. Commenters including AFL-CIO, National Partnership, and Nichols Kaster asserted annual updates, compared to triennial updates, offered better predictability and would ensure that the salary threshold keeps pace with the changes in wages. EPI similarly observed that annual updates would ensure that the salary threshold more closely adheres to the chosen percentile "rather than slipping further and further behind in between triennial updates[.]"

Most commenters that opposed updating did not separately comment on the updating frequency, but some addressed it in the context of discussing the impact of the updating mechanism on employers. Many of these commenters claimed triennial updates would impose substantial financial and compliance burdens on employers as they would need to engage in reclassification analysis and implement necessary changes to adjust to the updated thresholds every 3 years. *See, e.g.*, ABC; CUPA-HR; HR Policy Association; NAM. Most of the commenters opposing the updating mechanism did not suggest an alternative updating frequency. Notwithstanding their objection to automatic updating, however, a few commenters, including AHLA, ASTA, WFCA, and YMCA, suggested a longer updating frequency ranging from 4 to 6 years.

The Department agrees with the commenters that stated annual updates would keep the salary level more up to date given that employee earnings are constantly changing. However, as stated in the NPRM, the Department is also mindful of the potential burden that possible changes

to the tests for exemption on an annual basis would impose on employers, including costs associated with evaluating the exemption status of employees on an annual basis. Conversely, the Department is not convinced by commenter claims that triennial updates would impose an undue financial and compliance burden on employers. Many of these commenters did not address the fact that the alternative to automatic updating is not a permanent fixed earnings threshold, but instead larger changes to the threshold that could occur during irregular future updates. Since the updating mechanism will change the thresholds regularly and incrementally, and based on actual earnings of salaried workers, the Department predicts that employers will be in a better position to be able to adjust to the changes resulting from triennial updates. The Department remains persuaded that triennial updates are frequent enough to ensure that the part 541 earnings thresholds are kept up to date—and continue to serve the purpose of helping to identify exempt employees—while not being overly burdensome for employers. The final rule, therefore, adopts an updating frequency of 3 years as proposed.

The comments regarding the method through which the Department's proposed updating mechanism would reset the salary and compensation thresholds were also divided. Commenters favoring routine updates also supported the proposal to update the thresholds using the fixed percentile approach—to keep the thresholds at the same percentile of earnings of full-time salaried worker as established by the regulations. NELA, for example, asserted that updating the thresholds using a fixed percentile of earnings "is the fairest way to maintain consistency in workers' FLSA eligibility in light of inevitable economic change." EPI similarly noted updating the thresholds through the proposed methodology ensures that the standard under the Department's rule "is simply preserved – neither strengthened nor weakened."

Commenters that opposed automatic updating opposed the proposed updating methodology. Several of these commenters reiterated an assertion from comments on the 2016 rulemaking that the proposed updating mechanism—tied to a fixed percentile—would result in the salary level being "ratcheted" upward over time due to the resulting actions of employers. *See, e.g.*, Chamber; NAM; NRF (including a report by Oxford Economics); SBA Advocacy. The commenters contended that in response to each automatic update, most employers would either reclassify employees earning below the new salary level to hourly status or raise the salaries of those employees to keep their exempt status. These responses, the commenters claimed, would skew the relevant data for future updates in favor of substantial increases because those employees who were reclassified as hourly would fall out of the data pool causing the data pool to be smaller and skew towards higher-paid workers. *See, e.g.*, Chamber; National Association of Convenience Stores; National Restaurant Association; NRF. While expressing a strong preference that automatic updates be abandoned altogether, some of the commenters concerned about this possible effect suggested that the Department adopt an updating mechanism tied to an inflation-related index. *See* Seyfarth Shaw; SHRM.

The Department notes that very similar comments concerning an alleged "ratcheting" effect were received during the 2016 rulemaking, which also proposed an updating mechanism based on earnings percentiles. In response to those comments, the Department examined historical data to determine the impact of its previous salary increase.[140] Specifically, the Department looked at the share of full-time white-collar workers paid on an hourly basis before and after the 2004 rule (January–March 2004; January–March 2005) both below and above the

[140] 81 FR 32441.

standard salary level. The Department found that following the 2004 rule, the share of full-time white-collar workers being paid hourly actually decreased marginally in the group below the standard salary level and increased slightly in the group above the standard salary level.[141]

The Department finds the claim that updating with a fixed percentile methodology would lead to the "ratcheting" upward of the thresholds to be unsubstantiated. The "ratcheting" claim is almost entirely based on the assumption that employers will respond to an automatically updated salary level by converting all or a large number of newly nonexempt workers to hourly status, thus removing them from the data set of full-time salaried workers. Yet none of the commenters advancing this claim presented any tangible data or evidence to support their assumption. Even those few commenters that provided economic analyses rested their views on the same unsubstantiated assumption that employers will generally reclassify newly nonexempt employees as hourly. *See, e.g.*, NRF (including a report by Oxford Economics); PPWO (quoting a study by Edgeworth Economics).[142] The results of the Department's close examination of the impact of the 2004 salary level increase provide no evidence that salary level increases due to regular triennial updating will result in employers converting significant numbers of affected EAP workers to hourly pay status and thus raising potential concerns about skewing future updates. Although many commenters made nearly identical ratcheting claims in this rulemaking, none of the commenters addressed the Department's analysis in response to those same claims in the 2016 rule.

[141] *See id.* at 32441, 32507–08.

[142] The Edgeworth Economic study that was quoted by PPWO and a few other commenters seemed to assume, without any support, that all affected workers or newly nonexempt workers who earn between $684 and $1,059 per week will be reclassified as hourly employees.

Having found no merit in the "ratcheting" claim, the Department declines to adopt the alternative methodologies suggested such as an updating mechanism tied to an inflation-related index. As noted in the NPRM, the fixed percentile approach, as opposed to other methods such as indexing the thresholds for inflation, eliminates the risk that future levels will deviate from the underlying salary setting methodology established through rulemaking. During the 2016 rule, the Department extensively considered whether to update the thresholds based on changes in the Consumer Price Index for All Urban Consumers (CPI-U)—a commonly used economic indicator for measuring inflation.[143] The Department chose to update the thresholds using the same methodology used to initially set them in that rulemaking (*i.e.*, a fixed percentile of weekly earnings of full-time salaried workers in the lowest-wage Census Region), observing that the objectives that justify setting the salary level using a fixed percentile methodology also supported updating the thresholds using the same methodology.[144] The Department is persuaded that updating the earnings thresholds by applying the same methodology used to originally set the levels instead of indexing them for inflation best ensures that the earnings thresholds continue to fulfill their objective of helping effectively differentiate between bona fide EAP employees and those who are entitled to overtime pay and work appropriately with the duties test.

New § 541.607 therefore establishes triennial updates of the standard salary level and the HCE total compensation threshold using the same methodologies used to set those thresholds. Assuming the Department has not engaged in further rulemaking, the Department anticipates the

[143] *See* 81 FR 32438–41.
[144] *See id*. at 32440.

second update under the updating mechanism—which will occur 3 years after the date of the initial update discussed in section V.A—will use the methodologies established by this final rule as those will become effective before the second update. Accordingly, the second update will reset the standard salary level to the 35th percentile of weekly earnings of full-time workers in the lowest-wage Census Region and will reset the HCE total annual compensation threshold to the annualized weekly earnings of the 85th percentile of full-time salaried workers nationally based on contemporaneous data at that time.

The Department further proposed to publish in the Federal Register a notice with the adjusted standard salary level and the HCE total annual compensation threshold at least 150 days before the date the adjusted thresholds are set to take effect and to publish the updated thresholds on WHD's website no later than their effective date. The Department proposed to update both thresholds using the most recent available 4 quarters of data, as published by BLS, preceding the publication of the Department's notice with the adjusted levels. The Department received fewer comments regarding these aspects of the proposal than on the updating mechanism itself.

Most commenters supporting the proposed updating mechanism did not separately comment on the 150-day notice period. Some commenters opposing automatic updates asserted that the 150-day notice period would not be adequate time to prepare for compliance with the new updated thresholds. *See, e.g.*, Association of Public and Land-grant Universities (APLU) (suggesting 180-day advance notice); Chamber (suggesting at least 1 year notice); National Association of Convenience Stores (same); The American Association of Advertising Agencies (The 4As) (same). Regarding the data set, EPI suggested the Department use the most recent quarter of data asserting that the salary threshold would be "suppressed" for 2 out of every 3

years if the Department adopts triennial updates. On the other hand, the National Association of Convenience Stores, while opposing automatic updating, recommended the Department use the most recent 6 quarters of data, or those quarters minus the 2 most recent, to account for changes it claimed employers may make preemptively to adjust to an upcoming update for budgetary reasons.

After considering the comments received, the Department is persuaded that a notice period of not less than 150 days provides sufficient time for employers to make the necessary adjustments to comply with the updated thresholds. This is especially true given that employers will be able to access the data set that will be used to make the adjustments as published by BLS and anticipate the extent of the adjustment even before the Department publishes the notice. A period substantially longer than 150 days would hinder the Department's ability to ensure that the thresholds that take effect are based on the most up-to-date data. Similarly, the Department believes that using the most recent available 4 quarters of data will account for the Department's goal that the thresholds reflect prevailing economic conditions while balancing the concerns of commenters that wanted a longer or shorter period for the data set. Therefore, the final rule establishes that for future updates under the updating mechanism, the Department will publish in the Federal Register a notice with the adjusted thresholds not fewer than 150 days before the date the new adjusted thresholds are set to take effect and will publish the updated thresholds on the WHD website no later than their effective date. The updates will be based on the most recent available 4 quarters of data as published by BLS.

Lastly, the Department's proposal included a provision providing for the delay of a scheduled update under the updating mechanism while the Department engages in notice and

comment rulemaking to change the earnings requirements and/or updating mechanism, where economic or other conditions merit. The Department explained that the delay would be triggered if the Department publishes an NPRM proposing to change the salary level methodology and/or modify the updating mechanism by the date on which it publishes the notice of the revised salary and compensation thresholds. In that instance, the notice with the adjusted thresholds must state that the scheduled update will be paused for 120 days from the day the update was set to occur while the Department engages in rulemaking, and that the pause will be lifted on the 121st day unless the Department finalizes a rule changing the salary level methodology and/or automatic updating mechanism by that time. In the event the Department does not issue a final rule by the prescribed deadline, the pause on the scheduled update will be lifted and the new thresholds will take effect on the 121st day after they were originally scheduled to take effect. The Department also explained the 120-day pause would not affect the date for the next scheduled triennial update given the relative shortness of the delay and so as not to disrupt the updating schedule. The next update, therefore, would occur 3 years from the date on which the delayed update would have originally been effective.

The Department received somewhat mixed comments regarding its proposed pausing mechanism. For example, notwithstanding their objection to automatic updating (and in some cases, certain aspects of the pause mechanism), some employer organizations such as CUNA, AHLA, and the National Association of Professional Insurance Agents commended the Department for recognizing that there may be circumstances that may require temporarily delaying a scheduled update. Some commenters that supported the updating proposal agreed. For example, the Coalition of State AGs described the delay provision as "a fail-safe mechanism"

that would provide the Department flexibility to adjust to changed circumstances as necessary. On the other hand, Sanford Heisler Sharp, while otherwise favoring the updating mechanism, objected to the pause feature asserting that it would "inject uncertainty into the administration of the threshold, undermining the stated purpose of the NPRM to simplify enforcement of overtime and minimum wage protections."

Some commenters took issue with the phrase "unforeseen economic or other conditions" in the NPRM's preamble which generally described the circumstances in which the Department may trigger the pause mechanism. AHLA, CUNA, and NAIS/NBOA asserted it is not clear what circumstances would constitute "unforeseen economic or other conditions." AFPI similarly pointed out the phrase was found only in the preamble and not in the proposed § 541.607. American Council of Engineering Companies expressed concern that the proposed pause mechanism does not provide sufficient flexibility for the Department to respond to unexpected economic conditions and recommended that the provision be modified to allow the Secretary "to suspend automatic updates if economic conditions warrant." RILA asserted the pause feature is an inflexible process asserting that if a catastrophic event were to occur within 150 days of the date of a scheduled update, the Department would have no flexibility or ability to delay or stop the update. A few commenters claimed that the 120-day pause period is not sufficient time to provide the Department the flexibility it needs to adjust to unforeseen circumstances or complete a rulemaking. *See, e.g.*, National Association of Convenience Stores; NRF.

Most of the comments objecting to or otherwise criticizing the pause mechanism seem to assume the only way the Department can alter a scheduled update or change any other aspect of the rule is through the updating mechanism's pause provision. That is not correct. Nothing in the

proposed updating mechanism limits the Department's ability to engage in future rulemaking to change any aspect of the part 541 regulations at any time. The pause mechanism offers the Department added flexibility—in addition to its ability to engage in rulemaking at any time to change the rule—by allowing it the ability to delay a scheduled update as it engages in rulemaking. As the Department noted in the NPRM, the pause mechanism offers the Department 270 days—150 days before, and 120 days after, the effective date for the scheduled update—to complete the rulemaking process. The Department can still engage in rulemaking outside of this period and through that rulemaking can stop or delay a scheduled update or change any other aspect of the part 541 regulations. This is true regardless of whether the Department adopts the delay provision. The Department believes that the pause provision will provide additional flexibility in the context of the triennial updates and will not impact the Department's normal rulemaking powers.

The Department recognizes that the phrase "unforeseen economic or other conditions" was not in proposed § 541.607 and agrees that the lack of this language in the regulatory text creates ambiguity about the standard for pausing a triennial update. Therefore, the Department is revising § 541.607(d) to include similar language. The Department believes this revision clarifies the standard for when the pause mechanism may be triggered but does not impinge on the Department's normal authority to engage in rulemaking for other reasons. The Department is disinclined to further define what circumstances would trigger the pause mechanism, as some commenters suggested. In proposing the pause mechanism, the Department was mindful of previous statements from stakeholders, and the Department's own prior statements, about the need to preserve flexibility to adapt to unanticipated circumstances. As an example, the

Department referenced the COVID pandemic and its widespread impact on workplaces. However, it is not feasible for the Department to outline every possible circumstance that could warrant a delay of a scheduled update. Doing so would unduly limit the Department's flexibility to adjust to truly unanticipated circumstances.

For these reasons, the Department has concluded that the proposed pause mechanism, with the modification noted above, provides the Department sufficient flexibility to adopt to unforeseen circumstances where necessary. Therefore, the new § 541.607(b)(4) establishes that the Department can trigger the pause, where unforeseen economic or other conditions warrant, by issuing an NPRM proposing to change the salary level methodology and/or modify the updating mechanism by the date on which it publishes the notice with the adjusted salary and compensation thresholds. Section 541.607(b)(4) further clarifies that the notice with the adjusted thresholds must state that the scheduled update will be paused for 120 days from the day the update was set to occur while the Department engages in rulemaking, and that the pause will be lifted on the 121st day unless the Department finalizes a rule changing the salary level methodology and/or automatic updating mechanism by that time.

Lastly, as discussed in more detail in section V.D, the Department intends for the triennial updates of the standard salary level and the HCE total annual compensation threshold using current earnings data to be severable from the revision to those methodologies discussed in section V.B and section V.C. In implementing routine triennial updates, the Department intends to ensure that the salary and compensation thresholds set in the regulations reflect changes in earnings data and continue to function effectively in helping identify exempt white-collar employees. As already noted, the Department has different objectives for changing the

methodologies for setting the standard salary level and HCE total annual compensation threshold. Specifically, in changing the methodology for the standard salary level, the Department intends to fully restore the salary level's historic screening function and account for the shift in the 2004 rule from a two-test to a one-test system for defining and delimiting the EAP exemption.[145] In changing the methodology for the HCE total annual compensation threshold, the Department intends to ensure the HCE threshold's role as a streamlined alternative for those employees most likely to meet the standard duties test by excluding all but those employees "at the very top of [the] economic ladder[.]"[146] These are independent objectives of this rulemaking and the provisions implementing them can each stand alone. Therefore, the Department intends for the triennial updates to remain in force even if the methodologies for the standard salary level and the HCE total annual compensation threshold established by this final rule are stayed or do not take effect. Similarly, the Department intends for the triennial updates under § 541.607(b) to remain in force even if the initial update for wage growth in § 541.607(a) is stayed or does not take effect.

B. Standard Salary Level

In its NPRM, the Department proposed to update the salary level by setting it equal to the 35th percentile of earnings of full-time salaried workers in the lowest-wage Census Region (the South), resulting in a proposed salary level of $1,059 per week ($55,068 for a full-year worker). The proposed salary level methodology built on lessons learned in the Department's most recent rulemakings to more effectively define and delimit employees employed in a bona fide EAP

[145] *See* section V.B.
[146] *See* section V.C.

capacity. Specifically, the Department's intent in the NPRM was to fully restore the salary level's screening function and account for the switch in the 2004 rule from a two-test system to a one-test system for defining the EAP exemption, while also updating the standard salary level for earnings growth since the 2019 rule.

The Department is finalizing the proposed standard salary level methodology and applying it to the most recent available earnings data, resulting in a salary level of $1,128 per week ($58,656 for a full-year worker). Setting the standard salary level at the 35th percentile of weekly earnings of full-time salaried workers in the lowest-wage Census Region will, in combination with the standard duties test, better define and delimit which employees are employed in a bona fide EAP capacity in a one-test system. Because the salary level is above the equivalent of the long test salary level, the final rule will (unlike the 2004 and 2019 rules) ensure that lower-paid white-collar employees who perform significant amounts of nonexempt work, and were historically considered by the Department not to be employed in a bona fide EAP capacity because they failed the long duties test, are not all included in the exemption. At the same time, by setting the salary level well below the equivalent of the short test salary level, the final rule will address potential concerns that the salary level test should not be determinative of EAP exemption status for too many white-collar employees. The combined result will be a more effective test for exemption. The final salary level will also reasonably distribute between employees and their employers what the Department now understands to be the impact of the 2004 shift from a two-test to a one-test system on employees earning between the long and short test salary levels.

1. History of the Salary Level

The FLSA became law in 1938 and the first version of the part 541 regulations, issued later that year, set a minimum compensation requirement of $30 per week for executive and administrative employees.[147] Since then, the Department has increased the salary levels eight times—in 1940, 1949, 1958, 1963, 1970, 1975, 2004, and 2019.

In 1940, the Department maintained the $30 per week salary level for executive employees but established a higher $200 per month salary level test for administrative and professional employees. In selecting these thresholds, the Department used salary surveys from Federal and state government agencies, experience gained under the National Industrial Recovery Act, and Federal government salaries to determine the salary level that was a reasonable "dividing line" between employees performing exempt and nonexempt work.[148]

In 1949, recognizing that the "increase in wage rates and salary levels" since 1940 had "gradually weakened the effectiveness of the present salary tests as a dividing line between exempt and nonexempt employees," the Department calculated the percentage increase in weekly earnings from 1940 to 1949, and then adopted new salary levels at a "figure slightly lower than might be indicated by the data" to protect small businesses.[149] In 1949, the Department also established a short test for exemption, which paired a higher salary level with a less rigorous duties test. The justification for this short test was that employees who met the higher salary level were more likely to meet all the requirements of the exemption (including the 20 percent limit on nonexempt work), and thus a "short-cut test of exemption . . . would facilitate

[147] 3 FR 2518.
[148] *See* Stein Report at 20–21, 31–32.
[149] Weiss Report at 8, 14.

the administration of the regulations without defeating the purposes of section 13(a)(1)."[150] Employees who met only the lower long test salary level, and not the higher short test salary level, were required to satisfy the long duties test, which included a limit on the amount of nonexempt work that an exempt employee could perform. The two-test system remained part of the Department's regulations until 2004. In 1958, the Department reiterated that salary is a "mark of [the] status" of an exempt employee and reinforced the importance of salary as an enforcement tool, adding that the Department had "found no satisfactory substitute for the salary tests."[151] To set the salary levels, the Department considered data collected during 1955 WHD investigations on the "actual salaries paid" to employees who "qualified for exemption" (*i.e.*, met the applicable salary and duties tests in place at the time) and set the salary levels at $80 per week for executives and $95 per week for administrative and professional employees.[152] The Department set the long test salary levels so that only a limited number of employees performing EAP duties (about 10 percent) in the lowest-wage regions and industries would fail to meet the new salary level and therefore become entitled to overtime pay.[153] In laying out this methodology, often referred to as the "Kantor" methodology and generally referenced in this rule as the "long test" methodology, the Department echoed its prior comments stating that the salary tests "simplify enforcement by providing a ready method of screening out the obviously nonexempt employees."[154]

[150] *Id*. at 22–23.
[151] Kantor Report at 2–3.
[152] *Id.* at 6, 9.
[153] *Id.* at 6–7.
[154] *Id.* at 2–3; *see* Weiss Report at 8.

The Department followed a similar methodology when determining the appropriate long test salary level in 1963, using data regarding salaries paid to exempt workers collected in a 1961 WHD survey.[155] The salary level for executive and administrative employees was increased to $100 per week, and the professional exemption salary level was increased to $115 per week.[156] The Department noted that these salary levels approximated the methodology used in 1958 to set the long test salary levels.[157]

The Department continued to use a similar methodology when it updated the salary levels in 1970. After examining data from 1968 WHD investigations, 1969 BLS wage data, and information provided in a report issued by the Department in 1969 that included salary data for executive, administrative, and professional employees,[158] the Department increased the long test salary level for executive and administrative employees to $125 per week and increased the long test salary level for professional employees to $140 per week.[159]

In 1975, instead of following the previous long test methodology, the Department set the long test salary levels "slightly below" the amount suggested by adjusting the 1970 salary levels for inflation based on increases in the Consumer Price Index.[160] The long test salary level for executive and administrative employees was set at $155, while the professional level was set at $170. The salary levels adopted were intended to be interim levels "pending the completion and analysis of a study by [BLS] covering a six-month period in 1975[,]" and were not meant to set a

[155] 28 FR 7002 (July 9, 1963).
[156] *Id.* at 7004.
[157] *Id*.
[158] *See* 34 FR 9934, 9935 (June 24, 1969).
[159] 35 FR 885.
[160] 40 FR 7091.

precedent for future salary level increases.[161] The envisioned process was never completed, however, and the "interim" salary levels remained unchanged for the next 29 years.

The short test salary level increased in tandem with the long test level throughout the various rulemakings between 1949 and 2004. Because the short test was designed to capture only those white-collar employees whose salary was high enough to indicate a stronger likelihood of being employed in a bona fide EAP capacity and thus warrant a less stringent duties requirement, the short test salary level was always set significantly higher than the long test salary level (approximately 130 percent to 180 percent of the long test level).

When the Department updated the part 541 regulations in 2004, it created a single standard test for exemption instead of retaining the two-test system from prior rulemakings. The Department set the new standard salary level at $455 per week and paired it with a duties test that was substantially equivalent to the less rigorous short duties test. The Department set a salary level that would exclude from exemption roughly the bottom 20 percent of full-time salaried employees in each of two subpopulations: (1) the South and (2) the retail industry nationally. In setting the salary level the Department looked to earnings data for all white-collar workers—exempt and nonexempt—and looked to a higher percentile than the long test methodology (10th percentile of exempt workers in low-wage industries and areas). The Department acknowledged, however, that the salary arrived at by this method was, at the time, equivalent to the salary derived from the long test method using contemporaneous data.[162]

---

[161] *Id*. at 7091–92.

[162] *See* 69 FR 22168. The 2004 rule looked to the 20th percentile of a data set of all full-time salaried workers and the long test methodology looked to the lowest paid 10 percent of exempt salaried workers. The two methodologies resulted in equivalent salary levels because exempt salaried workers generally have higher earnings than nonexempt salaried workers.

In the 2016 rule, the Department set the standard salary level equal to the 40th percentile of weekly earnings of full-time salaried workers in the lowest-wage Census Region (the South). This resulted in a standard salary level of $913 per week, which was at the low end of the historic range of short test salary levels. The Department explained that the increase in the standard salary level was needed because, in moving from a two-test to a one-test system, the 2004 rule exempted lower-salaried employees performing large amounts of nonexempt work who had historically been, and should continue to be, covered by the overtime compensation requirement.[163] Since the standard duties test was equivalent to the short duties test, the Department asserted that a salary level in the short test salary range—traditionally 130 to 180 percent of the long test salary level—was necessary to address this effect of the 2004 rule. As explained earlier, the U.S. District Court for the Eastern District of Texas held the 2016 rule invalid.

In the 2019 rule, the Department reapplied the methodology for setting the standard salary threshold from the 2004 rule, setting the salary level equal to the 20th percentile of weekly earnings of full-time salaried workers in the South and/or in the retail sector nationwide.[164] This methodology addressed concerns that had been raised that the 2016 methodology excluded too many employees from the exemption based on their salary alone and produced the current standard salary level of $684 per week (equivalent to $35,568 per year).[165] Unlike in 2004, however, where the 20th percentile of weekly earnings of full-time salaried workers in the South and retail nationally was essentially the same as the long test, in 2019 this methodology now

[163] 81 FR 32405.
[164] *See* 84 FR 51260 (Table 4).
[165] *Id*. at 51238.

produced a salary level amount that was lower than the equivalent of the long test salary level using contemporaneous data ($724 per week, $37,648 per year). Put another way, the salary level set in the 2019 rule was $40 per week below the long test level (used to validate the salary level in the 2004 rule) and $292 per week below the low end of the short test range (used to set the salary level in the 2016 rule).

2. Standard Salary Level Proposal

In its NPRM, the Department proposed to update the salary level by setting it equal to the 35th percentile of earnings of full-time salaried workers in the lowest-wage Census Region (the South), resulting in a proposed salary level of $1,059 per week ($55,068 for a full-year worker). The Department's proposal explained that fully restoring the salary level's screening function required setting a salary level at least equal to the long test salary level. The Department elaborated that prior to the 2019 rule (when the Department set the salary level $40 per week below the long test level), employees who earned below the long test salary level were screened from the EAP exemption by virtue of their pay—either by the long test salary level itself or, in the case of the 2004 rule, a standard salary level set equal to the long test salary level. The Department stated that the long test salary level provided what it believed should be the lowest boundary of the new salary level methodology because it would ensure the salary level's historic screening function was restored.

In selecting the proposed salary level methodology, the Department also considered the impact of its switch in 2004 to a one-test system for determining exemption status. The Department explained that a single-test system cannot fully replicate both the two-test system's heightened protection for employees performing substantial amounts of nonexempt work and its

increased efficiency for determining exemption status for employees who are highly likely to perform EAP duties. Rather than reinstate the long duties test with its limitation on nonexempt work, the Department examined earnings ventiles that would produce a salary level between the long and short test salary levels (which were, respectively, equivalent to between the 26th and 27th percentiles, and the 53rd percentile, of full-time salaried worker earnings in the lowest-wage Census Region). The Department explained that the long and short tests had served as the foundation for nearly all the Department's prior rulemakings, either directly under the two-test system, or indirectly as a means of evaluating the Department's salary level methodology under the one-test system, and therefore were useful parameters. The Department concluded that setting the salary level equal to the 35th percentile would, in combination with the standard duties test, more effectively identify in a one-test system who is employed in a bona fide EAP capacity in a manner that reasonably distributes among employees earning between the long and short test salary levels and their employers the impact of the Department's move to a one-test system.

After reviewing the comments received, the Department is finalizing its proposal to set the standard salary level equal to the 35th percentile of full-time salaried worker earnings in the lowest-wage Census Region (the South), which is below the midpoint of the long and short test salary levels. Applying this methodology to data for calendar year 2023 results in a salary level of $1,128 per week ($58,656 annually for a full-year worker). This approach will fully restore the salary level's function of screening obviously nonexempt workers from the EAP exemption, and account for the switch in the 2004 rule to a one-test system in a way that reasonably distributes the impact of this shift among employees earning between the long and short test

salary levels and their employers. The resulting salary level will work effectively with the standard duties test to better define who is employed in a bona fide EAP capacity.

3. Salary Level Test Function and Effects

For 85 years, the Department's regulations have consistently looked at both the duties performed by the employee and the salary paid by the employer in defining and delimiting who is a bona fide executive, administrative, or professional employee exempt from the FLSA's minimum wage and overtime protections. From 1949 to 2004, the Department determined EAP exemption status using a two-test system comprised of a long test (a lower salary level paired with a more rigorous duties test that limited performance of nonexempt work to no more than 20 percent for most employees) and a short test (a higher salary level paired with a less rigorous duties test that looked to the employee's primary duty and did not have a numerical limit on the amount of nonexempt work). The two-test system facilitated the determination of whether white-collar workers across the income spectrum were employed in a bona fide EAP capacity, and employees who met either test could be classified as EAP exempt.

In a two-test system, the long test salary level screens from the exemption the lowest-paid white-collar employees, thereby ensuring their right to overtime compensation. The Department has often referred to many of the employees who are screened from the exemption by virtue of their earning below the lower long test salary level as "'obviously nonexempt employees[.]'"[166] The long test salary level helped distinguish employees who were not employed in a bona fide EAP capacity because the Department found that employees who were screened from exemption

[166] *See id.* at 51237 (quoting Kantor Report at 2–3).

by the long test salary level generally did not meet the other requirements for exemption.[167] Since 1958, the long test salary level was generally set to exclude from exemption approximately the lowest-paid 10 percent of salaried white-collar employees who performed EAP duties in the lowest-wage regions and industries.[168] The long test salary level also served as a line delimiting the population of white-collar employees for whom the duties test determined their exemption status. In the two-test system, this duties analysis included an examination of the amount of nonexempt work performed by lower-salaried employees, which ensured that these employees were employed in an EAP capacity by limiting the amount of time they could spend on nonexempt work. The duties and salary level tests worked in tandem to properly define and delimit the exemption: lower-paid workers had to satisfy a more rigorous duties test with strict limits on nonexempt work, and higher-paid employees were subject to a less rigorous duties test because they were more likely to satisfy all the requirements of the exemption (including the limit on nonexempt work).[169]

Because employees who met the short test salary level were paid well above the long test salary level, the short test salary level did not perform the same function as the long test salary level of screening obviously nonexempt employees. Instead, the short test salary level was used to determine whether the full duties test or the short-cut duties test would be applied to determine EAP exemption status. The exemption status of employees paid more than the long and less than the short test salary levels was determined by applying the more rigorous long duties test that

[167] *See* Kantor Report at 2–3; Weiss Report at 8 ("In an overwhelming majority of cases, it has been found by careful inspection that personnel who did not meet the salary requirements would also not qualify under other sections of the regulations[.]").
[168] *See* 84 FR 51236.
[169] Weiss Report at 22–23.

ensured overtime protections for employees who performed substantial amounts of nonexempt work. The exemption status of employees paid at or above the higher short test salary level was determined by the less rigorous short duties test that looked to the employee's primary duty and did not cap the amount of nonexempt work an employee could perform. The short test thus provided a faster and more efficient duties test based on the Department's experience that employees paid at the higher short test salary level "almost invariably" met the more rigorous long duties test, including its 20 percent limit on nonexempt work, and therefore a shortened analysis of duties was a more efficient test for exemption status.[170]

In 2004, rather than updating the two-test system, the Department chose to establish a new, single-test system for determining exemption status. The new single standard test for exemption used a duties test that was substantially equivalent to the less rigorous short duties test in the two-test system.[171] Since the creation of the standard test, the Department has taken two different approaches to set the standard salary level that pairs with the standard duties test.

In 2004, as noted above, the Department set the new salary level roughly equivalent to the 20th percentile of weekly earnings of full-time salaried workers in the South and in the retail industry nationwide.[172] The Department acknowledged that the salary level ($455 per week) was, in fact, equivalent to the lower long test salary level amount under the two-test system using contemporaneous data.[173] Because it was equivalent to the long test salary level, the standard salary test continued to perform the same initial screening function as the long test salary level:

[170] *Id.*
[171] 69 FR 22214.
[172] *See id.* at 22168–69.
[173] *See id.*

employees who historically were entitled to overtime compensation because they earned below the long test salary level remained nonexempt under the new standard test.

Without a higher salary short test, however, all employees who met the standard salary level were subject to the same duties test. Since the single standard duties test was equivalent to the short duties test, some employees who previously did not meet the long duties test met the standard duties test. As a result, the shift from a two-test to a one-test system significantly broadened the EAP exemption because employees who historically had not been considered bona fide EAP employees were now defined as falling within the exemption and would not be eligible for overtime compensation. This broadening specifically impacted lower-paid, salaried white-collar employees who earned between the long and short test salary levels and performed substantial amounts of nonexempt work. Under the two-test system, these employees had been entitled to overtime compensation if their nonexempt duties exceeded the long test's strict 20 percent limit on such work. Under the 2004 standard test, these employees became exempt because they met both the low standard salary level and the less rigorous standard duties test, which does not have a numerical limit on the amount of nonexempt work.

The Department's discussion of the elimination of the long duties test in the 2004 rule focused primarily on the minimal role played by the long test at that time due to the erosion of the long salary level, and on the difficulties employers would face if they were again required to track time spent on nonexempt work when the dormancy of the long duties test meant that they had generally not been performing such tracking for many years.[174] While asserting that employees who were then subject to the long test would be better protected under the higher

[174] *See* 69 FR 22126-27.

salary level of the new standard test, the Department in the 2004 rule did not compare the protection lower salaried employees would receive under the standard test with the protection they would have received under an updated long test with a salary level based on contemporaneous data and the existing long duties test.

To address the concern that lower-salaried employees performing large amounts of nonexempt work historically were not considered bona fide EAP employees and thus should be entitled to overtime compensation, in 2016 the Department set the standard salary level at the 40th percentile of weekly earnings of full-time salaried workers in the lowest-wage Census Region (the South). This methodology produced a salary level ($913 per week) that was at the low end of the historical range of short test salary levels, which had traditionally been paired with the short duties test, and above the midpoint between the long and short test salary levels.[175] This approach restored overtime protection for employees performing substantial amounts of nonexempt work who earned between the long and short test salary levels, as they failed the new salary level test. However, this approach generated potential concerns that the salary level test should not be determinative of exemption status for too many individuals. Specifically, the 2016 rule's narrowing of the exemption prevented employers from using the exemption for employees who earned between the long test salary level and the low end of the short test salary range and would have met the more rigorous long duties test. Prior to 2004, employers could use the long test to exempt these employees, and under the 2004 rule these employees remained exempt under the one-test system. Thus, while the 2016 rule accounted for the absence of the long duties test by restoring overtime protections to employees earning between the long test salary level and the

[175] 81 FR 32405, 32467.

low end of the short test salary range who perform significant amounts of nonexempt work, it also made a group of employees who had been exempt under the two-test system newly nonexempt under the one-test system: employees earning between the long test level and the short test salary range who perform only limited nonexempt work.

In its 2019 rule, the Department determined that the 2016 rule had not sufficiently considered the impact of the increased standard salary level on employers' ability to use the exemption for this group of lower-paid employees who performed only limited amounts of nonexempt work.[176] The Department emphasized that "[f]or most . . . employees the exemption should turn on an analysis of their actual functions, not their salaries," and that the 2016 rule's effect of making nonexempt lower-paid, white-collar employees who traditionally were exempt under the long test "deviated from the Department's longstanding policy of setting a salary level that does not 'disqualify[] any substantial number of' bona fide executive, administrative, and professional employees from exemption."[177] To address these concerns, the Department simply returned to the 2004 rule's methodology for setting the salary threshold. Applying the 2004 method to the earnings data available in 2019 produced a standard salary level of $684 per week, which was below the equivalent of what the long test salary level would have been using contemporaneous data ($724 per week).[178] The 2019 rule was the first time the Department paired the standard duties test with a salary level that was not at least equivalent to the long test level.

[176] 84 FR 10908.
[177] *Id.* (quoting Kantor Report at 5).
[178] 84 FR 51260.

The 2019 rule, like the 2004 rule, exempted all employees who earned between the long and short test salary levels and performed too much nonexempt work to meet the long duties test, but passed the standard duties test (equivalent to the short duties test). The 2019 rule also for the first time permitted the exemption of a group of low-paid white-collar employees (those earning between $684 and $724 per week) who had always been protected by the salary level test's initial screening function—either under the long test or under the 2004 rule salary level that was equivalent to the long test salary level. The Department stated that the standard salary level's "fairly small difference" from the long test level did not justify using the long test methodology to set the salary level and emphasized that its approach preserved the salary level's principal function as a tool for screening from exemption obviously nonexempt employees.[179] In response to commenter concerns about the 2019 rule exempting employees who traditionally earned between the long and short test salary levels and received overtime compensation because they did not meet the long duties test, the Department cited the legal risks posed by the 2016 methodology (drawing on the district court's decisions as evidence) and explained that such employees were already exempt in the years leading up to 2004 because the Department's outdated salary levels had rendered the long test with its more rigorous duties requirement largely dormant.[180] As in the 2004 rule, the Department did not address the protection such lower salaried employees would have received had the Department updated the long test using contemporary data.

[179] *Id.* at 51244.
[180] *Id.* at 51243.

As explained in the NPRM, the Department's experience with a one-test system shows that it is less nuanced than the two-test system, which allowed for finer calibration in defining and delimiting the EAP exemption. In a two-test system, there are four variables (two salary levels and two duties tests) that can be adjusted to define and delimit the exemption. In a one-test system, there are only two variables (one salary level and one duties test) that can be adjusted, necessarily yielding less nuanced results. The loss in precision does not impact the lowest-paid white-collar employees, who were screened from exemption by the long test salary level, because they maintain their right to overtime pay so long as the standard salary level is set at least equivalent to the lower long test salary level—a condition that was met by the 2004 rule's salary level but not by the 2019 rule's salary level. Instead, the Department's experience shows that the shift from a two-test system to a one-test system impacts employees earning between the long and short test salary levels and, in turn, employers' ability to use the exemption for these employees.

In the two-test system, employees who earned between the long and short test salary levels and performed large amounts of nonexempt work were protected by the long duties test, while bona fide EAP employees in that earnings range who performed only limited amounts of nonexempt work were exempt. Meanwhile, the short test provided a time-saving short-cut test for higher-earning employees who would almost invariably pass the more rigorous, and thus more time consuming, long duties test. But the more rigorous long duties test, with its limitation on the amount of nonexempt work that could be performed, was always core to the two-test system, with the higher short test salary level and less rigorous short duties test serving as a time-

saving mechanism for employees who would likely have met the more rigorous long duties test.[181]

As explained in the NPRM, one way in a one-test system to ensure appropriate overtime protection to lower-salaried employees earning between the long and short test salary levels who were historically entitled to overtime compensation under the long test would be to reinstate the long duties test with its limitation on nonexempt work. A one-test system with a more rigorous duties test would appropriately emphasize the important role of duties in determining exemption status. However, the Department did not propose in this rulemaking to replace the standard duties test with the long duties test or to return to a two-test system with the long duties test. The Department has not had a one-test system with a limit on nonexempt work other than from 1940 to 1949,[182] when the Department replaced this approach with its two-test system, and the two-test system was replaced 20 years ago. Returning to the two-test system would eliminate the benefits of the current duties test, including having a single test with which employers and employees are familiar.

In light of these considerations, the Department's goal in this rulemaking is not only to update the single standard salary level to account for earnings growth since the 2019 rule through the use of the updating mechanism, but also to build on the lessons learned in its most recent rulemakings to more effectively define and delimit employees employed in a bona fide EAP capacity. Consistent with its broad authority under section 13(a)(1), the Department's aim is to

[181] Numerous employer organizations supported the Department's decision in 2004 to move to a one-test system. *See* 69 FR 22126-27. Commenters likewise opposed returning to the two-test structure in the 2016 and 2019 rulemakings. *See* 84 FR 10905; 81 FR 32444.
[182] *See* 5 FR 4077.

have a single salary level test that will work effectively with the standard duties test to better define who is employed in a bona fide EAP capacity and will both fully perform the salary level's initial screening function and account for the change to a single-test system.

4. Discussion of Comments and Final Standard Salary Level

i. Overall Commenter Feedback.

The Department received a significant number of comments in response to its proposal to set the standard salary level equal to the 35th percentile of weekly earnings of full-time salaried workers in the lowest-wage Census Region. Numerous commenters supported the Department's proposed salary level. Supporters included thousands of individual employees, writing separately or as part of comment campaigns, and many groups representing employees or employee interests. *See, e.g.*, American Association of Retired Persons (AARP); AFSCME; AFT; NEA; Restaurant Opportunities Center United; United Auto Workers Region 6; United Steelworkers; WorkMoney. Many other commenters, including advocacy groups, academics, and State officials also supported the Department's proposal. *See, e.g.*, Administrative Law Professors; CLASP; Coalition of Gender Justice and Civil Rights Organizations; Coalition of State AGs; Common Good Iowa; EPI; The Leadership Conference on Civil and Human Rights; National Partnership; NWLC. A number of supportive commenters urged the Department to set a higher salary level than the one it proposed. *See, e.g.*, AFL-CIO; Demos; Nichols Kaster; Sanford Heisler Sharp; SEIU; Winebrake & Santillo, LLC (Winebrake & Santillo). A minority of employers, including most notably a campaign of small business commenters, also supported the proposed salary level. *See, e.g.*, Business for a Fair Minimum Wage; Dr. Bronners; Firespring; Small Business Majority. Some members of Congress also commented in support of the proposed salary level.

See 19 Democratic Senators; 10 Democratic Representatives; U.S. Representative Maxwell Frost (D-FL).

Commenters that supported increasing the salary level often emphasized that the FLSA's minimum wage and overtime requirements are fundamental employee protections, intended to spread employment to more workers and provide extra compensation (above the statutory minimum) to employees who work more than 40 hours in a week. *See, e.g.*, AARP; AFL-CIO; Coalition of State AGs; NELA; NELP; Nichols Kaster; United Steelworkers. Some supportive commenters, including Sanford Heisler Sharp, Texas RioGrande Legal Aid, and Washington State Department of Labor and Industries, stressed that the EAP exemption was premised in part on the expectation that exempt employees received high salaries and other privileges to compensate for their long hours of work and lack of FLSA protections. Other commenters similarly stressed that the exemption is intended for employees who, based on the nature of their work and their compensation, have sufficient bargaining power not to need the Act's protections. *See, e.g.*, Business for a Fair Minimum Wage; CLASP; NELP; NWLC.

Supportive commenters often also emphasized that the salary level test has an important and longstanding role in helping define which employees are employed in a bona fide executive, administrative, or professional capacity. Some commenters, including AARP and NELA, stressed that the salary level provides an important "bright line" test for helping determine exemption status, and NWLC similarly stated that the salary level provides a "clear, objective, and straightforward" test that is "easy for employers to apply and for employees to understand[.]" NELP, quoting testimony from EPI at a 2015 Congressional hearing on this issue, stated that salary level tests have been used since the Department's earliest part 541 regulations

because the "'final and most effective check on the validity of the claim for exemption is the payment of a salary commensurate with the importance supposedly accorded the duties in question.'" The Coalition of State AGs stated that a salary level that is too low "no longer accurately delimits the boundaries of who is an EAP" employee.

The vast majority of employers and commenters supporting employer interests opposed the proposed salary level. As discussed in section III, many employer representatives opposed any salary level increase and urged the Department to withdraw its proposal. *See, e.g.*, AHLA; Americans for Prosperity; Chamber; CUPA-HR; FMI; NAM; National Restaurant Association; Oregon Restaurant and Lodging Association; PPWO; Wisconsin Bankers Association. Some Members of Congress also opposed the proposed salary level and urged that the proposal be withdrawn. *See* 10 Republican Senators; 16 Republican Representatives; U.S. Senator Mike Braun (R-IN). Some commenters opposed to the proposal, writing separately or as part of comment campaigns, expressed general opposition to the rule but did not specifically address what, if any, salary level increase they would support in a final rule. *See, e.g.*, American Dental Association; Humane Society of Manatee County; National Sporting Goods Association. Others that opposed or questioned any salary level change stated, in the alternative, what method they preferred if the Department updated the salary level in the final rule. Most such commenters favored applying the methodology that the Department used to set the salary level in its 2004 and 2019 rulemakings (the 20th percentile of earnings of full-time salaried workers in the South and in the retail industry nationally) or updating for inflation the current salary level, which was set using that methodology. *See, e.g.*, ABC; CWC; NAM; National Restaurant Association. A handful of employer commenters supported, or stated that they did not oppose, an increase based

on the 2004/2019 methodology (resulting in a salary level of $822 per week based on data used in the NPRM), citing, for example, that this approach promoted predictability, *see* RILA, and accounted for regional and industry-specific differences, *see* YMCA. *See also, e.g.*, SHRM; WFCA. Others supported or suggested a salary level that was higher, but below the Department's proposed level. *See, e.g.*, American Society of Association Executives; Ho-Chunk, Inc.; University System of Maryland.

Commenters that opposed the Department's proposal almost always objected to the size and/or timing of the proposed salary level increase rather than to the existence of the salary test itself. Most employer commenters, whether favoring no increase or a smaller increase, presumed the salary level test's continued existence and lawfulness, with some, such as National Restaurant Association, expressly referencing their support for the 2019 rule's salary level increase. As discussed in detail below, many commenters acknowledged the salary level's longstanding function of screening obviously nonexempt employees from the exemption. *See* section V.B.4.ii. Other commenters that opposed the proposal nonetheless cited benefits of having a salary level test, including helping to ensure that the EAP exemption is not abused, *see, e.g.*, AASA/AESA/ASBO, Bellevue University, and "sav[ing] investigators and employers time by giving them a quick, short-hand test[.]" *See* National Restaurant Association. APLU recognized "DOL's mission and responsibility to update the Fair Labor Standards Act overtime regulations and ensure a baseline of protections for our nation's workers, including periodic updates to the minimum salary threshold for overtime exemptions." In rather stark contrast, AFPI asserted that employee "[c]ompensation is no more helpful than would be a dress code test" in determining exemption status. AFPI was one of only a small number of commenters, as

previously discussed in section V.A.1, that asserted the Department lacks authority under section 13(a)(1) to adopt a salary level test. *See, e.g.*, Job Creators Network Foundation; NFIB; Pacific Legal Foundation.

As the Department stated in its 2019 rule, an employee's salary level "is a helpful indicator of the capacity in which an employee is employed, especially among lower-paid employees."[183] The amount an employee is paid is also a "valuable and easily applied index to the 'bona fide' character of employment for which exemption is claimed," as well as the principal "delimiting requirement . . . prevent[ing] abuse" of the exemption.[184] As the Department has explained, if an employee "is of sufficient importance . . . to be classified" as a bona fide executive employee, for example, and "thereby exempt from the protection of the [A]ct, the best single test of the employer's good faith in attributing importance to the employee's services is the amount [it] pays for them."[185] Employee compensation is a relevant indicator of exemption status given that, as many commenters observed, the EAP exemption is premised on the understanding that individuals who are employed in a bona fide executive, administrative, or professional capacity typically earn higher salaries and enjoy other privileges to compensate them for their long hours of work, setting them apart from nonexempt employees entitled to overtime pay.[186] Accordingly, the Department agrees with the overwhelming majority

[183] 84 FR 51239 (internal quotation marks omitted).
[184] Stein Report at 19, 24; *see also* 81 FR 32422.
[185] Stein Report at 19*; see also id.* at 26 ("[A] salary criterion constitutes the best and most easily applied test of the employer's good faith in claiming that the person whose exemption is desired is actually of such importance to the firm that he is properly describable as an employee employed in a bona fide administrative capacity.").
[186] *See* Report of the Minimum Wage Study Commission, Vol. IV, at 236, 240; *see also, e.g.*, Stein Report at 19 (explaining that the "term 'executive' implies a certain prestige, status, and importance" denoted by pay "substantially higher than" the federal minimum wage).

of commenters that, explicitly or implicitly, supported the salary level continuing to have a role in helping determine whether employees are employed in a bona fide executive, administrative, or professional capacity.[187]

The Department nonetheless recognizes that commenters had a wide range of views about the salary level test and that no salary level methodology can satisfy all stakeholders. As discussed below, competing commenter views were often grounded in differing opinions about the salary level test's role in defining the EAP exemption. Broadly speaking, commenters that opposed the proposal generally favored a far more limited role for the salary level test and emphasized perceived negative effects on employers of the proposed increase, while commenters that supported the proposal or urged the Department to set a higher salary level often deemed the proposal modest by historical standards and emphasized perceived positive effects on employees of the proposed increase. Against this backdrop, the Department has reviewed the comments received on its proposed methodology, with particular focus on feedback on the NPRM's rationale that the proposed methodology will better define and delimit the EAP exemption by fully restoring the salary level's screening function and accounting for the switch from a two-test to a one-test system.

ii. Fully Restoring the Salary Level's Screening Function

Some employer advocates that opposed the Department's proposal emphasized the salary level's limited function of screening obviously nonexempt employees from the EAP exemption.

[187] Consistent with its longstanding practice, the Department declines requests from commenters, including Defiance College, International Bancshares Corporation, Rachel Greszler, and WFCA, that suggested the Department adopt multiple salary level tests for different regions, industries, and/or small businesses, rather than a single salary level that applies to all entities nationwide. *See* 84 FR 51239; 81 FR 32411; 69 FR 22171.

See, e.g., Independent Community Bankers of America; IFDA; National Council of Farmer Cooperatives (NCFC); SHRM. Many employer representatives stated that the proposed salary level exceeded this purpose by excluding from the exemption too many employees who pass the duties test, particularly in low-wage regions and industries. *See, e.g.*, Chamber; NAW; PPWO; RILA; Seyfarth Shaw. AFPI quoted the statement in the Department's 2019 rule that any salary level increase must "have as its primary objective the drawing of a line separating exempt from nonexempt" employees, and the Chamber asserted that to the extent employee "protection or fairness" concerns motivated the proposed increase, such considerations exceed the Department's statutory authority.

Employer representatives that focused on the salary level's screening function often contrasted the Department's proposal with prior rules that they stated met this objective. CWC referenced the Department's 1958 and 2004 rules as such examples, while AHLA stated more broadly that the Department historically set a salary level that was "intentionally low" to screen out nonexempt employees, and that the Department's proposed methodology "is objectively not the low end of the salary range as that has been understood since 2004[.]" Other commenters similarly cited the 2004 and 2019 rules as fulfilling the salary level test's screening function, with National Restaurant Association, for example, emphasizing the salary level's screening function when explaining that the "2004 methodology's chief virtue is its consistency with historical practice." *See also, e.g.*, Bellevue University. Some commenters, including NCFC and PPWO, stated that the proposed salary level would change the salary level from a "screening device" to a "de facto sole test" for exemption, while others cautioned that the salary level set in

the 2016 rule was declared invalid for exceeding this screening function. *See also, e.g.*, Argentum & ASHA; NAM.

Though some employee representatives addressed the salary level's screening function, they generally emphasized other considerations that they believed justified setting a salary level equal to or higher than what the Department proposed. A number of commenters stated that, along with the duties test, the salary level "is intended to set a guardrail so that employers do not incorrectly classify lower-paid salaried employees as" exempt. *See, e.g.*, AFSCME; Family Values @ Work; North Carolina Justice Center; United Steelworkers; Yezbak Law Offices. Similarly alluding to the salary level's screening function, AFL-CIO emphasized that until 2019 the Department had never set the salary level below the long test level and that as a result more than half of the employees affected by the proposed salary level would have been nonexempt under every prior rule (because they earned below the long test or long test-equivalent salary level). EPI similarly stated that the 2019 rule set a salary level "that was even lower than what the long-test methodology would have yielded." *See also* Coalition of State AGs (referencing the salary level's screening function).

The Department has considered commenter feedback about the salary level test's screening function. The Department agrees with all commenters that emphasized the salary level test's function of screening obviously nonexempt employees from the exemption, a principle that, as the Department observed in the 2019 rule and in the NPRM, "has been at the heart of the Department's interpretation of the EAP exemption for over 75 years."[188] Fully effectuating the salary level's screening function is a key part of ensuring that the salary level sets an appropriate

[188] 88 FR 62165 (citing 84 FR 51241).

dividing line separating exempt and nonexempt employees. In response to the Chamber's concern about the motivations underlying the proposed salary level, the Department notes that while its proposal protects employees and promotes fairness (by helping ensure that only employees employed in a bona fide executive, administrative, or professional capacity are deprived of the FLSA's minimum wage and overtime protections), these beneficial effects are a byproduct of any higher salary level, not a basis for the proposed salary level.

As the Department explained in its NPRM, the concept of the salary level's screening function dates back to the two-test system, when the lower long test salary level provided "a ready method of screening out the obviously nonexempt employees, making an analysis of duties in such cases unnecessary."[189] When the Department updated the long test in 1958, it reaffirmed the long test salary's function as a screening tool.[190] When the Department moved to a one-test system in 2004, the standard salary test had to perform the initial screening function that the long test salary level performed in the two-test system. In the 2004 rule, the Department reaffirmed its historical statements emphasizing the salary level's critical screening function and, most significantly, used the long test salary level methodology to validate its new salary level of $455 per week.[191] The Department stressed in its final rule that both the 2004 rule standard salary level methodology and the long test salary level methodology "are capable of reaching exactly the same endpoint" and demonstrated that the two methods, in fact, produced equivalent salary

[189] Weiss Report at 8.
[190] Kantor Report at 2–3.
[191] 69 FR 22165–22166.

levels using contemporaneous data.[192] By setting a salary level equivalent to the long test level, the Department ensured that employees earning at levels that would have entitled them to overtime compensation under the two-test system because they earned below the long test salary level remained screened from the exemption by the new standard salary test, regardless of whether they met the less rigorous standard duties test. The Department rejected requests from commenters that supported a salary level that was $30 to $95 lower than the level the Department ultimately adopted,[193] thus maintaining the historic screening function by declining to set a salary level lower than the long test level.

In its 2019 rule, the Department reemphasized the salary level's screening function.[194] The Department distinguished the 2016 rule, which was invalidated because it "'untethered the salary level test from its historical justification' of '[s]etting a dividing line between nonexempt and potentially exempt employees' by screening out only those employees who, based on their compensation level, are unlikely to be bona fide executive, administrative, or professional employees."[195] In contrast, the Department explained, reapplying the 2004 methodology to contemporaneous data was likely to pass muster because the district court that invalidated the 2016 rule "endorsed the Department's historical approach to setting the salary level" and

[192] *See id.* at 22167–71 (showing that for all full-time salaried employees, $455 in weekly earnings corresponded to just over the 20th percentile in the South and the 20th percentile in retail, and that for employees performing EAP duties, $455 in weekly earnings corresponded to just over the 8th percentile in the South and the 10th percentile in retail). AFPI commented that in the 2003 NPRM the Department "acknowledged that 'equivalency to either the current long or short test salary levels is not appropriate' *because of* the switch to a one-test system." (quoting 68 FR 15560, 11570 (Mar. 31, 2003)). However, the Department shifted in its final rule and validated its chosen methodology using the long test salary level.
[193] *See* 69 FR 22164.
[194] 84 FR 51237.
[195] *Id.* at 51231 (quoting 84 FR 10901).

"explained that setting 'the minimum salary level as a floor to screen[] out the obviously nonexempt employees' is 'consistent with Congress's intent.'"[196]

In its NPRM, the Department explained that it needed to set a salary level at least equal to the long test—$925 per week, equating to between the 26th and 27th percentiles of weekly earnings of full-time salaried workers in the South—to fully restore the salary level's screening function. As noted above, employer commenters that emphasized the salary level's screening function generally viewed this function (which they often construed narrowly) as a justification for limiting the size of any potential salary increase. However, such commenters did not directly address the NPRM's explanation of the long test salary level's key role in the salary level's screening function or the relationship between the 2004/2019 methodology and the long test. Other commenters that endorsed the screening function as embodied in the 2004 rule did not grapple with the fact that in the 2019 rule, that methodology did not fully fulfill that function because it no longer arrived at the same endpoint as prior rules (*i.e.*, a long test or long-test equivalent salary level).

The Department's position remains that a core function of the salary level test is to screen from the EAP exemption employees who, based on their low pay, should receive the FLSA's overtime protections. For decades under the Department's two-test system, the long test salary level performed this screening function. In the 2004 rule, the Department used a different approach to reach the same outcome—setting a single salary level test that was equivalent to, and thus set the same line of demarcation as, the long test salary level. The Department deviated from this approach in 2019, setting a salary level that was $40 per week below the level produced

[196] *Id.* at 51241 (quoting 275 F. Supp.3d at 806).

using the long test methodology.[197] In doing so, the Department for the first time expanded the exemption to include employees who were paid below the equivalent of the long test salary level.

The Department reaffirms its position stated in the NPRM that the salary level test must equal at least the long test salary level in order to fulfill its historical screening function. From 1938 to 2019, all salaried white-collar employees paid below the long test salary level were entitled to the FLSA's protections, regardless of the duties they performed. This was true from 1938 to 1949 under the salary level test that became the long test;[198] from 1949 to 2004 under the long test; and from 2004 to 2019 under the standard salary level test that was set equivalent to the long test level—a key fact that commenters that opposed the Department's proposal generally did not address. Setting the salary level below the long test level as was done in the 2019 rule—because the 2004 methodology no longer matched the long test salary level based on contemporaneous data—departed from this history by enlarging the exemption to newly include employees who earned less than the long test salary level. As an initial step, the new salary level methodology must fully restore the salary level's screening function by ensuring that employees who were nonexempt because they earned less than the long test or long test-equivalent salary level are also nonexempt under the standard test. Achieving this objective requires a standard salary level amount at least equal to the long test level ($942 per week using current data, which equates to approximately the 25th percentile of full-time salaried worker earnings in the South).

As discussed in section V.B.5.iii, fully restoring the salary level's screening function would affect 1.8 million employees. These are currently exempt employees who earn between

[197] *Id.* at 51244.
[198] During this period the Department used a one-test system that paired a lower salary level with a more rigorous duties test. *See, e.g.*, 5 FR 4077.

$684 (the current salary level) and $942 per week (the long test level calculated using current data) and would become nonexempt absent intervening action by their employers. In every rule prior to 2019, employees who earned below the long test or long-test equivalent salary level have always been excluded from the exemption based on their salary alone—even if they passed the standard duties test or (prior to 2004) the more rigorous long duties test. The Department's approach does not, as commenters asserted, create an impermissible "de facto" salary-only test or make nonexempt too many employees who pass the duties test, and is compatible with the district court decision's emphasis on the salary level test's historic screening function.[199]

iii. Accounting for the Shift to a One-Test System

In addition to fully restoring the salary level test's screening function, the Department's proposed salary level methodology also accounted for the shift from a two-test to a one-test system for determining who is employed in a bona fide executive, administrative, or professional capacity. Commenters that supported the proposed salary level and specifically addressed this rationale agreed with it. A group of Administrative Law Professors stated that the Department's move to a one-test system in 2004 "significantly expanded the number of relatively low-income workers who might fall within the exemption . . . despite engaging in substantial nonexempt work[,]" and concluded that the Department's proposal was "reasonably geared" to restoring nonexempt status to this class of workers. The Coalition of State AGs similarly stated that the proposal "does more to take into account the shift to a one-test system in 2004 and establishes more of a middle ground between . . . the previous short- and long-test methodologies." They

[199] The district court was principally concerned with the 2016 rule exceeding the salary level's screening function and making too many employees nonexempt based on salary alone. *See Nevada* 275 F.Supp.3d at 806 & n.6.

elaborated that "the balance struck is a more appropriate one" because most salaried white-collar employees paid less than the proposed standard salary level do not meet the duties test, whereas a substantial majority of salaried white-collar employees earning above the proposed standard salary level meet the duties test. Some commenters asserted that this aspect of the Department's rationale supported setting a salary level higher than proposed. For example, AFL-CIO stated that the proposed salary level captures only "a portion of workers who have been wrongly excluded from nonexempt status since the 2004 elimination of the long and short test in favor of a single test," and Sanford Heisler Sharp stated that the proposal "does not go far enough towards meeting [the] goal" of "'ensur[ing] that fewer white-collar employees who perform significant amounts of nonexempt work and earn between the long and short test salary levels are included in the exemption.'"[200] NELA similarly urged the Department to adopt its 2016 methodology to more fully account for the shift to a one-test system.

Employer commenters that directly addressed the shift to a one-test system generally rejected the premise that any adjustment for this change was warranted or appropriate. Some commenters emphasized that the long test's limit on nonexempt work became inoperative in 1991 and/or that the Department fully accounted for the move to the standard duties test in its 2004 rule. *See* Bellevue University; Chamber; NAM; RILA. The National Association of Convenience Stores, which likewise emphasized that the short and long tests have not existed since 2004, stated that to "the extent the two-test system still has any limited relevancy to the current inquiry, it is that the salary level should be closer to what the pre-2004 long test would have produced" rather than "to what the pre-2004 'short' test would have produced" today. AFPI

[200] Quoting 88 FR at 62158.

asserted that "[a]ny salary level that excludes employees who are not 'obviously nonexempt' is invalid[,]" that the long test salary level is a "made-up concept[,]" and that the "'long test' and the 'short test' are terms [that have not been] considered since the Department's regulatory changes in 2004 . . . [and] should have no place in determining an appropriate increase to the minimum salary level for exemption today."[201]

The Department agrees with commenters that supported the NPRM's objective of updating the salary level in part to account for the move to a one-test system. As previously explained in detail in the NPRM and in section V.B.3 of this preamble, the Department traditionally considered employees earning between the long and short test salary levels to be employed in a bona fide EAP capacity only if they were not performing substantial amounts of nonexempt work. With the adoption of a duties test based on the less rigorous short duties test, the shift to a single-test system significantly decreased the examination of the amount of nonexempt work employees performed. Following this shift, the Department has taken two approaches to setting the salary level to pair with the standard duties test. The approach taken in the 2004 rule permitted the exemption of all employees earning above the long test salary level who met the standard duties test—including many employees who performed substantial amounts of nonexempt work and traditionally were protected by the long duties test. The approach taken in the 2016 rule was challenged and criticized as making employees earning between the long test salary level and the low end of the short test salary range nonexempt—

[201] NRF included an Oxford Economics report that questioned the Department's long test figure ($925 per week), and, observing that the long test methodology varied over time, stated that a "more reasonable" approach for replicating the long test would be to adjust the 1975 long test level for inflation (which it concluded would result in a salary level of $843 per week in 2022 dollars).

including employees who performed very little nonexempt work and would have been exempt under the long duties test.

The Department recognizes that a single-test system cannot fully replicate both the two-test system's heightened protection for employees performing substantial amounts of nonexempt work and its increased efficiency for determining exemption status for employees who are highly likely to perform EAP duties. Inevitably, any attempt to pair a single salary level with the current duties test will result in some employees who perform substantial amounts of nonexempt work being exempt, and some employees who perform almost exclusively exempt work being nonexempt.[202] But such a result is inherent in setting any salary level. The Department continues to believe that it can better identify which employees are employed in a bona fide EAP capacity by, in combination with the current duties test, using a salary level methodology that accounts for the shift to a one-test system, and that doing so will both restore overtime eligibility for many individuals who perform substantial amounts of nonexempt work and historically would have been protected by the long duties test, and address potential concerns that the salary level test should not be determinative of exemption status for too many individuals. Such a salary level will also more reasonably distribute between employees and their employers what the Department now understands to be the impact of the shift to a one-test system on employees earning between the long and short test salary levels.

[202] *See* Stein Report at 6 ("In some instances the rate selected will inevitably deny exemption to a few employees who might not unreasonably be exempted, but, conversely, in other instances it will undoubtedly permit the exemption of some persons who should properly be entitled to benefits of the act.").

The Department disagrees with commenters that disputed this aspect of the NPRM based on their view that the only valid salary level function is to screen from exemption obviously nonexempt employees. Section 13(a)(1)'s broad grant of statutory authority for the Department to define and delimit the EAP exemption provides the Department a degree of latitude in determining an appropriate salary level for identifying individuals who are employed in a bona fide EAP capacity. As discussed in section V.B.3, for decades, the short test salary level did not perform a screening function, but rather was used to determine whether the full duties test or the short-cut duties test would be applied to determine EAP exemption status. In a one-test system, the Department can change the duties test, the salary level, or both, to ensure that the test for exemption appropriately distinguishes bona fide EAP employees from nonexempt workers. As discussed at length in the NPRM,[203] while acknowledging that it could lessen the salary level test's role by returning to a duties test that explicitly limited the amount of nonexempt work that could be performed, the Department ultimately declined to propose changes to the duties test in this rulemaking. Given that decision, it is appropriate for the Department to choose to better define the EAP exemption by accounting for the shift to a one-test system, and to select a salary level methodology that excludes from exemption some employees who historically were nonexempt because of the more rigorous long duties test. The 2004 and 2019 rules' significant broadening of the statutory exemption (a fact employer commenters generally did not address) to permit all salaried employees earning between the long and short tests who passed the standard duties test to be exempt was not unlawful, but it leaves room for refinement. Section 13(a)(1)

[203] 88 FR 62164–65. Although some commenters addressed changes to the duties test, *see, e.g.*, AFL-CIO, AHLA, NELA, FMI, such changes are beyond the scope of the current rulemaking.

does not require the Department to forever maintain the regulatory choice it made 20 years ago to pair the current duties test with a salary level that places the entire burden of the move to a one-test system on employees who historically were entitled to the FLSA's overtime protection because they performed substantial amounts of nonexempt work and earned between the long and short test salary levels.

The Department continues to believe that the long and short tests provide useful parameters for determining the new salary level test methodology in this rulemaking. The Department disagrees with AFPI that variations in the long test methodology render it a "made-up concept" or that the long and short tests have "no place" in determining the new salary level. The long test salary level has played a crucial role in defining the EAP exemption for the better part of a century, either directly under the two-test system or indirectly under the one-test system. As the Department explained in detail in its 2004 rule, the long test salary level "regulatory history reveals a common methodology used, with some variations, to determine appropriate salary levels[,]" and (with the exception of the 1975 rule) beginning in 1958 "the Department set the [long test] salary levels to exclude approximately the lowest-paid 10 percent of exempt salaried employees" in low-wage areas and industries.[204] The Department "[u]se[d] this regulatory history as guidance" in its 2003 NPRM and, most importantly, validated its chosen methodology in the 2004 rule by showing that it produced the same salary level as the long test methodology—a critical fact employer representatives generally did not address in their comments.[205] While the Department agrees with AFPI and the Oxford Economics report that the

[204] 69 FR 22166.
[205] *See id.* at 22166–70; *see also* section V.B.3.

data set used to set the long test salary level was not exactly the same in each regulatory update, just as in 2004, minor historical variations do not deprive the long test of its usefulness in helping determine an appropriate salary level now. The Oxford Economics report's suggestion to calculate the long test by updating the 1975 long test salary level for inflation would not faithfully replicate the long test because it would produce a salary level below the 10th percentile of exempt workers in low-wage regions and industries and would conflict with the Department's historical practice of avoiding the use of inflation indicators in updating the salary level.[206]

The Department also disagrees with commenters who asserted that no adjustment is needed to account for the shift to a one-test system because the long test became largely dormant in 1991. In the 2004 rule, the Department acknowledged this dormancy resulting from its outdated salary levels and asserted that employees who were then subject to the long test would be better protected under the higher salary level of the new standard test.[207] But as previously explained, section V.B.3, in the 2004 rule the Department did not compare the overtime protection lower-salaried employees would receive under the standard test with the protection they would have received had the Department updated the long test with a salary level based on contemporaneous data and kept the existing long duties test. Instead, the Department's discussion of the elimination of the long duties test in the 2004 rule focused primarily on the minimal role played by the long test at that time due to the erosion of the long salary level, and on the difficulties employers would face if they were again required to track time spent on nonexempt

[206] *See, e.g.*, 84 FR 51245; 69 FR 22167.
[207] *See* 69 FR 22126.

work when the dormancy of the long duties test meant that they had generally not been performing such tracking for many years.[208]

The Department also disagrees with commenters that asserted that the 2004 rule fully accounted for the move to the standard duties test. Because the 2004 rule did not fully account for the lessened overtime protection for employees who would have been nonexempt under an updated long test (as just described), it created a group of employees with lessened protection under the standard test—those who earned between the long and short test salary levels. These employees were traditionally nonexempt because they failed the long duties test, but were exempt under the 2004 rule because they passed the more lenient standard duties test.[209] By setting the standard salary level equivalent to the long test salary, the 2004 rule in effect created a group of employees who bore the impact of the change from the two-test to the one-test system.

iv. Selecting the Salary Level Methodology

In its NPRM, the Department explained that fully restoring the salary level's screening function and accounting for the move to a one-test system supported setting the salary level at the 35th percentile of full-time salaried worker earnings in the lowest-wage Census Region (the South)—resulting in a proposed salary level of $1,059 per week. Commenters provided competing views on this proposed increase. Employers and employer representatives that

[208] *See id.* at 22126–27.

[209] The Chamber asserted that the Department's decision to adjust the salary level to account for the shift to a one-test system "fails to appreciate the continued importance of the 'primary duty' principles, the application of which includes an analysis of non-exempt work performed and its relation to the employee's exempt work." Although the Chamber is correct that the standard duties test accounts for nonexempt work, it does so in a less rigorous manner than the long duties test, resulting in some lower-paid white-collar employees who pass the standard duties test but (due to their nonexempt work) would have failed the long duties test.

opposed the proposed salary level often characterized it as "too much, too soon"—stating that an increase of 54.8 percent (or 69.3 percent, based on the $60,209 projected salary level figure included in footnote 3 of the NPRM)[210] less than 4 years after the most recent increase was unnecessary and unprecedented. *See, e.g.*, Air Conditioning Contractors of America; Americans for Prosperity; Joint Comment from Argentum and American Seniors Housing Association; CUPA-HR; International Sign Association; NRF. Some commenters, including American Association of Community Colleges and Associated Builders and Contractors, observed that, by contrast, prior salary level updates have ranged from 5 to 50 percent, and others commented that the proposed increase greatly exceeded the rate of inflation since the 2019 rule, *see* Independent Community Bankers of America, Ohio Township Association. Many employer organizations asserted that the Department was trying to resurrect a methodology akin to the invalidated 2016 rule and that, like that rule, the proposed salary level (which many stressed is a higher dollar figure than the level set in the 2016 rule) would unlawfully supplant the duties test. *See, e.g.*, Americans for Prosperity; National Restaurant Association; PPWO.

Commenters that opposed the proposed salary level were particularly concerned about the impact of this change on specific industries and on businesses in low-wage regions. Some commenters, such as the American Outdoors Association, CUPA-HR, NAHB, and SHRM, provided information from internal surveys to support how the proposal would negatively affect their members. SBA Advocacy similarly summarized concerns received from small businesses. *See also, e.g.*, NFIB. Some commenters emphasized the proposal's impact on particular

[210] Several commenters criticized the Department for providing projected salary level figures in footnote 3. *See, e.g.*, PPWO; NRF. NAM stated that footnote 3 was "inconsistent" with the Administrative Procedure Act.

occupations in their industries, including first-line supervisors, *see, e.g.*, AHLA, NAHB, and entry-level managers, *see, e.g.*, NAM, NRF. Emphasizing the proposed salary level's geographic impact, National Restaurant Association and PPWO warned that the proposal would exclude from exemption a high percentage of employees who pass the duties test in lower-wage regions, and could result in employees in the same job classification being treated differently based on where they live. A number of educational institutions opposed the proposed increase due to cost-related concerns specific to the educational sector. *See, e.g.*, American Association of Community Colleges; Association of Independent Colleges and Universities of Ohio; National Association of Independent Colleges and Universities. The National Association of Counties raised similar concerns about the impact of the increased salary level on local governments. Nonprofit sector feedback was more mixed, with the National Council of Nonprofits characterizing the industry response as one of "moral support" and "operational anxiety." Some nonprofit organizations opposed the proposal, *see, e.g.*, Children's Alliance of Kentucky, U.S. Public Interest Research Group (U.S. PIRG), some supported it, *see, e.g.*, CLASP, Justice at Work, and some agreed with the Department's intent but raised cost and other concerns, *see, e.g.*, Catholic Charities, Open Roads Bike Program.

Commenters had different suggestions for how the Department should account for such regional and industry-specific differences. For example, RILA urged the Department to include the retail industry in its data set, AFPI suggested setting the salary level equal to the 20th percentile of non-hourly employee earnings in the ten lowest-wage states, and Seyfarth Shaw recommended using the East South Central Census Division. The Chamber asked the Department to focus on data from the lowest-wage types of entities (such as small businesses,

small nonprofits or small public employers), in the lowest-wage industries, in rural areas, in the lowest-wage Census Region. The Chamber and National Association of Convenience Stores favored excluding nonexempt workers from the data set (and using a lower earnings percentile) and questioned the Department's use of Current Population Survey (CPS) Merged Outgoing Rotation Group (MORG) data for nonhourly earnings for full-time workers as a proxy for salaried worker earnings.

Commenters that supported increasing the salary level viewed the Department's proposal very differently than employer representatives. Whereas many employer representatives focused on specific regions or industries to assert that the proposed salary level was too high, supportive commenters focused on the national impact to assert that the salary level was appropriate or too low. Many supportive commenters considered it "modest." *See, e.g.*, AFSCME; CLASP; Family Caregiving Coalition; National Partnership. Others stated that the salary level "could have reasonably been significantly higher and still within historical precedent." *See, e.g.*, Common Good Iowa; Jobs to Move America; Louisiana Budget Project; Maine Center for Economic Policy; North Carolina Justice Center. The statistic most often cited to support that the proposal was conservative by historical standards was that whereas 62.8 percent of full-time salaried workers earned less than the short test salary level in 1975, 28.2 percent of full-time salaried workers earned less than the proposed standard salary level (and several of these commenters noted that only approximately 9 percent earned less than the current salary level). *See, e.g.*, EPI; National Center for Law and Economic Justice; Worker Justice Center of New York; Workplace Justice Project. AFL-CIO and others highlighted that the proposed salary level was 19 percent lower than the inflation-adjusted value of the 1975 short test salary level, and EPI stated that, on

average, the proposed salary level was 16 percent lower than inflation-adjusted short test salary levels set from 1949 and 1975. Some supportive commenters stressed that a significant salary level increase was needed in part to account for the 2004 rule's elimination of the long duties test, *see, e.g.*, EPI, NELP, while NWLC stated that the proposed methodology would "not eclipse the role of the duties test" and instead would "restore[] a reasonable balance between the strength of the duties test and the height of the salary threshold."

Some commenters advocated for a much higher salary level than the Department proposed, and a number of commenters specifically proposed alternate methodologies for the Department to adopt in the final rule. For example, NELA stated that the proposed level was "too low from a historical perspective" and, favoring "[b]older federal action[,]" asked the Department to (like in the 2016 rule) set the salary level equal to the 40th percentile of weekly earnings of full-time salaried workers in the lowest-wage Census Region (which would produce a salary level of $1,196 per week based on the data used in this final rule). Winebrake & Santillo similarly favored a return to that methodology. AFL-CIO supported setting the salary level higher—at the historical average short test salary level (which would result in a salary level of $1,404 per week based on current data). Other commenters sought a salary level that they stated would exclude from exemption the same proportion of full-time salaried workers as under the 1975 salary level test. For example, Demos urged the Department to set the salary level at the 55th percentile of weekly earnings of full-time salaried workers nationwide to meet this "high-water" mark, and Nick Hanauer supported a salary level of at least $83,000 to "restore the overtime threshold" to a time "when the American middle class was strongest[.]" Commenters that sought a higher salary level than the Department proposed often expressed their

disagreement with the district court's decision invalidating the 2016 rule. *See, e.g.*, NELA; Sanford Heisler Sharp; Winebrake & Santillo.

After considering the comments received, the Department is finalizing the salary level methodology as proposed, setting it equal to the 35th percentile of full-time salaried worker earnings in the lowest-wage Census Region (the South)—which produces a salary level of $1,128 per week using calendar year 2023 data. Consistent with the Department's responsibility to "not only … determin[e] which employees are entitled to the exemption, but also [to] draw[] the line beyond which the exemption is not applicable[,]"[211] this salary level will, in combination with the standard duties test, effectively calibrate the scope of the exemption for bona fide EAP employees and do so in a way that distributes across the population of white-collar employees earning between the long and short test salary levels the impact of the shift to a one-test system. As previously discussed, updating the salary level for wage growth since the 2019 rule produces a salary level of $844 per week, and fully restoring the salary level's historic screening function would result in a salary level of $942 per week, equivalent to the 25th percentile of full-time salaried worker earning in the South (*i.e.*, the long test level). Accordingly, the increase from the 25th percentile to the 35th percentile is to account for the shift to a one-test system.[212] The Department set the standard salary level at (or below) the long test level in the 2004 and 2019 rules and set it at the low end of the historic range of short test salary levels in the 2016 rule.

[211] Stein Report at 2.

[212] AFPI mistakenly asserts that the increase from the 20th percentile to the 35th percentile "is based entirely on the switch to a one-test system in 2004." The majority of the salary level increase (from $684 to $942) is to update the salary level for wage growth and fully restore the salary level's historic screening function, with less than half (the increase from the $942 to $1,128) made to account for the shift from the two-test system.

Setting the salary level at either the long test salary level or equivalent to a short test salary level in a one-test system with the standard duties test, however, results in either denying overtime protection to lower-paid employees who are performing large amounts of nonexempt work, and thus, would have been exempt under the Department's historical view of the EAP exemption, or in raising concerns that the salary level is determining the exemption status of too many employees. In contrast, an appropriately calibrated salary level between the long and short test salary levels better defines and delimits which employees are employed in a bona fide EAP capacity, and thus better fulfills the Department's duty to define and delimit the EAP exemption.

The Department's methodology established in this final rule uses the second-to-lowest of the earnings ventiles between the long test salary level (the 25th percentile of full-time salaried worker earnings in the lowest-wage Census Region) and the short test salary level (approximately the 51stth percentile of this data set). These ventiles are the 30th, 35th, 40th, 45th, and 50th percentiles of full-time salaried worker earnings in the lowest-wage Census Region. The Department continues to believe that its methodology produces a salary level high enough above the long test salary level to ensure overtime protection for some lower-paid employees who were traditionally entitled to overtime compensation under the two-test system by virtue of their performing large amounts of nonexempt work, and also low enough, as compared with higher salary levels, to significantly shrink the group of employees performing EAP duties who are excluded from the exemption by virtue of their salary alone. Whereas the 2004 and 2019 rules permitted the exemption of employees earning between the long and short test salary levels even if they performed significant amounts of nonexempt work, and the 2016 rule prevented employers from using the exemption for such employees earning below the short

test salary range even if they performed EAP duties, the methodology adopted in this final rule falls between these two methodologies and thus, as commenters including the Administrative Law Professors and Coalition of State AGs agreed, reasonably balances the effect of the switch to a one-test system in a way that better differentiates between those who are and are not employed in a bona fide EAP capacity. Of the 10.8 million salaried white-collar employees earning between the equivalent of the long and short test salary levels, approximately 40 percent earn between $942 (the equivalent of the long test salary level) and $1,128 (the new salary level) and would receive overtime protection by virtue of their salary, while approximately 60 percent earn between $1,128 and $1,404 (the equivalent of the short test salary level) and would have their exemption status turn on whether they meet the duties test. These and other statistics, discussed in section V.B.5.iii, demonstrate that the salary level will not "essentially eliminate[] the role of the duties test" as National Restaurant Association and others contended. *See also, e.g.*, AHLA; CWC.

Even though the Department's decision to select a salary level below the midpoint between the long and short tests means that the effect of the salary level on employees earning within this range and their employers is not exactly equal, a higher salary level could disrupt the reliance interests of employers who (due in part to the Department's failure to update the salary level tests between 1975 and 2004), have been able to use a lower salary level and more lenient duties test to determine exemption status since 1991. However, a significantly lower salary level akin to the long test salary level would avoid disrupting such reliance interests only by continuing to place the burden of the move to a one-test system entirely on employees who historically were entitled to the FLSA's overtime protections because they perform substantial

amounts of nonexempt work. The Department believes that employer reliance interests should inform where the salary level is set between the long and short test levels, and that its approach appropriately balances the impact of the move to a one-test system between employees' right to receive overtime compensation and employers' ability to use the exemption. Such balancing is fully in line with the Department's authority under the FLSA to "mak[e] certain by specific definition and delimitation" the "general phrases" "bona fide executive, administrative, or professional capacity." [213] This grant of authority confers discretion upon the Department to determine the boundaries of these general categories; any such line-drawing, as courts have recognized, will "necessarily" leave out some employees "who might fall within" these categories.[214]

The Department recognizes the tension between the methodology adopted in this final rule and some statements made in its 2016 and 2019 rules. The Department stated in its 2016 rule that the current duties test could not be effectively paired with a salary level below the short test salary range, and for this reason expressly rejected setting the salary level at the 35th percentile of weekly earnings of full-time salaried workers in the South.[215] But that rule, which would have prevented employers from using the EAP exemption for some employees who were considered exempt under the prior two-test system, was challenged in court, and a return to it would result in significant legal uncertainty for both workers and the regulated community. In the 2019 rule, the Department expressly rejected setting the salary level equal to the long test or higher.[216]

[213] *See Walling*, 140 F.2d at 831-32.
[214] *Id.* at 832.
[215] 81 FR 32410.
[216] *See* 84 FR 51244.

However, as noted above, the Department did not fully address in that rule the implications of the switch from a two-test to a single-test system. Having now grappled with those implications, the Department concludes that not only can it pair the current duties test with a salary between the long and short test salary levels, but that doing so appropriately recalibrates the salary level in a one-test system to ensure that it effectively identifies bona fide EAP employees.

In setting the salary level, the Department continues to believe that it is important to use a methodology that is transparent and easily understood. As in its prior rulemakings, the Department is setting the salary level using earnings data from a lower-salary regional data set (as opposed to nationwide data) to accommodate businesses for which salaries generally are lower due to geographic or industry-specific reasons.[217] Specifically, the Department is setting the salary level using the data set of full-time nonhourly[218] workers in the lowest-wage Census Region (the South). This approach promotes transparency because BLS routinely compiles this data. It also promotes regulatory simplification because the data set is not limited to exempt EAP employees and thus does not require the Department to model which employees pass the duties test.[219] In keeping with the Department's past practice, it is relying on up-to-date data to determine the salary level.[220] In the NPRM, the Department used 2022 salary data for estimating the salary level resulting from the proposed methodology, which was current at the time the

[217] *See id.* at 51238; 81 FR 32404.
[218] Consistent with recent rulemakings and the NPRM, *see* 88 FR 62188, 84 FR 51258, in determining earnings percentiles the Department looked at nonhourly earnings for full-time workers from the CPS MORG data collected by BLS.
[219] As discussed in the economic analysis, *see* section VII, this modeling is done using the Department's probability codes. *See* 84 FR 51244; 69 FR 22167.
[220] *See* 84 FR 51245; 81 FR 32405; 69 FR 22168.

Department developed its proposal. In this final rule, the Department is relying on calendar year 2023 salary data, as published by BLS, to set the salary level.[221]

Given the strong views expressed by commenters, including those opposing the proposal or favoring a higher salary level, the Department did not arrive lightly at its decision to finalize the salary level methodology as proposed. Commenter feedback often reflected competing vantage points for assessing the Department's proposal. Commenters that supported the Department's proposal or a higher salary level (most often, the 2016 rule methodology) often compared the proposed salary to short test salary levels, while commenters that opposed the proposed increase often stressed the size of the change from the current salary level. The Department agrees with supportive commenters that past salary levels should inform the current update, and agrees that statistics such as the percentage of salaried white-collar workers who earn below the salary level or statistics comparing the new salary level to inflation-adjusted prior levels, reinforce the reasonableness of the Department's approach. However, the Department is wary of comments urging a return to the 2016 rule methodology that do not account for subsequent court decisions and the Department's 2019 rulemaking. The Department also recognizes concerns from some commenters about the size of the salary level increase. But this metric is influenced by many factors and thus does not, in and of itself, establish whether a salary level sets an appropriate dividing line for determining whether an employee is employed in a bona fide EAP capacity. For example, the size of the current increase is influenced by factors including significant wage growth since the 2019 rule (simply adjusting the current salary level

[221] BLS currently publishes this data at https://www.bls.gov/cps/research/nonhourly/earnings-nonhourly-workers.htm.

methodology for wage growth would result in a roughly 23 percent increase); the Department for the first time updating a salary level that was set below the long test; and the Department adjusting the salary level to account for the move to a one-test system. While the 65 percent increase is greater in percentage terms than most prior updates, the Department does not consider this factor dispositive.[222]

The salary level methodology adopted in this final rule ($1,128 per week; $58,656 annually) produces a salary level that is lower than the two salary level estimates provided in footnote 3 of the NPRM ($59,284 and $60,209), which were based on a quarter of data. The Department disagrees with commenters that criticized the Department for providing projected salary level figures in its NPRM. These comments overlook that the NPRM proposed a methodology for updating the salary level test, not just a salary level figure. Providing commenters an estimate of the salary level that the proposed methodology could produce in a final rule based on updated data promoted rulemaking transparency and the opportunity for fully informed commenter feedback. That many commenters used the figures in footnote 3 in their comments, and the final salary level based on calendar year 2023 data is between the proposed salary level and the two estimates in the footnote, reinforces that footnote 3 in no way deprived commenters of the opportunity to meaningfully comment on the NPRM.

As previously discussed, most employer commenters that opposed the proposed salary level opposed any increase or at most supported a return to the 2004/2019 methodology, and so they did not address the NPRM's analysis examining where to set the salary level between the

[222] As discussed in section IV, in part to provide employers more time to adjust, the new methodology will not be applicable until January 1, 2025.

long and short test salary levels. The Department does not find these comments persuasive because they in effect sought a salary level below the long test level, which would not even fully restore the salary level's screening function, let alone account at all for the move to a one-test system. As for commenter concerns about the salary level's impact on low-wage regions and industries, the Department accounts for these concerns by setting the salary level using the lowest-wage Census Region. This aspect of the rulemaking differs from the 2016 rulemaking, where the Department proposed to set the salary level using a national data set and then, in response to commenters concerns, shifted to the lowest-wage Census Region in the final rule to account for low-wage regions and industries.[223] The Department used this past experience to account for the impact on low-wage regions and industries in developing the NPRM and, having done so, is again basing the salary level on the earnings of workers in the lowest-wage Census Region in this final rule.

The Department declines requests from some commenters to change the data set it used to set the salary level. Some asked the Department to add earnings data from a specific industry to the CPS earnings data. The Department is not altering the data set in this way because it believes that using earnings data from the lowest-wage Census Region produces a salary level that accounts for differences across industries and regional labor markets. The Department also is not altering the Census region data set so that it excludes all states with higher earnings, nor is the Department creating a new data set that includes only States with the lowest earnings. The Department's chosen approach is consistent with its practice since the 2004 rule of using the South, rather than a narrower geographic region, when setting the salary level. Restricting the

[223] *See* 81 FR 32408.

data set to the ten lowest-wage states or to the East South Central Region (made up of just four states, Alabama, Kentucky, Mississippi, and Tennessee) would give undue weight to low-wage areas and skew the salary level. The Chamber's suggestion to restrict the data set even further (by focusing on low-wage entities within low-wage industries within rural areas within the South) would even further compound this concern.

The purpose of the data set is not simply to produce the lowest possible salary level. The Department's approach directly accounts for low-wage areas while producing a salary level that is appropriate to apply nationwide. The Department also declines requests to limit its data set to exempt workers, instead continuing to set the salary level using earnings data for exempt and nonexempt workers—as it has done in every one of its rulemakings under the one-test system. As explained in the 2004 rule, the Department's chosen approach is preferable in part because restricting the data set to exempt employees requires "uncertain assumptions regarding which employees are actually exempt[.]"[224] The Department is also continuing to use data on nonhourly worker earnings as a proxy for compensation paid to salaried workers. Although some commenters challenged this approach, the Department is not aware of, and commenters did not provide, any statistically robust data source that more closely reflects salary as defined in the Department's regulations. Also, as discussed in section VII, the Department believes that relatively few nonhourly workers were paid by methods other than salaried.

In response to commenter opposition to the proposed salary level and the concerns described above, the Department considered setting the salary level equal to the 30th percentile of earnings of full-time salaried workers in the lowest-wage Census Region. The Department

[224] 69 FR 22167.

ultimately decided not to adopt this approach, however, because it would less effectively account for the shift to a one-test system. This methodology would set the salary level based on the lowest earnings ventile between the short and long test salary levels and produce a salary level that is only $77 above the long test level. As a result, for the population of white-collar workers earning between the long and short tests, only 18 percent would earn below the salary level (whereas 40 percent of this population earn below the new salary level). This approach thus would not sufficiently address the problem inherent in the 2004 methodology of including in the exemption employees who perform significant amounts of nonexempt work, including those earning salaries close to the long test salary level—where the Department would expect a higher proportion of workers to perform more nonexempt work.[225] In contrast, the Department's approach addresses these concerns in a manner that more reasonably distributes among employees earning between the long and short test salary levels and their employers the impact of the Department's move to a one-test system.

The Department disagrees with commenters that stated that the chosen methodology simply resurrects the 2016 methodology—which set the salary level equal to the 40th percentile of full-time salaried worker earnings in the lowest-wage Census Region. The fact that the new salary level is higher in nominal dollars than the level set in the 2016 rule ($913 per week) is

[225] The Department has repeatedly recognized that increasing salary level tends to correlate with the performance of bona fide EAP duties. *See* section V.B.1 (discussing role of long test and short test salary levels); section V.C (discussing the role of the HCE total annual compensation threshold). Thus, increasing overtime protection specifically for workers earning at the lower end of the range between the long test salary level and short test salary level—but not those earning at the higher end of that range—is an especially appropriate approach to balancing these concerns.

irrelevant because that level was calculated using 2015 data.[226] Applying the 2016 methodology to current data produces a salary level of $1,196 per week. Whereas under this rule an employee's salary level will be determinative of exemption status for 40 percent of the 10.8 million employees earning between the long and short test levels, under the 2016 methodology salary would be determinative for 55 percent of such employees. A salary level equivalent to the 40th percentile in the South would also result in 5.0 million affected workers. Although some of these workers earn below the long test level and would be nonexempt under either approach, this alternative approach would result in 949,000 more affected workers than the Department's chosen methodology. The Department's decision to deviate from the 2016 methodology is significant, as underscored by the fact that (as discussed in more detail below) a number of employee representatives urged the Department to adopt that methodology or a higher percentile.

The Department recognizes that many commenters found the proposed methodology conservative, or overly conservative, with some commenters urging the Department to select a methodology that produces a higher salary level. Repeating the 2016 rule methodology, as some commenters requested, by setting the salary level at the 40th percentile of weekly earnings of full-time salaried workers in the lowest-wage Census Region would further reduce the impact of the move to a one-test system on lower-paid white-collar employees who perform significant amounts of nonexempt work. As discussed above, commenters that supported the 2016 rule methodology provided statistics demonstrating that this approach yields a salary level within historical norms. The 40th percentile would produce a salary level ($1,196 per week) that is above the midpoint between the long and short test salary levels. As noted above, of the

[226] *See* 81 FR 32393.

approximately 10.8 million salaried white-collar employees who earn between the long and short test salary levels, approximately 55 percent earn between the long test salary level and $1,196 and would receive overtime protection by virtue of their salary, while approximately 45 percent earn between $1,196 and the short test salary level and would have their exemption status turn on whether they meet the duties test.

The Department believes this rule appropriately distributes the burden of the change from a two-test to one-test system between employees and employers. By contrast, the Department remains concerned that courts could find that adopting the 2016 rule methodology would make the salary level test determinative of overtime eligibility for too many employees. Setting the salary level equal to a higher percentile of weekly earnings (such as the 55th percentile as Demos recommended), would further amplify this concern. Setting the salary level based on a lower percentile of earnings will (compared to such higher levels) increase the number of employees for whom duties is determinative of exemption status, and in turn increase the ability of employers to use the exemption for more lower-paid employees who meet the EAP duties requirements. This outcome is consistent with the important role of the duties test in identifying bona fide EAP employees. EPI did not find the number of workers affected by a salary level increase to be an informative metric for assessing whether a threshold is appropriate and the Department agrees that this statistic has significant limitations. In particular, it is notable that although the standard salary level changes will result in 4.0 million affected workers (1.0 million from the initial update and 3.0 million from applying the new standard salary level),[227] only 2.2 million of these workers are due to the increase from the long test to the new methodology, while

[227] *See* Table 25.

1.8 million affected workers (or 45 percent) are a result of restoring the historic screening function of the long test salary level. By comparison, updating the salary level using the 2016 methodology and current data would result in 5.0 million affected workers. Although the number of affected workers for this rule is above the number of affected workers in the 2019 rule, the difference is necessary to fully restore the salary level's screening function and account for the shift to a one-test system, and the overall impact of this change on the workforce is relatively small (*see* section V.B), such that the new salary level is a proper exercise of the Department's authority to define and delimit the scope of the EAP exemption.

In declining to adopt the 2016 rule methodology, the Department is also responding to concerns that setting the salary level equal to the 40th percentile of weekly earnings of full-time salaried workers in the lowest-wage Census Region would foreclose employers from exempting any white-collar employees who earn less than that amount ($1,196 per week based on the data used in this final rule) and perform EAP duties, including those who were exempt under the long test and remained exempt when the Department established the one-test system in 2004 and set the salary level equivalent to the long test level.[228] Litigants challenging the 2016 rule emphasized this consequence of setting a salary level above the long test in a one-test system, and those arguments have contributed to the Department more fully attempting to account for the impact of the shift to a one-test system. Although some commenters favored a salary level equivalent to the short test level, such an approach would result in employers being unable to use the exemption for any employees who earn between the long and short test and have previously been exempt, either under the long test, or under the standard test set equal to the long test. In

[228] *See* 84 FR 51242.

contrast, the methodology in this final rule produces a salary level that is not only below any short test level, but also lower than the midpoint between the long and short test salary levels. This approach appropriately balances the goal of ensuring that employees earning above the long test salary level who perform substantial amounts of nonexempt work are not exempt with the goal of enabling employers to use the exemption for employees who do not perform substantial amounts of nonexempt work.

v. Salary Level Effects

In selecting the salary level methodology, the Department also considered commenter views that the proposed salary level would generate a range of repercussions. Many commenters that opposed the proposed salary level stated that it would cause widespread reclassification of currently exempt employees to nonexempt status and a corresponding decrease in flexible work arrangements, including remote work opportunities. *See, e.g.*, FMI; IFDA; National Lumber and Building Material Dealers Association; NRF. Others stated that employers would convert newly nonexempt employees from salaried to hourly status, which they contended would harm employee morale, *see, e.g.*, Independent Electrical Contractors, National Small Business Association, and create an undesirable "punch the clock" mentality, *see, e.g.*, North Carolina Center for Nonprofits, The 4A's. Some commenters that opposed the proposal stated that the rule would "harm the very workers the Department says it is trying to benefit," asserting, for example, that the proposal would result in reduced employee benefits and career advancement opportunities, and increased turnover. *See* Americans for Prosperity; *see also* PPWO. Other commenters expressed concern that the proposed increase would decrease employee productivity, *see, e.g.*, John. C. Campbell Folk School, decrease social services, *see, e.g.*, Social

Current, increase employer costs, prices, and inflation, *see, e.g.*, Chamber, and/or cause salary compression issues, *see, e.g.*, Seyfarth Shaw.

Commenters that supported the Department's proposed salary level or a higher salary level than proposed often highlighted what they viewed as positive effects of the proposed increase. Many emphasized that the updated salary level would make it more difficult to exempt lower-paid employees who they believed should be nonexempt, particularly low-level managers with many duties equivalent to non-managerial employees. *See, e.g.*, Coalition of Gender Justice and Civil Rights Organizations; NELP; Winebrake & Santillo. Restaurant Opportunities Center United stated that the current "low salary threshold discourages restaurant employees from taking managerial and supervisory positions, thereby gaining skills and experience that would enable them to advance their careers[.]" Sanford Heisler Sharp stated that the "need for monitoring and protecting white-collar workers' hours is critical today" because the significant increase in telework since 2020 has meant that employers are "no longer constrained by the practical limitation of the worker leaving the workplace." Other employee representatives explained that the rule would produce positive societal benefits such as increased economic security, *see, e.g.*, NELP, improved worker health due to decreased work hours, *see, e.g.*, SEIU, decreased poverty, *see, e.g.*, NEA, and disproportionate benefits for women, people of color, and workers with disabilities, *see, e.g.*, National Partnership.

Taken together, the above comments do not provide a compelling justification for deviating from the Department's proposed salary level methodology. The Department agrees that the salary level increase will result in some currently exempt employees becoming nonexempt and therefore receiving minimum wage and overtime protections. Employee reclassification is a

consequence of any salary level increase, and the number of reclassified employees will depend on how employers choose to respond to this rule for their employees who earn between the current and new salary levels. Moreover, there is no prohibition on paying nonexempt employees a salary as long as any overtime hours are appropriately compensated, and employers may therefore choose to continue to pay a salary to affected workers. Employers likewise have latitude to determine what flexible work arrangements to provide employees and, more broadly, need not structure their pay plans in a manner that results in the potentially adverse effects (such as decreased employee benefits) that some employers identified. Significantly, employees and employee representatives did not share employer commenter concerns about potential adverse consequences of the proposed salary level, let alone view them as a justification for deviating from the proposed salary level. This includes comments from individual employees. For example, an exempt manager for a small nonprofit organization stated that they "would love the opportunity to be reclassified to nonexempt and be compensated for time worked beyond 40 hours, or alternatively be given a raise if that level of flexibility is deemed necessary by my employer." As to potential consequences of the updated salary level on the economy more broadly, such implications are speculative and in dispute (as discussed in some detail in section VII), and do not provide a basis for a different salary level methodology.

iv. Other Issues

The Department also addresses some other issues stakeholders raised in their comments.

Many nonprofit organizations worried that the proposed salary level would disproportionately affect them, raising concerns related to, for example, their reliance on government grants, *see, e.g.*, Asclepius Initiative, Catholic Charities, National Council of

Nonprofits, and their inability to raise prices, *see, e.g.*, Advancing States, Independent Sector, YMCA. Some commenters asked the Department to exempt at least certain nonprofit organizations from the salary level test. *See, e.g.*, Oklahoma Wesleyan University; U.S. PIRG. Many nonprofit organization commenters opposed this idea. *See, e.g.*, A Second Chance; Delaware Alliance for Nonprofit Advancement; National Council for Nonprofits; North Carolina Center for Nonprofits. The Department recognizes and values the enormous contributions that nonprofit organizations make to the country. Nonprofit organizations provide services and programs that benefit many vulnerable individuals in a variety of facets of life, including services that benefit the vulnerable workers who the Department also works to protect by ensuring that their workplaces are fair, safe, and secure. However, the Department's EAP exemption regulations have never had special rules for nonprofit organizations; the employees of nonprofits have been subject to the EAP exemption if they satisfied the same salary level, salary basis, and duties tests as other employees.[229] Consistent with this history, the Department declines to exempt nonprofit organizations from the salary level test. As with other industries, as discussed above, the Department accounts for nonprofit industry concerns by setting the salary level using the lowest-wage Census Region.

A number of community-based service providers for people with intellectual and developmental disabilities urged the Department to work closely with other government agencies, including the Centers for Medicare and Medicaid Services (CMS) and the Administration for Community Living (ACL), to implement the Department's proposed changes in the context of Medicaid home and community-based services (HCBS). *See, e.g.*, ANCOR;

[229] *See* 81 FR 32398, 32421; *see also* 84 FR 51234.

BrightSpring Health Services; NASDDDS; United Cerebral Palsy Association. Some commenters specifically referenced a policy that was adopted by the Department related to the enforcement of the 2016 regulation for providers of Medicaid-funded services for individual with intellectual or developmental disabilities in residential homes or facilities with 15 or fewer beds.[230] *See, e.g.*, Chimes; The Arc of the United States. Consistent with its approach in the 2019 rule, the Department is not adopting a similar policy in this rulemaking. The Department believes following this approach is appropriate given that the initial update (to $844 per week) is less than salary level increase in the 2019 rule, and service providers will have approximately 8 months from publication of this rule to comply with the new salary level ($1,128 per week). Additionally, the Department intends (as many commenters requested) to issue technical assistance to help employers comply with the FLSA and will continue to coordinate (as other commenters requested) with ACL and CMS on supporting Medicaid-funded service providers impacted by this rule.

Some commenters asked the Department to permit employers to prorate the salary level for part-time employees. *See, e.g.*, NCFC; PPWO; Seyfarth Shaw; University System of Maryland. The Department has never prorated the salary level for part-time positions; considered and rejected similar requests in its 2004, 2016, and 2019 rules; and declines to establish a prorated salary level for part-time positions in this rule.[231] As the Department has previously explained, employees hired to work part time generally do not work in excess of 40 hours in a workweek, and overtime pay is not at issue for these employees. An employer may pay a

[230] *See* 81 FR 32390 (May 23, 2016).
[231] 84 FR 51239; 81 FR 32422; 69 FR 22171.

nonexempt employee a salary to work part time without violating the FLSA, so long as the salary equals at least the minimum wage when divided by the actual number of hours (40 or fewer) the employee worked.[232]

The Chamber objected to the Department's proposed change to the example provided in § 541.604(b), a salary basis test regulation establishing that an exempt employee may be paid on an hourly, daily, or shift basis if the employment arrangement "includes a guarantee of at least the minimum weekly required amount paid on a salary basis regardless of the number of hours, days or shifts worked, and a reasonable relationship exists between the guaranteed amount and the amount actually earned." The Department did not propose any substantive change to this regulation and only proposed to update the dollar amounts in light of the proposed increase in the standard salary level. The Department has again updated the figures in the regulation to account for the salary level change from the NPRM to the final rule. The updated numbers in this final rule produce the same ratios between actual and guaranteed earnings as example in the current regulations. The Department declines the Chamber's suggestion to change the numbers, which would change the ratio.

Some commenters urged the Department to increase the percentage of the salary level that employers could satisfy using nondiscretionary bonuses and incentive payments (including commissions). *See, e.g.*, FMI; National Automobile Dealers Association; National Golf Course Owners Association; TechServe Alliance. The Department did not propose any changes to how bonuses are counted toward the salary level requirement,[233] and declines to make any such

[232] *See* FLSA2008–1NA (Feb. 14, 2008).
[233] *See* 88 FR 62169.

changes in this final rule. Consistent with the current regulations, employers can satisfy up to 10 percent of the new salary level ($112.80 per week under this final rule) through the payment of nondiscretionary bonuses and incentive payments (including commissions) paid annually or more frequently.

5. Assessing the Impact of the Salary Level

i. The Department's Assessment of the Impact of the Proposed Salary Level

As stated in the NPRM, the Department sought to achieve three objectives in proposing to set the standard salary level at the 35th percentile of weekly earnings of full-time salaried workers in the lowest-wage Census Region: preserve the primary role that the duties test plays in determining EAP exemption status; fully restore the initial screening function of the salary level; and more effectively identify in a one-test system who is employed in a bona fide EAP capacity in a manner that reasonably distributes among employees earning between the long and short test salary levels and their employers the impact of the Department's move from a two-test to a one-test system.

In assessing whether the proposal met these objectives, the Department first considered the impact of its proposed salary level on salaried white-collar workers across the income spectrum. The Department noted that almost three-quarters of salaried white-collar workers earned above the proposed salary level, and therefore duties, rather than salary, would remain determinative of exemption status for a significant majority of white-collar workers. The Department also concluded that a minority of the smaller share of salaried white-collar workers who earn less than the proposed standard salary level would meet the duties test, whereas approximately three-quarters of the far-larger share of salaried white-collar workers who earn at

least the proposed standard salary level would meet the duties test. The Department noted that this supported that the proposed salary level would be an effective indicator of the capacity in which salaried white-collar workers are employed. The Department also examined the impact of the proposed salary level on currently exempt EAP workers—salaried white-collar employees who meet the standard duties test and earn at least $684 per week. The Department found that 1.8 million of the workers who would be affected by the proposed salary level earned less than the long test salary level and therefore would have been screened from the exemption under every prior rule issued by the Department except for the 2019 rule, thus confirming that the proposed standard salary level would play a relatively modest role in determining EAP exemption status.

ii. Comments Received

The Department received relatively few comments directly addressing its estimates of the impact of the proposed salary level or the metrics it identified to assess those impacts. As previously discussed, some commenters representing employer interests stated that the proposal would exclude too many workers from the exemption based on their earnings. *See, e.g.*, Chamber; PPWO; Seyfarth Shaw. However, commenters that expressed such views generally did not challenge the Department's analysis of the impact of its proposed salary level on all salaried white-collar workers,[234] nor did they generally address the Department's conclusion that under the proposed standard salary level, duties would be determinative of exemption status for a

[234] Some commenters asserted that the proposed salary level would make nonexempt too many workers in lower-wage regions and industries. *See, e.g.*, AHLA; CUPA-HR; NAHB; National Restaurant Association. As discussed above, the Department has accounted for low-wage industries and regions by using earnings data from the lowest-wage Census Region to set the salary level.

large majority of full-time salaried white-collar workers.[235] As noted in section V.B, employer advocates that opposed the Department's proposed salary level instead often emphasized the salary level's function of screening obviously nonexempt employees from the exemption, albeit asserting that the proposed salary level would exceed its screening function, *see, e.g.*, PPWO, RILA, SHRM, whereas worker advocates often favored a greater role for the salary level than employer representatives, *see, e.g.,* AFSCME, EPI, Family Values @ Work.

AFPI challenged the Department's estimate of the number of workers who earn between the proposed salary level and the long test salary level, which it claimed is a "made-up number."[236] Some commenters representing employer interests stated that the Department underestimated the number of currently exempt workers who would be impacted by its proposed salary level. *See, e.g.*, AFPI; NAM; NRF (including a report by Oxford Economics); Rachel Greszler; Seyfarth Shaw. The Oxford Economics report claimed that up to 7.2 million workers could be affected by the proposed salary level; AFPI asserted that approximately "7.5 million

[235] AFPI objected to the Department's use of nonhourly workers' earnings to estimate the impact of the proposed salary level on salaried workers. *See also* Chamber; National Association of Convenience Stores. The Department disagrees with the suggestion that data on compensation paid to full-time nonhourly workers is not representative of the earnings of full-time salaried workers. The Department used the same approach in the 2004, 2016, and 2019 rules. *See* 84 FR 51258; 81 FR 32414; 69 FR 22197. As explained in greater detail below, *see* section VII, while the CPS MORG data on full-time nonhourly workers on which the Department has relied includes workers paid on a salary basis along with workers paid on other bases, such as on a piece-rate or day-rate basis, the Department's analysis of data from the Panel Study of Income Dynamics (PSID) shows that relatively few nonhourly workers were paid by methods other than salaried.

[236] NRF included a report from Oxford Economics which stated that a more reasonable methodology for modeling the long test salary level would be to update the 1975 long test level for inflation. As discussed in section V.B, the Department disagrees with Oxford Economics' suggestion, which would conflict with the Department's historical practice of avoiding the use of inflation indicators in updating the salary level.

employees would be non-exempt for the first time based on salary alone"; and Rachel Greszler stated that the correct figure is as high as 12.3 million workers. NAM stated that the Department "underestimated the impact," though it did not elaborate. Some of these commenters also challenged the probability codes the Department used to estimate the number of workers who meet the duties test. *See, e.g.*, AFPI; Rachel Greszler.

On the other hand, AFL-CIO, the Coalition of State AGs, and EPI relied on the Department's estimates in their comments. For instance, the Coalition of State AGs observed that "'most salaried white-collar employees paid less than the proposed standard salary level do not meet the duties test, whereas a substantial majority of salaried white-collar employees earning above the proposed standard salary level meet the duties test,'" quoting the NPRM, in opining that the proposed salary level struck a more appropriate balance between the long and short test salary levels than the 2004 and 2019 rules. In asserting that the proposed salary level, although "too low[,]" would restore overtime protections to lower-paid workers "who were wrongly classified as exempt[,]" AFL-CIO referenced the Department's estimate that the proposed salary level would be "restorative for more than half of the workers it affects" since "these employees would have been entitled to overtime in every rule prior to the 2019 rule." EPI noted that the 3.4 million workers that the Department estimated would be affected by the proposed salary level, plus the approximately 248,000 workers who would be affected by the proposed change in the total compensation threshold for the HCE test, discussed below, together constituted "just 2.6% of workers subject to [the] FLSA . . . and just 2.3% of all workers." As discussed in section V.B, numerous commenters representing workers also pointed to additional data points which, they stated, show that the Department's proposed salary level would fulfill a

relatively limited role in determining exemption status, particularly by historical standards. For instance, multiple commenters stated that approximately 28.2 percent of all full-time salaried workers earn below the proposed salary level, whereas in 1975 approximately 62.8 percent of full-time salaried workers earned below the short test salary level. *See, e.g.*, AFL-CIO; EPI; NELP; NWLC.

iii. Assessing the Impact of the New Salary Level

As discussed in section V.B, the Department is finalizing its proposal to set the standard salary level equal to the 35th percentile of earnings of full-time salaried workers in the lowest-wage Census Region, which, based on the most recent earnings data, produces a salary level of $1,128 per week. The Department has analyzed the impact of the new salary level, applying generally the same metrics that it applied in the NPRM. Upon consideration of the comments received, the Department concludes that this salary level meets the objectives it sought to achieve in undertaking this rulemaking: preserving the primary role of an analysis of employee duties in determining EAP exemption status; fully restoring the initial screening function of the salary level; and more effectively identifying in a one-test system who is employed in a bona fide EAP capacity in a manner that reasonably distributes among employees earning between the long and short test salary levels and their employers the impact of the Department's move from a two-test to a one-test system.

The Department intentionally chose a salary level methodology that will ensure that EAP exemption status for the great majority of white-collar employees will continue to depend on their duties. Consistent with the NPRM, the Department thus began by analyzing the impact of the new salary level on all full-time white-collar salaried workers. The Department continues to

believe that an analysis of how the new salary level will impact all full-time salaried white-collar workers is necessary to put the salary level and its relation to an examination of duties in the appropriate context, as this is the universe of workers who could potentially be impacted by an increase in the standard salary level. As noted above, commenters representing employers did not directly challenge this aspect of the Department's analysis. And many commenters representing workers effectively endorsed this approach in stating that the proportion of full-time salaried workers who earn less than the proposed salary level shows the relatively modest impact of the proposed salary level in determining EAP exempt status, in comparison to an examination of duties. *See, e.g.*, AFL-CIO; EPI; NELP; NWLC.[237]

The Department's analysis confirms that the number of full-time salaried white-collar workers who will be excluded from the EAP exemption due to the Department's salary level is greatly exceeded by the far-larger population of full-time salaried white-collar workers for whom duties will continue to determine their exemption status. As illustrated in Figure A below, of the approximately 45.4 million full-time salaried white-collar workers in the United States subject to the FLSA,[238] about 12.7 million earn below the new salary level of $1,128 per week, and about 32.7 million earn above the salary level.[239] Thus, approximately 28 percent of full-time salaried

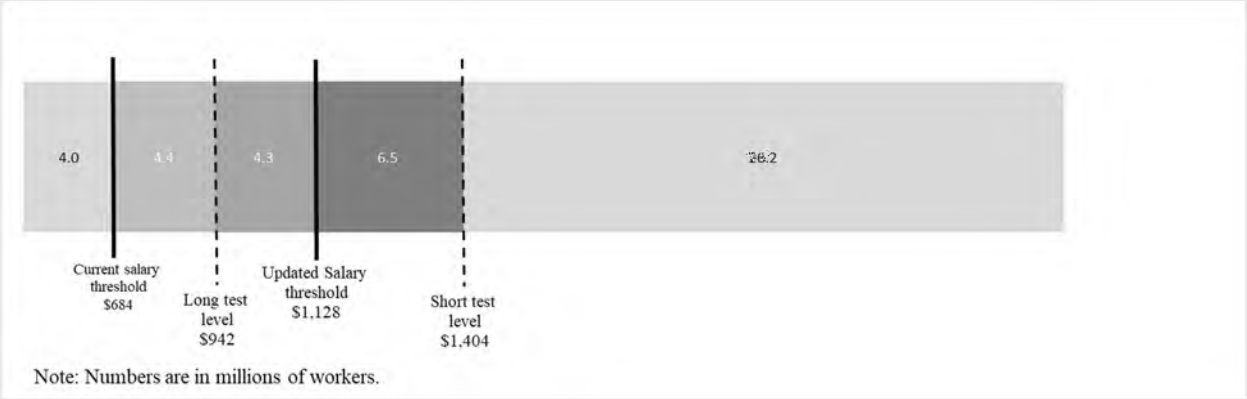
[237] As discussed further below, the Department does not believe, as some commenters representing workers suggested, that the proportion of full-time salaried workers who earned below the short test salary level in 1975 is the most appropriate comparator for the population of workers who earn below the new salary level.

[238] Excluded from this number are workers in named occupations and those exempt under another non-EAP overtime exemption. The exemption status of these groups will not be impacted by a change in the standard salary level. Commenters did not address the Department's exclusion of these workers from its analysis of the impact of the proposed salary level.

[239] This estimate is conservative, as it excludes 8.1 million white-collar workers employed as teachers, attorneys, and physicians, for whom there is no salary level requirement under the part

white-collar workers (most of whom, as discussed below, do not perform EAP duties) earn below the new salary level, whereas approximately 72 percent of full-time salaried white-collar workers earn above the salary level and would have their exemption status turn on their job duties.

Figure A: Distribution of Full-Time Salaried White-Collar Workers by Weekly Earnings



Scrutinizing these figures more closely reinforces the continued importance of the duties test under the final rule. Of the approximately 12.7 million full-time salaried white-collar workers who earn below the new salary level of $1,128 per week, about 8.3 million earn below the long test salary level of $942 per week. With the exception of the 2019 rule when the Department set the salary level slightly lower, the Department has always set salary levels that screened from exemption workers earning below the long test salary level. As discussed in section V.B, the long test salary level is a key parameter for determining an appropriate salary

541 regulations and whose exemption status is therefore always determined by their duties. If these workers in "named occupations" are included, the percentage of salaried full-time white-collar employees for whom exemption status would depend on duties, rather than salary, increases to 76 percent. *See* §§ 541.303–304.

level.[240] The number of full-time salaried white-collar workers for whom salary would be determinative of their nonexempt status and who earn at least the long test salary level—4.3 million—is over seven times smaller than the number of full-time salaried white-collar workers for whom job duties would continue to be determinative of their exemption status because they earn at least the new salary level—32.7 million.

In analyzing how the Department's new salary level will impact all salaried white-collar workers, the Department also considered the extent to which full-time salaried white-collar workers across the income distribution perform EAP duties. As the Department stated in the NPRM and the 2019 rule, the salary level has historically served as "a helpful indicator of the capacity in which an employee is employed, especially among lower-paid employees; however, the salary level should not eclipse the duties test.[241] In considering the extent to which full-time salaried white-collar workers perform EAP duties, the Department uses probability estimates of passing the standard duties test, as it did in the NPRM.[242]

The Department's analysis shows that the new salary level is a helpful indicator of whether salaried workers perform EAP duties, since a minority of full-time salaried white-collar workers who earn less than the salary level meet the standard duties test, whereas a large majority of such workers who earn more than the salary level meet the standard duties test. As illustrated in Figure B, of the 12.7 million full-time salaried white-collar workers who earn less

[240] The Department calculated the value of the long test salary level using the same methodology it used in the NPRM, updated for current earnings data: the 10th percentile of earnings of likely exempt workers in low-wage industries and regions. As explained in section V.B, any minor historical variations in the long test methodology do not deprive it of its usefulness in helping determine an appropriate salary level now.
[241] 88 FR 62171;84 FR 51239, 51237.
[242] *See* section VII.

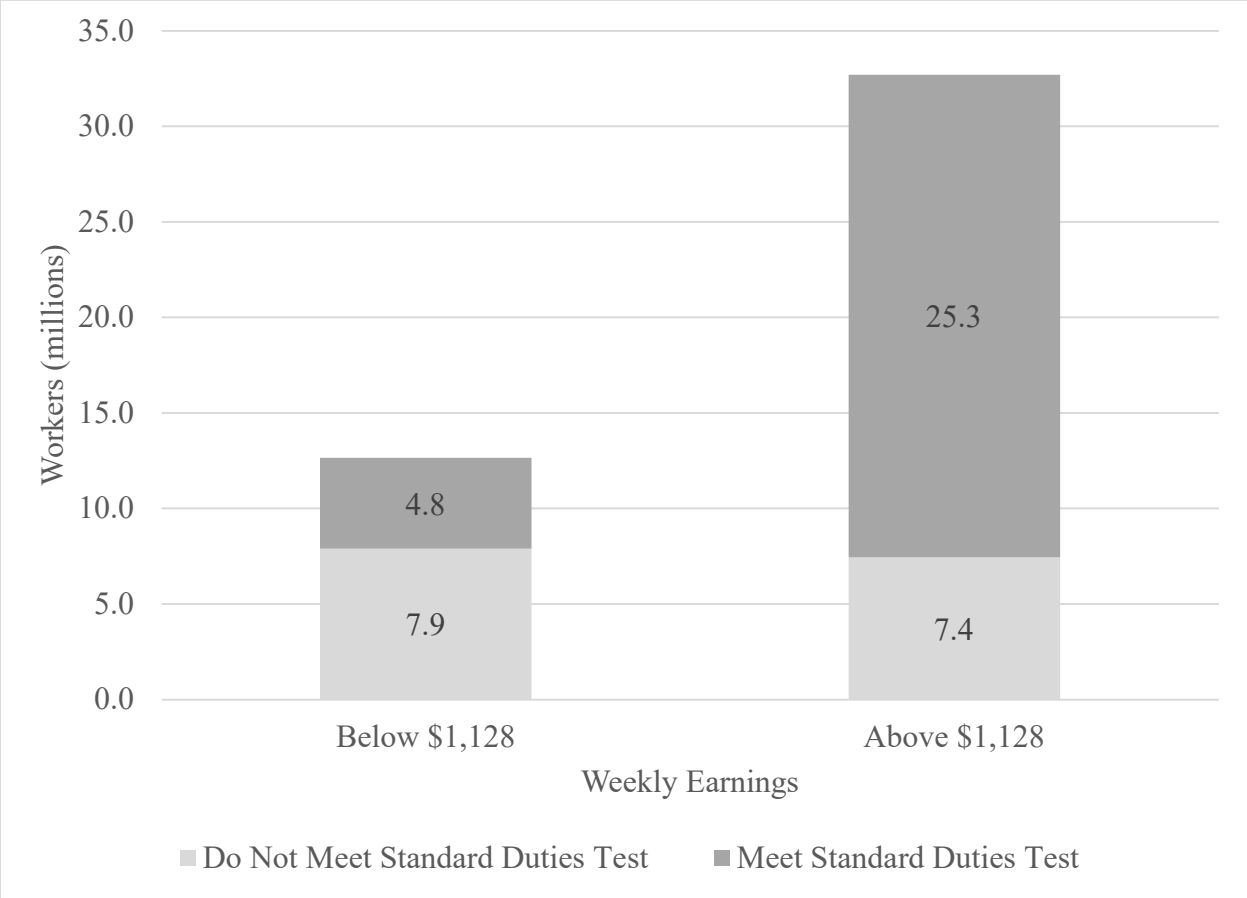
than $1,128 per week, the Department estimates that only 38 percent—about 4.8 million workers—meet the standard duties test. In contrast, of the 32.7 million full-time salaried white-collar workers who earn at least $1,128 per week, a large majority—77 percent, or about 25.3 million workers—meet the standard duties test.[243] The number of full-time salaried white-collar workers who meet the standard duties test and earn below the salary level is thus over five times smaller than the number of full-time salaried white-collar workers who meet the standard duties test and earn at least the salary level amount.[244] And 84 percent of all full-time salaried white-collar workers who meet the standard duties test—25.3 million out of a total of approximately 30.0 million—earn at least the new salary level.[245]

Figure B: Salaried White-Collar Workers Earning Above and Below the Standard Salary Level Who Meet or Do Not Meet the Standard Duties Test

[243] While a significant majority of full-time salaried white-collar workers who earn above the new salary level meet the duties test, helping confirm its appropriateness as an indicator of the capacity in which individuals are employed, a large number of full-time salaried white-collar workers who earn above the salary level—7.4 million—do not meet the duties test. A comparable number of salaried white-collar workers who earned above the proposed salary level did not meet the duties test, as EPI and AFI-CIO noted in their comments. PPWO's statement that "[t]he Department seem[ed] to be setting the salary level at a point at which all employees above the line would be exempt" is thus incorrect. The Department agrees with EPI that the fact that a large number of salaried white-collar workers who earn above the salary level will be nonexempt because they do not meet the duties test underscores the importance of an examination of duties under this rule. These 7.4 million workers will continue to be entitled to overtime because of their duties, not their salaries. Notably, this population is significantly larger than the population of workers who will become nonexempt under the new salary level. Rather than indicating that the salary level must be set higher, as AFL-CIO suggested, this fact indicates that this rule meets the Department's objective of preserving a primary role for an examination of duties.

[244] As noted above, *see supra* note 239, these figures exclude salaried white-collar workers who are not subject to the part 541 salary criteria.

[245] Note that these numbers refer only to salaried white-collar workers at all salary levels who meet the standard duties test, including workers who are nonexempt because they earn below the current standard salary level.



The Department disagrees with commenters that challenged its use of its probability codes to determine whether a worker meets the duties test in light of changes in occupational codes and the duties test since the probability codes were first developed. The Department has used the probability codes to estimate the number of workers who meet the duties test in its last three EAP rules.[246] As noted in section VII, although the probability codes were developed 25 years ago, the standard duties test is not substantively different from the former short duties tests reflected in the probability codes,[247] and the Department used occupational crosswalks to map the occupational codes on which the probability codes were originally based onto the 2018

[246] *See* 84 FR 51258-59; 81 FR 32458; 69 FR 22198.
[247] *See* 69 FR 22214.

Census occupational codes, which are used in the most recent CPS MORG data.[248] Additionally, the Department verified the continued appropriateness of the probability codes in 2016 through a review of the O*NET database,[249] which confirmed that the probability codes reflected current occupational duties.[250] The Department's probability codes remain reliable and appropriate indicators for evaluating whether workers meet the standard duties test.

Consistent with the NRPM, the Department next examined how the new salary level will impact salaried white-collar workers earning between the historic long and short test thresholds. As discussed in section V.B, the long and short test salary levels are important parameters for assessing the appropriateness of the salary level. Under the final rule, duties will continue to be determinative of exemption status for a majority of white-collar workers earning between these thresholds. As illustrated in Figure C, of the approximately 10.8 million salaried white-collar workers who earn between the long test salary level of $942 per week and the short test salary level of $1,404 per week, about 40 percent (4.3 million) earn below the new salary level, and about 60 percent (6.5 million) earn at or above the new salary level. Moreover, of the 4.3 million workers earning between the long test and the new standard salary level, almost half do not meet the standard duties test.[251]

---

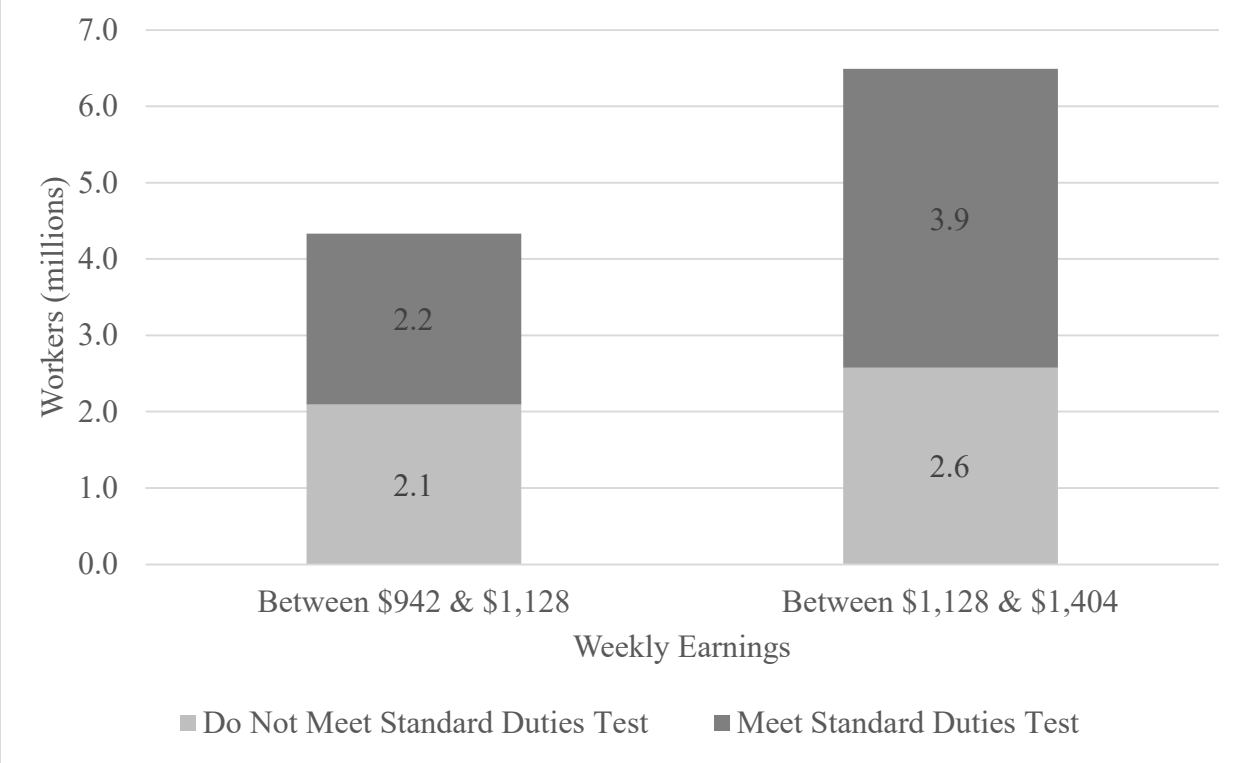
[248] *See* section VII.

[249] The O*NET database contains hundreds of standardized and occupation-specific descriptors. *See* https://www.onetcenter.org.

[250] *See* 81 FR 32459.

[251] As discussed further below, about 2.1 million of the approximately 4.3 million salaried white-collar workers who earn between the long test salary threshold and the Department's new salary level (about 48 percent of these workers) do not meet the standard duties test. Thus, in effect, only 21 percent of salaried white-collar workers who earn between the long and short test salary levels—2.2 million out of a total of 10.8 million—have their exemption status determined solely by the new standard salary level.

Figure C: Salaried White-Collar Workers Between the Long and Short Test Salary Levels Who Meet or Do Not Meet the Standard Duties Test



Commenters representing workers pointed to the proportion of full-time salaried workers who earned below the short test salary level in 1975, as compared to the proportion of full-time salaried workers who earned below the proposed salary level, in stating that the Department could or should set the salary level higher than the proposed salary level. *See, e.g.*, AFL-CIO; EPI; NELP; NWLC. As emphasized above, the Department agrees that the short test and long test salary levels are key parameters for assessing the appropriateness of a salary level in a one-test system. It is also useful to put any salary level in historical context.

However, the Department notes that under the two-test system, employers could also use the long test, which paired a lower salary level with a more rigorous duties test. Accordingly, a segment of the workers who earned below the short test salary level in 1975—those who earned between the short and long test salary levels and performed limited amounts of nonexempt work—were still exempt from overtime under the long test even though they earned below the short test salary level. As explained in section V.B.4, the Department has elected to set the salary level well below the short test salary level in part because setting it in the short test salary range would prevent employers from using the EAP exemption for this entire population of historically exempt workers.

Lastly, the Department also looked at the impact of the new salary level on currently exempt employees—those salaried white-collar workers who meet the standard duties test and earn at least $684 per week. As with every prior rulemaking to increase the part 541 salary levels, a relatively small percentage of currently exempt workers will become nonexempt. Of the approximately 45.4 million salaried white-collar workers in the United States, approximately 29.3 million currently qualify for the EAP exemption.[252] Of these 29.3 million presently exempt workers, just 4.0 million earn at or above the current $684 per week standard salary level but less than $1,128 per week and will, without some intervening action by their employers, become entitled to overtime protection as a result of the combined effect of the initial update and the

[252] Note that the 29.3 million worker figure only refers to workers who meet the standard EAP exemption and thus differs from the population of potentially affected EAP workers identified in the economic analysis (29.7 million), which includes workers who qualify only for the HCE exemption. As noted above, this is a conservative estimate because there are also 8.1 million workers in the "named occupations" who, under the Department's regulations, are exempt based on their duties alone.

subsequent application of the new standard salary level in this rule. A test for exemption that includes a salary level component will necessarily result in a number of workers who earned at or above the prior salary level and pass the duties test becoming nonexempt when the salary level is increased. As the Department has consistently found since 1938, salary is an important indicator of whether an individual is employed in a bona fide EAP capacity and therefore a key element in defining the exemption.

As the Department explained in its analysis of the impact of the proposed salary level, the new salary level will impact the exemption status of two distinct and important, but relatively small, groups of lower-paid EAP workers. First, the new salary level will restore overtime protections to 1.8 million currently exempt workers who meet the standard duties test but earn less than the equivalent of the long test salary level ($942 per week). Such employees were excluded from the EAP exemption under every rule prior to 2019, either by the long test salary level itself, or under the 2004 rule standard salary level, which was set equivalent to the long test salary level. Fully restoring the salary level's initial screening function requires a salary level that will ensure all employees who earn below the long test level are excluded from the exemption.

Second, the new salary level will result in overtime protections for an additional 2.2 million currently exempt workers who meet the standard duties test and earn between the long test salary level ($942 per week) and the final salary level. As explained earlier, the Department is setting the standard salary level above the long test level to account for the shift to a one-test system in a manner that reasonably distributes the impact of this switch. The final rule will limit the number of affected workers by setting a standard salary level below the midpoint between the

long and short test salary levels and by using earnings data from the lowest-wage Census Region (the South).

Even among the 4.0 million workers affected by the combination of the initial update and the subsequent application of the new standard salary level in this rule, the fact that a large share of these workers earn below the long test level underscores the modest role of the final salary level. Beyond the 1.8 million workers earning less than the long test salary level—to whom the final rule will simply restore overtime protections that they had under every rule prior to 2019—the increase in the salary level will affect the exemption status of 2.2 million workers. This group makes up about 8 percent of all currently exempt, salaried white-collar workers and just under 5 percent of all salaried white-collar workers.[253] The salary level methodology adopted in this rule will thus maintain the "useful, but limited, role" of the salary level in defining and delimiting the EAP exemption.[254]

Finally, the Department does not agree with commenters that stated that it underestimated the number of affected workers in the NPRM. Commenters that asserted the number of affected workers could be much higher generally referenced estimates of the number of workers earning between the current salary level and the proposed salary level, regardless of whether they passed the duties test, and then posited that up to that many workers (e.g., 7.2 million, 7.5 million, or 12.3 million) could be affected. *See* AFPI; NRF; Rachel Greszler. The position that all workers earning below the new salary level, regardless of their duties, will be affected by the new salary

[253] The 4.0 million workers affected by the new salary level represent only 13.8 percent of the 29.3 million salaried white-collar workers who currently qualify for the standard EAP exemption.
[254] *See* 88 FR 62173; 84 FR 51238.

level fails to account for the fact that that millions of these workers are already nonexempt because they fail the duties test. The exemption status of workers who fail the duties test will not be affected by this rule.

Determining the workers who will be affected by a change in the salary level requires an examination of workers' earnings and their duties. Consistent with the NPRM, the Department determined the populations of currently exempt workers who will be affected by the salary level by applying its probability codes. For the reasons discussed earlier in this section and in section VII below, the Department's probability codes are reliable and appropriate indicators of whether an employee meets the standard duties test. The Department has consistently applied this methodology in all its recent part 541 rules.[255] Though some commenters criticized the Department's method for calculating the affected worker figure, they did not offer an alternate methodology for determining which workers pass the current duties test, let alone one as robust and proven as the Department's probability codes.

C. Highly Compensated Employees

In the 2004 rule, the Department created the HCE test for certain highly compensated employees. Combining a much higher compensation requirement with a minimal duties test, the HCE test is based on the rationale that employees who earn at least a certain amount annually—an amount substantially higher than the annual equivalent of the weekly standard salary level—will almost invariably pass the standard duties test.[256] The HCE test's primary purpose is

[255] *See* 84 FR 51258–59; 81 FR 32458; 69 FR 22198.

[256] 84 FR 51249; *see also* § 541.601(c) ("A high level of compensation is a strong indicator of an employee's exempt status, thus eliminating the need for a detailed analysis of the employee's job duties.").

therefore to serve as a streamlined alternative for very highly compensated employees because a very high level of compensation is a strong indicator of an employee's exempt status, thus eliminating the need for a detailed duties analysis.[257]

As outlined in § 541.601, to be exempt under the HCE test, an employee must earn at least the amount specified in the regulations in total annual compensation—presently $107,432 per year.[258] Of this HCE threshold amount, no less than the full standard salary level amount must be paid on a salary or fee basis.[259] Finally, the employee must "customarily and regularly perform[] any one or more of the exempt duties or responsibilities of an executive, administrative, or professional employee[.]"[260] The HCE test applies only to employees whose primary duty includes performing office or non-manual work.[261]

Employees qualifying for exemption under the HCE test must receive at least the standard salary level per week on a salary or fee basis, while the remainder of the employee's total annual compensation may include commissions, nondiscretionary bonuses, and other nondiscretionary compensation.[262] Total annual compensation does not include board, lodging, or other facilities, and does not include payments for medical insurance, life insurance,

---

[257] *See* 69 FR 22173–74.
[258] § 541.601(a)(1).
[259] § 541.601(b)(1). Although § 541.602(a)(3) allows employers to use nondiscretionary bonuses, incentives, and commissions to satisfy up to 10 percent of the weekly standard salary level when applying the standard salary and duties tests, the Department's regulation at § 541.601(b)(1) does not permit employers to use such payments to satisfy the weekly standard salary level requirement for HCE workers. *See* 84 FR 51249.
[260] § 541.601(c).
[261] § 541.601(d).
[262] § 541.601(b)(1). The criteria for determining if an employee is paid on a "salary basis" are identical under the standard exemption criteria and the HCE test. *See Helix Energy Solutions,* 143 S.Ct. at 683.

retirement plans, or other fringe benefits. An employer is permitted to make a final "catch-up" payment during the last pay period or within 1 month after the end of the 52-week period to bring an employee's compensation up to the required level.

As stated in the NPRM, the Department continues to believe that the HCE test is a useful alternative to the standard salary level and duties tests for highly compensated employees. However, as with the standard salary level, the HCE total annual compensation level must be updated to ensure that it remains a meaningful and appropriate standard to pair with the minimal HCE duties test. To maintain the HCE test's role as a streamlined alternative for those employees most likely to meet the standard duties test, the HCE total annual compensation level must be high enough to exclude all but those employees "at the very top of [the] economic ladder[.]"[263] The proposal noted that when it was created in 2004, the HCE test featured a $100,000 threshold that exceeded the annual earnings of approximately 93.7 percent of salaried workers nationwide.[264] More recently in the 2019 rule, the Department set the HCE test threshold so it would be equivalent to the annual earnings of the 80th percentile of full-time salaried workers nationwide. At the time of the NPRM, however, the $107,432 per year HCE threshold covered only 72 percent of full-time salaried workers nationwide.[265]

The Department proposed to update the HCE test by setting the total compensation amount equal to the annualized weekly earnings of the 85th percentile of full-time salaried workers nationwide. Based on earnings data used in the NPRM, this proposed methodology resulted in a proposed HCE threshold of $143,988, of which at least $1,059 per week (the

[263] 69 FR 22174.
[264] *See* 88 FR 62159.
[265] *Id*.

proposed standard salary level) would have to be paid on a salary or fee basis.[266] The Department noted that its proposed methodology would produce an HCE threshold that was higher than under the methodology adopted in the 2019 final rule (which set the HCE threshold equal to the annualized weekly earnings of the 80th percentile of full-time salaried workers nationwide),[267] but lower than under the 2004 rule (which covered 93.7 percent of salaried workers nationwide) and the method adopted in the 2016 rule (which would have covered 90 percent of salaried workers nationwide).[268] In justifying the proposed HCE threshold, the Department explained in the NPRM that it was concerned that repeating the 2019 rule's methodology now would not produce a threshold high enough to reserve the HCE test for employees at the top of today's economic ladder and could risk the unintended exemption of large numbers of employees in high-wage regions.[269]

The Department is finalizing its proposal to increase the HCE total compensation threshold to the 85th percentile of annualized weekly earnings of full-time salaried workers nationwide. Applying this methodology to calendar year 2023 earnings data results in a total compensation threshold of $151,164 per year. This approach will guard against the unintended exemption of workers who are not bona fide executive, administrative, or professional employees, including those in higher-income regions and industries.

---

[266] It is the Department's intent that the increase in the HCE total annual compensation threshold is independent of, and severable from, the increase in the standard salary level to the 35th percentile of weekly earnings of full-time salaried employees in the lowest-wage Census Region (the South) and the updating provision, pursuant to which the HCE total annual compensation threshold will be regularly updated to reflect current earnings.
[267] *See* 84 FR 51250.
[268] *See* 69 FR 22169–70 (Tables 3 and 4); 81 FR 32429.
[269] 88 FR 62176.

As in prior rulemakings, the Department received significantly less feedback from commenters on the proposed increase to the HCE threshold than on the proposed increase to the standard salary level. Most commenters did not address the issue. Among the comments that addressed the proposed HCE threshold, stakeholder sentiment was split; employee representatives generally supported the proposed increase or asked for a higher increase, while most employer representatives favored a smaller increase or no increase at all.

A number of commenters expressed support for the proposed increase to the HCE threshold. *See, e.g.*, AFT; AFL-CIO; Coalition of State AGs. For example, the Coalition of State AGs asserted that "[s]ignificant inflation since the 2019 rule became effective in January 2020 has eroded the purchasing power of the HCE salary level" and remarked that the HCE threshold "could arguably be made even higher than the proposed level, particularly for high-cost, high-wage states[.]" The National Partnership described the proposed HCE threshold as "in line with historic and economic precedent," while the AFT commented that the proposed HCE threshold "will ensure [that] workers in the health care sector, and workers who provide a wide range of services and expertise for state and local governments, are not completely excluded from possibly qualifying for overtime."

A handful of commenters advocated for the adoption of a higher HCE threshold than proposed. Noting that the HCE threshold originally exceeded the earnings of 93.7 percent of all salaried employees nationwide when it was introduced in 2004, Sanford Heisler Sharp asserted that the Department's proposal to set the HCE threshold at the 85th percentile "introduces a substantial risk of harming employees who truly need overtime protections." NELA and Nichols Kaster urged the Department to repeat the approach it took in the 2016 rule, which set the HCE

threshold equal to the 90th percentile of salaried earnings nationwide. Invoking the FLSA's policy goal of spreading employment, NELA also opined that "an overly permissive HCE [test] will result in fewer 'highly compensated' jobs available for workers aspiring to climb the economic ladder to benefit themselves and their families."

Employer stakeholders that addressed the HCE threshold opposed the Department's proposed increase, with many commenters disputing that the current HCE threshold should be increased at all. *See, e.g.*, ABC; AHLA; Argentum & ASHA; NAW; Visiting Angels. A number of commenters that opposed the proposed HCE threshold asserted that it would be administratively burdensome to reevaluate the exemption status of employees who earn between the current and proposed HCE thresholds. *See, e.g.*, HR Policy Association; NAM; NCFC. PPWO commented that "[e]mployers will be faced with the task of reviewing the basis on which each employee was accorded exempt status, including employees for whom the exempt status decision was made a decade ago and who may be among the most highly paid employees in the company."

Other employer-side stakeholders opposed the proposed HCE threshold but indicated (either in the alternative or outright) that they would be open to a smaller increase. Several commenters stated an increase to the HCE threshold using the 80th percentile methodology applied in the 2019 rule would be preferable. *See, e.g.*, CWC; LeadingAge; RILA; *see also* Chamber (asserting that the NPRM "does not address whatsoever why the 80th percentile [methodology] would be insufficient"). National Restaurant Association asserted that if the Department changes the HCE threshold, it "should calculate any new HCE highly compensated level by using data from the South Census Region, rather than on a nationwide basis, to ensure

that the HCE exemption is at least within reach of some employers in the lowest-wage regions in the country." WFCA similarly recommended that the Department set the HCE threshold at the 85th percentile of salaried earnings in lowest-wage Census Region or, alternatively, use the 80th percentile of national data for full-time salaried workers (*i.e.*, the 2019 rule's approach).

Having considered the comments received, the Department is finalizing its proposal to increase the HCE threshold to the 85th percentile of annualized weekly earnings of full-time salaried earnings nationwide. This results in a new HCE threshold of $151,164 per year, using calendar year 2023 earnings data, of which at least $1,128 per week (the standard salary level) must be paid on a salary or fee basis.[270]

As an initial matter, the Department maintains that the current HCE threshold must be increased. In nominal terms, the current $107,432 HCE threshold is only 7 percent higher than the $100,000 HCE threshold that was introduced in 2004 and, as multiple commenters noted, it has failed to keep up with wage growth over the last 20 years. According to 2023 earnings data, the current HCE threshold ($107,432) now covers just 70 percent of full-time salaried workers nationwide, less than the 80 percent of such workers that it covered when it was set in 2019. This coverage would continue to decrease in the absence of an increase, which is needed to reserve the HCE test for employees "at the very top of today's economic ladder,"[271] as the Department originally intended. Inaction could risk the unintended exemption of employees in higher-income regions and industries who clearly are outside of the scope of the exemption.[272]

[270] As discussed in section IV, the increase in the HCE threshold and the standard salary level using the new methodologies will be applicable on January 1, 2025.
[271] 69 FR 22174.
[272] *Id*.

The Department concludes that increasing the HCE threshold to the 85th percentile of annualized weekly earnings of full-time salaried workers nationwide will ensure that the threshold is sufficiently high to provide a meaningful and appropriate complement to the minimal HCE duties test, and that nearly all of the highly paid white-collar workers earning above this threshold "would satisfy any duties test."[273] The Department considered keeping the 2019 rule's methodology for the HCE threshold (*i.e.*, the 80th percentile of earnings of full-time salaried employees nationwide) and applying it to current earnings data. However, the Department reaffirms its determination from the NPRM that this methodology is not appropriate because it does not produce a threshold high enough to reserve the HCE test for employees who would almost invariably pass the standard duties test. The Department agrees with commenters that stated that setting the HCE threshold at the annualized weekly earnings of the 85th percentile of full-time salaried workers nationwide will guard against the unintended exemption of workers who are not bona fide executive, administrative, or professional employees, including those in higher-income regions and industries.

The Department disagrees that the new HCE threshold is too high. Adjusting for wage growth, the proposed HCE threshold is significantly lower than the original HCE threshold that was introduced in 2004 (which surpassed the earnings of 93.7 percent of full-time salaried workers). Going forward, employers with employees affected by the increased HCE threshold can still use the standard exemption criteria to take advantage of the EAP exemption. The HCE test is a streamlined alternative to the standard exemption criteria for a select class of employees

[273] 84 FR 51250 (internal citation omitted).

who are so highly paid that they will almost invariably pass the standard duties test.[274] By design, the HCE test is reserved for employees "at the very top of today's economic ladder" who would satisfy "any duties test" in "virtually every" case.[275] This exclusivity is necessary because of the risk that the HCE test poses to salaried employees in high-income regions and industries who are not bona fide EAP employees, which the Department acknowledged when the HCE test was created in 2004.[276]

Although the Department has previously acknowledged that the HCE test may exempt some employees who fail the standard duties test and would otherwise be entitled to overtime pay, such outcomes should be "rare," involving employees whose pay is high enough that their exemption "would not defeat the objectives of section 13(a)(1) of the Act."[277] The only way to ensure that the HCE test serves its intended purpose—*i.e.*, serving as an efficient, streamlined test for employees who would "almost invariably" meet the standard duties test—is for the test to include an earnings threshold high enough to exclude nearly all employees whose EAP status may be questionable. The exemption status of such employees should be determined by the standard exemption criteria.

The Department acknowledges that some commenters requested the adoption of a higher HCE threshold, closer in magnitude to the original $100,000 HCE threshold that was adopted in

[274] *See* § 541.601(c) ("A high level of compensation is a strong indicator of an employee's exempt status, thus eliminating the need for a detailed analysis of the employee's job duties."); *see also* 84 FR 51249.
[275] 69 FR 22174.
[276] *See id*. (explaining the need to avoid the unintended exemption of employees "such as secretaries in New York City or Los Angeles . . . who clearly are outside the scope of the exemptions and are entitled to the FLSA's minimum wage and overtime pay protections.").
[277] *See* 84 FR 51249.

2004. As noted above, the original HCE threshold exceeded the earnings of over 93 percent of salaried white-collar workers when it was adopted. Germane to these comments, the Department considered repeating the approach it took in the 2016 final rule and proposed in the 2019 NPRM of setting the HCE threshold at the annualized weekly earnings of the 90th percentile of full-time salaried workers nationwide, which would result in a threshold of $179,972 per year. As noted in the NPRM, however, the Department is concerned that an HCE threshold set at $179,972 could unduly restrict the use of the HCE test for employers in lower-wage regions and industries.[278] While the new HCE threshold does not exclude from the HCE test as high a percentage of full-time salaried employees as the HCE threshold initially adopted in 2004, it excludes a sufficiently large percentage (*i.e.*, 85 percent of full-time salaried employees nationwide) to guard against the unintended exemption of employees in higher-income regions and industries who are not bona fide EAP employees.

For all of the reasons provided above, the Department adopts its proposal to set the HCE threshold equal to the annualized weekly earnings of the 85th percentile of full-time salaried workers ($151,164). This new level will be applicable on January 1, 2025.

D. Severability

1. The Department's Proposal

The Department proposed to add a severability provision to its part 541 regulations at § 541.5. Proposed § 541.5 stated that if any provision of this part is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, the Department intended that the provision be given the fullest effect

[278] *See* 88 FR 62176*; see also* 84 FR 51250.

permitted by law, unless the provision is held to be completely invalid or unenforceable, in which case, the Department intended the provision to be severable and not to affect the remaining provisions.

The Department illustrated the intended effect of proposed § 541.5 with some examples. The Department noted that it was its intent that the proposed updating mechanism be effective even if the proposed increase in the standard salary level were invalidated. It was also the Department's intent that the proposed increase in the HCE total annual compensation threshold be effective even if the increase in the standard salary level were invalidated. And it was the Department's intent that the proposed increases in the standard salary level and HCE annual total compensation requirement apply even if the updating mechanism was determined to be invalid.[279]

The Department is finalizing § 541.5, Severability, as proposed, with that addition of clarifying language as discussed below.

2. Discussion of Comments and Final Rule

Most commenters did not address proposed § 541.5. Of the few commenters that did address the Department's severability proposal, the Administrative Law Professors and NELP supported the inclusion of a severability provision in the final rule.

[279] The Department also stated that it was the Department's intent that its proposal to apply the standard salary level to the U.S territories subject to the Federal minimum wage remain in effect even if the proposed change to the standard salary level were invalidated. As discussed above, *see supra* note 9, at this time the Department is not finalizing in this final rule its proposal to apply the standard salary level to the U.S. territories subject to the Federal minimum wage and to update the special salary levels for American Samoa and the motion picture producing industry.

In expressing their support, the Administrative Law Professors provided the most in-depth discussion of the Department's proposed severability provision. The Administrative Law Professors explained that a provision of a rule is severable where the agency intends for the remainder of the rule to be effective, even if the provision is invalidated, and the rule would be workable absent the provision, citing precedent from the U.S. Supreme Court and the U.S. Court of Appeals for the District of Columbia Circuit.[280] The professors noted that the Department "clearly state[d] [its] intention" in proposed § 541.5 that the updating mechanism in proposed § 541.607 "be effective even if the proposed increase in the standard salary level is invalidated." They further noted that the Department "expresse[d] the same intention with regard to the implementation of the HCE total annual compensation requirement whether or not the standard salary level is invalidated" and "the application of the Department's proposed 2023 earnings thresholds, whether or not automatic updating is upheld."

The Administrative Law Professors observed that the Department's inclusion of a severability provision in the NPRM was consistent with guidance from the Administrative Conference of the United States (ACUS), which advised agencies in a 2018 report[281] to address severability in the text and preamble of both the NPRM and the final rule where the agency intends the provisions of a rule to be severable and anticipates that the rule may be challenged in court. The professors suggested that the Department further explain in the final rule how the rule "would remain workable" if any of its provisions were declared invalid. As an example, the

[280] *See K-Mart Corp. v. Cartier*, 486 U.S. 281, 294 (1988); *Davis Cnty. Solid Waste Mgmt. v. EPA*, 108 F.3d 1454, 1459-60 (D.C. Cir. 1997).
[281] *See* Admin. Conf. of the U.S., Recommendation 2018-2, *Severability in Agency Rulemaking*, 83 FR 30683, 30685 (June 29, 2018).

professors suggested stating explicitly that invalidation of the updating provision "would have no bearing on the rationality or administrability of the standard salary and HCE salary thresholds" as set in the rule. They further noted that in the event of the invalidation of either the standard salary level or the HCE compensation threshold, the updating provision could function independently because "updating would simply take as the 2023 baseline the thresholds left in place from the 2019 rule." The Administrative Law Professors made clear that expanding the explanation of "the independent workability of any of the rule's provisions" should not be seen as an indication of legal vulnerability but instead as merely an acknowledgement of the possibility of legal challenge.

NELP also supported the proposed severability provision, noting the "vital importance" of the proposed rule to millions of workers. Specifically, NELP stated that if any provision of the rule "is deemed legally questionable, only that provision should be stayed while litigation proceeds."

A small number of commenters representing employer interests specifically opposed the proposed severability provision or criticized the Department's severability proposal. Indiana Chamber of Commerce and U-Haul Holding Company (U-Haul) stated that the proposed severability provision was an acknowledgement of the legal vulnerability of the Department's proposed updating section. The YMCA stated that the Department failed to explain the need for, or appropriateness of, the proposed severability provision, and RILA asserted that the Department failed to explain how the proposed rule would function if any of its provisions were declared invalid. The Chamber and the National Association of Convenience Stores asserted that the Department should withdraw the severability provision.

The Chamber further asserted that, pursuant to the district court decision invalidating the 2016 rule, "the automatic increase provision in the Proposed Rule cannot survive if the increase to the minimum salary level is struck down." The Department does not read the court's decision as substantively examining the validity of the 2016 rule's automatic updating provision or analyzing whether that provision was severable from the remainder of the rule. And importantly, the 2016 rule did not contain a severability provision or discuss the Department's intent regarding severability of the provisions of that rule. In contrast, the Department's current NPRM included a severability provision and a detailed discussion of the Department's intent that specifically addressed severability of the updating provision. As the Administrative Law Professors noted, as proposed, the updating provision was not dependent on the proposed increases to the standard salary level and the HCE compensation threshold. If either of the new thresholds were vacated, the updating provision would simply use the existing methodologies set in the 2019 rule as the baseline for the update (*i.e.*, the Department would apply those methodologies triennially to update the earnings thresholds as established in § 541.607). This is a significant change from the 2016 updating provision, which would have updated the standard salary level and HCE total compensation requirement based on the specific methodologies set in that rule and facially could not function if those methodologies were invalidated.[282]

Upon consideration of the comments received, the Department is finalizing the severability provision in § 541.5 as proposed, with an additional sentence to further clarify its intent. The Department intends that each of this rule's provisions be considered separate and severable and operate independently from one another. The Department is revising § 541.5 to

[282] *See* 81 FR 32251.

state this explicitly. In this regard, the Department intends that if any application of a provision is stayed, enjoined, or invalidated, the provision be construed to continue to give the maximum effect to the provision permitted by law. In the event any provision within a section of the rule is stayed, enjoined, or invalidated, the Department intends that all remaining provisions within that section, plus all other sections, remain effective and operative. And in the event any whole section of the rule is stayed, enjoined, or invalidated, the Department intends that all remaining sections remain effective and operative.

It is the Department's position that the provisions and sections of the rule can function sensibly in the event that any specific provisions, sections, or applications are invalidated, enjoined, or stayed. To begin, the new standard salary level set forth in § 541.600(a)(2) of $1,128 per week—the 35th percentile of weekly nonhourly earnings in the lowest-wage Census Region—can function sensibly, even if, for instance, the rule's new updating section or the revision to the HCE total compensation requirement are stayed, enjoined, or invalidated. The revision to the standard salary level under the new methodology operates independently of and does not depend on either the new updating section or the revision to the HCE total compensation requirement. If, for instance, the triennial updating of the standard salary level were invalidated, the new salary level of $1,128 would still go into effect, and it would remain $1,128 per week until the Department conducts further rulemaking. The new standard salary level of $1,128 per week would also still take effect if the initial update to the standard salary level were invalidated.[283] And the new standard salary level would still go into effect and

[283] As noted in section IV, the initial update to the standard salary level and HCE total annual compensation requirement are applicable July 1, 2024, whereas the new standard salary level and HCE total annual compensation requirement are applicable 6 months later on January 1, 2025.

function sensibly if the revision to the HCE total compensation requirement were invalidated as well. Notably, in such an event, the total annual compensation an employee would need to receive to qualify for the HCE test would remain at the existing level;[284] however, the employee's total annual compensation would need to include at least $1,128 per week paid on a salary or fee basis. As discussed in section V.B, the revised standard salary level will work effectively with the standard duties test to better define who is employed in a bona fide EAP capacity by restoring the initial screening function that the salary level long fulfilled and adjusting the salary level to account for the change to a single-test system. Finalizing the new standard salary level will thus accomplish several of the key objectives the Department is seeking to achieve in undertaking this rulemaking, even if all or part of the updating section or the revisions to the HCE total compensation requirement do not also go into effect.

The revised HCE total compensation requirement of $151,164 per year set forth in § 541.601(a)(1)—the 85th percentile of annualized weekly earnings of full-time nonhourly workers nationally—can also function sensibly, even if the other provisions of this final rule are stayed, enjoined, or invalidated. The revision to the HCE total compensation requirement under the new methodology operates independently of, and does not depend on, either the new updating provision or the revision to the standard salary level. Accordingly, if, for instance, the triennial updating of the HCE total compensation requirement were invalidated, the new HCE total compensation requirement of $151,164 per year would still become effective, and the HCE total compensation requirement would remain at that amount until the Department undertakes

[284] Under these circumstances, the HCE total annual compensation requirement would be $132,964 per year or, if the initial update to the earnings thresholds under this rule did not go into effect, the current HCE total annual compensation requirement of $107,432 per year.

further rulemaking. If the initial update to the HCE total compensation requirement were invalidated, the revised HCE total compensation requirement would still go into effect, too. And the revised HCE total compensation requirement would still go into effect and function sensibly if the revision to the standard salary level were invalidated. In such an event, an employee would need to be paid the new total annual compensation amount of $151,164 per year to qualify as exempt under the HCE test, though the total annual compensation would need to include only the existing standard salary level[285] per week paid on a salary or fee basis. As noted in section V.C, the HCE test was intended to be limited to those highly paid employees who would almost invariably meet the standard duties test. The revision to the HCE total compensation requirement would restore it to a level that is high enough to avoid the unintended exemption of large numbers of employees in high-wage regions but not so high as to unduly restrict the use of the HCE test in lower-wage regions and industries, even if the revisions to the standard salary level and all or part of the updating provision do not go into effect.

The new updating section can also function sensibly, independent of the other provisions of this final rule. As explained in section V, the updating section provides in § 541.607(a) and (b) that the Department will update the standard salary level and HCE total compensation requirement, respectively, initially on July 1, 2024 and every 3 years thereafter, to reflect current earnings data, in accordance with the methodology used to set each threshold. Both the triennial updating of the earnings thresholds for exemption and the initial update to these thresholds can function sensibly on their own.

[285] Under these circumstances, the standard salary level would be $844 per week or, if the initial update to the earnings thresholds under this rule did not go into effect, the current standard salary level of $684 per week.

The triennial updating of the earnings thresholds for exemption can function sensibly, even if the new standard salary level and new HCE total compensation requirement are stayed, enjoined, or invalidated, as the triennial updates are based on the methodology used to set each threshold that is in place at the time of the update. If all the provisions of this rule do go into effect (and assuming the Department has not engaged in further rulemaking), as discussed in section V.A, the triennial updates to the standard salary level and HCE total compensation threshold will be based on the new methodologies established in this rule: the 35th percentile of weekly nonhourly earnings in the lowest-wage Census Region and the 85th percentile of annualized weekly earnings of full-time nonhourly workers nationally, respectively. However, the updating provision does not depend on the revisions to the standard salary level and HCE methodologies also going into effect. If, for instance, both the new standard salary level and HCE total compensation requirement were invalidated, the updating provision would, as the Administrative Law Professors noted, use the existing methodologies set in the 2019 rule as the baseline for the each triennial update: the 20th percentile of weekly earnings of full-time nonhourly workers in the lowest-wage Census Region and/or retail nationally, in the case of the standard salary level, and the 80th percentile of annualized weekly earnings of full-time nonhourly workers nationally, in the case of the HCE test. The updating section thus ensures that the standard salary level and HCE total compensation requirement continue to reflect current earnings—among the key objectives the Department is seeking to achieve in undertaking this rulemaking, *see* section V.A—even if the new methodologies for setting these earnings thresholds do not go into effect.

The initial update of the earnings thresholds for exemption can function sensibly as well, even if this rule's other revisions do not go into effect, as the baseline for the initial update to each threshold is the current methodology established in 2019. Accordingly, if, for instance, the new standard salary level, new HCE total compensation requirement, and the triennial updating provision were invalidated, the standard salary level and HCE total compensation requirement would still be updated on July 1, 2024 to $844 per week and $132,964 per year, respectively. In undertaking this rulemaking, the Department sought (among other objectives) to account for the considerable earnings growth that has taken place since it last updated the earnings thresholds for exemption.[286] The initial updating of the standard salary level and HCE total compensation requirement ensures these thresholds reflect earnings growth since the Department's 2019 rule, even if the new methodologies for setting the standard salary level and the HCE total compensation requirement and the future triennial updates to these earnings thresholds do not go into effect.

In sum, the Department has taken care to draft this final rule such that its provisions function independently and is including a severability section, § 541.5, to make clear that all the rule's provisions are separate and severable and should be given the fullest possible effect. As the Administrative Law Professors observed, this discussion of severability is not an acknowledgement of the legal vulnerability of any particular provision. However, since some commenters have indicated that they may challenge all or part of this rule, *see e.g.*, AFPI, Chamber, NFIB, and the 2016 and 2019 rules were both subject to legal challenge, the Department, consistent with ACUS guidance, makes explicit in the regulatory text that it

[286] *See* section V.A.2.

considers the provisions of this rule to be severable and explains here how the various provisions of the rule can operate sensibly in the event another provision of the rule is stayed, enjoined, or declared invalid.

VI. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.*, and its attendant regulations, 5 CFR part 1320, require the Department to consider the agency's need for its information collections, the information collections' practical utility, the impact of paperwork and other information collection burdens imposed on the public, and how to minimize those burdens. Under the PRA, an agency may not collect or sponsor an information collection requirement unless it displays a currently valid Office of Management and Budget (OMB) control number.[287]

OMB has assigned control number 1235-0021 to the information collection that gathers information from complainants alleging violations of the labor standards that WHD administers and enforces, and OMB has assigned control number 1235-0018 to the information collection, Records to be kept by Employers—Fair Labor Standards Act. In accordance with the PRA, the Department solicited public comments on the proposed burden changes to the information collection under control number 1235-0021 and the proposed burden changes to the information collection under OMB control number 1235-0018.[288] Because OMB control number 1235-0021 was encumbered by a different rulemaking at the time of submission of the NPRM to OMB, the Department at that time created a duplicate ICR of 1235-0021 under OMB control number 1235-

[287] *See* 5 CFR 1320.8(b)(3)(vi).
[288] *See* 88 FR 62181.

0NEW to allow the public to comment on the proposed estimates. The Department submitted a contemporaneous request for OMB review of the proposed revisions to the existing information collection and the duplicate ICR in accordance with 44 U.S.C. 3507(d). On October 12, 2023, OMB issued a notice that assigned the duplicate information collection control number 1235-0035 and indicated the Department should address comments received during the NPRM comment period and resubmit for approval at the time of the final rule. Also on October 12, 2023, OMB issued a notice that continued the previous approval of the information collection under 1235-0018 under the existing terms of clearance and advised the Department to address any comments received during the NPRM comment period and resubmit at the time of the final rule.

Circumstances Necessitating this Collection: This rulemaking revises 29 CFR part 541 and affects provisions that could be considered to entail collections of information including (1) the complaint process under which employees may file a complaint with the Department to investigate potential violations of the laws administered by the Department, including the FLSA; and (2) disclosure and recordkeeping requirements for covered employers under the FLSA. This rulemaking does not impose new information collection requirements. Rather, burdens under the existing requirements would increase due to the changes in the universe of employees for whom employers are required to maintain records. The changes adopted in this rulemaking may also cause an initial increase in burden if more employees file complaints with WHD to collect back wages under the overtime pay requirements.

Information and technology: There is no particular order or form of records prescribed by the regulations. A respondent may meet the requirements of this final rule using paper or

electronic means. WHD, to reduce burden caused by the filing of complaints that are not actionable by the agency, uses a complaint filing process in which complainants discuss their concerns with WHD professional staff. This process allows agency staff to refer complainants raising concerns that are not actionable under federal wage and hour laws and regulations to an agency that may be able to assist.

Public comments: The Department invited public comment on its analysis that the rule would create a slight increase in the paperwork burden associated with the complaint ICR 1235–0021 (submitted as a duplicate ICR at the NPRM stage under control number 1235-0NEW and later assigned by OMB as 1235-0035) and on the burden associated with ICR 1235–0018, Records to be kept by employers—Fair Labor Standards Act. The Department did not receive comments on the ICRs themselves or any comments submitted regarding the PRA analysis in particular, including the methodology. No comments were received with respect to the complaint ICR (1235-0021). However, commenters addressed aspects of the information collections while commenting on the text of the proposed rule as it relates the records ICR (1235-0018).

For example, Horizon Health Services commented that "[r]equiring supervisors to record their hours worked and request overtime, as needed, would [be] a disruption to business operations by adding a significant administrative burden." The University of Dayton agreed that a change would require additional administrative burden stating, "new training and systems would need to be put in place for newly nonexempt employees to record their time and for their supervisors to track and approve their time. They would have to become accustomed to tracking their hours, being sure not to work unbudgeted hours and overtime unless approved, and so forth." Others, like Argentum & ASHA and Oklahoma Wesleyan University, similarly expressed

concerns about the costs associated with having newly nonexempt employees record their time. SBA Advocacy stated that "DOL should consider" that "small entities face vast administrative and operational costs to schedule and track employee hours to minimize overtime costs." In addition, some commenters expressed concern that the Department's cost estimates related to recordkeeping were too low, given among other things that employers would need to adjust their recordkeeping and payroll systems for newly overtime-eligible employees. *See, e.g.*, NFIB; PPWO; Seyfarth Shaw. The National Roofing Contractors Association stated that it "is concerned the proposed regulation would result in dramatically increased labor costs and additional paperwork burdens for employers, while also reducing workplace flexibility and compensation for many workers."

In response to these comments, the Department observes that most employers currently have both exempt and nonexempt workers and therefore have systems already in place for employers to track hours. Additionally, commenters did not offer alternatives for estimates or make suggestions regarding the methodology for calculating the PRA burdens. The actual recordkeeping requirements are not changing in the final rule. However, the pool of workers for whom employers will be required to make and maintain records has increased under the final rule, and as a result the burden hours have increased. Included in this PRA section are the regulatory familiarization costs for this final rule. However, this is a duplication of the regulatory familiarization costs contained in section VII, economic impact analysis.

The Department plans to submit these ICR's to OMB upon publication of the final rule. The agency will publish a notice in the FEDERAL REGISTER to inform the public of OMB's decision.

Total burden for the subject information collections, including the burdens that will be unaffected by this final rule and any changes, is summarized as follows:

Type of review: Revision to currently approved information collections.

Agency: Wage and Hour Division, Department of Labor.

Title: Employment Information Form.

OMB Control Number: 1235–0021.

Affected public: Private sector, businesses or other for-profits and Individuals or Households.

Estimated number of respondents: 29,160 (2,150 from this rulemaking).

Estimated number of responses: 29,160 (2,150 from this rulemaking).

Frequency of response: On occasion.

Estimated annual burden hours: 9,720 (717 burden hours due to this rulemaking).

Capital/Start-up costs: $0 ($0 from this rulemaking).

Title: Records to be kept by Employers—Fair Labor Standards Act.

Type of review: Revision to currently approved information collections.

Agency: Wage and Hour Division, Department of Labor.

OMB Control Number: 1235–0018.

Affected public: Private sector, businesses or other for-profits and Individuals or Households.

Estimated number of respondents: 4,068,419 (0 from this rulemaking).

Estimated number of responses: 42,725,207 (10,320,000 from this rulemaking).

Frequency of response: on occasion.

Estimated annual burden hours: 1,157,993 (344,000 from this rulemaking).

Capital/Start-up costs: $0 ($0 from this rulemaking).

VII. Analysis Conducted in Accordance with Executive Order 12866, Regulatory Planning and Review, and Executive Order 13563, Improving Regulation and Regulatory Review

Under Executive Order 12866, OMB's Office of Information and Regulatory Affairs (OIRA) determines whether a regulatory action is significant and, therefore, subject to the requirements of the Executive Order and OMB review. As amended by Executive Order 14094, section 3(f) of Executive Order 12866 defines a "significant regulatory action" as a regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of $200 million or more; or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, territorial, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees or loan programs or the rights and obligations of recipients thereof; or (4) raise legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in the Executive Order. OIRA has determined that this rule is a "significant regulatory action" within the scope of section 3(f)(1) of Executive Order 12866.

Executive Order 13563 directs agencies to, among other things, propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs; that it is tailored to impose the least burden on society, consistent with obtaining the regulatory objectives; and

that, in choosing among alternative regulatory approaches, the agency has selected those approaches that maximize net benefits. Executive Order 13563 recognizes that some costs and benefits are difficult to quantify and provides that, when appropriate and permitted by law, agencies may consider and discuss qualitatively values that are difficult or impossible to quantify, including equity, human dignity, fairness, and distributive impacts. The analysis below outlines the impacts that the Department of Labor (Department) anticipates may result from this rule and was prepared pursuant to the above-mentioned executive orders.

A. Introduction

1. Background

The Fair Labor Standards Act (FLSA or Act) requires covered employers to (1) pay employees who are covered and not exempt from the Act's requirements not less than the Federal minimum wage for all hours worked and overtime premium pay at a rate of not less than one and one-half times the employee's regular rate of pay for all hours worked over 40 in a workweek, and (2) make, keep, and preserve records of their employees and of the wages, hours, and other conditions and practices of employment.

The FLSA provides a number of exemptions from the Act's minimum wage and overtime pay provisions, including one for bona fide executive, administrative, and professional (EAP) employees. The exemption applies to employees employed in a bona fide executive, administrative, or professional capacity, as those terms are "defined and delimited" by the Department.[289] The Department's regulations implementing these "white-collar" exemptions are codified at 29 CFR part 541. Since 1940, the regulations implementing the exemption have

[289] 29 U.S.C. 213(a)(1).

generally required each of the following three tests to be met: (1) the employee must be paid a predetermined and fixed salary that is not subject to reduction because of variations in the quality or quantity of work performed (the salary basis test); (2) the amount of salary paid must meet a minimum specified amount (the salary level test); and (3) the employee's job duties must primarily involve executive, administrative, or professional duties as defined by the regulations (the duties test).

The Department has updated the salary level test many times since its implementation in 1938. Table 1 presents the weekly salary levels associated with the EAP exemptions since 1938, organized by exemption and long/short/standard duties tests. From 1949 to 2004, the Department determined exemption status using a two-test system comprised of a long test (a lower salary level paired with a more rigorous duties test that limited performance of nonexempt work to no more than 20 percent for most employees) and a short test (a higher salary level paired with a less rigorous primary duties requirement that did not have a numerical limit on the amount of nonexempt work). In 2004, rather than update the two-test system, the Department chose to establish a new single-test system for determining exemption status, setting the standard salary level test at $455 a week, which was equivalent to the long test salary level, and pairing it with a standard duties test that was substantially equivalent to the more lenient short duties test. Because the single standard duties test was equivalent to the short duties test, employees who met the long test salary level and previously passed either the more rigorous long, or less rigorous short, duties test passed the standard duties test. The Department also added a new highly compensated employee (HCE) test, which used a very minimal duties test and a very high total compensation test set at $100,000 per year (*see* section II.B.2 for further discussion). In

2016, to address the concern that the standard test exempted lower-paid salaried employees performing large amounts of nonexempt work who had previously been protected by the more rigorous long duties test, the Department published a final rule setting the standard salary level at $913 per week, which was equivalent to the low end of the historic range of short test salary levels, and the HCE annual compensation level at $134,004. This approach restored overtime protection for employees performing substantial amounts of nonexempt work who earned between the long test salary level and the low end of the short test salary range, as they failed the new standard salary level test. As previously discussed, the U.S. District Court for Eastern District of Texas held the 2016 rule invalid. In 2019, in part to address the concern raised in the litigation that the approach taken in the 2016 rulemaking would have prevented employers from using the exemption for employees who earned between the long test salary level and the low end of the short test salary range and met the more rigorous long duties test, the Department returned to the methodology used in the 2004 rule and set the salary level at the 20th percentile of weekly earnings of full-time salaried workers in the South and in the retail industry nationally. Applying this method to the earnings data available in 2019 produced a standard salary level that was below the long test salary level. The current earnings thresholds, as published in 2019, are $684 a week for the standard salary test and $107,432 per year for the HCE test.

Table 1: Historical Weekly Salary Levels for the EAP Exemptions

Date Enacted	Long Duties Test			Short Duties Test
	Executive	Administrative	Professional	
1938	$30*	$30	-	-
1940	$30	$200 (per month)	$200 (per month)	-
1949	$55	$75	$75	$100
1958	$80	$95	$95	$125
1963	$100	$100	$115	$150
1970	$125	$125	$140	$200

1975	$155	$155	$170	$250
Standard Duties Test				
2004	$455			
2019	$684			

*Unless otherwise specified, all figures are dollars per week

2. Need for Rulemaking

The goal of this rulemaking is to set effective earnings thresholds to help define and delimit the FLSA's EAP exemption. To this end, the Department is finalizing its proposed change to the standard salary level. Specifically, the Department is adjusting the standard salary level by setting it equal to the 35th percentile of weekly earnings of full-time salaried workers in the lowest-wage Census Region (currently the South), based on the most recent year of Current Population Survey (CPS) data at the time of drafting.[290] Using the Bureau of Labor Statistics (BLS) 2023 data on percentiles of usual weekly earnings of nonhourly full-time workers, the standard salary level will be set at $1,128 per week.[291] Additionally, to maintain the effectiveness of this test, the Department is finalizing an updating mechanism that will update the earnings thresholds to reflect current wage data initially on July 1, 2024 and every 3 years thereafter.

The Department's new standard salary level will, in combination with the standard duties test, better define and delimit which employees are employed in a bona fide EAP capacity in a one-test system. As explained in greater detail in sections III and V.B, setting the standard salary

[290] The Department uses the terms *salaried* and *nonhourly* interchangeably in this rule because, consistent with its 2004, 2016, and 2019 rules, the Department considered data representing compensation paid to nonhourly workers to be an appropriate proxy for compensation paid to salaried workers. The Department also notes that the terms *employee* and *worker* are used interchangeably throughout this analysis.

[291] BLS publishes quarterly and annual estimates of percentile earnings values beginning with 2022 data at https://www.bls.gov/cps/research/nonhourly/earnings-nonhourly-workers.htm.

level at or below the long test salary level, as the 2004 and 2019 rules did, results in the exemption of lower-salaried employees who traditionally were entitled to overtime protection under the long test either because of their low salary or because they perform large amounts of nonexempt work, in effect significantly broadening the exemption compared to the two-test system. Setting the salary level at the low end of the historic range of short test salary levels, as the 2016 rule did, would have restored overtime protections to those employees who perform substantial amounts of nonexempt work and earned between the long test salary level and the low end of the short test salary range. However, it also would have resulted in denying employers the use of the exemption for lower-salaried employees who traditionally were not entitled to overtime compensation under the long test, which raised concerns that the Department was in effect narrowing the exemption. By setting a salary level above the equivalent of the long test salary level (using current data), the final rule will restore the right to overtime pay for salaried white-collar employees who prior to the 2019 rule were always considered nonexempt if they earned below the long test (or long test-equivalent) salary level. And it will ensure that fewer lower paid white-collar employees who perform significant amounts of nonexempt work are included in the exemption. At the same time, by setting it well below the equivalent of the short test salary level (using current data), the rule will allow employers to continue to use the exemption for many lower paid white-collar employees who were made exempt under the 2004 standard duties test. The new salary level will also more reasonably distribute between employees and their employers what the Department now understands to be the impact of the shift from a two-test to a one-test system on employees earning between the long and short test salary levels.

As the Department has previously noted, the amount paid to an employee is "a valuable and easily applied index to the 'bona fide' character of the employment for which exemption is claimed, as well as the "principal[]" "delimiting requirement . . .prevent[ing] abuse" of the exemption.[292] Additionally, the salary level test facilitates application of the exemption by saving employees and employers from having to apply the more time-consuming duties analysis to a large group of employees who will not pass it. For these reasons, the salary level test has been a key part of how the Department defines and delimits the EAP exemption since the beginning of its rulemaking on the EAP exemption.[293] At the same time, the salary test's role in defining and delimiting the scope of the EAP exemption must allow for appropriate examination of employee duties.[294] Under the final rule, duties will continue to determine the exemption status for most salaried white-collar employees.

The Department also will adjust the HCE total annual compensation requirement to the annualized weekly earnings of the 85th percentile of full-time salaried workers nationally ($151,164 using 2023 data). Though not as high a percentile as the HCE threshold initially adopted in 2004, which covered 93.7 percent of all full-time salaried workers,[295] the Department's new HCE threshold will ensure it continues to serve its intended function, because the HCE total annual compensation level will be high enough to exclude all but those employees at the very top of the economic ladder.

[292] Stein Report at 19, 24; *see also* 81 FR 32422.
[293] *See* 84 FR 51237.
[294] *See* 84 FR 51238.
[295] *See* 69 FR 22169 (Table 3).

In this final rule, the Department is not finalizing its proposal in section IV.B.1 and B.2 of the NPRM to apply the standard salary level to the U.S. territories subject to the federal minimum wage and to update the special salary levels for American Samoa and the motion picture industry.[296]

In its three most recent part 541 rulemakings, the Department has expressed its commitment to keeping the earnings thresholds up to date to ensure that they remain effective in helping differentiate between exempt and nonexempt employees. Long intervals between rulemakings have resulted in eroded earnings thresholds based on outdated earnings data that were ill-equipped to help identify bona fide EAP employees. In contrast, routine updates of the earnings thresholds to reflect wage growth will bring certainty and stability to employers and employees alike. Based on its long experience with updating the salary levels, the Department has determined that adopting a regulatory provision for regularly updating the salary levels, with an exception for pausing future updates under certain conditions, is the most viable and efficient way to ensure the EAP exemption earnings thresholds keep pace with changes in employee pay and thus remain effective in helping determine exemption status. Accordingly, in addition to the salary level changes discussed above, the Department is including in this rule a mechanism for updating the salary and compensation levels to reflect current wage data initially on July 1, 2024 and every 3 years thereafter. As explained in greater detail in section V.A, employees and employers alike will benefit from the certainty and stability of regularly scheduled updates.

[296] The Department will address these aspects of its proposal in a future final rule. While the Department is not finalizing its proposal, it is making nonsubstantive changes in provisions addressing the territories as a result of other changes in this final rule.

3. Summary of Affected Workers, Costs, Benefits, and Transfers

The Department estimated the number of affected workers and quantified costs and transfer payments associated with this final rule using pooled CPS Merged Outgoing Rotation Group (MORG) data. *See* section VII.B.2. The Department estimates in the first year after implementation, there will be 4.3 million affected workers.[297] This includes 4.0 million workers (1.0 million at the first update and 3.0 million when the new salary level is applied) who meet the standard duties test and earn at least $684 per week but less than $1,128 per week and will either become eligible for overtime or have their salary increased to at least $1,128 per week (Table 2).[298] An estimated 292,900 workers will be affected by the increase in the HCE compensation test from $107,432 per year to $151,164 per year. In Year 10, with triennial updating of the standard salary and HCE thresholds, the Department projects that 5.0 million workers will be affected by the change in the standard salary level test and 1.0 million workers will be affected by the change in the HCE total annual compensation test.[299]

[297] The term "affected workers" refers to the population of potentially affected EAP workers who either pass the standard duties test and earn at least $684 but less than the new salary level of $1,128 per week or pass only the HCE duties test and earn at least $107,432 but less than the new HCE compensation level of $151,164 per year.

[298] Here and elsewhere in this analysis, numbers are reported at varying levels of aggregation, and are generally rounded to a single decimal point. However, calculations are performed using exact numbers. Therefore, some numbers may not match the reported totals or the calculations shown due to rounding of components.

[299] In later years, earnings growth will cause some initially affected workers to no longer be affected because their earnings will exceed the new salary or compensation threshold. This occurs both in update years (i.e., triennially) and non-update years but will occur to a much greater degree in non-update years. Additionally, some workers will become newly affected because their earnings will reach at least $684 per week, and in the absence of this rule they would lose their overtime protections. To estimate the total number of affected workers over time, the Department accounts for both of these effects.

This analysis quantifies three direct costs to employers: (1) regulatory familiarization costs; (2) adjustment costs; and (3) managerial costs (*see* section VII.C.3). Total annualized direct employer costs over the first 10 years were estimated to be $802.9 million, assuming a 7 percent discount rate.[300] This rule will also transfer income from employers to employees in the form of increased wages. The Department estimated annualized transfers will be $1.5 billion. Most of these transfers will be attributable to wages paid under the FLSA's overtime provision; a smaller share will be attributable to the FLSA's minimum wage requirement. These transfers also account for employers who may choose to increase the salary of some affected workers to at least the new threshold so that they can continue to use the EAP exemption.

The Department also provides a qualitative discussion of the potential benefits and unquantified transfers of this rule, including strengthened overtime protections for some workers, increased worker productivity, increased personal time for workers, and reduced reliance on social assistance programs. *See* section VII.C.5.

Table 2: Summary of Affected Workers, Regulatory Costs, and Transfers - Standard and HCE Salary Levels

Impact	Year 1	Future Years [a]		Annualized Value	
		Year 2	Year 10	3% Real Discount Rate	7% Real Discount Rate
Affected Workers (1,000s)					
Standard	4,045	3,783	4,978	[b]	[b]
HCE	293	323	1,015	[b]	[b]
Total	4,337	4,106	5,993	[b]	[b]
Costs and Transfers (Millions in $2022) [c]					

[300] Hereafter, unless otherwise specified, annualized values will be presented using the 7 percent real discount rate.

Direct employer costs	$1,436.2	$641.5	$906.1	$794.0	$802.9
Transfers [d]	$1,509.2	$1,094.3	$2,490.1	$1,565.2	$1,534.1

[a] These cost and transfer figures represent a range over the nine-year span.
[b] Not annualized.
[c] Costs and transfers for affected workers passing the standard and HCE tests are combined.
[d] This is the net transfer from employers to workers. There may also be transfers of hours and income from some workers to others.

B. Number of Affected EAP Workers

1. Overview

This section explains the methodology used to estimate the number of workers who will be affected by the final rule. The pool of potentially affected workers is workers who are currently EAP exempt. In this final rule, as in previous rules, the Department estimated the current number of EAP exempt workers because there is no data source that identifies workers as EAP exempt. Employers are not required to report EAP exempt workers to any central data collection agency or as part of any employee or establishment survey. The methodology described in this final rule is consistent with the approach the Department used in the 2004, 2016, and 2019 final rules.[301] To estimate the number of workers who will be affected by the rule, the new standard salary level and the new HCE total annual compensation threshold are applied to the earnings of current EAP exempt workers.

[301] *See* 69 FR 22196–209; 81 FR 32453–60; 84 FR 51255–60. Where the proposal follows the methodology used to determine affected workers in the 2004, 2016, and 2019 final rules, citations to these rules are not always included.

2. Data

All estimates of numbers of workers used in this analysis were based on data from the CPS MORG, which is sponsored jointly by the U.S. Census Bureau and BLS.[302] The CPS is a large, nationally representative sample. Households are surveyed for 4 months, excluded from the survey for 8 months, surveyed for an additional 4 months, then permanently dropped from the sample. During the last month of each rotation in the sample (month 4 and month 16), employed respondents complete a supplementary questionnaire in addition to the regular survey.[303] The data in this supplement contain the detailed information on earnings necessary to estimate a worker's exemption status. Responses are based on the reference week, which is always the week that includes the 12th day of the month.

Although the CPS MORG is a large-scale survey, administered to approximately 15,000 households monthly representing the entire nation, it is still possible to have relatively few observations when looking at subsets of employees, such as workers in a specific occupation employed in a specific industry, or workers in a specific geographic location. To increase the sample size, the Department pooled 3 years of CPS MORG data (2021-2023). Earnings for each observation from 2021 and 2022 were inflated to 2023 dollars using the Consumer Price Index

[302] In 2015, RAND released results from a survey conducted to estimate EAP exempt workers. However, this survey does not have the variables or sample size necessary for the Department to base its regulatory impact analysis (RIA) on this analysis. Rohwedder, S. and Wenger, J.B. (2015). The Fair Labor Standards Act: Worker Misclassification and the Hours and Earnings Effects of Expanded Coverage. RAND Labor and Population.

[303] This is the outgoing rotation group (ORG); however, this analysis uses the data merged over 12 months and thus it is referred to as MORG.

for All Urban Consumers (CPI-U).[304] The weight of each observation was adjusted so that the total number of potentially affected EAP workers in the pooled sample remained the same as the number for the 2023 CPS MORG. Thus, the pooled CPS MORG sample uses roughly three times as many observations to represent the same total number of workers in 2023. The additional observations allow the Department to better characterize certain attributes of the potentially affected labor force. This pooled dataset is used to estimate all impacts of the final rule.

Some assumptions and adjustments were necessary to use these data as the basis for the analysis. For example, the Department eliminated workers who reported that their weekly hours vary and who provided no additional information on hours worked. This was done because the Department cannot estimate effects for these workers since it is unknown whether they work overtime and therefore unknown whether there would be any need to pay for overtime if their status changed from exempt to nonexempt. The Department reweighted the rest of the sample to account for this change (*i.e.*, to keep the same total employment estimates).[305] This adjustment assumes that the distribution of hours worked by workers whose hours do not vary is

[304] Previous rulemakings also adjusted salaries in the pooled data using the CPI-U, but the Department recognizes that the relationship between wage growth and inflation between 2021 and 2023 may not be consistent. During the pandemic, large employment losses in low-wage industries resulted in stronger wage growth at the aggregate level. In part of the 2021–2023 period, high inflation outpaced overall wage growth. Given these mixed effects, the Department decided to continue its prior practice of adjusting these observations using CPI-U.

[305] The Department also reweighted for workers reporting zero earnings. In addition, the Department eliminated, without reweighting, workers who reported both usually working zero hours and working zero hours in the past week.

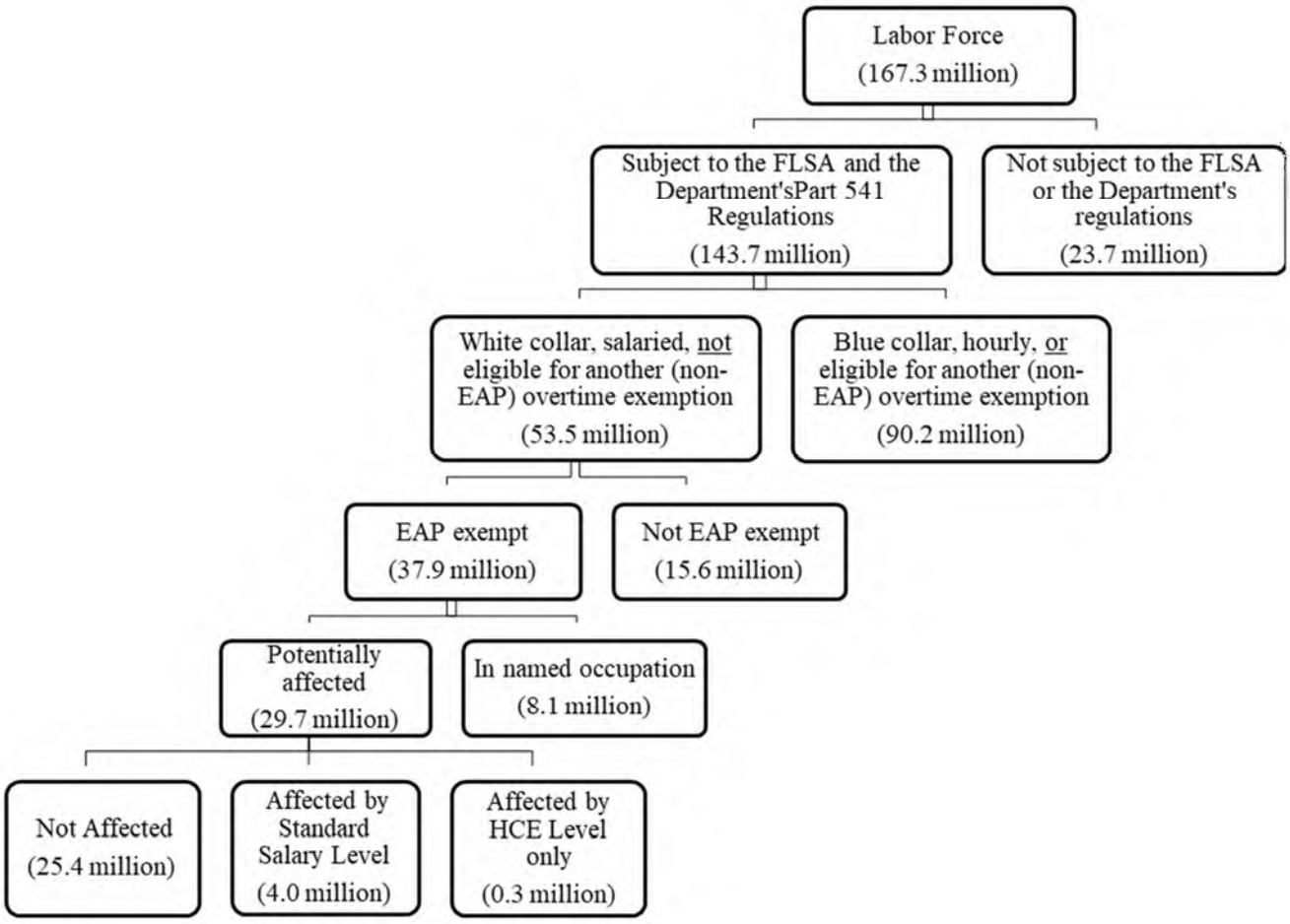
representative of hours worked by workers whose hours vary. The Department believes that without more information, this is an appropriate assumption.[306]

3. Number of Workers Subject to the FLSA and the Department's Part 541 Regulations

As a starting point for the analysis, based on the CPS MORG data, the Department estimates that there would be 167.3 million wage and salary workers in Year 1. Figure 1 illustrates how the Department analyzed the U.S. civilian workforce through successive stages to estimate the number of affected workers.

Figure 1: Flow Chart of FLSA Exemptions and Estimated Number of Affected Workers

[306] This is justifiable because demographic and employment characteristics are similar across these two populations (*e.g.*, age, gender, education, distribution across industries, share paid nonhourly). The share of all workers who stated that their hours vary (but provided no additional information) is 4.4 percent. To the extent these excluded workers are exempt, if they tend to work more overtime than other workers, then transfer payments and costs may be underestimated. Conversely, if they work fewer overtime hours, then transfer payments and costs may be overestimated.



Note: The NPRM referred to the group in the top box as "Wage and salary workers." Because the estimate in this box includes the unemployed, it has been renamed to "Labor Force" for accuracy.

The Department first excluded workers who are unemployed, not subject to its regulations, or not covered by the FLSA from the overall total number of wage and salary workers. Excluded workers include military personnel, unpaid volunteers, self-employed individuals, clergy and other religious workers, and Federal employees (with a few exceptions described below).

Many of these workers are excluded from the CPS MORG, including members of the military on active duty and unpaid volunteers. Self-employed and unpaid workers are included in

the CPS MORG, but have no earnings data reported and thus are excluded from the analysis. The Department identified religious workers by their occupation codes: 'clergy' (Census occupational code 2040), 'directors, religious activities and education' (2050), and 'religious workers, all other' (2060). Most employees of the Federal Government are covered by the FLSA but not the Department's part 541 regulations because the Office of Personnel Management (OPM) regulates their entitlement to minimum wage and overtime pay.[307] Exceptions exist for U.S. Postal Service employees, Tennessee Valley Authority employees, and Library of Congress employees.[308] The analysis identified and included these covered Federal workers using occupation and/or industry codes and removed other Federal employees.[309]

The FLSA also does not cover employees of firms that have annual revenue of less than $500,000 and who are not engaged in interstate commerce. The Department does not exclude them from the analysis, however, because there is no data set that would adequately inform an estimate of the size of this worker population, although the Department believes it is a small percentage of workers. The 2004, 2016, and 2019 final rules similarly did not adjust for these workers.

Of the 167.3 million wage and salary workers in the United States, the Department estimates that 143.7 million are covered by the FLSA and subject to the Department's regulations

[307] *See* 29 U.S.C. 204(f). Federal workers are identified in the CPS MORG with the class of worker variable PEIO1COW.
[308] *See id.*
[309] Postal Service employees were identified with the Census industry classification for postal service (6370). Tennessee Valley Authority employees were identified as Federal workers employed in the electric power generation, transmission, and distribution industry (570) and in Kentucky, Tennessee, Mississippi, Alabama, Georgia, North Carolina, or Virginia. Library of Congress employees were identified as Federal workers under Census industry 'libraries and archives' (6770) and residing in Washington DC.

(85.9 percent). The remaining 23.7 million workers are excluded from FLSA coverage for the reasons described above.

4. Number of Workers Who Are White-Collar, Salaried, Not Eligible for Another (Non-EAP) Overtime Exemption

After limiting the analysis to workers covered by the FLSA and subject to the Department's part 541 regulations, several other groups of workers were identified and excluded from further analysis since this final rule is unlikely to affect them. These include blue-collar workers,[310] workers paid on an hourly basis, and workers who are exempt under certain other (non-EAP) exemptions.

The Department excluded a total of 90.2 million workers from the analysis for one or more of these reasons, which often overlapped (*e.g.*, many blue-collar workers are also paid hourly). For example, the Department estimated that there are 49.1 million blue-collar workers. These workers were identified in the CPS MORG data following the methodology from the U.S. Government Accountability Office's (GAO) 1999 white-collar exemptions report[311] and the Department's 2004, 2016, and 2019 regulatory impact analyses.[312] Supervisors in traditionally blue-collar industries were classified as white-collar workers because their duties are generally managerial or administrative, and therefore they were not excluded as blue-collar workers. Using

[310] "The section 13(a)(1) exemptions and the regulations in [Part 541] do not apply to manual laborers or other 'blue collar' workers who perform work involving repetitive operations with their hands, physical skill and energy." § 541.3(a).
[311] GAO/HEHS. (1999). Fair Labor Standards Act: White Collar Exemptions in the Modern Work Place. GAO/HEHS-99-164, 40-41, https://www.gao.gov/assets/230/228036.pdf.
[312] *See* 69 FR 22240–44.

the CPS variable indicating a respondent's hourly wage status, the Department determined that 80.3 million workers were paid on an hourly basis in 2023.[313]

Also excluded from further analysis were workers who are exempt under certain other (non-EAP) exemptions. Although some of these workers may also be exempt under the EAP exemptions, they would independently remain exempt from the FLSA's minimum wage and/or overtime pay provisions based on the non-EAP exemptions. The Department excluded an estimated 3.7 million workers, including some agricultural and transportation workers, from further analysis because they are subject to another (non-EAP) overtime exemption. *See* Appendix A: Methodology for Estimating Exemption Status, contained in the rulemaking docket, for details on how this population was identified.

Agricultural and transportation workers are two of the largest groups of workers excluded from the population of potentially affected EAP workers in the current analysis, and with some exceptions, they were similarly excluded in other recent rulemakings. The 2004 rule excluded all workers in agricultural industries from the analysis,[314] while more recent analyses only excluded agricultural workers from specified occupational-industry combinations since not all workers in agricultural industries qualify for the agricultural overtime pay exemptions. This final rule followed the more recent analyses and only excluded agricultural workers in certain occupation-industry combinations.[315] The exclusion of transportation workers matched the method for the 2004, 2016, and 2019 final rules.[316] Transportation workers are defined as those who are subject

[313] CPS MORG variable PEERNHRY.
[314] 69 FR 22197.
[315] 84 FR 51257; 81 FR 32456, n.114.
[316] 84 FR 51257; 81 FR 32456–57; 69 FR 22197.

to the following FLSA exemptions: section 13(b)(1), section 13(b)(2), section 13(b)(3), section 13(b)(6), or section 13(b)(10). The Department excluded 1.0 million agricultural workers and 2.1 million transportation workers from the analysis.

In addition, the Department excluded another 22,700 workers who qualify for one or more other FLSA minimum wage and overtime exemptions (and are not either blue-collar or hourly). The criteria for determining exemption status for these workers are detailed in Appendix A.

After excluding workers not subject to the Department's FLSA regulations and workers who are unlikely to be affected by this final rule (*i.e.*, blue-collar workers, workers paid hourly, workers who are subject to another (non-EAP) overtime exemption), the Department estimated there are 53.5 million salaried white-collar workers for whom employers might claim either the standard EAP exemption or the HCE exemption.

5. Number of Current EAP Exempt Workers

To determine the number of workers for whom employers might currently claim the EAP exemption, the standard EAP test and HCE test were applied. Both tests include earnings thresholds and duties tests. Aside from workers in named occupations (which are not subject to an earnings requirement and are discussed in the next subsection), to be exempt under the standard EAP test, the employee generally must:

- be paid a predetermined and fixed salary that is not subject to reduction because of variations in the quality or quantity of work performed (the salary basis test);[317]

[317] Some computer employees may be exempt even if they are not paid on a salary basis. Hourly computer employees who earn at least $27.63 per hour and perform certain duties are exempt

- earn at least a designated salary amount (the standard salary level test, currently $684 per week); and
- primarily perform exempt work, as defined by the regulations (the standard duties test).

The HCE test allows certain highly paid employees to qualify for exemption if they customarily and regularly perform one or more exempt job duties (the HCE duties test). The current HCE annual compensation level is $107,432, including at least $684 per week paid on a salary or fee basis.

i. Salary Basis

The Department included only nonhourly workers in the analysis based on CPS data.[318] For this NPRM, the Department considered data representing compensation paid to nonhourly workers to be an appropriate proxy for compensation paid to salaried workers. The Department notes that it made the same assumption regarding nonhourly workers in the 2004, 2016, and 2019 final rules.[319]

The CPS population of "nonhourly" workers includes salaried workers along with those who are paid a piece rate, day rate, or largely on bonuses or commissions. Data in the CPS are not available to distinguish between salaried workers and these other nonhourly workers.

---

under section 13(a)(17) of the FLSA. These workers are considered part of the EAP exemptions but were excluded from the analysis because they are paid hourly and will not be affected by this rule (these workers were similarly excluded in the 2004, 2016, and 2019 analyses). Salaried computer workers are exempt if they meet the salary and duties tests applicable to the EAP exemptions and are included in the analysis since they will be impacted by this rule. Additionally, administrative and professional employees may be paid on a fee basis, as opposed to a salary basis. § 541.605(a). Although the CPS MORG does not identify workers paid on a fee basis, they are considered nonhourly workers in the CPS and consequently are correctly classified as "salaried" (as was done in previous rules).

[318] The CPS variable PEERNHRY identifies workers as either hourly or nonhourly.

[319] *See* 69 FR 22197; 81 FR 32414; 84 FR 51258.

However, the Panel Study of Income Dynamics (PSID) provides additional information on how nonhourly workers are paid.[320] In the PSID, respondents are asked how they are paid on their main job and are also asked for more detail if their response is other than salaried or hourly. Possible responses include piecework, commission, self-employed/farmer/profits, and by the job/day/mile. The Department analyzed the PSID data and found that relatively few nonhourly workers were paid by methods other than salaried. The Department is not aware of any statistically robust source that more closely reflects salary as defined in its regulations.

ii. Salary Level

Weekly earnings are available in the CPS MORG data, which allowed the Department to estimate how many nonhourly workers pass the compensation thresholds.[321] However, the CPS earnings variable does not perfectly reflect the Department's definition of earnings. First, the CPS includes all nondiscretionary bonuses and commissions if they are part of usual weekly earnings. However, the regulation allows nondiscretionary bonuses and commissions to satisfy up to 10 percent of the standard salary level. This discrepancy between the earnings variable used and the regulatory definition of salary may cause a slight overestimation or underestimation of the number of workers estimated to meet the standard salary level and HCE compensation tests.[322] Second, CPS earnings data include overtime pay. The Department notes that employers

[320] University of Michigan, Institute for Social Research. 2019 PSID. Data available at: https://simba.isr.umich.edu/data/data.aspx.

[321] The CPS MORG variable PRERNWA, which measures weekly earnings, is used to identify weekly salary.

[322] In some instances, this may include too much nondiscretionary bonuses and commissions (*i.e.*, when it is more than 10 percent of usual earnings). But in other instances, it may not include enough nondiscretionary bonuses and commissions (*i.e.*, when the respondent does not count them as usual earnings).

may factor into an employee's salary a premium for expected overtime hours worked. To the extent they do so, that premium would be reflected accurately in the data. Third, the earnings measure includes tips and discretionary commissions which do not qualify towards the required salary. The Department believes tips are an uncommon form of payment for these white-collar workers. Discretionary commissions tend to be paid irregularly and hence are unlikely to be counted as "usual earnings." Additionally, as noted above, most salaried workers do not receive commissions.

Lastly, the CPS annual earnings variable is topcoded at $150,000 through the March 2023 data.[323] Topcoding refers to how data sets handle observations at the top of the distribution and is performed to protect the confidentiality of data provided by CPS respondents. For the CPS annual earnings variable, workers earning above $2,884.61 ($150,000 ÷ 52 weeks) per week are reported as earning $2,884.61 per week. The Department imputed earnings for topcoded workers in the CPS data to adequately estimate impacts.[324]

iii. Duties

The CPS MORG data do not capture information about job duties. Therefore, the Department used probability estimates of passing the duties test by occupational title to estimate the number of workers passing the duties test. This is the same methodology used in recent part 541 rulemakings, and the Department believes it continues to be the best available methodology.

[323] Beginning in the April 2023 data, the CPS data are topcoded independently each month and represent the average earnings of the top 3 percent of earnings reported. *See* https://www.census.gov/content/dam/Census/programs-surveys/cps/updated-2022-cps-puf-changes.pdf for additional details.

[324] The Department used the standard Pareto distribution approach to impute earnings above the topcoded value as described in Armour, P. and Burkhauser, R (2013). Using the Pareto Distribution to Improve Estimates of Topcoded Earnings. Center for Economic Studies (CES).

The probabilities of passing the duties test are from an analysis performed by WHD in 1998 in response to a request from the GAO. Because WHD enforces the FLSA's overtime requirements and regularly assesses workers' exempt status, WHD was uniquely qualified to provide the analysis. The analysis was originally published in the GAO's 1999 white-collar exemptions report.[325]

WHD examined 499 occupational codes and determined that 251 occupational codes likely included EAP exempt workers.[326] For each, WHD assigned one of four probability codes reflecting the estimated likelihood, expressed as ranges, that a worker in that occupation would perform duties required to meet the EAP duties tests (Table 3). All occupations and their associated probability codes are listed in Appendix A. Just as in the 2004, 2016, and 2019 final rules, the Department has supplemented this analysis to account for the HCE exemption. The Department modified the four probability codes to reflect probabilities of passing the HCE duties test based on its analysis of the provisions of the highly compensated test relative to the standard duties test. To illustrate, WHD assigned exempt probability code 4 to the occupation "first-line supervisors/managers of construction trades and extraction workers" (Census code 6200), which indicates that a worker in this occupation has a 0 to 10 percent likelihood of meeting the standard EAP duties test. However, if that worker earned at least $100,000 annually (now $107,432

[325] Fair Labor Standards Act: White Collar Exemptions in the Modern Work Place, *supra* note 311, at 40-41.

[326] WHD excluded nine that were not relevant to the analysis for various reasons. For example, one code was assigned to unemployed persons whose last job was in the Armed Forces, some codes were assigned to workers who are not FLSA covered, others had no observations.

annually), they were assigned a 15 percent probability of passing the more lenient HCE duties test.[327]

Table 3: Probability Worker in Category Passes the Duties Tests

Probability Code	The Standard EAP Test		The HCE Test	
	Lower Bound	Upper Bound	Lower Bound	Upper Bound
0	0%	0%	0%	0%
1	90%	100%	100%	100%
2	50%	90%	94%	96%
3	10%	50%	58.4%	60%
4	0%	10%	15%	15%

The occupations identified in GAO's 1999 report map to an earlier occupational classification scheme (the 1990 Census occupational codes).[328] For this final rule, the Department used occupational crosswalks to map the previous occupational codes to the 2018 Census occupational codes, which are used in the CPS MORG 2021 through 2023 data. If a new occupation comprises more than one previous occupation, then the new occupation's probability code is the weighted average of the previous occupations' probability codes, rounded to the closest probability code.

These codes provide information on the likelihood that an employee met the duties tests, but they do not identify which workers in the CPS MORG met the duties test. For example, for every ten public relations managers, between five and nine are assumed to meet the standard

[327] The HCE duties test is used in conjunction with the HCE total annual compensation requirement to determine eligibility for the HCE exemption. It is much less stringent than the standard and short duties tests to reflect that very highly paid employees are much more likely to be properly classified as exempt.

[328] Census occupation codes were also updated in 2002 and 2010. References to occupational codes in this analysis refer to the 2002 Census occupational codes. Crosswalks and methodology available at: https://www.census.gov/topics/employment/industry-occupation/guidance/code-lists.html.

duties test (based on probability category 2). However, it is unknown which of these ten workers are exempt; therefore, for the purposes of producing an estimate, the Department must assign a status to these workers. Exemption status could be randomly assigned with equal probability, but this would ignore the earnings of the worker as a factor in determining the probability of exemption. The probability of qualifying for the exemption increases with earnings because higher paid workers are more likely to perform the required duties.[329]

The Department estimated the probability of qualifying for the standard exemption for each worker as a function of both earnings and the occupation's exempt probability category using a gamma distribution.[330] Based on these revised probabilities, each worker was assigned exempt or nonexempt status based on a random draw from a binomial distribution using the worker's revised probability as the probability of success. Thus, if this method is applied to ten workers who each have a 60 percent probability of being exempt, six workers would be expected to be designated as exempt.[331] For details, *see* Appendix A (in the rulemaking docket).

---

[329] For the standard exemption, the relationship between earnings and exemption status is not linear and is better represented with a gamma distribution. For the HCE exemption, the relationship between earnings and exemption can be well represented with a linear function because the relationship is linear at high salary levels (as determined by the Department in the 2004 rule). Therefore, the gamma model and the linear model would produce similar results for highly compensated workers. *See* 69 FR 22204–08, 22215–16.

[330] The gamma distribution was chosen because, during the 2004 revision, this non-linear distribution best fit the data compared to the other non-linear distributions considered (*i.e.*, normal and lognormal). A gamma distribution is a general type of statistical distribution that is based on two parameters that control the scale (alpha) and shape (in this context, called the rate parameter, beta).

[331] A binominal distribution is frequently used for a dichotomous variable where there are two possible outcomes; for example, whether one owns a home (outcome of 1) or does not own a home (outcome of 0). Taking a random draw from a binomial distribution results in either a zero or a one based on a probability of "success" (outcome of 1). This methodology assigns exempt status to the appropriate share of workers without biasing the results with manual assignment.

As previously discussed in section V.B.5, some commenters challenged the Department's use of its probability codes to determine whether a worker meets the duties test. The Department acknowledges that the probability codes used to determine the share of workers in an occupation who are EAP exempt are 25 years old. However, the Department believes the probability codes continue to estimate exemption status accurately given the fact that the standard duties test is not substantively different from the former short duties tests reflected in the codes. For the 2016 rulemaking, the Department reviewed O*NET[332] to determine the extent to which the 1998 probability codes reflected current occupational duties. The Department's review of O*NET verified the continued appropriateness of the 1998 probability codes.[333] The 2019 final rule also used these probability codes and likewise found that these codes are the best available methodology to accurately estimate exemption status.[334]

The Department estimates that of the existing 53.5 million salaried white-collar workers considered in the analysis, 37.9 million currently qualify for the EAP exemption.

6. Potentially Affected Exempt EAP Workers

The Department excluded some of the current EAP exempt workers from further analysis because the final rule will not affect them. Specifically, the Department excluded workers in named occupations who are not required to pass the salary requirements (although they must still pass a duties test) and therefore whose exemption status does not depend on their earnings. These occupations include physicians (identified with Census occupation codes 3010, 3040, 3060,

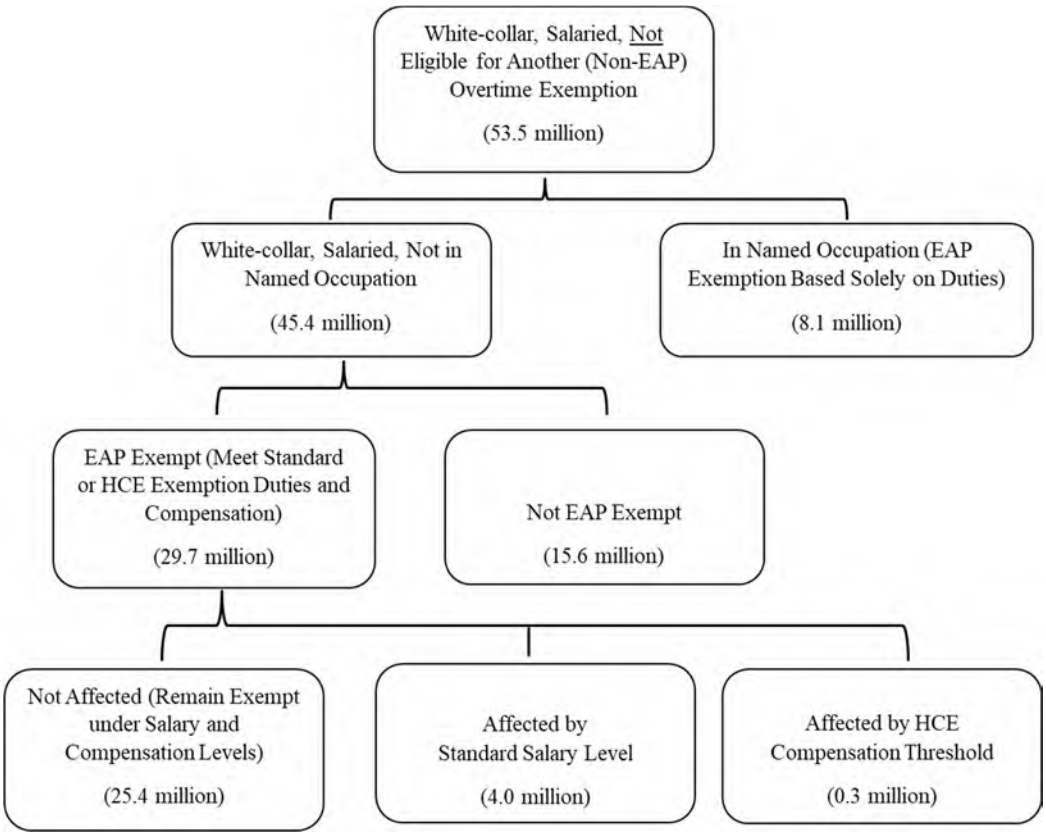
[332] The O*NET database contains hundreds of standardized and occupation-specific descriptors. *See* https://www.onetcenter.org.
[333] 81 FR 32459.
[334] 84 FR 51259.

3120), lawyers (2100), teachers (occupations 2200–2550 and industries 7860 or 7870), academic administrative personnel (school counselors (occupation 2000 and industries 7860 or 7870) and educational administrators (occupation 0230 and industries 7860 or 7870)), and outside sales workers (a subset of occupation 4950). Out of the 37.9 million workers who were EAP exempt, 8.1 million, or 21.4 percent, were expected to be in named occupations. Thus, the changes to the standard salary level and HCE compensation tests would not affect these workers. The 29.7 million EAP exempt workers remaining in the analysis are referred to in this final rule as "potentially affected" (17.8 percent of all workers).

Based on analysis of the occupational codes and CPS earnings data (described above), the Department has concluded there are 29.7 million potentially affected EAP workers.[335]

Figure 2: Exemption Status and Number of Affected Workers

[335] Of these workers, approximately 16.5 million pass only the standard test, 12.8 million pass both the standard and the HCE tests, and 446,600 pass only the HCE test.



As shown in Figure 2 above, 8.1 million of the 53.5 million salaried white-collar workers are in named occupations and will not be affected by a change in the earnings requirements. The Department also estimates that of the remaining 45.4 million salaried white-collar workers, about 12.7 million earn below the Department's new standard salary level of $1,128 per week and about 32.7 million earn above the Department's new salary level. Thus, approximately 28 percent of salaried white-collar employees earn below the new salary level, whereas approximately 72 percent of salaried white-collar employees earn above the salary level and will have their exemption status turn on their job duties.

7. Number of Affected EAP Workers

The Department estimated that the increase in the standard salary level from $684 per week to $1,128 per week will affect 4.0 million workers in Year 1 (of these 4.0 million affected

employees, 1.8 million earn less than the long test salary level ($942)).[336] The Department estimated that the increase in the HCE annual compensation level from $107,432 to $151,164 will impact 292,900 workers (Figure 3).[337] In total, the Department expects that 4.3 million workers out of the 29.7 million potentially affected workers will be affected in Year 1. This estimate of 4.3 million affected workers represents only approximately 10 percent of all salaried white-collar workers who are not in named occupations (45.4 million).

As illustrated in Figure 1 above, this final rule affects a specific and small portion of all employed workers. In particular, the number of affected workers is 2.6% of total employed workers in 2023 and represents about 8 percent of all white-collar salaried workers (including workers in named occupations). While Figure 1 provides a snapshot of the impacts of this rule in the context of the broader labor market of 2023, it may also be helpful to understand how the labor market has grown since the Department first introduced a one-test system in 2004. Broadly, since 2004 the size of the labor force and the white-collar workforce has grown considerably. Between 2004 and 2023, total employment grew by 21.8 million, with employment increasing by nearly 10 million since 2016 and 3.5 million since 2019.[338] Over this period, the size of the white-collar workforce has also increased considerably. In 2004, the total number of white-collar

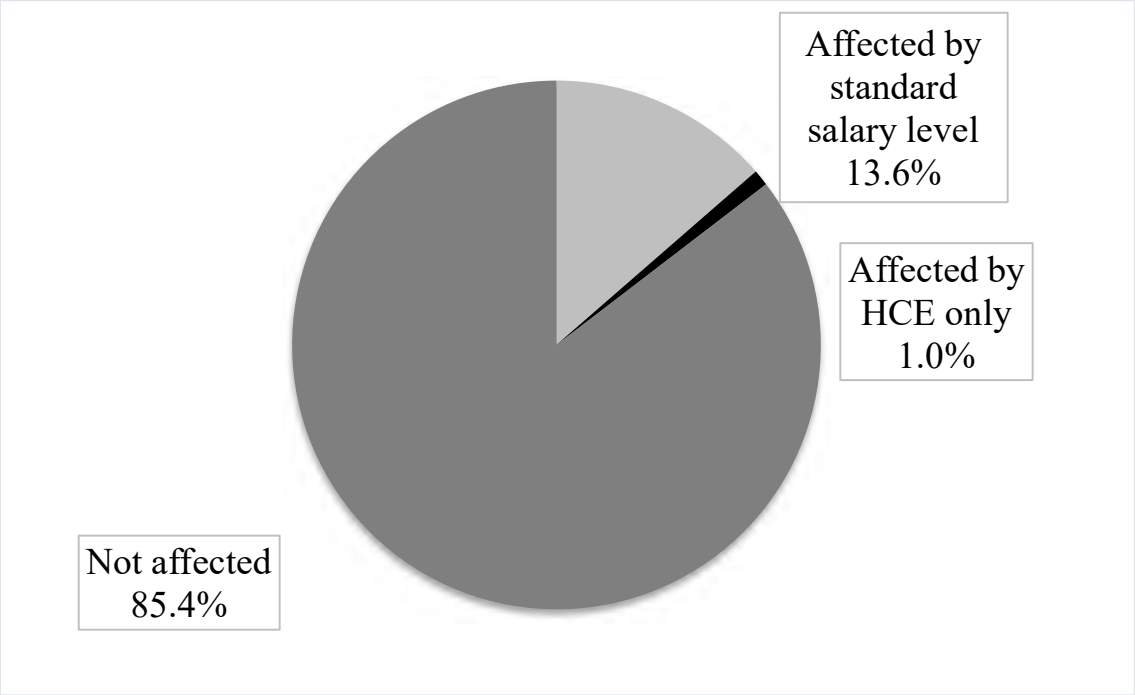
[336] *See* section VII.C.8 (Alternative 2). As discussed in section V.B, such employees were always excluded from the EAP exemption prior to 2019, either by the long test salary level itself, or under the 2004 rule salary level, which was equivalent to the long test salary level. The remaining 2.2 million of these affected employees earn between the long test salary level and the Department's new standard salary level.

[337] This group includes workers who may currently be nonexempt under more protective state EAP laws and regulations, such as some workers in Alaska, California, Colorado, Maine, New York, Washington, and Wisconsin.

[338] Employment status of the civilian noninstitutional population, 1953 to date. BLS Current Population Survey. https://www.bls.gov/cps/cpsaat01.htm

workers who were subject to the Part 541 regulations, including the salary level test, was 31.7 million. By 2016 it had reached 37.4 million; in 2019 it was 39.8 million; and in 2023 it was nearly 45.4 million.

Figure 3: Pie Chart of Potentially Affected Employees and Their Affected Status



Several commenters stated that the Department's estimates of affected workers were incorrect because of the application of the probability codes. For example, NCFC stated that "the Department's impact calculations rely on outdated and flawed data" because the "Department's predictions as to the probability of employees passing the duties test are based on a 1999 study . . . which itself relied upon information provided by DOL in the 1990s—more than three decades ago." AFPI further added that since the Department's probability codes were developed, "occupational codes have changed; the Part 541 duties tests have changed; and litigation has resulted in thousands of court decisions finding employees to be exempt or non-exempt."

Similarly, NRF included a report by Oxford Economics stating that there have been numerous economics changes since 1998, "includ[ing] increases in automation, virtual work, computerized scheduling, and the effects of a global pandemic."[339] The Oxford Economics report also stated that "if the relationship between salaried [status] and EAP exemption status is tighter than the [Department] . . . assumes," the number of affected workers could be as high as 7.2 million. AFPI asserted that approximately "7.5 million employees would be non-exempt for the first time based on salary alone[.]" Rachel Greszler stated that the correct figure is as high as 12.3 million workers.

The Department disagrees with commenters that challenged its use of its probability codes. The Department has used its probability codes to estimate the number of workers who meet the duties test in its 2004, 2016, and 2019 rules. The Department reiterates that these codes have been updated and mapped onto current occupational codes, as explained above. As also noted above, the standard duties test is not substantively different from the former short duties tests reflected in the codes. In consequence, the probability codes remain relevant and are currently the most accurate way to estimate the probability of a worker satisfying the duties test. Furthermore, while several occupations have changed over time, modifications affecting specific occupations would only affect the validity of these probability codes if they systematically

[339] The Oxford Economics report also noted that there has been a 6-percent rise in "the share of salaried workers in the economy . . . since 1998." However, any increase in the number of salaried workers does not have any bearing on the validity of the probability codes, which the Department uses to estimate whether a worker passes the duties test. Being paid on a salary basis is one of the three tests for exemption, *see* § 541.602(a), and is distinct from the duties test. Accordingly, the Department only applies the probability codes to nonhourly workers—whom, as discussed above, the Department considers to be an appropriate proxy for workers paid on a salary basis.

affected an occupation's probability of performing exempt tasks. In contrast, other changes, such as employees performing remotely the job duties they once performed in-person, do not affect the validity of these probabilities. Additionally, the probability codes can still effectively predict whether employees in new industries will meet the duties test insofar as these occupations existed in other industries. Finally, as previously noted, the Department used the O*NET database to confirm the appropriateness of the probability codes in 2016. Commenters did not provide a basis for concluding that the Department's 2016 evaluation is obsolete or that the probability codes no longer provide the most reasonable basis for estimating the population of affected workers.

The Department also does not agree with commenters that stated that it underestimated the number of affected workers in the NPRM. As discussed above, *see* section V.B.5.iii, commenters that asserted the number of affected workers could be much higher generally referenced estimates of the number of workers earning between the current salary level and the proposed salary level, regardless of whether they passed the duties test, and then posited that up to that many workers (e.g., 7.2 million, 7.5 million, or 12.3 million) could be affected. The position that all workers earning below the new salary level, regardless of their duties, will be affected by the new salary level fails to account for the fact that that millions of these workers are already nonexempt because they do not meet the duties test.

C. Effects of Revised Salary and Compensation Levels

1. Overview and Summary of Quantified Effects

The Department is setting the standard salary level using the 35th percentile of earnings of full-time salaried workers in the lowest-wage Census region (currently the South) and setting

the HCE compensation level at the annualized weekly earnings of the 85th percentile of full-time salaried workers nationwide. In both cases the Department used 2023 CPS data to calculate the levels.[340]

Transfers both from employers to employees and between employees, and direct employer costs, will depend on how employers respond to this rulemaking. Employer response is expected to vary by the characteristics of the affected EAP workers. Assumptions related to employer responses are discussed below.

Table 4 presents the estimated number of affected workers, costs, and transfers associated with increasing the standard salary and HCE compensation levels. The Department estimated that the direct employer costs of this rule will total $1.4 billion in the first year, with 10-year annualized direct costs of $802.9 million per year using a 7 percent discount rate.

In addition to these direct costs, this rule will transfer income from employers to employees. Estimated Year 1 transfers will equal $1.5 billion, with annualized transfers of $1.5 billion per year using the 7 percent real discount rates and $1.6 billion using the 3 percent discount rate. Potential employer costs due to reduced profits and additional hiring were not quantified but are discussed in section VII.C.3.v. These estimates encompass in Year 1 both the impact of the initial update to the earnings thresholds and the change in those thresholds that will become applicable 6 months later.[341]

---

[340] Full-time is defined as 35 or more hours per week.

[341] The Department estimates the initial update to the standard salary level will result in 959,000 affected workers earning between $684 and $844 per week. The Department estimates the adjustment and managerial costs for this update will be $202.3 million and transfers will be $204.3 million. For the initial update to the HCE total annual compensation threshold, the Department estimates that the update will result in 223,000 affected workers, $58.7 million in adjustment and managerial costs, and $164.5 million in transfer payments.

Table 4: Summary of Affected Workers and Regulatory Costs and Transfers

Impact [a]	Year 1	Future Years [b]		Annualized Value	
		Year 2	Year 10	3% Real Discount Rate	7% Real Discount Rate
Affected Workers (1,000s)					
Standard	4,045	3,783	4,978	[c]	[c]
HCE	293	323	1,015	[c]	[c]
Total	4,337	4,106	5,993	[c]	[c]
Direct Employer Costs (Millions in $2023)					
Regulatory familiarization	$451.6	$0.0	$68.9	$71.8	$79.3
Adjustment [c]	$299.1	$9.4	$20.9	$44.6	$50.0
Managerial	$685.5	$632.1	$816.3	$677.6	$673.6
Total direct costs [d]	$1,436.2	$641.5	$906.1	$794.0	$802.9
Transfers from Employers to Workers (Millions in $2023) [e]					
Due to minimum wage	$87.5	$46.5	$22.6	$43.2	$44.8
Due to overtime pay	$1,421.7	$1,047.8	$2,467.5	$1,522.0	$1,489.3
Total transfers [f]	$1,509.2	$1,094.3	$2,490.1	$1,565.2	$1,534.1

[a] Additional costs and benefits of the rule that could not be quantified or monetized are discussed in the text.

[b] These costs/transfers represent a range over the nine-year span.

[c] Not annualized.

[d] Adjustment costs occur in all years when there are newly affected workers. Adjustment costs may occur in years without updated earnings thresholds because some workers' projected earnings are estimated using negative earnings growth.

[e] Components may not add to total due to rounding.

[f] This is the net transfer from employers to workers. There may also be transfers between workers.

2. Characteristics of Affected EAP Workers

Table 5 presents the number of affected EAP workers, the mean number of overtime hours they work per week, and their average weekly earnings. The Department considered two types of overtime workers in this analysis: regular overtime workers and occasional overtime

workers.[342] Regular overtime workers typically worked more than 40 hours per week. Occasional overtime workers typically worked 40 hours or less per week, but they worked more than 40 hours in the week they were surveyed. The Department considered these two populations separately in the analysis because labor market responses to overtime pay requirements may differ for these two types of workers.

The 4.0 million workers affected by the combined effect of the initial update and the subsequent application of the new standard salary level work on average 1.6 usual hours of overtime per week and earn on average $948 per week.[343] However, most of these workers (about 86 percent) usually do not work overtime. The 14 percent of affected workers who usually work overtime average 11.1 hours of overtime per week. In a representative week, roughly 135,000 (or 3.3 percent) of the 4.0 million affected workers occasionally work overtime; they averaged 8.5 hours of overtime in the weeks they worked overtime.[344] Finally, 20,000 (or 0.5 percent) of all workers affected by the increase in the standard salary level earn less than the minimum wage. [345]

---

[342] Regular overtime workers were identified in the CPS MORG with variable PEHRUSL1. Occasional overtime workers were identified with variables PEHRUSL1 and PEHRACT1.
[343] CPS defines "usual hours" as hours worked 50 percent or more of the time.
[344] This group represents the number of workers with occasional overtime hours in the week the CPS MORG survey was conducted. Because the survey week is a representative week, the Department believes the prevalence of occasional overtime in the survey week and the characteristics of these workers are representative of other weeks (even though a different group of workers would be identified as occasional overtime workers in a different week).
[345] A small proportion (0.5 percent) of all affected EAP workers earn implicit hourly wages that are less than the applicable minimum wage (the higher of the state or Federal minimum wage). The implicit hourly wage is calculated as total weekly earnings divided by total weekly hours worked. For example, workers earning the $684 per week standard salary level would earn less than the Federal minimum wage if they work 95 or more hours in a week ($684 ÷ 95 hours = $7.20 per hour).

The 292,900 workers affected by the change in the HCE compensation level average 2.9 hours of overtime per week and earn an average of $2,397 per week ($124,668 per year). About 73 percent of these workers do not usually work overtime, while the 27 percent who usually work overtime average 11.0 hours of overtime per week. Among the 2.6 percent who occasionally work overtime, they averaged 8.2 hours in the weeks that they worked overtime.

Although most affected workers who typically do not work overtime will be unlikely to experience significant changes in their daily work routine, those who regularly work overtime may experience significant changes. Moreover, affected EAP workers who routinely work overtime and earn less than the minimum wage will be most likely to experience significant changes. Impacts on employee hours and earnings are discussed further in section VII.C.4.

Table 5: Number of Affected EAP Workers, Mean Overtime Hours, and Mean Weekly Earnings, Year 1

Type of Affected EAP Worker	Affected EAP Workers [a]		Mean Overtime Hours	Mean Usual Weekly Earnings
	Number (1,000s)	% of Total		
Standard Salary Level				
All affected EAP workers	4,045	100%	1.6	$948
Earn less than the minimum wage [b]	20	0.5%	25.8	$828
Regularly work overtime	575	14.2%	11.1	$959
Occasionally work overtime [c]	135	3.3%	8.5	$955
HCE Compensation Level				
All affected EAP workers	293	100%	2.9	$2,397
Earn less than the minimum wage [b]	--	--	--	--
Regularly work overtime	78	26.7%	11.0	$2,406
Occasionally work overtime [c]	8	2.6%	8.2	$2,392

Note: Pooled CPS data for 2021–2023 adjusted to reflect 2023.
[a] Estimated number of workers exempt under the EAP exemptions who will be entitled to overtime protection under the updated salary levels (if their weekly earnings do not increase to the new salary levels).
[b] The applicable minimum wage is the higher of the Federal minimum wage and the state minimum wage. These workers all regularly work overtime and are also included in that row. HCE workers will not be affected by the minimum wage provision.

[c] Workers who do not usually work overtime but did in the CPS reference week. Mean overtime hours are actual overtime hours in the reference week. Other workers may occasionally work overtime in other weeks.

This section characterizes the population of affected workers by industry, occupation, employer type, location of residence, and demographics. The Department chose to provide as much detail as possible while maintaining adequate sample sizes.

Table 6 presents the distribution of affected EAP workers by industry and occupation, using Census industry and occupation codes. The industry with the most affected EAP workers is professional and business services (827,000), while the industry with the highest percentage of EAP workers affected is leisure and hospitality (about 24 percent). The occupational category with the most affected EAP workers is management, business, and financial (2.0 million), while the occupation category with the highest percentage of EAP workers affected is farming, fishing, and forestry (about 45 percent).

Potentially affected workers in private-sector nonprofits are more likely to be affected than workers in private-sector for-profit firms (18.9 percent compared with 13.6 percent). However, as discussed in section VII.B.3, the estimates of workers subject to the FLSA include workers employed by enterprises that are not subject to the FLSA under the law's enterprise coverage requirements because there is no data set that would adequately inform an estimate of the size of this worker population in order to exclude them from these estimates. Although failing to exclude workers who work for non-covered enterprises would only affect a small percentage of workers generally, it may have a larger effect (and result in a larger overestimate) for workers in nonprofits because when determining FLSA enterprise coverage only revenue derived from business operations, not charitable activities, is included.

Table 6: Estimated Number of Workers and Whether They Will be Affected by the New Earnings Thresholds, by Industry and Occupation, Year 1

Industry / Occupation / Nonprofit	Workers subject to FLSA (Millions)	Potentially Affected EAP Workers (Millions) [a]	Not-Affected (Millions) [b]	Affected (Millions) [c]	Affected as Share of Potentially Affected
Total	143.68	29.75	25.41	4.34	14.6%
By Industry [d]					
Agriculture, forestry, fishing, & hunting	1.31	0.06	0.05	0.01	22.8%
Mining	0.59	0.16	0.14	0.02	11.8%
Construction	9.31	1.27	1.08	0.18	14.6%
Manufacturing	15.52	4.06	3.71	0.35	8.6%
Wholesale trade	3.16	0.85	0.74	0.11	13.2%
Retail trade	15.65	1.97	1.59	0.38	19.2%
Transportation & utilities	8.90	1.07	0.92	0.15	14.3%
Information	2.71	1.08	0.95	0.13	12.2%
Financial activities	9.93	4.35	3.79	0.56	13.0%
Professional & business services	17.46	7.13	6.30	0.83	11.6%
Education	14.29	1.20	0.96	0.24	20.3%
Healthcare & social services	21.03	3.75	3.01	0.74	19.8%
Leisure & hospitality	12.53	0.94	0.71	0.23	24.3%
Other services	5.53	0.76	0.60	0.16	21.5%
Public administration	5.75	1.10	0.88	0.23	20.6%
By Occupation [d]					
Management, business, & financial	24.74	15.32	13.33	1.99	13.0%
Professional & related	35.90	10.72	9.23	1.49	13.9%
Services	22.85	0.15	0.10	0.04	28.7%
Sales and related	12.66	2.41	1.96	0.46	18.9%
Office & administrative support	15.98	0.93	0.61	0.32	34.4%
Farming, fishing, & forestry	0.91	0.00	0.00	0.00	44.7%
Construction & extraction	6.97	0.03	0.02	0.01	21.9%

Installation, maintenance, & repair	4.58	0.05	0.04	0.01	15.3%
Production	8.18	0.09	0.08	0.01	10.8%
Transportation & material moving	10.91	0.05	0.04	0.01	24.8%
By Nonprofit and Government Status					
Nonprofit, private	10.17	2.44	1.98	0.46	18.9%
For profit, private	114.56	24.95	21.56	3.39	13.6%
Government (state, local, and Federal)	18.95	2.35	1.86	0.48	20.6%

Note: Pooled CPS data for 2021–2023 adjusted to reflect 2023.
[a] Exempt workers who are white-collar, salaried, not eligible for another (non-EAP) overtime exemption, and not in a named occupation.
[b] Workers who continue to be exempt after the increases in the salary levels (assuming affected workers earning below the new salary level do not have their weekly earnings increased to the new level).
[c] Estimated number of workers exempt under the EAP exemptions who will be entitled to overtime protection under the updated salary levels (if their weekly earnings do not increase to the new salary levels).
[d] Census industry and occupation categories.

Table 7 presents the distribution of affected EAP workers based on Census Regions and Divisions, and metropolitan statistical area (MSA) status. The region with the most affected workers will be the South (1.9 million), but the South's percentage of potentially affected workers who are estimated to be affected is relatively small (17.9 percent). Although 90 percent of affected EAP workers will reside in MSAs (3.92 of 4.34 million), so do a corresponding 88 percent of all workers subject to the FLSA.[346]

Employers in low-wage industries, regions, and in non-metropolitan areas may be more affected because they typically pay lower wages and salaries. The Department believes the salary level included in this rule is appropriate for these lower-wage sectors, in part because the

[346] Identified with CPS MORG variable GTMETSTA.

methodology uses earnings data from the lowest-wage census region. Moreover, the duties test will continue to determine exemption status for the vast majority of workers in low-wage regions and industries under the rule. For example, as displayed in Table 7, 82.1 percent of potentially affected EAP workers in the South Census Region earn more than the new salary levels and thus will not be affected by the rule (8.59 ÷ 10.46). Effects by region and industry are considered in section VII.C.7.

Table 7: Estimated Number of Workers and Whether They Will be Affected by the New Earnings Thresholds, by Region, Division, and MSA Status, Year 1

Region / Division / Metropolitan Status	Workers subject to FLSA (Millions)	Potentially Affected EAP Workers (Millions) [a]	Not-Affected (Millions) [b]	Affected (Millions) [c]	Affected as Share of Potentially Affected
Total	143.68	29.75	25.25	4.49	15.1%
By Region / Division					
Northeast	25.51	6.04	5.30	0.74	12.3%
New England	7.01	1.80	1.61	0.20	11.0%
Middle Atlantic	18.50	4.23	3.69	0.54	12.8%
Midwest	31.14	6.08	5.15	0.93	15.4%
East North Central	21.06	4.14	3.52	0.62	14.9%
West North Central	10.08	1.94	1.63	0.32	16.3%
South	53.18	10.46	8.59	1.87	17.9%
South Atlantic	27.71	5.80	4.77	1.03	17.7%
East South Central	7.92	1.24	0.99	0.25	20.4%
West South Central	17.54	3.42	2.83	0.59	17.2%
West	33.85	7.17	6.38	0.79	11.0%
Mountain	11.12	2.21	1.89	0.32	14.4%
Pacific	22.73	4.95	4.48	0.47	9.5%
By Metropolitan Status					
Metropolitan	126.89	27.91	23.98	3.92	14.1%
Non-metropolitan	15.74	1.70	1.32	0.38	22.3%
Not identified	1.05	0.14	0.11	0.03	23.8%

Note: Pooled CPS data for 2021–2023 adjusted to reflect 2023.

[a] Exempt workers who are white-collar, salaried, not eligible for another (non-EAP) overtime exemption, and not in a named occupation.
[b] Workers who continue to be exempt after the increases in the salary levels (assuming affected workers earning below the new salary level do not have their weekly earnings increased to the new level).
[c] Estimated number of workers exempt under the EAP exemptions who will be entitled to overtime protection under the updated salary levels (if their weekly earnings do not increase to the new salary levels).

Table 8 presents the distribution of affected EAP workers by demographics. Potentially affected women, Black workers, Hispanic workers, young workers, and workers with less education are all more likely to be affected than other worker types. This is because EAP exempt workers with these characteristics are more likely to earn within the affected standard salary range than EAP exempt workers without these characteristics. For example, of potentially affected workers, women tend to have lower salaries and are therefore more likely to be in the affected range. Median weekly earnings for potentially affected women are $1,709 compared to $2,108 for men.

Among potentially affected workers, certain demographic groups—women, Black workers, Hispanic workers, young workers, and workers with less education—have an increased likelihood of being affected by this rulemaking, even though workers in these demographic groups are less likely to be EAP exempt in the first place. Therefore, as a share of all workers, not just potentially affected workers, workers in these demographic groups may not be more likely to be affected. For example, when looking at potentially affected workers, 21.7 percent of potentially affected Black workers are affected, while only 14.5 percent of potentially affected white workers are affected. However, when looking at total workers, about the same shares of

total Black and total white workers would be affected (2.9 percent of Black workers and 3.0 percent of white workers).

Table 8: Estimated Number of Workers and Whether They Will be Affected by the New Earnings Thresholds, by Demographics, Year 1

Demographic	Workers subject to FLSA (Millions)	Potentially Affected EAP Workers (Millions) [a]	Not-Affected (Millions) [b]	Affected (Millions) [c]	Affected as Share of All Workers	Affected as Share of Potentially Affected
Total	143.68	29.75	25.41	4.34	3.0%	14.6%
By Sex						
Male	74.37	17.38	15.46	1.92	2.6%	11.0%
Female	69.31	12.37	9.95	2.42	3.5%	19.6%
By Race						
White only	109.96	22.95	19.63	3.32	3.0%	14.5%
Black only	18.47	2.48	1.94	0.54	2.9%	21.7%
All others	15.25	4.32	3.83	0.48	3.2%	11.2%
By Ethnicity						
Hispanic	27.02	2.80	2.25	0.55	2.0%	19.5%
Not Hispanic	116.66	26.95	23.15	3.79	3.3%	14.1%
By Age						
16-25	22.34	1.37	0.96	0.40	1.8%	29.6%
26-35	34.25	7.51	6.20	1.30	3.8%	17.4%
36-45	30.91	7.96	6.97	0.99	3.2%	12.4%
46-55	27.89	7.00	6.13	0.87	3.1%	12.4%
56+	28.30	5.92	5.15	0.77	2.7%	13.1%
By Education						
No degree	10.77	0.15	0.09	0.06	0.5%	39.7%
High school diploma	59.52	4.75	3.55	1.19	2.0%	25.1%
Associate's degree	15.09	2.01	1.56	0.45	3.0%	22.5%
Bachelor's degree	37.05	14.30	12.43	1.86	5.0%	13.0%
Master's degree	16.08	7.11	6.46	0.65	4.0%	9.1%
Professional degree	2.06	0.40	0.36	0.04	2.0%	10.4%
PhD	3.11	1.03	0.95	0.08	2.6%	7.8%

Note: Pooled CPS data for 2021–2023 adjusted to reflect 2023.

[a] Exempt workers who are white-collar, salaried, not eligible for another (non-EAP) overtime exemption, and not in a named occupation.
[b] Workers who continue to be exempt after the increases in the salary level (assuming affected workers' weekly earnings do not increase to the new salary level).
[c] Estimated number of workers exempt under the EAP exemptions who would be entitled to overtime protection under the updated salary levels (if their weekly earnings do not increase to the new salary level).

3. Costs

i. Summary

The Department quantified three direct costs to employers in this analysis: (1) regulatory familiarization costs; (2) adjustment costs; and (3) managerial costs. These are the same costs quantified in the 2016 and 2019 rulemakings. The Department estimated that in Year 1, regulatory familiarization costs will be $451.6 million, adjustment costs will be $299.1 million, and managerial costs will be $685.5 million (Table 9). Total direct employer costs in Year 1 will be $1.4 billion. Recurring costs are projected in section VII.C.10. The Department discusses costs that are not quantified in section VII.C.3.v.

Table 9: Summary of Year 1 Direct Employer Costs (Millions)

Direct Employer Costs	Standard Salary Level	HCE Compensation Level	Total
Regulatory familiarization [a]	--	--	$451.6
Adjustment	$279.0	$20.1	$299.1
Managerial	$626.3	$59.2	$685.5
Total direct costs	$905.4	$79.2	$1,436.2

[a] Regulatory familiarization costs are assessed jointly for the change in the standard salary level and the HCE compensation level.

ii. Regulatory Familiarization Costs

This rulemaking will impose direct costs on firms by requiring them to review the regulation. To estimate these "regulatory familiarization costs," three pieces of information must be estimated: (1) the number of affected establishments; (2) a wage level for the employees reviewing the rule; and (3) the amount of time spent reviewing the rule. The Department generally used the same methodology for calculating regulatory familiarization costs that it used in the NPRM and recent rulemakings.

Regulatory familiarization costs can be calculated at an establishment level or at a firm level. The Department assumed that regulatory familiarization occurs at a decentralized level and used the number of establishments in its cost estimate; this results in a higher estimate than would result from using the number of firms. The most recent data on private sector establishments and firms at the time this rule was drafted are from the 2021 Statistics of U.S. Businesses (SUSB), which reports 8.15 million establishments with paid employees.[347] Additionally, there were an estimated 90,126 state and local governments in 2017, the most recent data available.[348] The Department thus estimated 8.24 million entities (the term "entities" is used to refer to the combination of establishments and governments).

The Department assumes that all entities will incur some regulatory familiarization costs, even if they do not employ exempt workers, because all entities will need to confirm whether this rulemaking affects their employees. Entities with more affected EAP workers will likely spend more time reviewing the regulation than entities with fewer or no affected EAP workers

[347] Statistics of U.S. Businesses 2021, https://www.census.gov/programs-surveys/susb.html.
[348] 2017 Census of Governments. Table 1, https://www.census.gov/data/tables/2017/econ/gus/2017-governments.html.

(since a more careful reading of the regulation will probably follow the initial decision that the entity is affected). However, the Department did not know the distribution of affected EAP workers across entities, so it used an average cost per entity.

The Department believes an average of 1 hour per entity is appropriate because the regulated community is likely to be familiar with the content of this rulemaking. EAP exemptions have existed in one form or another since 1938, and a final rule was published as recently as 2019. Furthermore, employers who use the exemptions must apply them every time they hire an employee whom they seek to classify as exempt. Thus, employers should be familiar with the exemptions. The most significant changes in this rulemaking are setting a new standard salary level and a new HCE compensation level for exempt workers and establishing a mechanism for keeping these thresholds up to date. The changed regulatory text is only a few pages, and the Department will provide summaries and other compliance assistance materials that will help inform employers that are implementing the final rule. The Department thus believes, consistent with its approach in the 2016 and 2019 rules, that 1 hour is an appropriate average estimate for the time each entity will spend reviewing the changes made by this rulemaking. Additionally, the estimated 1 hour for regulatory familiarization represents an assumption about the average for all entities in the U.S., even those without any affected or exempt workers, which are unlikely to spend much time reviewing the rulemaking. Some businesses, of course, will spend more than 1 hour, and some will spend less.

The Department's analysis assumes that compensation, benefits, and job analysis specialists (SOC 13-1141) with a median wage of $32.59 per hour will review the rulemaking.[349,]

[349] OEWS 2022. Available at: https://www.bls.gov/oes/current/oes131141.htm.

[350] The Department also assumed that benefits are paid at a rate of 45 percent of the base wage[351] and overhead costs are paid at a rate of 17 percent of the base wage,[352] resulting in an hourly rate of $54.82 in 2023 dollars.[353] The Department thus estimates regulatory familiarization costs in Year 1 would be $451.6 million ($54.82 per hour × 1 hour × 8.24 million entities).

The Department also conducted a sensitivity analysis. First, as previously noted, the Department used the number of establishments rather than the number of firms, which results in a higher estimate of the regulatory familiarization cost. Using the number of firms, 6.4 million, would result in a reduced regulatory familiarization cost estimate of $350.0 million in Year 1.

Some commenters representing employer interests stated that rule familiarization costs are underestimated. *See, e.g.*, ABC; IEC; Job Creators Network Foundation; NSBA; SBA Office of Advocacy. For instance, ABC commented that "compliance with the proposal will not be as simple as reviewing the salary level and making a one-time decision" and that "82% of recently surveyed ABC members . . . responded that reviewing the final rule would take three hours or longer, with 47% saying it would take five hours or more."

---

[350] Previous related rulemakings used the CPS to estimate wage rates. The Department is using OEWS data now to conform with standard practice for the Department's economic analyses.
[351] The benefits-earnings ratio is derived from BLS's Employer Costs for Employee Compensation (ECEC) data using variables CMU1020000000000D and CMU1030000000000D. This fringe benefit rate includes some fixed costs such as health insurance. As of when this final rule was drafted, 2023 ECEC data were available only through the third quarter, so the Department continued to use the 2022 full-year data to calculate the benefits share.
[352] The Department believes that the overhead costs associated with this rulemaking are small because existing systems maintained by employers to track currently hourly employees can be used for newly overtime-eligible workers. However, acknowledging that there might be additional overhead costs, the Department has included an overhead rate of 17 percent.
[353] The 2022 fully-loaded hourly wage was adjusted to 2023 using the CPI-U.

While the Department acknowledges that some employers will spend more than an hour reviewing the rule, the estimate of 1 hour for rule familiarization is an assumption about the average representing all establishments, even those without any affected or exempt workers. Those establishments will likely not need to spend any time reviewing the rule. Employers in industries with more affected workers may spend more time reviewing the rule, but across all industries, the Department believes that 1 hour continues to be appropriate. The Department used the same 1 hour estimate in its 2016 and 2019 rules,[354] and the Department did not receive comments with concrete data that is representative across all industries from which to conclude that its average estimate of one hour is incorrect. The Department continues to believe that businesses are already familiar with this rulemaking. The EAP exemptions have existed for a long time, and recent rules were published in 2016 and 2019. This rulemaking sets a new standard salary level and a new HCE compensation level for exempt workers and establishes a mechanism for keeping these thresholds up to date. However, this rulemaking does not fundamentally change the existing method for determining whether an employee qualifies for the EAP exemption. To the extent commenters' familiarization cost concerns related to time needed to comply with the rule, these costs are addressed separately under the Department's managerial and adjustment cost estimates. As for concerns relating to the hourly wage rate used to calculate rule familiarization costs, the Department notes that it relies on the standard occupation used in previous WHD and DOL rulemakings.

[354] 81 FR 32474; 84 FR 51266.

iii. Adjustment Costs

This rulemaking will also impose direct costs on establishments by requiring them to evaluate the exemption status of employees, update and adapt overtime policies, notify employees of policy changes, and adjust their payroll systems. For each affected worker who works overtime, an employer will need to decide whether they will increase their salary, adjust their hours, or some combination of the two. The Department believes the size of these "adjustment costs" will depend on the number of affected EAP workers and will occur in any year when exemption status is changed for any workers. To estimate adjustment costs, three pieces of information must be estimated: (1) a wage level for the employees making the adjustments; (2) the amount of time spent making the adjustments; and (3) the estimated number of newly affected EAP workers. The Department again estimated that the average wage with benefits and overhead costs for a mid-level human resource worker is $54.82 per hour (as explained above).

The Department estimated that it will take establishments an average of 75 minutes per affected worker to make the necessary adjustments. This is the same time estimate as used in the 2016 and 2019 rulemakings, as well as in the NPRM. Little applicable data were identified from which to estimate the amount of time required to make these adjustments. The estimated number of affected EAP workers in Year 1 due to the change in the standard salary level to $1,128 per week and the HCE level to $151,164 per year is 4.3 million (as discussed in section VII.B.7). However, because the compensation thresholds will undergo an initial update on July 1, 2024 and then an increase using the new methodologies 6 months later, employers may have

additional adjustment costs when the standard salary level is initially updated to $844 per week and the HCE level is initially updated to $132,964.

Some employers may make two adjustments for affected workers – one at the initial update to the standard salary level and then again with the salary level adjustment 6 months later. To estimate the costs associated with multiple adjustments, the Department assumed that at the initial update, some employers could experience additional adjustment costs for the affected workers who will have their weekly earnings increased to $844 per week. In order to estimate the number of affected workers who would have their weekly earnings increased to $844 per week, the Department looked at EAP exempt workers earning at least $684 per week but less than $844 per week. Using the methodology laid out in the transfer analysis in section VII.C.4.iii, the Department then estimated the share of these workers who regularly work overtime and would remain exempt, because it is less expensive for the employer to pay the updated salary level than to pay overtime (described in that section as Type 4 workers). The Department estimated that there would be 27,692 workers who earn between $684 and $844 and would have their earnings increased at the initial update. The Department does not have data to determine how many employers would increase earnings twice for workers earnings between $684 and $844. For these workers, unless they are working large numbers of overtime hours, it is likely to be more economically beneficial for employers to make other changes in response to the rule instead of increasing their salary to $1,128 a week, such as limiting overtime hours worked. Despite this, in case there are limited cases in which workers do have their earnings increased twice, the Department has included these additional adjustment costs in the total adjustment cost estimate.

Therefore, total estimated Year 1 adjustment costs would be $299.1 million ($54.82 × 1.25 hours × (4,337,469 + 27,692 workers)).

The Department used a time estimate per affected worker, rather than per establishment, because the distribution of affected workers across establishments is unknown. However, it may be helpful to present the total time estimate per establishment based on a range of affected workers. If an establishment has five affected workers, the time estimate for adjustment costs is 6.25 hours. If an establishment has 25 affected workers, the time estimate for adjustment costs is 31.25 hours. And if an establishment has 50 affected workers, the time estimate for adjustment costs is 62.5 hours.

A reduction in the cost to employers of determining employees' exemption status may partially offset adjustment costs. Currently, to determine whether an employee is exempt, employers must apply the duties test to salaried workers who earn $684 or more per week. However, under the final rule, firms will no longer be required to apply the duties test to the 8.7 million employees earning above the current standard salary level of $684 and less than the new standard salary level of $1,128. While this will be a clear cost savings to employers for these employees, the Department did not estimate the potential size of this cost savings.

Some commenters representing employer interests stated that the Department underestimated adjustment costs. *See, e.g.*, NAHB; NSBA; PPWO. NAHB, for instance, stated that "the Department's economic analysis," including its estimate of "75 minutes per affected worker for adjustment," "dramatically understate[d] the . . . cost burden on employers," and PPWO stated that adjustment costs (and regulatory familiarization and managerial costs) were "all dramatically understated." SBA Advocacy and Seyfarth Shaw asserted that the Department

underestimated adjustment costs for small businesses, with both commenters stating that smaller employers would be more likely than larger ones to hire outside assistance to make needed adjustments. *See also* NFIB ("The NPRM underestimates compliance costs for small businesses[.]"). Some commenters asserted that the Department failed to account for adjustment costs that employers would need to incur beyond the first year the rule is in effect, such as costs associated with determining whether an employee remains exempt, reclassifying newly-exempt employees as hourly, and making other adjustments to time and attendance systems, given that the earnings thresholds for exemption will be updated on a triennial basis. *See* PPWO; The 4As. Additionally, some commenters expressed particular concern with adjustment costs stemming from the proposed increase in the HCE compensation level, noting that for workers who were previously exempt under the HCE test but earn below the proposed HCE compensation level, employers would need to evaluate the worker's duties to determine whether they remain exempt under the standard test. *See, e.g.,* HR Policy Association; NAM; PPWO. NAM stated that "[a]cross the manufacturing sector, the change in the HCE threshold may be as difficult and consequential as the proposed increases to the standard salary threshold."

The Department is retaining its estimate of adjustment costs as 75 minutes per affected worker in the final rule. This estimate is consistent with the Department's estimate in the 2016 and 2019 rules.[355] The Department notes that the 75-minute-per-worker average time estimate is an assumption about the average across all workers, and it believes this estimate takes into account adjustment time for workers affected by the new standard salary level and the smaller portion of workers affected by the new HCE total compensation threshold. This estimate

[355] *See* 84 FR 51267; 81 FR 32475.

assumes that the time is focused on analyzing more complicated situations. For example, employers are likely to incur relatively low adjustment costs for some workers, such as the 69 percent of affected workers who work no overtime (described below as Type 1 workers). This leaves more time for employers to spend on adjustment costs for the 31 percent of affected workers who work overtime either occasionally or regularly. To demonstrate, if the aggregate time spent on adjustments (75 min × 4.37 million workers) was spread out over only workers who work overtime, then the time estimate is 4.0 hours per worker. Lastly, the Department did not receive any comments with data providing a different estimate for the Department to rely on.

Contrary to commenters that stated that the Department failed to take into account adjustment costs beyond the first year the rule is in effect, the Department's estimated adjustment costs include costs in all years for newly affected workers. The Department limits adjustment costs in projected years to newly affected workers because there is no need to "adjust" for workers who are already overtime eligible (due to a prior adjustment of the salary level) when the salary level is updated again. Table 26 provides adjustment (and other) cost projections in future years due to the updating mechanism.

iv. Managerial Costs

If an employee becomes nonexempt due to the changes in the salary levels, then firms may incur ongoing managerial costs because the employer may spend more time developing work schedules and closely monitoring an employee's hours to minimize or avoid paying that employee overtime. For example, the manager of a newly nonexempt worker may have to assess whether the marginal benefit of scheduling the worker for more than 40 hours exceeds the marginal cost of paying the overtime premium. Additionally, the manager may have to spend

more time monitoring the employee's work and productivity since the marginal cost of employing the worker per hour has increased. Unlike regulatory familiarization and adjustment costs, which occur primarily in Year 1, managerial costs are incurred more uniformly every year.

The Department applied managerial costs to workers who (1) become nonexempt, overtime-protected and (2) either regularly work overtime or occasionally work overtime, but on a predictable basis—an estimated 911,000 workers (*see* Table 13 and accompanying explanation). Consistent with its approach in its 2019 rule and the NPRM, the Department assumed that management would spend an additional ten minutes per week scheduling and monitoring each affected worker expected to become nonexempt, overtime-eligible as a result of this rule, and whose hours would be adjusted.

As discussed in detail below, most affected workers do not currently work overtime, and there is no reason to expect their hours worked to change when their status changes from exempt to nonexempt. For that group of workers, management will have little or no need to increase their monitoring of hours worked; therefore, these workers are not included in the managerial cost calculation. Under these assumptions, the additional managerial hours worked per week will be 151,800 hours ((10 minutes ÷ 60 minutes) × 911,000 workers).

The median hourly wage in 2022 for a manager was $51.62.[356] Together with a 45 percent benefits rate and a 17 percent overhead cost, this totals $86.82 per hour in 2023

[356] OEWS 2022. Available at: https://www.bls.gov/oes/current/oes110000.htm. This may be an overestimate of the wage rate for managers who monitor workers' hours because (1) it includes very highly paid employees such as CEOs, and (2) some lower-level supervisors are not counted as managers in the data.

dollars.[357] Thus, the estimated Year 1 managerial costs total $685.5 million (151,835 hours per week × 52 weeks[358] × $86.82/hour). Although the exact magnitude will vary each year with the number of affected EAP workers, the Department anticipates that employers would incur managerial costs annually.

Some commenters expressed concerns that the regulation will increase managerial costs, with some specifically asserting that the Department's estimate was too low, *see, e.g.*, PPWO, SBA Advocacy, NCFC, IEC. Commenter concerns with managerial costs were often tied to the additional costs they asserted would result from tracking the work hours of newly nonexempt employees. *See, e.g.*, 16 Republication Representatives; APLU. Commenters specifically asserted tracking hours of currently exempt employees would increase human resources paperwork and technology costs for their companies. *See, e.g.*, The Chamber of Commerce for Greater Philadelphia; John C. Campbell Folk School.

The Department continues to believe that 10 minutes per worker per week is an appropriate managerial cost estimate. Currently, EAP exempt employees account for about 24 percent of total employment; as such, the Department expects that many employers of EAP exempt workers also employ nonexempt workers. Those employers already have in place recordkeeping systems and standard operating procedures for ensuring employees only work

[357] The benefits ratio is derived from BLS' 2022 Employer Costs for Employee Compensation data using variables CMU1020000000000D and CMU1030000000000D. The fully-loaded hourly wage rate was inflated to 2023 dollars using the BLS CPI-U.

[358] Fifty-two weeks may be an overestimate of the amount of time that an employer would incur management costs in Year 1. For affected workers who earn below $1,128, but at least $844, their employers may not incur additional managerial costs until January 1, 2025 if they decide to wait to make changes in response to the rule. Therefore, these managerial costs would not occur for the full 52 weeks of the year. Because the Department does not know when employers would make changes in response to the rule, this estimate of 52 weeks is used for the entire population.

overtime under employer-prescribed circumstances. Thus, such systems generally do not need to be created or acquired for managing formerly exempt EAP employees. The Department also notes that under the FLSA recordkeeping regulations in part 516, employers determine how to make and keep an accurate record of hours worked by employees. For example, employers may tell their workers to write their own time records and any timekeeping plan is acceptable if it is complete and accurate. Additionally, if the nonexempt employee works a fixed schedule, *e.g.*, 9:00 a.m. – 5:30 p.m. Monday – Friday, the employer may keep a record showing the exact schedule of daily and weekly hours and merely indicate exceptions to that schedule.[359] The Department believes its estimate, which tracks the approach taken in its 2019 rule, accurately predicts management costs, including costs firms may incur for monitoring and managing the hours of formerly exempt employees.

v. Other Potential Costs

In addition to the costs discussed above, commenters raised other potential costs that could not be quantified. These potential costs are discussed qualitatively below.

(a) Reduced Scheduling Flexibility

Several commenters claim that this rule would restrict employee workplace flexibility, such as remote work and flexible scheduling. *See, e.g.*, HR Policy Association; NAM; NRF; SBA; Chamber. For example, the Chamber stated, "workers will lose their ability to work from home and the flexibility that they have enjoyed in salaried positions, particularly since the COVID-19 pandemic changed the face of the American workplace in 2020." However,

[359] *See* Fact Sheet #21: Recordkeeping Requirements under the Fair Labor Standards Act, available at: https://www.dol.gov/agencies/whd/fact-sheets/21-flsa-recordkeeping.

commenters did not provide any specific evidence to support this claim. The Department notes that even those workers that are paid on an hourly basis can still take advantage of workplace flexibilities such as remote work. According to the CPS data, of all workers who reported working at home any time in the past week, 74.2 percent of them were categorized as hourly workers.

To the extent that some employers spend more time monitoring nonexempt workers' hours than exempt workers' hours, some employers could respond to this rule by limiting the ability of newly nonexempt workers to adjust their schedules. However, employers can continue to offer flexible schedules and require workers to monitor their own hours and to follow the employers' timekeeping rules. Additionally, some exempt workers already monitor their hours for billing purposes and so monitoring their hours as newly nonexempt workers should not be unduly burdensome. A study by Lonnie Golden found, using data from the General Social Survey (GSS), that "[i]n general, salaried workers at the lower (less than $50,000) income levels don't have noticeably greater levels of work flexibility that they would 'lose' if they become more like their hourly counterparts."[360] Because there is little data or literature on these potential costs, the Department did not quantify potential costs regarding scheduling flexibility.

Organizations such as the American Beverage Licensees and educational institutions in CUPA-HR and APLU, also asserted that the rule would reduce employer flexibility to allocate work hours based on schedules that include non-traditional work hours. The Hinton Rural Life Center said that the rule would make it financially unfeasible for nonexempt employees to attend

[360] Golden, L. (2014). Flexibility and Overtime Among Hourly and Salaried Workers. Economic Policy Institute. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2597174.

specific activities such as "overnight training sessions or marketing events." NCFC stated that because of the increased attention that must be paid to the hours worked by nonexempt employees, they are likely to be at a competitive disadvantage with exempt employees in the same role. Under this assumption, they asserted that "many training opportunities" would now require additional compensation if "those opportunities would put the nonexempt employee into an overtime situation," and therefore "access to those opportunities may be limited" for nonexempt employees. The Department notes that if an employer believes that training opportunities are sufficiently important, it can ensure employees attend the trainings during their 40-hour workweek or pay the overtime premium where training attendance causes the employee to work over 40 hours in a workweek. Given this, and because there is no data and literature to quantify any potential costs to workers, the Department did not quantify these costs.

(b) Preference for Salaried Status

Many commenters contended that the employers of some of the workers who will become nonexempt as a result of the rule could change their pay basis to hourly status despite the employee preferring to remain salaried. *See, e.g.*, AHLA; NSBA; SIGMA. Some commenters, such as SIGMA, stated that conversion of employees to hourly status that will negatively affect morale, as employees may perceive the change as a demotion or a loss of status because of, among other reasons, the lost flexibility associated with salaried status. Conversely, commenters such as the Coalition of State AGs and the Family Caregiving Coalition asserted that the proposed rule would increase employee satisfaction and retention, improve work-life balance, reduce stress and health problems, and make jobs more attractive to qualified applicants primarily because employees will now be compensated for hours worked beyond a standard

workweek. Notably, a strong majority of the individual commenters who said they would be personally affected by the proposed rule expressed support for the rule.

If a worker does prefer to be salaried rather than hourly, then the employer changing them from salaried to hourly may impact the worker. However, the Department believes that for most employees their feelings of importance and worth come not from their FLSA exemption status, but from the increased pay, flexibility, fringe benefits, and job responsibilities that traditionally have accompanied exempt status, and that these factors are not incompatible with overtime eligibility. And while research has shown that salaried workers (who are not synonymous with exempt workers, but whose status is correlated with exempt status) are more likely than hourly workers to receive certain benefits, as discussed below, such research generally does not control for differences between salaried and hourly workers such as education, job title, or earnings.

(c) Reduction in Employer-Provided Benefits

Several commenters stated that in response to the proposed salary level employers would likely decrease employee benefits. *See, e.g.*, PPWO; Rachel Greszler. These and similar comments were mostly general statements, often listing types of benefits employees may lose. Others stated that employees would lose benefits due to being reclassified as hourly workers. *See, e.g.*, Independent Women's Forum (IWF); NRF. Some commenters stated that these employees would have reductions in their ability to earn bonuses or other types of incentive payments, but these commenters generally did not discuss the net impact on these employees' earnings. *See, e.g.*, NRF. These comments did not provide information that would allow the Department to estimate the purported impact of the final rule on employee benefits.

Research has shown that salaried workers are more likely than hourly workers to receive benefits such as paid vacation time and health insurance[361] and are more satisfied with their benefits.[362] However, this literature generally does not control for differences between salaried and hourly workers such as education, job title, or earnings; therefore, this correlation is not necessarily attributable to hourly status.

If workers become nonexempt and the employer chooses to pay them on an hourly rather than salary basis, this may result in the employer reducing the workers' benefits. These newly nonexempt workers may continue to be paid a salary, as long as that salary is equivalent to a base wage at least equal to the minimum wage rate for every hour worked, and the employee receives a 50 percent premium on that employee's regular rate for any overtime hours each week.[363] Similarly, employers may continue to provide these workers with the same level of benefits as before, whether paid on an hourly or salary basis. Lastly, the nature of the market mechanism may be such that employers cannot reduce benefits without risking workers leaving, resulting in turnover costs to employers. The Department did not quantify potential costs regarding reduction in workers' benefits.

(d) Increased Prices

Several commenters such as AAHOA, the Chamber, CUPA-HR, Indiana Chamber of Commerce, NAHB, and the National Association of Wholesaler-Distributors stated that the

[361] Lambert, S. J. (2007). Making a Difference for Hourly Employees. In A. Booth, & A. C. Crouter, Work-Life Policies that Make a Real Difference for Individuals, Families, and Communities. Washington, D.C.: Urban Institute Press.
[362] Balkin, D. B., & Griffeth, R. W. (1993). The Determinants of Employee Benefits Satisfaction. Journal of Business and Psychology, 7(3), 323-339.
[363] 29 CFR 778.113–114.

regulation will result in increased prices due to increased employee salaries and other costs to employers. Some of these commenters assert that employers increasing their workers' salaries to maintain their exempt status would induce a general price increase if anticipated wage increases do not result in productivity increases. *See, e.g.*, Chamber; NAW. NAHB conducted a survey among its members about the proposal, and 50 percent of survey respondents stated that finalizing the salary level as proposed would lead them to raise home prices, while 25 percent of respondents stated that the change would make some projects unprofitable.

The Department acknowledges that, as discussed in the transfers section below, businesses may be able to help mitigate increased labor costs following this rulemaking by rebalancing the hours that employees are working. Businesses that are unable to rebalance these hours and do incur increased labor costs might pass along these increased labor costs to consumers through higher prices for goods and services. However, because costs and transfers will be, on average, small relative to payroll and revenues, the Department does not expect the rule to have a significant effect on prices. The Department estimated that, on average, costs and transfers make up less than 0.04 percent of payroll and 0.006 percent of revenues, although for specific industries and firms this percentage may be larger (*see* Table 24). Therefore, any potential change in prices related to costs and transfers from this rulemaking would be modest, and the Department notes that commenter predictions (such as those in the NAHB survey described above) reflect speculation about what will occur in the future and thus may not reflect actual economic responses by employers. Further, any significant price increases would not represent a separate category of effects from those estimated in this economic analysis. Rather,

such price increases (where they occur) would be the channel through which consumers, rather than employers or employees, bear rule-induced costs (including transfers).

While economic theory suggests that an increase in labor costs in excess of productivity gains would lead to increases in prices, much of the empirical literature has found that wage inflation does not predict price inflation.[364] For example, Peneva et al. (2015) explore the relationship between labor costs and price inflation between 1965 and 2012, finding that the influence of labor costs on prices has decreased over the past several decades and have made a relatively small contribution to price inflation in recent years.[365]

(e) Reduced Services

Some commenters expressed concern that, by reducing the number of exempt employees, this rulemaking will negatively impact the amount or quality of services that employers can provide. *See, e.g.*, ANCOR; Boy Scouts of America; Catholic Charities USA; YMCA. The National Association of Counties raised similar concerns with respect to county governments. A number of colleges, universities, and other higher-education stakeholders, such as APLU and CUPA-HR, similarly asserted that the proposed rule would negatively affect support services for students. The Department appreciates that employers in some industries have less flexibility than

[364] Church, J.D. and Akin, B. (2017). "Examining price transmission across labor compensation costs, consumer prices, and finished-goods prices," *Monthly Labor Review*, U.S. Bureau of Labor Statistics; Emery, K. & Chang, C. (1996). Do Wages Help Predict Inflation?, Federal Reserve Bank of Dallas, Economic Review First Quarter 1996. https://www.dallasfed.org/~/media/documents/research/er/1996/er9601a.pdf; Jonsson, M. & Palmqvist, S. (2004). Do Higher Wages Cause Inflation? Sveriges Riksbank Working Paper Series 159. http://archive.riksbank.se/Upload/WorkingPapers/WP_159.pdf.

[365] Pevena, E. V. and Rudd, J. B. (2015). "The Passthrough of Labor Costs to Price Inflation," Finance and Economics Discussion Series 2015-042. Washington: Board of Governors of the Federal Reserve System. https://dx.doi.org/10.17016/FEDS.2015.042.

others to account for new labor costs and that the services provided by such employers could be negatively affected. However, the Department believes the effect of the rule on public services will be small. The Department acknowledges that some newly nonexempt employees who currently work overtime providing public services may see a reduction in hours as an effect of the rulemaking. But if the services are in demand, the Department believes additional workers may be hired, as funding availability allows, to make up some of these hours, and productivity increases may offset some reduction in services. In addition, the Department expects some employers will adjust base wages downward to some degree so that even after paying the overtime premium, overall pay and hours of work for many employees will be relatively minimally impacted. Additionally, many nonprofits are noncovered enterprises because when determining enterprise coverage only revenue derived from business operations, not charitable activities, is included.

(f) Reduced Profits

Some commenters asserted that the rule would lead to decreased profits. *See e.g.,* Quad Cities Chamber of Commerce, ESEI, DT-Trak Consulting. The Department acknowledges that the increased employer costs and transfer payments as a result of this rule may reduce the profits of business firms, although (1) some firms may offset some of these costs and transfers by making payroll adjustments, and (2) some firms may mitigate their reduced profits due to these costs and transfers through increased prices. Because costs and transfers are, on average, small relative to payroll revenues, the Department does not expect this rulemaking to have a significant effect on profits.

(g) Hiring Costs

To the extent that firms respond to this rule by reducing overtime hours, they may do so by spreading hours to other workers, including current workers employed for fewer than 40 hours per week by that employer, current workers who remain exempt, and newly hired workers. If new workers are hired to absorb these transferred hours, then the associated hiring costs would be a cost of this rule. (However, new employees would likely only be hired if their wages, onboarding costs, and training costs are less than the cost of overtime pay for the newly nonexempt workers.) The Department does not know how many new employees would be hired and thus did not estimate this cost.

(h) Hours-Related Worker Effects

Some employer representatives highlighted the possibility that some workers might work more hours as a consequence of this rulemaking. For example, Construction Industry Roundtable commented that employers responding to the increased salary level might "require the remaining exempt employees to absorb some of the duties of the newly non-exempt employees—which would be viewed as an unfair burden by the remaining exempt employees who are at or near capacity already." *See also* SIGMA (providing similar statements).

The Department acknowledges that for some affected workers, if their employers respond to the rule by increasing their salary to keep their exemption status, the change may also be accompanied by an increase in assigned hours. Additionally, some employers might respond to this regulation by reducing the overtime hours of affected workers and transferring those hours to other workers who remain exempt. The Department believes that while some workers may see an

increase in hours, others may see their hours decline (discussed further in the Benefits section below).

(i) Wage Compression

Some commenters contended that the update to the salary threshold in this rule would lead to wage compression. For example, PPWO stated that the Department did not account for this potential cost, stating, "Where employees below the proposed salary minimum have their salaries raised to meet the new minimum, employees above the new minimum will likewise need to have their salaries raised to account for the relative value of the work being performed." *See also, e.g.,* Seyfarth Shaw.

However, as discussed in section VII.C.4.iii.f., the Department estimates that only 2.2 percent of affected workers will have their earnings increased to the updated salary level. Thus, in the overwhelming majority of cases wage compression concerns should not arise. The Department recognizes that there may be some cases in which employers that raise the pay of affected employees to the new salary level will also choose to increase the earnings of more highly paid employees to avoid wage compression, but the Department does not have data to estimate this impact.

4. Transfers

i. Overview

Transfer payments occur when income is redistributed from one party to another. The Department has quantified two transfers from employers to employees that will result from the rule: (1) transfers to ensure compliance with the FLSA minimum wage provision; and (2) transfers to ensure compliance with the FLSA overtime pay provision. Transfers in Year 1 due to the minimum wage provision were estimated to be $87.5 million. The increase in the HCE

compensation level does not affect minimum wage transfers because workers eligible for the HCE exemption earn well above the minimum wage. The Department estimates that transfers due to the applicability of the FLSA's overtime pay provision will be $1.4 billion: $1.2 billion from the increased standard salary level and $255.6 million from the increased HCE compensation level. Total Year 1 transfers are estimated at $1.5 billion (Table 10).

Table 10: Total Annual Change in Earnings for Affected EAP Workers by Provision, Year 1 (Millions)

Provision	Total	Standard Salary Level	HCE Compensation Level
Total	$1,509.2	$1,253.6	$255.6
Minimum wage only	$87.5	$87.5	--
Overtime pay only [a]	$1,421.7	$1,166.1	$255.6

Because the overtime premium depends on the employee's regular rate of pay, the estimates of minimum wage transfers and overtime transfers are linked. This can be considered a two-step approach. The Department first identified affected EAP workers with an implicit regular hourly wage lower than the minimum wage, and then calculated the wage increase necessary to reach the minimum wage. Then, the Department estimated overtime payments.

ii. Transfers Due to the Minimum Wage Provision

For this analysis, the hourly rate of pay was calculated as usual weekly earnings divided by usual weekly hours worked. To earn less than the Federal or most state minimum wages, this set of workers must work many hours per week. For example, a worker paid $684 per week must work 94.3 hours per week to earn less than the Federal minimum wage of $7.25 per hour ($684 ÷

$7.25 = 94.3).[366] The applicable minimum wage is the higher of the Federal minimum wage and the state minimum wage as of January 1, 2023. Most affected EAP workers already receive at least the minimum wage; only an estimated 0.5 percent (19,900 in total) earn an implicit hourly rate of pay less than the Federal minimum wage. The Department estimated transfers due to payment of the minimum wage by calculating the change in earnings if wages rose to the minimum wage for workers who become nonexempt.[367]

In response to an increase in the regular rate of pay to the minimum wage, employers may reduce the workers' hours. In theory, since the quantity of labor hours demanded is inversely related to wages, a higher mandated wage would, all things being equal, result in fewer hours of labor demanded. However, the weight of the empirical evidence finds that increases in the minimum wage that are similar in magnitude to what would be caused by this regulatory provision have caused little or no significant job loss.[368] Thus, in the case of this regulation, the Department believes that any disemployment effect due to the minimum wage provision will be negligible. This is partially due to the small number of workers affected by this provision.

---

[366] The Federal minimum wage has not increased since 2009. Workers in states with minimum wages higher than the Federal minimum wage could earn less than the state minimum wage working fewer hours.

[367] Because these workers' hourly wages will be set at the minimum wage after this rule, their employers will not be able to adjust their wages downward to offset part of the cost of paying the overtime pay premium (which will be discussed in the following section). Therefore, these workers will generally receive larger transfers attributed to the overtime pay provision than other workers.

[368] Wolfson, Paul J. and Belman, Dale, 15 Years of Research on U.S. Employment and the Minimum Wage (December 10, 2016). Tuck School of Business Working Paper No. 2705499. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2705499. Dube, Arindrajit, Impacts of Minimum Wages: Review of the International Evidence (November 2019). https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/844350/impacts_of_minimum_wages_review_of_the_international_evidence_Arindrajit_Dube_web.pdf.

According to the Wolfson and Belman (2016) meta-analysis cited above, the consensus range for labor demand elasticity was -0.05 to -0.12. However for Year 1 of this analysis, the Department estimated the potential disemployment effects (*i.e.*, the estimated reduction in hours) of the transfer attributed to the minimum wage by multiplying the percent change in the regular rate of pay by a labor demand elasticity of −0.2 (years 2 – 10 use a long run elasticity of −0.4).[369, 370] The Department chose this labor demand elasticity because it was used in the 2019 final rule and is consistent with the labor demand elasticity estimates used when estimating other transfers further below.

At the new standard salary level, the Department estimated that 19,900 affected EAP workers will, on average, see an hourly wage increase of $1.57, work 2.1 fewer hours per week and receive an increase in weekly earnings of $84.73 as a result of coverage by the minimum wage provisions (Table 11). The total change in weekly earnings due to the payment of the minimum wage was estimated to be $1.7 million per week ($84.73 × 19,900) or $87.5 million in Year 1.

Table 11: Minimum Wage Only: Mean Hourly Wages, Usual Weekly Hours and Weekly Earnings for Affected EAP Workers, Year 1

Time Period	Hourly Wage [a]	Usual Weekly Hours	Usual Weekly Earnings	Total Weekly Transfer (1,000s)
Before rule	$12.85	65.8	$827.66	--
After rule	$14.42	63.6	$912.39	--
Change	$1.57	-2.1	$84.73	$1,683

Note: Pooled data for 2021 – 2023 adjusted to reflect 2023.

[369] Labor demand elasticity is the percentage change in labor hours demanded in response to a one percent change in wages.

[370] This elasticity estimate represents a short run demand elasticity for general labor, and is based on the Department's analysis of Lichter, A., Peichl, A. & Siegloch, A. (2014). The Own-Wage Elasticity of Labor Demand: A Meta-Regression Analysis. IZA DP No. 7958.

[a] The applicable minimum wage is the higher of the Federal minimum wage and the state minimum wage.

iii. Transfers Due to the Overtime Pay Provision

(a) Introduction

The FLSA requires covered employers to pay an overtime premium to nonexempt covered workers who work in excess of 40 hours per week. For workers who become nonexempt, the rulemaking will result in a transfer of income to the affected workers, increasing the marginal cost of labor, which employers may try to offset by adjusting the wages and/or hours of affected workers. The size of the transfer will depend largely on how employers choose to respond to the updated salary levels. Employers may respond by: (1) paying overtime premiums to affected workers; (2) reducing overtime hours of affected workers and potentially transferring some of these hours to other workers; (3) reducing the regular rate of pay for affected workers working overtime (provided that the reduced rates still exceed the minimum wage); (4) increasing affected workers' salaries to the updated salary or compensation level to preserve their exempt status; or (5) using some combination of these responses. How employers will respond depends on many factors, including the relative costs of each of these alternatives. In turn, the relative costs of each of these alternatives are a function of workers' earnings and hours worked.

(b) Literature on Employer Adjustments

Two conceptual models are useful for thinking about how employers may respond to when certain employees become eligible for overtime: (1) the "fixed-wage" or "labor demand"

model, and (2) the "fixed-job" or "employment contract" model.[371] These models make different assumptions about the demand for overtime hours and the structure of the employment agreement, which result in different implications for predicting employer responses.

The fixed-wage model assumes that the standard hourly wage is independent of the statutory overtime premium. Under the fixed-wage model, a transition of workers from overtime exempt to overtime nonexempt would cause a reduction in overtime hours for affected workers, an increase in the prevalence of a 40-hour workweek among affected workers, and an increase in the earnings of affected workers who continue to work overtime.

In contrast, the fixed-job model assumes that the standard hourly wage is affected by the statutory overtime premium. Thus, employers can neutralize any transition of workers from overtime exempt to overtime nonexempt by reducing the standard hourly wage of affected workers so that their weekly earnings and hours worked are unchanged, except when minimum wage laws prevent employers from lowering the standard hourly wage below the minimum wage. Under the fixed-job model, a transition of workers from overtime exempt to overtime nonexempt would have different effects on minimum-wage workers and above-minimum-wage workers. Similar to the fixed-wage model, minimum-wage workers would experience a reduction in overtime hours, an increase in the prevalence of a 40-hour workweek at a given employer (though not necessarily overall), and an increase in earnings for the portion of minimum-wage workers who continue to work overtime for a given employer. Unlike the fixed-wage model, however, above-minimum-wage workers would experience no change.

---

[371] *See* Trejo, S.J. (1991). The Effects of Overtime Pay Regulation on Worker Compensation. American Economic Review, 81(4), 719–740, and Barkume, A. (2010). The Structure of Labor Costs with Overtime Work in U.S. Jobs. Industrial and Labor Relations Review, 64(1), 128-142.

The Department conducted a literature review to evaluate studies of how labor markets adjust to a change in the requirement to pay overtime. These studies are generally supportive of the fixed-job model of labor market adjustment, in that wages adjust to offset the requirement to pay an overtime premium as predicted by the fixed-job model, but do not adjust enough to completely offset the overtime premium as predicted by the model.

As in the 2016 and 2019 rules, the Department believes the two most important papers in this literature are the studies by Trejo (1991) and Barkume (2010). Analyzing the economic effects of the overtime pay provisions of the FLSA, Trejo (1991) found "the data analyzed here suggest the wage adjustments occur to mitigate the purely demand-driven effects predicted by the fixed-wage model, but these adjustments are not large enough to neutralize the overtime pay regulations completely." Trejo noted, "In accordance with the fixed job model, the overtime law appears to have a greater impact on minimum-wage workers." He also stated, "[T]he finding that overtime-pay coverage status systematically influences the hours-of-work distribution for nonminimum-wage workers is supportive of the fixed-wage model. No significant differences in weekly earnings were discovered between the covered and non-covered sectors, which is consistent with the fixed-job model." However, "overtime pay compliance is higher for union than for nonunion workers, a result that is more easily reconciled with the fixed wage model." Trejo's findings are supportive of the fixed-wage model whose adjustment is incomplete largely due to the minimum-wage requirement.[372]

[372] Trejo, S. J. (1991). The Effects of Overtime Pay Regulation on Worker Compensation. American Economic Review, 81(4), 719-740.

A second paper by Trejo (2003) took a different approach to testing the consistency of the fixed-wage adjustment models with overtime coverage and data on hours worked.[373] In this paper, he examined time-series data on employee hours by industry. After controlling for underlying trends in hours worked over 20 years, he found changes in overtime coverage had no impact on the prevalence of overtime hours worked. This result supports the fixed-job model. Unlike the 1991 paper, however, he did not examine impacts of overtime coverage on employees' weekly or hourly earnings, so this finding in support of the fixed-job model only analyzes one implication of the model.

Barkume (2010) built on the analytic method used in Trejo (1991).[374] However, Barkume observed that Trejo did not account for "quasi-fixed" employment costs (*e.g.*, benefits) that do not vary with hours worked, and therefore affect employers' decisions on overtime hours worked. After incorporating these quasi-fixed costs in the model, Barkume found results consistent with those of Trejo (1991): "though wage rates in otherwise similar jobs declined with greater overtime hours, they were not enough to prevent the FLSA overtime provisions from increasing labor costs." Barkume also determined that the 1991 model did not account for evidence that in the absence of regulation some employers may voluntarily pay workers some overtime premium to entice them to work longer hours, to compensate workers for unexpected changes in their schedules, or as a result of collective bargaining. Barkume found that how much

[373] Trejo, S. J. (2003). Does the Statutory Overtime Premium Discourage Long Workweeks? Industrial and Labor Relations Review, 56(3), 375-392.
[374] Barkume, A. (2010). The Structure of Labor Costs with Overtime Work in U.S. Jobs. Industrial and Labor Relations Review, 64(1), 128-142.

wages and hours worked adjusted in response to the overtime pay requirement depended on what overtime pay would be in absence of regulation.

In addition, Bell and Hart (2003) examined the standard hourly wage, average hourly earnings (including overtime), the overtime premium, and overtime hours worked in Britain.[375] Unlike the United States, Britain does not have national labor laws regulating overtime compensation. Bell and Hart found that after accounting for overtime, average hourly earnings are generally uniform in an industry because firms paying below-market level straight-time wages tend to pay above-market overtime premiums and firms paying above-market level straight-time wages tend to pay below-market overtime premiums. Bell and Hart concluded "this is consistent with a model in which workers and firms enter into an implicit contract that specifies total hours at a constant, market-determined, hourly wage rate. Their research is also consistent with studies showing that employers may pay overtime premiums either in the absence of a regulatory mandate (*e.g.*, Britain), or when the mandate exists but the requirements are not met (*e.g.*, United States).[376]

On balance, consistent with its 2016 and 2019 rulemakings, the Department finds strong support for the fixed-job model as the best approximation for the likely effects of a transition of above-minimum-wage workers from overtime exempt to overtime nonexempt and the fixed-wage model as the best approximation of the likely effects of a transition of minimum-wage workers from overtime exempt to overtime nonexempt. In addition, the studies suggest that

[375] Bell, D. N. F. and Hart, R. A. (2003). Wages, Hours, and Overtime Premia: Evidence from the British Labor Market, Industrial and Labor Relations Review, 56(3), 470-480.
[376] Hart, R. A. and Yue, M. (2000). Why Do Firms Pay an Overtime Premium? IZA Discussion Paper No. 163.

although observed wage adjustment patterns are consistent with the fixed-job model, this evidence also suggests that the actual wage adjustment might, especially in the short run, be less than 100 percent as predicted by the fixed-job model. Thus, the hybrid model used in this analysis may be described as an incomplete fixed-job adjustment model.

To determine the magnitude of the adjustment, the Department accounted for the following findings. Earlier research had demonstrated that in the absence of regulation some employers may voluntarily pay workers some overtime premium to entice them to work longer hours, to compensate workers for unexpected changes in their schedules, or as a result of collective bargaining.[377] Barkume (2010) found that the measured adjustment of wages and hours to overtime premium requirements depended on what overtime premium might be paid in absence of any requirement to do so. Thus, when Barkume assumed that workers would receive an average voluntary overtime pay premium of 28 percent in the absence of an overtime pay regulation, which is the average overtime premium that Bell and Hart (2003) found British employers paid in the absence of any overtime regulations, the straight-time hourly wage adjusted downward by 80 percent of the amount that would occur with the fixed-job model.[378] When Barkume assumed workers would receive no voluntary overtime pay premium in the absence of an overtime pay regulation, the results were more consistent with Trejo's (1991) findings that the adjustment was a smaller percentage. The Department modeled an adjustment

[377] Barzel, Y. (1973). The Determination of Daily Hours and Wages. The Quarterly Journal of Economics, 87(2), 220–238, demonstrated that modest fluctuations in labor demand could justify substantial overtime premiums in the employment contract model. Hart, R. A. and Yue, M. (2000). Why Do Firms Pay an Overtime Premium? IZA Discussion Paper No. 163, showed that establishing an overtime premium in an employment contract can reduce inefficiencies.
[378] Barkume, A. (2010). The Structure of Labor Costs with Overtime Work in U.S. Jobs. Industrial and Labor Relations Review, 64(1), 128-142.

process between these two findings. Although it seemed reasonable that some premium was paid for overtime in the absence of regulation, Barkume's assumption of a 28 percent initial overtime premium is likely too high for the salaried workers potentially affected by a change in the salary and compensation level requirements for the EAP exemptions because this assumption is based on a study of workers in Britain. British workers were likely paid a larger voluntary overtime premium than American workers because Britain did not have a required overtime pay regulation and so collective bargaining played a larger role in implementing overtime pay.[379] In the sections that follow, the Department uses a method between these two papers to model transfers.

(c) Comments Regarding Transfers

Many commenters representing employer interests indicated that employers would respond to the changes proposed in the NPRM by making a variety of adjustments to wages, hours worked, or both. Some commenters responded with results from surveys of their constituents. Although these surveys may be helpful as background information, they generally cannot be used in a quantitative analysis due to issues such as insufficient or uncertain sample sizes, missing sampling methodology, and missing magnitudes. For example, NAHB referenced results from a survey of an unknown number of its members, asserting that 38 percent of respondents indicated they would respond to the proposed increase in the salary level by "[m]inimiz[ing] overtime hours." The Department agrees that firms may reduce the hours of some workers and has included this in the quantitative analysis below; however, the modeling

[379] Bell, D. N. F. and Hart, R. A. (2003). Wages, Hours, and Overtime Premia: Evidence from the British Labor Market, Industrial and Labor Relations Review, 56(3), 470-480.

question is to what degree employers will adjust hours.[380] As discussed below, the Department estimates that employers will reduce hours for Type 2B and Type 3 workers, which together make up 21% of all affected workers. The Department's model is based on worker-specific adjustments and does not assume that a firm would respond the same way for all affected workers that they employ. Moreover, such surveys were often sector-specific, making it difficult to extrapolate economy-wide trends, because the distribution of affected workers varies across sectors. Also, these surveys were often based not on actual economic responses, but rather on expressions of intentions. *See, e.g.*, AHLA; ANCOR; NAIS and NBOA; NDA.

Despite the inability to incorporate these survey results into the analysis, select results are presented here. For instance, according to AHLA, of the members it surveyed, "70% anticipat[ed] reclassifying workers, 60% anticipat[ed] reducing hours and career development opportunities to reduce potential overtime costs, and 51% anticipat[ed] position consolidation." ANCOR found that "approximately 61 percent of [its constituents] would employ a mitigation strategy of converting currently exempt salaried workers to hourly workers," "[f]ifty-six percent . . . would increase the salary of full-time exempt workers to meet the projected threshold," "49 percent . . . would prohibit or significantly restrict" permitted overtime, and "33 percent indicated the necessity of reducing salaried full-time employees." NAIS and NBOA stated that 13 percent of schools that responded to its survey said they would "raise salaries of those exempt

[380] Illustrating the limitations of commenter-provided surveys for this quantitative analysis, the responses to NAHB's survey have inconsistencies that make them hard to interpret. For example, concerning the 2019 rule, NAHB reported that 94 percent of respondents stated that the rule's increase in the salary level to $35,568 did not affect anyone on their payroll. Nevertheless, of the same respondents, 20% stated that they responded to the 2019 rule by minimizing overtime hours and 18% stated that they raised salaries above the threshold.

employees who do not meet the new threshold," 27 percent said they would "convert employees to non-exempt and limit hours where possible," 11 percent said they would "convert employees to non-exempt and pay overtime if hours worked are over 40 in a week" and "47% of schools said they will enact some combination of the available options." NAHB stated that, if the proposed salary threshold were implemented, 38 percent of respondents reported they would "[m]inimize overtime hours," as noted above; 24 percent would "[r]aise salaries above the threshold"; and 9 percent would "[r]educe salaries to compensate for overtime" (among other changes). And NDA stated that 66 percent of respondents "said they would have to reclassify exempt employees as hourly employees and restructure jobs if DOL raised the minimum salary threshold" as proposed in the NPRM.

Regarding the transfer calculations in the NPRM, SBA Advocacy expressed concern about the Department's estimates that affected small business establishments would have, on average, $360 to $2,683 in additional payroll costs in the first year of the proposed rule. SBA Advocacy stated that "an Arkansas restaurant with four locations stated it would cost almost $200,000 to increase manager salaries to make them compliant," and that "small amusement businesses reported estimated salary increases for their businesses" ranging from $57,000 to $250,000. It also provided hypothetical examples of potential salary increases that restaurants in two states would need to make to comply with the proposed rule based on various assumptions, including different salaries and amounts of overtime performed. These anecdotal reports and hypothetical examples do not have any information on the actual amount of overtime work being performed by newly nonexempt workers at these businesses. The Department expects that businesses that would be faced with large increases in payroll costs if they were to increase

salaries to the new threshold would instead find other responses more economically beneficial, such as limiting the number of overtime hours worked by workers who become nonexempt or paying such workers the overtime premium for hours in excess of 40 per week. Furthermore, this comment does not explain what methodological approach the Department should use to estimate transfers; what error(s), if any, the Department made in its transfer estimate in its NPRM; or how much the Department underestimated such transfers.

Some commenters indicated that employers may follow the fixed-job model rather than the incomplete fixed-job model used by the Department in the NPRM. *See, e.g.,* AFPI; Americans for Prosperity. AFPI, for instance, stated that "[r]esearch shows employers primarily respond to expanded overtime eligibility by reducing base earnings to reflect expected overtime—leaving total earnings unchanged." Americans for Prosperity similarly asserted that "[o]ver time, the natural response of business enterprises of all types to the higher wage costs occasioned by the proposed rule will be an adjustment in base pay and fringe benefits lower so that total compensation (base pay, benefits, overtime) does not rise."[381]

The Oxford Economics report included with NRF's comment pointed to a study by Quach (2022),[382] which analyzed the effects of the rescinded 2016 rule and the 2019 rule, along

[381] In support, AFPI and Americans for Prosperity both cited to reports regarding the NPRM for the 2016 rule. *See* James Sherk, *Salaried Overtime Requirements: Employers Will Offset Them with Lower Pay,* Heritage Foundation Backgrounder No. 3031, July 2, 2015. https://thf_media.s3.amazonaws.com/2015/pdf/BG3031.pdf (cited by AFPI); Donald J. Boudreaux & Liya Palagashvili, *An Economic Analysis of Overtime Pay Regulations 17–21* (Apr. 2016), available at https://www.mercatus.org/hayekprogram/research/working-papers/economic-analysis-overtime-pay-regulations (cited by Americans for Prosperity).

[382] Simon Quach, *The Labor Market Effects of Expanding Overtime Coverage.* This is a working paper that was published in both 2022 and 2024. The 2024 version can be found linked on Simon Quach's website:

with the impact of state-level increases to the overtime exemption threshold. According to Oxford Economics, "Quach finds evidence that overtime coverage decreases employment and increases earnings polarization" and "strong evidence of employee reclassifications from salaried to hourly status[.]" The Department notes that the revised 2024 version of the working paper did not find that increasing overtime exemption thresholds decreases employment. In fact, when summarizing his findings, he says, "I estimate that expansions in overtime coverage actually have little effect on employment." He also notes, "while the DOL accurately predicted that average weekly earnings would rise, they calculated an income effect of only 0.7%, whereas I show that earnings increased by nearly twice that amount for salaried workers." While the Department also reviewed the 2022 study, as discussed further below, it has not incorporated this study into its analysis as it has multiple limitations, including a reliance on a non-representative selection of employers, which makes it inappropriate as a model of aggregate effects across the economy. The Oxford Economics report also claimed that the Department's analysis in the NPRM demonstrated "a tendency to assume that which workers are paid on a salaried basis is determined by an exogenous occupational structure and to ignore the role that the DOL's overtime regulations themselves play in determining this."

The Department's review of the literature cited above supports a result between the fixed-job model and the fixed-wage model and thus the results were modeled accordingly. Specifically, the Department believes the incomplete fixed-job model is most appropriate and consistent with

---

https://raw.githubusercontent.com/SimonQuach1/Papers/main/Quach_OT.pdf?token=AH2DVMEDLJGBAWFAVXXUNMDAYGGDQ. The Department believes that Oxford Economics was citing to the 2022 version of the paper, which is Quach, S. (2022). The Labor Market Effects of Expanding Overtime Coverage. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3608506.

the literature. Therefore, the analysis has not been changed. The Department further notes that its estimates of transfers are informed by its projection that employers will respond to the final rule in many ways. If, for example, an employer simply pays each affected employee the overtime premium for each hour worked in excess of 40 hours per week, without making any adjustments to wages, hours, or duties, such an approach would maximize transfers from employers to employees. However, as discussed above, the Department believes that employers will respond to the final rule by adjusting wages, hours, and duties to minimize the cost of the rule. Accordingly, the actual amount of transfers will fall well short of the transfers that would result if employers simply paid each affected employee overtime premiums without adjusting wages, hours, or duties.

(d) Identifying Types of Affected Workers

The Department identified four types of workers whose work characteristics affect how it modeled employers' responses to the changes in both the standard salary level and HCE compensation level:

- Type 1: Workers who do not work overtime.
- Type 2: Workers who do not regularly work overtime but occasionally work overtime.
- Type 3: Workers who regularly work overtime and become overtime eligible (nonexempt).
- Type 4: Workers who regularly work overtime and remain exempt, because it is less expensive for the employer to pay the updated salary level than to pay overtime and incur additional managerial costs.

The Department began by identifying the number of workers in each type. After modeling employer adjustments, it estimated transfer payments. Type 3 and Type 4 workers were identified as those who regularly work overtime (CPS variable PEHRUSL1 greater than 40). To distinguish Type 3 workers from Type 4 workers, the Department first estimated each worker's weekly earnings if they became nonexempt, to which it added weekly managerial costs for each affected worker of $14.47 ($86.82 per hour × (10 minutes ÷ 60 minutes)).[383] Then, the Department identified as Type 4 those workers whose expected nonexempt earnings plus weekly managerial costs exceeds the updated standard salary level, and, conversely, as Type 3 those whose expected nonexempt earnings plus weekly managerial costs are less than the new standard salary. The Department assumed that firms will include incremental managerial costs in their determination of whether to treat an affected employee as a Type 3 or Type 4 worker because those costs are only incurred if the employee is a Type 3 worker.

Identifying Type 2 workers involved two steps. First, using CPS MORG data, the Department identified those who do not usually work overtime but did work overtime in the survey week (the week referred to in the CPS questionnaire, variable PEHRACT1 greater than 40). Next, the Department supplemented the CPS data with data from the Survey of Income and Program Participation (SIPP) to look at likelihood of working some overtime during the year. Based on 2021 data, the most recent available, the Department found that 31.3 percent of non-hourly workers worked overtime at some point in a year. Therefore, the Department classified a share of workers who reported they do not usually work overtime, and did not work overtime in the reference week, as Type 2 workers such that a total of approximately 31.3 percent of affected

[383] *See* section VII.C.3.iv (managerial costs).

workers were Type 2, 3, or 4. Type 2 workers are subdivided into Types 2A and 2B later in the analysis (Table 12).

Table 12: Types of Affected Workers

Type of Worker	Percent of Total
Type 1	69%
Type 2A	8%
Type 2B	8%
Type 3	13%
Type 4	2%

Note: Pooled CPS data for 2021-2023 adjusted to reflect 2023.
*Type 1: Workers who do not work overtime and gain overtime protection.
*Type 2: Workers who work occasional overtime and gain overtime protection.
- Type 2A: Those who work unexpected overtime hours.
- Type 2B: Those who work expected overtime.

*Type 3: Workers who work regular overtime and gain overtime protection.
*Type 4: Workers who work regular overtime and remain exempt (*i.e.*, earnings increase to the updated salary or compensation level).

(e) Modeling Changes in Wages and Hours

The incomplete fixed-job model predicts that employers will adjust wages of regular overtime workers but not to the full extent indicated by the fixed-job model, and thus some employees will receive a small increase in weekly earnings due to overtime pay coverage. The Department used the average of two estimates of the incomplete fixed-job model adjustments to model impacts of this rule:[384]

[384] Both studies considered a population that included hourly workers. Evidence is not available on how the adjustment towards the fixed-job model differs between salaried and hourly workers. The fixed-job model may be more likely to hold for salaried workers than for hourly workers since salaried workers directly observe their weekly total earnings, not their implicit equivalent hourly wage. Thus, applying the partial adjustment to the fixed-job model as estimated by these studies may overestimate the transfers from employers to salaried workers.

- Trejo's (1991) estimate that the overtime-induced wage change is 40 percent of the adjustment toward the amount predicted by the fixed-job model, assuming an initial zero overtime pay premium, and
- Barkume's (2010) estimate that the wage change is 80 percent of the predicted adjustment assuming an initial 28 percent overtime pay premium.

This is approximately equivalent to assuming that salaried overtime workers implicitly receive the equivalent of a 14 percent overtime premium in the absence of regulation (the midpoint between 0 and 28 percent).

Modeling changes in hourly wages, hours, and earnings for Type 1 and Type 4 workers was relatively straightforward. Type 1 affected EAP workers will become overtime-eligible, but because they do not work overtime, they will see no change in their wages, hours, or weekly earnings. Type 4 workers will remain exempt because their earnings will be raised to at least the updated EAP level (either the standard salary level or HCE compensation level). These workers' earnings will increase by the difference between their current earnings and the amount necessary to satisfy the new salary or compensation level. It is possible employers will increase these workers' hours in response to paying them a higher salary, but the Department did not have enough information to model this potential change.[385]

Modeling changes in wages, hours, and earnings for Type 2 and Type 3 workers was more complex. The Department distinguished those who regularly work overtime (Type 3

[385] Cherry, Monica, "Are Salaried Workers Compensated for Overtime Hours?" Journal of Labor Research 25(3): 485–494, September 2004, found that exempt full-time salaried employees earn more when they work more hours, but her results do not lend themselves to the quantification of the effect on hours of an increase in earnings.

workers) from those who occasionally work overtime (Type 2 workers) because employer adjustment to the rule may differ accordingly. Employers are more likely to adjust hours worked and wages for regular overtime workers because their hours are predictable. Conversely, in response to a transient, perhaps unpredicted, shift in market demand for the good or service such employers provide, employers are more likely to pay for occasional overtime rather than adjust hours worked and pay.

The Department treated Type 2 affected workers in two ways due to the uncertainty of the nature of these occasional overtime hours. The Department assumed that 50 percent of these occasional overtime workers worked unexpected overtime hours (Type 2A) and the other 50 percent worked expected overtime (Type 2B). Workers were randomly assigned to these two groups. Workers with expected occasional overtime hours were treated like Type 3 affected workers (incomplete fixed-job model adjustments). Workers with unexpected occasional overtime hours were assumed to receive a 50 percent pay premium for the overtime hours worked and receive no change in base wage or hours (full overtime premium model).[386] When modeling Type 2 workers' hour and wage adjustments, the Department treated those identified as Type 2 using the CPS data as representative of all Type 2 workers.[387] The Department estimated employer adjustments and transfers assuming that the patterns observed in the CPS reference

[386] The Department uses the term "full overtime premium" to describe the adjustment process as modeled. The full overtime premium model is a special case of the general fixed-wage model in that the Department assumes the demand for labor under these circumstances is completely inelastic. That is, employers make no changes to employees' hours in response to these temporary, unanticipated changes in demand.

[387] As explained in the previous section, to estimate the population of Type 2 workers, the Department supplemented workers who report working overtime in the CPS reference week with some workers who do not work overtime in the reference week to reflect the fact that different workers work occasional overtime in different weeks.

week are representative of an average week in the year. Thus, the Department assumes total transfers for the year are equal to 52 times the transfers estimated for a representative week for which the Department has CPS data. However, these transfers are spread over a larger group including those who occasionally work overtime but did not do so in the CPS reference week.[388]

Since employers will pay more for the same number of labor hours, for Type 2 and Type 3 EAP workers, the quantity of labor hours demanded by employers will decrease. The reduction in hours is calculated using the elasticity of labor demand with respect to wages. The Department used a short-term demand elasticity of −0.20 to estimate the percentage decrease in hours worked in Year 1 and a long-term elasticity of −0.4 to estimate the percentage decrease in hours worked in Years 2–10. These elasticity estimates are based on the Department's analysis of Lichter et al. (2014).[389, 390] Brown and Hamermesh (2019) estimated the elasticity of overtime hours for EAP-exempt workers.[391] This estimate is based on a difference-in-differences in hours for two groups

[388] If a different week was chosen as the survey week, then some of these workers would not have worked overtime. However, because the data are representative of both the population and all twelve months in a year, the Department believes the share of Type 2 workers identified in the CPS data in the given week is representative of an average week in the year.

[389] Lichter, A., Peichl, A. & Siegloch, A. (2014). The Own-Wage Elasticity of Labor Demand: A Meta-Regression Analysis. IZA DP No. 7958.

[390] Some researchers have estimated larger impacts on the number of overtime hours worked. For example, Hamermesh and Trejo (2000) conclude the price elasticity of demand for overtime hours is at least -0.5. The Department decided to use a general measure of elasticity applied to the average change in wages since the increase in the overtime wage is somewhat offset by a decrease in the non-overtime wage as indicated in the fixed-job model.
Hamermesh, D. and S. Trejo. (2000)). The Demand for Hours of Labor: Direct Evidence from California. The Review of Economics and Statistics, 82(1), 38–47.

[391] Brown, Charles C., and Daniel S. Hamermesh. (2019). "Wages and Hours Laws: What Do We Know? What Can Be Done?" RSF: The Russell Sage Foundation Journal of the Social Sciences 5(5): 68–87. DOI: 10.7758/RSF.2019.5.5.04.

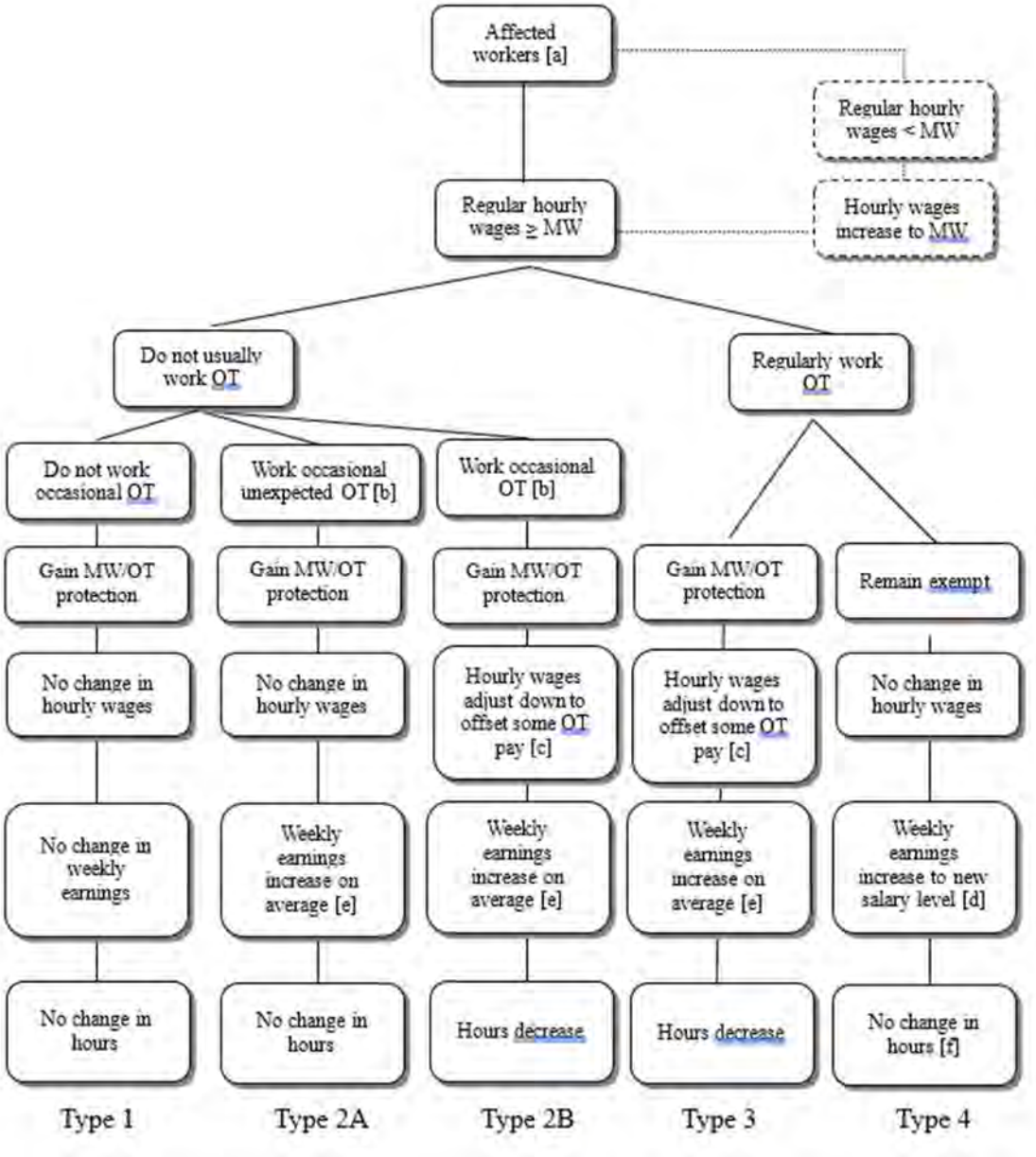
of workers between two time periods. However, some groups of workers are incorrectly defined, so the Department has not used these estimates.[392]

For Type 3 affected workers, and the 50 percent of Type 2 affected workers who worked expected overtime, the Department estimated adjusted total hours worked after making wage adjustments using the incomplete fixed-job model. To estimate adjusted hours worked, the Department set the percent change in total hours worked equal to the percent change in average wages multiplied by the wage elasticity of labor demand.[393] Figure 4 is a flow chart summarizing the four types of affected EAP workers. Also shown are the effects on exempt status, weekly earnings, and hours worked for each type of affected worker.

[392] For example, the authors defined the "non-exempt 1987-1989" group as workers earning above $223 but below $455 during this period. Because the salary level for the long test was $155 or $170 and was $250 for the short test, *see* section VII.A.1 (Table 1), some of these workers would be exempt.

[393] In this equation, the only unknown is adjusted total hours worked. Since adjusted total hours worked is in the denominator of the left side of the equation and is also in the numerator of the right side of the equation, solving for adjusted total hours worked requires solving a quadratic equation.

Figure 4: Flow Chart of the Rule's Effect on Earnings and Hours Worked



[a] Those who are exempt under the current EAP exemptions and will gain minimum wage and overtime protection or receive a raise to the increased salary or compensation level.
[b] The Department used two methods to identify occasional overtime workers. The first includes workers who report they usually work 40 hours or fewer per week (identified with variable PEHRUSL1 in CPS MORG), but in the reference week worked more than 40 hours (variable PEHRACT1 in CPS MORG). The second includes reclassifying some additional workers who usually work 40 hours or fewer per week, and in the reference week worked 40

hours or fewer, to match the proportion of workers measured in other data sets who work overtime at any point in the year.
[c] The amount wages are adjusted downwards depends on whether the fixed-job model or the fixed-wage model holds. The Department's primary method uses a combination of the two. Employers reduce the regular hourly wage rate somewhat in response to overtime pay requirements, but the wage is not reduced enough to keep total compensation constant.
[d] Based on hourly wage and weekly hours it is more cost efficient for the employer to increase the worker's weekly salary to the updated salary level than to pay overtime pay.
[e] On average, the Department's modeling of regulatory effects yields a result in which employees' overall weekly earnings will increase despite a small decrease in average hours worked. In some limited cases, employers might decrease employees' hours enough to cause those employees' weekly earnings to decrease.
[f] The Department assumed hours would not change; however, it is possible employers will increase these workers' hours in response to paying them a higher salary or to avoid paying overtime premiums to newly nonexempt coworkers.

(f) Estimated Number of and Effects on Affected EAP Workers

The Department estimated the rule will affect 4.3 million workers (Table 13), of which 3.0 million are Type 1 workers (68.7 percent of all affected EAP workers), 704,000 were estimated to be Type 2 workers (16.2 percent), 558,800 were Type 3 workers (12.9 percent), and 94,100 were estimated to be Type 4 workers (2.2 percent).

Table 13: Affected EAP Workers by Type (1,000s), Year 1

EAP Test	Total	No Overtime (T1)	Occasional Overtime (T2)	Regular Overtime	
				Newly Nonexempt (T3)	Remain Exempt (T4)
Standard salary level	4,044.6	2,778.7	691.3	486.7	87.9
HCE compensation level	292.9	201.4	13.2	72.1	6.2
Total	4,337.5	2,980.2	704.4	558.8	94.1

Note: Pooled CPS data for 2021 – 2023 adjusted to reflect 2023.
*Type 1: Workers who do not work overtime and gain overtime protection.
*Type 2: Workers who work occasional overtime and gain overtime protection.
*Type 3: Workers who work regular overtime and gain overtime protection.
*Type 4: Workers who work regular overtime and remain exempt (*i.e.*, earnings increase to the updated salary level).

The rule will affect some affected workers' hourly wages, hours, and weekly earnings. Predicted changes in implicit wage rates are outlined in Table 14, changes in hours in Table 15, and changes in weekly earnings in Table 16. How these will change depends on the type of worker, but on average the Department projects that weekly earnings will be unchanged or increase while hours worked will be unchanged or decrease.

Type 1 workers will have no change in wages, hours, or earnings due to the overtime pay provision because these workers do not work overtime.[394]

For Type 2A workers, the Department assumed employers will be unable to adjust the hours or regular rate of pay for these occasional overtime workers whose overtime is irregularly scheduled and unpredictable. These workers will receive a 50 percent premium on their regular hourly wage for each hour worked in excess of 40 hours per week, and so average weekly earnings would increase.[395]

For Type 3 workers and Type 2B workers (the 50 percent of Type 2 workers who regularly work occasional overtime, an estimated 969,100 workers), the Department used the incomplete fixed-job model to estimate changes in the regular rate of pay. These workers will see a decrease in their average regular hourly wage and a small decrease in hours. However, because

[394] It is possible that these workers may experience an increase in hours and weekly earnings because of transfers of hours from other newly nonexempt workers who do usually work overtime. Due to the high level of uncertainty in employers' responses regarding the transfer of hours, the Department did not have credible evidence to support an estimation of the number of hours transferred to other workers.

[395] Type 2 workers will not see increases in regular earnings to the new salary or compensation levels (as Type 4 workers do) even if their new earnings in this week exceed those new levels. This is because the estimated new earnings only reflect their earnings in those weeks when overtime is worked; their earnings in typical weeks when they do not work overtime do not exceed the salary or compensation level.

these workers will receive a 50 percent premium on their regular hourly wage for each hour worked in excess of 40 hours per week, their average weekly earnings will increase. The reduction in hours is relatively small and is due to a decrease in labor demand from the increase in the average hourly wage as predicted by the incomplete fixed-job model (Table 15).

Type 4 workers' implicit hourly rates of pay and weekly earnings will increase to meet the updated standard salary level or HCE annual compensation level. Type 4 workers' hours may increase to offset the additional earnings, but due to lack of data, the Department assumed hours would not change.

Table 14: Average Regular Rate of Pay by Type of Affected EAP Worker, Year 1

Time Period	Total	No Overtime (T1)	Occasional Overtime (T2)	Regular Overtime	
				Newly Nonexempt (T3)	Remain Exempt (T4)
Standard Salary Level					
Before rule	$24.26	$25.23	$24.61	$18.85	$20.62
After rule	$24.14	$25.23	$24.49	$17.90	$21.21
Change ($)	-$0.12	$0.00	-$0.12	-$0.95	$0.59
Change (%)	-0.5%	0.0%	-0.5%	-5.0%	2.9%
HCE Compensation Level					
Before rule	$57.97	$61.80	$59.78	$47.44	$52.13
After rule	$57.25	$61.80	$58.09	$44.74	$52.92
Change ($)	-$0.72	$0.00	-$1.69	-$2.70	$0.78
Change (%)	-1.2%	0.0%	-2.8%	-5.7%	1.5%

Note: Pooled CPS data for 2021 – 2023 adjusted to reflect 2023.
*Type 1: Workers who do not work overtime and gain overtime protection.
*Type 2: Workers who work occasional overtime and gain overtime protection.
*Type 3: Workers who work regular overtime and gain overtime protection.
*Type 4: Workers who work regular overtime and remain exempt (*i.e.*, earnings increase to the updated salary level).

Table 15: Average Weekly Hours by Type of Affected EAP Worker, Year 1

Time Period	Total			Regular OT

		No Overtime Worked (T1)	Occasional OT (T2)	Newly Nonexempt (T3)	Remain Exempt (T4)
Standard Salary Level [a]					
Before rule	41.0	38.9	40.7	50.4	54.7
After rule	40.9	38.9	40.7	50.0	54.7
Change (hours)	-0.1	0.0	0.0	-0.4	0.0
Change (%)	-0.1%	0.0%	-0.1%	-0.8%	0.0%
HCE Compensation Level [a]					
Before rule	42.7	39.4	44.7	50.5	56.4
After rule	42.6	39.4	44.6	50.2	56.4
Change (hours)	-0.1	0.0	-0.1	-0.3	0.0
Change (%)	-0.2%	0.0%	-0.3%	-0.6%	0.0%

Note: Pooled CPS data for 2021 – 2023 adjusted to reflect 2023.
[a] Usual hours for Types 1, 3, and 4 but actual hours for Type 2 workers identified in the CPS MORG.
*Type 1: Workers who do not work overtime and gain overtime protection.
*Type 2: Workers who work occasional overtime and gain overtime protection.
*Type 3: Workers who work regular overtime and gain overtime protection.
*Type 4: Workers who work regular overtime and remain exempt (*i.e.*, earnings increase to the updated salary level).

Table 16: Average Weekly Earnings by Type of Affected EAP Worker, Year 1

Time Period	Total	No Overtime (T1)	Occasional Overtime (T2)	Regular Overtime	
				Newly Nonexempt (T3)	Remain Exempt (T4)
Standard Salary Level [a]					
Before rule	$947.71	$936.67	$982.87	$934.77	$1,091.89
After rule	$953.67	$936.67	$994.47	$961.31	$1,128.00
Change ($)	$5.96	$0.00	$11.60	$26.53	$36.11
Change (%)	0.6%	0.0%	1.2%	2.8%	3.3%
HCE Compensation Level [a]					
Before rule	$2,397.46	$2,375.43	$2,683.04	$2,366.73	$2,864.13
After rule	$2,414.25	$2,375.43	$2,719.10	$2,424.68	$2,907.00
Change ($)	$16.79	$0.00	$36.06	$57.94	$42.87
Change (%)	0.7%	0.0%	1.3%	2.4%	1.5%

Note: Pooled CPS data for 2021 – 2023 adjusted to reflect 2023.
[a] The mean of the hourly wage multiplied by the mean of the hours does not necessarily equal the mean of the weekly earnings because the product of two averages is not necessarily equal to the average of the product.

*Type 1: Workers who do not work overtime and gain overtime protection.
*Type 2: Workers who work occasional overtime and gain overtime protection.
*Type 3: Workers who work regular overtime and gain overtime protection.
*Type 4: Workers who work regular overtime and remain exempt (*i.e.*, earnings increase to the updated salary level).

At the new standard salary level, the average weekly earnings of affected workers will increase $5.96 (0.6 percent), from $947.71 to $953.67. Multiplying the average change of $5.96 by the 4.0 million EAP workers affected by the combination of the initial update and the subsequent application of the new standard salary level and 52 weeks equals an increase in earnings of $1.3 billion in the first year. For workers affected by the change in the HCE compensation level, average weekly earnings will increase by $16.79. When multiplied by 292,900 affected workers and 52 weeks, the national increase will be $255.6 million in the first year. Thus, total Year 1 transfer payments attributable to this rule will equal $1.5 billion.

The Department is only aware of one paper that modeled the impacts of the 2019 rule's increases in the salary and compensation levels. Quach (2024)[396] used administrative payroll data from May 2008 to July 2021 to estimate the impacts of the rescinded 2016 rule and the 2019 rule on employment, earnings, and salary status.[397] The paper has not been published in a peer-reviewed journal and has significant limitations, including that its use of administrative payroll

[396] Quach, S. (2024). The Labor Market Effects of Expanding Overtime Coverage. https://raw.githubusercontent.com/SimonQuach1/Papers/main/Quach_OT.pdf?token=AH2DVMEDLJGBAWFAVXXUNMDAYGGDQ.
[397] The Department notes that the effective date of the 2019 final rule was in January 2020, so using data from this month may not fully capture the effects of the 2019 rule.

data from ADP means that the findings are not representative as ADP customers do not represent a random sample of the workplace.

In terms of its findings, concerning employment, the author found that expansions in overtime coverage actually had little effect on employment. He also found that average weekly earnings rose by about 1.4% for salaried workers, and found no evidence that firms reduced base pays in response to changes in the overtime threshold. Concerning salary status, he found that approximately 2.6% of affected workers are re-classified from salaried to hourly status. The Department has not adjusted its methodology in response to this paper given the concerns listed above.

Additionally, it can be informative to look at papers which predict the impact of rulemakings. For example, Rohwedder and Wenger (2015) analyzed the effects of increasing the standard salary level from the then baseline level of $455 per week.[398] They compared hourly and salaried workers in the CPS using quantile treatment effects. This methodology estimates the effect of a worker becoming nonexempt by comparing similar workers who are hourly and salaried. They found no statistically significant change in hours or wages on average. However, their point estimates, averaged across all affected workers, show small increases in earnings and decreases in hours, similar to the Department's analysis. For example, using a salary level of $750, they estimated weekly earnings may increase between $2 and $22 and weekly hours may decrease by approximately 0.4 hours.

[398] Rohwedder, S. and Wenger, J.B. (2015). The Fair Labor Standards Act: Worker Misclassification and the Hours and Earnings Effects of Expanded Coverage. RAND Labor and Population.

iv. Potential Transfers Not Quantified

This rule could lead to additional transfers that the Department is unable to quantify. For example, in response to this rule, some employers may decrease the hours of newly nonexempt workers who usually work overtime. These hours may be transferred to other workers, such as non-overtime workers and exempt workers who are not affected by the rule. Depending on how these hours are transferred, it could lead to either a reduction or increase in earnings for other workers. Employers may also offset increased labor costs by reducing bonuses or benefits instead of reducing base wages or hours worked. If this occurs, an employee's overall compensation may not be affected.

The rule could also reduce reliance on social assistance programs for some workers who may receive a transfer of income resulting from this rule. For low-income workers, this transfer could result in a reduced need for social assistance programs such as Medicaid, the Earned Income Tax Credit (EITC), the Supplemental Nutrition Assistance Program (SNAP), the Temporary Assistance for Needy Families (TANF) program, the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), and free or reduced-priced school meals. A worker earning the current salary level of $684 per week earns $35,568 annually, which is roughly equivalent to the Federal poverty level for a family of five and makes the family eligible for multiple social assistance programs.[399] Thus, transferring income to these workers could reduce eligibility for government social assistance programs. This could lead to an increase or a reduction in a family's total resources, depending on the relative size of the increase in earnings

[399] Department of Health and Human Services (2023). Federal Poverty Level. https://www.healthcare.gov/glossary/Federal-poverty-level-fpl/.

and the value of the decrease in assistance. Regardless, reduced eligibility for social assistance programs would reduce government expenditures at the Federal, State, and/or local level.

5. Benefits and Cost Savings

The Department expects that this rule could lead to multiple benefits, which were discussed qualitatively in the NPRM. These potential benefits and commenter feedback about them are addressed below.

The revised salary level will strengthen the overtime protection of salaried, white-collar employees who do not pass the standard duties test and who earn between the current salary standard salary level and the new standard salary level. These employees are nonexempt but, because they satisfy the current salary level threshold, employers must apply the duties test to determine their exemption status. At the new salary level, the number of white-collar salaried employees who earn between the current and the new salary levels and fail the duties test would decrease by 4.7 million. Because these nonexempt employees no longer meet the salary level, employers will be able to determine their exemption status based solely on the salary test. If any of these employers previously spent significant time evaluating the duties of these workers to determine exemption status, the change to determining exemption status based on the salary level could lead to some cost savings. Also, as many commenters observed, the new salary level will strengthen the right to overtime pay for nonexempt workers who earn between the current and new standard salary levels. *See, e.g.*, Coalition of State AGs; Coalition of Gender Justice and Civil Rights Organizations; Washington Dept. of Labor & Industries. Similarly, to the extent that some of these 4.7 million employees are currently misclassified as exempt, the new salary level

will make it more clear for workers and employers that such workers are not EAP exempt.[400] Thus, this aspect of the rule is responsive to commenter concerns that the current salary level is too low to prevent the misclassification of salaried employees who fail the duties test. *See e.g.*, AFSCME*;* EPI; NELP; Sanford Heisler Sharp.

Commenters disagreed over whether the proposed rule would improve or hinder the productivity of affected workers. Some commenters, such as the AFL-CIO, agreed with the analysis provided in the NPRM that this rulemaking could increase productivity "by reducing turnover, incentivizing workers to work harder, and increasing marginal productivity as fewer hours are worked." In contrast, a number of employer representatives asserted that the rule would hinder worker productivity. For example, PPWO asserted that affected workers who become nonexempt "will now need to account for their time in a way they have not had to previously, and in a way that their exempt co-workers do not." *See also, e.g.*, AFPI.

The Department continues to believe that the rule could potentially lead to increased worker productivity if workers receive an increase in compensation. Increased productivity could occur through numerous channels, such as employee retention and level of effort. A strand

[400] *See* Rohwedder, S. and Wenger, J.B. (2015). The Fair Labor Standards Act: Worker Misclassification and the Hours and Earnings Effects of Expanded Coverage. RAND Labor and Population. RAND conducted a survey to identify the number of workers who may have failed the standards duties test and yet are classified as EAP exempt. The survey, a special module to the American Life Panel, asked respondents: (1) their hours worked, (2) whether they are paid on an hourly or salary basis, (3) their typical earnings, (4) whether they perform certain job responsibilities that are treated as proxies for whether they would justify exempt status, and (5) whether they receive any overtime pay. Using these data, Rohwedder and Wenger found that "11.5 percent of salaried workers were classified as exempt by their employer although they did not meet the criteria for being so." This survey was conducted when the salary level was $455. The exact percentage may no longer be applicable, but the concern that in some instances the duties test may be misapplied remains.

of economic research, commonly referred to as "efficiency wage" theory, considers how an increase in compensation may be met with greater productivity.[401] Efficiency wages may elicit greater effort on the part of workers, making them more effective on the job.[402] Other research on increases in the minimum wage have demonstrated a positive relationship between increased compensation and worker productivity. For example, Kim and Jang (2019) showed that wage raises increase productivity for up to two years after the wage increase.[403] They found that in both full and limited-service restaurants productivity increased due to improved worker morale after a wage increase. Additionally, research demonstrates a correlation between increased earnings and reduced employee turnover.[404, 405] Reducing turnover, in turn, may increase productivity because longer-tenured employees have more firm-specific skills and knowledge and thus could be more productive and require less supervision and training.[406] Reduced turnover could also reduce firms' hiring and training costs. As a result, even though marginal

---

[401] Akerlof, G.A. (1982). Labor Contracts as Partial Gift Exchange. The Quarterly Journal of Economics, 97(4), 543–569.

[402] Another model of efficiency wages, which is less applicable here, is the adverse selection model in which higher wages raise the quality of the pool of applicants.

[403] Kim, H.S., & Jang, S. (2019). Minimum Wage Increase and Firm Productivity: Evidence from the Restaurant Industry. Tourism Management 71, 378–388. https://doi.org/10.1016/j.tourman.2018.10.029.

[404] Howes, Candace. (2005). Living Wages and Retention of Homecare Workers in San Francisco. *Industrial Relations,* 44(1), 139–163. Dube, A., Lester, T.W., & Reich, M.. (2014). Minimum Wage Shocks, Employment Flows and Labor Market Frictions. IRLE Working Paper #149–13.

[405] This literature tends to focus on changes in earnings for a specific sector or subset of the labor force. The impact on turnover when earnings increase across sectors (as would be the case with this regulation) may be smaller.

[406] Argote, L., Insko, C. A., Yovetich, N., & Romero, A. A. (1995). Group Learning Curves: The Effects of Turnover and Task Complexity on Group Performance. *Journal of Applied Social Psychology,* 25(6), 512–529. Shaw, J. D. (2011). Turnover Rates and Organizational Performance: Review, Critique, and Research Agenda. *Organizational Psychology Review,* 1(3), 187–213.

labor costs rise, they may rise by less than the amount of the wage change because the higher wages may be offset by increased productivity and reduced hiring costs for firms.

This rulemaking could also result in an increase in personal time for some affected workers. Worker advocacy organizations and individual commenters asserted that employees would generally enjoy more personal time as a consequence of the rule. For example, SEIU commented that "[w]hen workers are exempted from overtime pay protections, it disincentivizes employers from being efficient with [employees'] time." Due to the increase in marginal cost for overtime hours for newly overtime-eligible workers, employers could demand fewer hours from some of the workers affected by this rulemaking. If these workers' pay remains the same, they could benefit from increased personal time and improved work-life balance. Empirical evidence shows that workers in the United States typically work more than workers in other comparatively wealthy countries.[407] Workers in executive, administrative, and professional occupations tend to work longer hours.[408] They also have the highest percentage of workers who would prefer to work fewer hours compared to other occupational categories.[409] Therefore, the Department believes that this rule may result in reduced time spent working overtime for a group of workers, some of whom may prefer such an outcome.

---

[407] For more information, see OECD series, average annual hours actually worked per worker, available at: https://stats.oecd.org/index.aspx?DataSetCode=ANHRS.

[408] Boushey, H. and Ansel, B. (2016). Overworked America, The economic causes and consequences of long work hours. Washington Center for Equitable Growth. https://equitablegrowth.org/research-paper/overworked-america/?longform=true.

[409] Hamermesh, D.S., Kawaguchi, D., Lee, J. (2014). Does Labor Legislation Benefit Workers? Well-Being after an Hours Reduction. IZA DP No. 8077.
Golden, L., & Gebreselassie, T. (2007). Overemployment Mismatches: The Preference for Fewer Work Hours. *Monthly Labor Review,* 130(4), 18–37.
Hamermesh, D.S. (2014). Not Enough Time? *American Economist,* 59(2).

6. Sensitivity Analysis of Transfer Payments

Because the Department cannot predict employers' precise reactions to the rule, the Department calculated bounds on the size of the estimated transfers from employers to workers, relative to the primary estimates in this RIA. For the upper bound, the Department assumed that the full overtime premium model is more likely to occur than in the primary model. For the lower bound, the Department assumed that the complete fixed-job model is more likely to occur than in the primary model. Based on these assumptions, estimated transfers may range from $631.1 million to $2.9 billion, with the primary estimate equal to $1.5 billion.

For a reasonable upper bound on transfer payments, the Department assumed that all occasional overtime workers and half of regular overtime workers would receive the full overtime premium (*i.e.*, such workers will work the same number of hours but be paid 1.5 times their implicit initial hourly wage for all overtime hours) (Table 17). The full overtime premium model is a special case of the fixed-wage model where there is no change in hours. For the other half of regular overtime workers, the Department assumed in the upper-bound method that they would have their implicit hourly wage adjusted as predicted by the incomplete fixed-job model (wage rates fall and hours are reduced but total earnings continue to increase, as in the primary method). In the primary model, the Department assumed that only 50 percent of occasional overtime workers and no regular overtime workers would receive the full overtime premium.

The plausible lower bound on transfer payments also depends on whether employees work regular overtime or occasional overtime. For those who regularly work overtime hours and half of those who work occasional overtime, the Department assumed the employees' wages

would fully adjust as predicted by the fixed-job model.[410] For the other half of employees with occasional overtime hours, the lower bound assumes they would be paid one and one-half times their implicit hourly wage for overtime hours worked (full overtime premium).

Table 17: Summary of the Assumptions Used to Calculate the Lower Estimate, Primary Estimate, and Upper Estimate of Transfers

Lower Transfer Estimate	Primary Estimate	Upper Transfer Estimate
Occasional Overtime Workers (Type 2)		
50% fixed-job model 50% full overtime premium	50% incomplete fixed-job model 50% full overtime premium	100% full overtime premium
Regular Overtime Workers (Type 3)		
100% fixed-job model	100% incomplete fixed-job model	50% incomplete fixed-job model 50% full overtime premium

* Full overtime premium model: Regular rate of pay equals the implicit hourly wage prior to the regulation (with no adjustments); workers are paid 1.5 times this base wage for the same number of overtime hours worked prior to the regulation.
* Fixed-job model: Base wages are set at the higher of: (1) a rate such that total earnings and hours remain the same before and after the regulation; thus the base wage falls, and workers are paid 1.5 times the new base wage for overtime hours (the fixed-job model) or (2) the minimum wage.
* Incomplete fixed-job model: Regular rates of pay are partially adjusted to the wage implied by the fixed-job model.

7. Effects by Regions and Industries

This section compares the number of affected workers, costs, and transfers across regions and industries. Although impacts will be more pronounced in some regions or industries, the Department has concluded that in no region or industry are the costs overly burdensome. The proportion of total costs and transfers in each region will be fairly consistent with the proportion

[410] The straight-time wage adjusts to a level that keeps weekly earnings constant when overtime hours are paid at 1.5 times the straight-time wage. In cases where adjusting the straight-time wage results in a wage less than the minimum wage, the straight-time wage is set to the minimum wage.

of total workers in each region. Affected workers are overrepresented in some industries, but costs and transfers will still be manageable as a share of payroll and of total revenue (*See* Table 21 for regions and Table 24 for industries).

The Department also compared costs and transfers relative to total payrolls and revenues. This provides a common method of assessing the relative effects of the rule on different regions or industries, and the magnitude of adjustments the rule may require on the part of enterprises in each region or industry. The relative costs and transfers expressed as a percentage of payroll are particularly useful measures of the relative size of adjustment faced by organizations in a region or industry because they benchmark against the cost category directly associated with the labor force. Average estimated costs and transfers from this rule are very small relative to current payroll or current revenue—less than a tenth of a percent of payroll and of revenue in each region and in each industry.

Salaries vary across the U.S. geographically. To ensure the new standard salary level would not be too high in any region of the country, the Department has used only wages in the lowest-wage region, the South[411], to set the salary level. However, because wages are lower in the South and the Midwest[412] than the Northeast[413] and the West[414], impacts may be larger in

[411] The South Census region is comprised of the following states: Alabama, Arkansas, Delaware, District of Columbia, Florida, Georgia, Kentucky, Louisiana, Maryland, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, and West Virginia.
[412] The Midwest Census region is comprised of the following states: Kansas, Illinois, Indiana, Iowa, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, South Dakota, and Wisconsin.
[413] The Northeast Census region is comprised of the following states: Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont.
[414] The West Census region is comprised of the following states: Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, Nevada, New Mexico, Oregon, Utah, Washington, Wyoming.

these two lower-wage regions. This section considers impacts across the four Census regions to ensure the impacts in the lower-wage regions would be manageable. The South has by far the most affected workers (1.9 million), though it also has the most workers of any Census region (Table 18). As a share of potentially affected workers in the region, the South will have somewhat more affected workers relative to other regions (17.9 percent are affected compared with 11.0 to 15.4 percent in other regions). However, as a share of all workers in the region, the South will not be particularly affected relative to other regions (3.5 percent are affected compared with 2.3 to 3.0 percent in other regions).

Table 18: Potentially Affected and Affected Workers, by Region, Year 1

Region	Workers Subject to FLSA (Millions)	Potentially Affected Workers (Millions) [a]	Affected Workers (Millions) [b]	Affected Workers as a Precent of Potentially Affected Workers	Affected Workers as a Percent of All Workers
All	143.7	29.7	4.3	14.6%	3.0%
Northeast	25.5	6.0	0.7	12.3%	2.9%
Midwest	31.1	6.1	0.9	15.4%	3.0%
South	53.2	10.5	1.9	17.9%	3.5%
West	33.8	7.2	0.8	11.0%	2.3%

Note: Pooled CPS data for 2021-2023 adjusted to reflect 2023.
[a] EAP exempt workers who are white-collar, salaried, not eligible for another (non-EAP) overtime exemption, and not in a named occupation.
[b] Currently EAP exempt workers who will be entitled to overtime protection under the updated earnings levels or whose weekly earnings will increase to the new earnings levels to remain exempt.

Total transfers in the first year were estimated to be $1.5 billion (Table 19). As expected, the transfers in the South will be the largest portion because the largest number of affected workers would be in the South. However, transfers per affected worker will be less in the South

than in other Census regions. Annual transfers per affected worker will be $291 in the South, and between $346 and $462 in other regions.

Table 19: Annual Transfers by Region, Year 1

Region	Total Annual Change in Earnings (Millions)	Annual Transfer Per Affected Worker	Annual Transfers per Entity	Percent of Total Transfers by Region
All	$1,509.2	$348	$183	100.0%
Northeast	$256.4	$346	$172	17.0%
Midwest	$343.6	$368	$202	22.8%
South	$543.6	$291	$181	36.0%
West	$365.6	$462	$178	24.2%

Note: Pooled CPS data for 2021-2023 adjusted to reflect 2023.

Table 20: Annual Costs by Region, Year 1

Region	Total Direct Costs (Millions)	Total Direct Costs per Entity	Percent of Total Direct Costs by Region
All	$1,436.2	$174	100.0%
Northeast	$240.7	$162	16.8%
Midwest	$323.5	$190	22.5%
South	$581.7	$194	40.5%
West	$1,436.2	$174	100.0%

Note: Pooled CPS data for 2021-2023 adjusted to reflect 2023.

Direct employer costs are composed of regulatory familiarization costs, adjustment costs, and managerial costs. The Department estimates that total direct employer costs will be the highest in the South ($581.7 million) and lowest in the Northeast ($240.7 million). Transfers and direct employer costs in each region, as a percentage of the total transfers and direct costs, would range from 16.9 percent in the Northeast to 38.2 percent in the South. These proportions are almost the same as the proportions of the total workforce in each region: 17.8 percent in the

Northeast and 37.0 percent in the South. Costs and transfers per establishment would be slightly higher in the Midwest ($392) than on average, but still small (Table 21).

Another way to compare the relative effects of this rule by region is to consider the transfers and costs as a proportion of payroll and revenues (Table 21).[415] Nationally, employer costs and transfers will be approximately 0.031 percent of payroll. By region, direct employer costs and transfers as a percent of payroll will be approximately the same (between 0.025 and 0.036 percent of payroll). Employer costs and transfers as a percent of revenue will be 0.006 percent nationally and range between 0.005 and 0.006 percent in each region.

Table 21: Annual Transfers and Costs as Percent of Payroll and of Revenue by Region, Year 1

Region	Transfers and Costs per Entity	Payroll (Billions) [a]	Revenue (Billions) [a]	Costs and Transfers	
				As Percent of Payroll	As Percent of Revenue
All	$358	$9,471	$50,655	0.031%	0.006%
Northeast	$334	$2,010	$9,902	0.025%	0.005%
Midwest	$392	$1,947	$11,276	0.034%	0.006%
South	$375	$3,137	$17,812	0.036%	0.006%
West	$320	$2,377	$11,666	0.028%	0.006%

[a] Payroll and revenue data exclude the Federal Government.

Sources: Costs and transfers based on pooled CPS data for 2021-2023 adjusted to reflect 2023. Private sector payroll and revenue data from 2017 SUSB. State and local payroll and revenue data from State and Local Government Finances 2020. Inflated to $2023 using GDP deflator.

Impacts may be more pronounced in some industries. In particular, lower-wage industries where more workers may earn between $684 and the new salary level may be impacted more. Additionally, industries where EAP workers are more prevalent may experience larger impacts.

[415] The Department uses 2017 data here because although payroll data are available for more recent years, the most recent revenue data are for 2017.

To gauge the effect of the rule on industries, the Department estimated affected workers, costs, and transfers for the 13 major industry groups. The Department also compared estimates of combined costs and transfers as a percent of payroll and revenue across industries.

Table 22 presents the number of affected workers by industry. The industry with the most affected workers is professional and business services (827,400). The industry with the largest share of workers affected is financial activities (5.7 percent). This is because the financial activities industry is heavily composed of salaried white-collar workers. As a share of potentially affected workers, the industry with the highest share affected is leisure and hospitality (24.3 percent), followed by agriculture, forestry, fishing, & hunting (22.8 percent).

Table 22: Potentially Affected and Affected Workers, by Industry, Year 1

Industry	Workers Subject to FLSA (1,000s)	Potentially Affected Workers (1,000s) [a]	Affected Workers (1,000s) [b]	Affected Workers as a Percent of Potentially Affected Workers	Affected Workers as a Percent of All Workers
All	143,677.6	29,746.7	4,337.5	14.6%	3.0%
Agriculture, forestry, fishing, & hunting	1,312.6	58.5	13.3	22.8%	1.0%
Mining	587.4	156.6	18.5	11.8%	3.1%
Construction	9,305.3	1,266.9	184.6	14.6%	2.0%
Manufacturing	15,521.5	4,062.0	350.6	8.6%	2.3%
Wholesale trade	3,164.1	852.5	112.3	13.2%	3.5%
Retail trade	15,649.0	1,966.1	377.4	19.2%	2.4%
Transportation & utilities	8,902.5	1,072.9	152.9	14.3%	1.7%
Information	2,711.7	1,082.4	132.4	12.2%	4.9%
Financial activities	9,925.6	4,349.8	564.5	13.0%	5.7%
Professional & business services	17,462.0	7,126.2	827.4	11.6%	4.7%

Education	14,294.5	1,202.7	244.1	20.3%	1.7%
Healthcare & social services	21,025.7	3,745.2	740.2	19.8%	3.5%
Leisure & hospitality	12,529.3	940.3	228.5	24.3%	1.8%
Other services	5,532.2	761.7	163.5	21.5%	3.0%
Public administration	5,754.2	1,103.0	227.2	20.6%	3.9%

Note: Pooled CPS data for 2021-2023 adjusted to reflect 2023.
[a] EAP exempt workers who are white-collar, salaried, not eligible for another (non-EAP) overtime exemption, and not in a named occupation.
[b] Currently EAP exempt workers who will be entitled to overtime protection under the updated earnings levels or whose weekly earnings will increase to the new earnings levels to remain exempt.

Both transfers and costs will be the largest in the professional and business services industry because this industry is large and heavily composed of salaried white-collar workers (Table 23). Combined, in Year 1, these total $564.7 million and represent 19.2 percent of nationwide transfers and costs. Transfers and costs are also large in the healthcare and social services industry, at least partially due to the large size of this industry. However, transfers per affected worker will be relatively low in this industry, $229 in the first year compared with $348 nationally. A third industry with relatively large total transfers and costs is the retail trade industry.

Table 23: Annual Transfers and Costs by Industry, Year 1

Industry	Transfers (Millions)	Transfer Per Affected Worker	Direct Costs (Millions) [a]	Transfers and Costs (Millions)	Percent of Total Transfers and Costs by Industry
All	$1,509.2	$348	$1,435.7	$2,944.9	100.0%
Agriculture, forestry, fishing, & hunting	$2.4	$178	$4.3	$6.6	0.2%

Mining	$5.2	$284	$4.5	$9.8	0.3%
Construction	$63.5	$344	$87.5	$151.1	5.1%
Manufacturing	$142.9	$408	$101.4	$244.3	8.3%
Wholesale trade	$52.2	$465	$50.7	$102.9	3.5%
Retail trade	$192.8	$511	$166.9	$359.7	12.2%
Transportation & utilities	$59.8	$391	$50.7	$110.5	3.8%
Information	$49.7	$375	$35.8	$85.5	2.9%
Financial activities	$184.2	$326	$168.0	$352.2	12.0%
Professional & business services	$303.9	$367	$260.8	$564.7	19.2%
Education	$48.3	$198	$53.4	$101.6	3.5%
Healthcare & social services	$169.6	$229	$197.4	$367.0	12.5%
Leisure & hospitality	$138.6	$607	$121.3	$259.9	8.8%
Other services	$48.1	$294	$82.7	$130.8	4.4%
Public administration	$47.9	$211	$50.3	$98.2	3.3%

Sources: Pooled CPS data for 2021-2023 adjusted to reflect 2023.

[a] Regulatory familiarization costs exclude 10,440 establishments whose industry is "not classified."

To measure the impact on businesses, a comparison of transfers and costs to payroll, revenue, or profit is more helpful than looking at the absolute size of transfers and costs per industry. As a percent of payroll, transfers and costs would be highest in agriculture, forestry, fishing, and hunting; retail trade; leisure and hospitality; and education (Table 24). However, the magnitude of the relative shares will be small, representing less than 0.1 percent of payroll costs in all industries. The Department's estimates of transfers and costs as a percent of revenue by industry also indicated a very small effect of less than 0.03 percent of revenues in any industry. The industries with the largest transfers and costs as a percent of revenue will be education; leisure and hospitality; and professional and business services. Table 24 illustrates that the

differences in costs and transfers relative to revenues will be quite small across industry groupings.

The overall magnitude of costs and transfers as a percentage of profits represents less than 1.0 percent of overall profits in each industry.[416, 417] By industry, the value of total costs and transfers as a percent of profits ranges from a low of 0.02 percent (wholesale trade) to a high of 0.62 percent (agriculture, forestry, fishing, and hunting). Benchmarking against profits is potentially helpful in the sense that it provides a measure of the rule's effect against returns to investment. However, this metric must be interpreted carefully as it does not account for differences across industries in risk-adjusted rates of return which are not readily available for this analysis. The ratio of costs and transfers to profits also does not reflect differences in the firm-level adjustment to profit impacts reflecting cross-industry variation in market structure.[418]

Table 24: Annual Transfers, Total Costs, and Transfers and Costs as Percent of Payroll, Revenue, and Profit by Industry, Year 1

Industry	Costs and Transfers per Entity	Payroll (Billions) [a]	Revenue (Billions) [a]	Costs and Transfers As Percent of:		
				Payroll [a]	Revenue [a]	Profit [a]

[416] Internal Revenue Service. (2023). SOI Tax Stats - Corporation Income Tax Returns Complete Report (Publication 16). Available at: https://www.irs.gov/statistics/soi-tax-stats-corporation-income-tax-returns-complete-report-publication-16.

[417] Table 1 of the IRS report provides total receipts, net income, and deficits by industry. For each industry, the Department calculated the profit-to-revenue ratio as net income (column (7)) less any deficit (column (8)) divided by total receipts (column (3)). Profits were then calculated as revenues multiplied by profit-to-revenue ratios. Profits could not be used directly because they are limited to only active corporations.

[418] In particular, a basic model of competitive product markets would predict that highly competitive industries with lower rates of return would adjust to increases in the marginal cost of labor arising from the rule through an overall, industry-level increase in prices and a reduction in quantity demanded based on the relative elasticities of supply and demand. Alternatively, more concentrated markets with higher rates of return would be more likely to adjust through some combination of price increases and profit reductions based on elasticities as well as interfirm pricing responses.

All	$357.9	$9,470.5	$50,655.8	0.031%	0.006%	0.060%
Agriculture, forestry, fishing, & hunting	$284.9	$8.6	$42.5	0.077%	0.016%	0.617%
Mining	$424.2	$61.9	$493.6	0.016%	0.002%	[b]
Construction	$193.6	$488.1	$2,430.8	0.031%	0.006%	0.107%
Manufacturing	$863.3	$834.6	$6,755.6	0.029%	0.004%	0.034%
Wholesale trade	$263.3	$531.0	$10,656.1	0.019%	0.001%	0.022%
Retail trade	$346.9	$543.4	$5,980.4	0.066%	0.006%	0.186%
Transportation & utilities	$369.5	$382.2	$1,781.5	0.029%	0.006%	0.329%
Information	$527.6	$436.3	$1,927.0	0.020%	0.004%	0.027%
Financial activities	$376.7	$928.5	$6,091.6	0.038%	0.006%	0.027%
Professional & business services	$386.2	$1,956.4	$3,575.3	0.029%	0.016%	0.141%
Education	$911.2	$174.9	$501.7	0.058%	0.020%	0.316%
Healthcare & social services	$387.4	$1,217.5	$3,093.5	0.030%	0.012%	0.159%
Leisure & hospitality	$288.1	$438.6	$1,480.7	0.059%	0.018%	0.214%
Other services	$167.3	$221.2	$881.1	0.059%	0.015%	0.220%
Public administration	$1,089.8	$1,247.4	$4,964.4	0.008%	0.002%	[c]

Sources: Pooled CPS data for 2021-2023 adjusted to reflect 2023. Private sector payroll and revenue data from 2017 SUSB. State and local payroll and revenue data from State and Local Government Finances 2020 are used for the Public Administration industry. Profit-to-revenue data from the Internal Revenue Service 2019. Inflated to $2023 using GDP deflator.

[a] Payroll and revenue data exclude the Federal Government. Profit-to-revenue data limited to active corporations. Regulatory familiarization costs, payrolls, and revenues exclude 10,440 establishments whose industry is "not classified." Because transfer payments include all workers, the estimates of costs and transfers as a share of payroll or revenue are slightly overestimated.

[b] Profits were negative in this industry in this year.

[c] Profit is not applicable for public administration.

8. Regulatory Alternatives

The Department considered a range of alternatives before selecting its methods for setting the standard salary level and the HCE compensation level. As seen in Table 25, the Department has calculated the salary/compensation levels, the number of affected workers, and the associated costs and transfers for these alternative levels.

The Department is increasing the standard salary level using earnings for the 35th percentile of full-time salaried workers in the South Census Region, $1,128 per week. The alternative methods considered for setting the standard salary level are:

- Alternative 1: 2004/2019 method – $844 per week – 20th percentile of earnings of nonhourly full-time workers in the South Census region and/or in the retail industry nationally.
- Alternative 2: Kantor long test method – $942 per week – 10th percentile of earnings of likely exempt workers.
- Alternative 3: 2016 method – $1,196 per week – 40th percentile of earnings of nonhourly full-time workers in the South Census region
- Alternative 4: Kantor short test method – $1,404 per week – Kantor long test level multiplied by 149 percent (the historical average relationship between the long and short test levels).

The Department considered using the 2004 methodology (the 20th percentile of full-time salaried white-collar workers in the lowest-wage Census region (currently the South) and/or in retail nationally), which is currently $844 per week ($43,888 per year). This is also the

methodology that the Department used in the 2019 rule.[419] However, the salary level produced by the 2004 methodology is below the current equivalent long test salary level ($942 per week), which the Department considers to be a key parameter for determining an appropriate salary level.

The Department also considered setting the standard salary level at the long test level ($942 per week or $48,984 per year). Doing so would ensure the initial screening function of the salary level by restoring overtime protections to those employees who were consistently excluded from the EAP exemption under each iteration of the regulations prior to 2019, either by the long test salary level itself, or under the 2004 rule salary level, which was set equivalent to the long test salary level.[420] However, as explained above, setting the standard salary level at the long test level would not address the impact of the change from a two-test to a one-test system.

The Department also considered setting the standard salary level at the 40th earnings percentile of salaried white-collar workers in the lowest-wage Census Region (currently the South) ($1,196 per week or $62,192 per year). However, the Department is concerned that this approach could be seen by courts as making salary level determinative of exemption status for too large a portion of employees, as this salary level would make the salary paid by the employer determinative of exemption status for more than half (55 percent) of white-collar employees who earn between the long and short test salary levels. The Department is also concerned that this approach would generate the same concerns that led to the district court decision invalidating the 2016 rule (which adopted the same methodology).

[419] 84 FR 51260.
[420] *See* section V.B.4.ii.

Finally, the Department considered setting the standard salary level at the current equivalent of the short test salary level ($1,404 per week or $73,008 per year). This would ensure that all employees who earn between the long and short test salary levels and perform substantial amounts of nonexempt work would be entitled to overtime compensation. However, by making exemption status for all employees who earn between the long and short test levels depend on the salary paid by the employer, this approach would prevent employers from being able to use the EAP exemption for employees earning between these salary levels who do not perform substantial amounts of nonexempt work and thus were historically exempt under the long test.

As described above, the Department is setting the HCE compensation level using earnings for the 85th percentile of all full-time salaried workers nationally, $151,164 per year. The Department also evaluated the following alternative methods to set the HCE compensation levels:

- HCE alternative 1: 2019 method[421] – $132,964 annually – 80th percentile of earnings of nonhourly full-time workers nationally.
- HCE alternative 2: 2016 method[422] – $179,972 annually – 90th percentile of earnings of nonhourly full-time workers nationally.

The Department believes that HCE alternative 1 does not produce a threshold high enough to reserve the HCE test for employees who would "almost invariably pass the standard duties test." The Department also considered setting the HCE threshold at the 90th percentile; however, the Department is concerned that the resulting level ($179,972) would restrict the use

[421] *See* 84 FR 51250.
[422] *See* 81 FR 32429.

of the HCE exemption for employers in low-wage regions and industries. The Department believes its proposal to adjust the HCE total annual compensation threshold to reflect the 85th percentile of earnings of nonhourly full-time workers nationally strikes the appropriate balance and ensures that the HCE test continues to serve its intended function as a streamlined alternative for employees who are highly likely to pass the standard duties test.

Table 25: Updated Standard Salary and HCE Compensation Levels and Alternatives, Affected EAP Workers, Costs, and Transfers, Year 1

Alternative	Salary Level	Affected EAP Workers (1,000s)	Year 1 Effects (Millions)	
			Adj. & Managerial Costs	Transfers
Standard Salary Level (Weekly)				
Alt. #1: 2004/2019 method [a]	$844	959	$202.3	$204.3
Alt #2: Kantor long test [b]	$942	1,806	$385.9	$432.0
Final rule: 35th pct South [c]	$1,128	4,045	$905.4	$1,253.6
Alt. #3: 2016 method - 40th pct South [d]	$1,196	4,993	$1,116.1	$1,642.9
Alt. #4: Kantor short test [e]	$1,404	7,961	$1,860.0	$3,035.1
HCE Compensation Level (Annually)				
HCE alt. #1: 2019 method - 80th pct [f]	$132,964	223	$58.7	$164.5
Final rule: 85th pct [g]	$151,164	293	$79.2	$255.6
HCE alt. #2: 2016 method - 90th pct [h]	$179,972	340	$97.6	$359.2

Note: Regulatory familiarization costs are excluded because they do not vary based on the selected values of the salary levels. Additionally, they cannot be disaggregated by exemption type (i.e., standard versus HCE). The Department did not receive comments on how to refine familiarization cost estimates in a manner that distinguishes among regulatory alternatives.
[a] 20th percentile earnings of nonhourly full-time workers in the South Census region or retail industry (excludes workers not subject to the FLSA, not subject to the salary level test, and in agriculture or transportation). Pooled CPS data for 2021-2023 adjusted to reflect 2023.
[b] 10th percentile earnings of likely exempt workers. Pooled CPS data for 2021-2023 adjusted to reflect 2023.
[c] 35th percentile of earnings of nonhourly full-time workers in the South Census region. CPS 2023. Available at https://www.bls.gov/cps/research/nonhourly/earnings-nonhourly-workers.htm.

[d] 40th percentile of earnings of nonhourly full-time workers in the South Census region. CPS 2023 data. Available at https://www.bls.gov/cps/research/nonhourly/earnings-nonhourly-workers.htm.
[e] Kantor short test is set as the long test level multiplied by 149 percent. This is the historical average relationship between the two levels.
[f] 80th percentile of earnings of nonhourly full-time workers nationally (excludes workers not subject to the FLSA, not subject to the salary level test, and in agriculture or transportation). Pooled CPS data for 2021-2023 adjusted to reflect 2023.
[g] 85th percentile of earnings of nonhourly full-time workers nationally. CPS 2023 data. Available at https://www.bls.gov/cps/research/nonhourly/earnings-nonhourly-workers.htm.

[h] 90th percentile of earnings of nonhourly full-time workers nationally CPS 2023 data. Available at https://www.bls.gov/cps/research/nonhourly/earnings-nonhourly-workers.htm

9. Triennial Updates to the Standard Salary and Annual Compensation Thresholds

Between updates to the standard salary and HCE compensation levels, nominal wages typically increase, resulting in an increase in the number of workers qualifying for the EAP exemption, even if there has been no change in their real earnings. Thus, workers whom Congress intended to be covered by the minimum wage and overtime pay provisions of the FLSA may lose those protections. The mechanism the Department established in this rulemaking for updating the salary and compensation levels allows these thresholds to keep pace with changes in earnings and continue to serve as an effective dividing line between potentially exempt and nonexempt workers. Furthermore, the updating mechanism will provide employers more certainty in knowing that these levels will change by smaller amounts on a regular basis, rather than the more disruptive increases caused by much larger changes after longer, uncertain increments of time. This will allow firms to better predict short- and long-term costs and employment needs. In addition to the changes being made to the standard salary level and HCE compensation threshold, the Department is including in this rule a mechanism for updating the

salary and compensation levels initially on July 1, 2024 and every 3 years thereafter to reflect current earnings.

i. Initial Update

As discussed in section IV, the new standard salary level and HCE total annual compensation threshold methodologies do not become applicable until approximately 8 months after publication of this final rule. Therefore, the initial update on July 1, 2024 will use the methodologies in place at the time of the update (i.e., the 2019 rule methodologies), which results in a $844 per week standard salary level and a $132,964 HCE total annual compensation threshold. Consistent with the 2019 rule, the Department used pooled CPS data for the most recent 3 years (2021, 2022, 2023), adjusted to reflect 2023, for the initial updates to the standard salary and annual compensation thresholds.

As previously discussed, the Department's affected worker, cost, and transfer estimates for Year 1 have accounted for the initial update and the new standard salary and annual compensation thresholds that become applicable 6 months after the initial update. Just looking at the initial update, the Department estimated the initial update to the standard salary level will affect workers who earn between $684 and $844 per week. The Department estimates that this update will result in 959,000 affected workers. Of these affected workers, 68.7 percent of them do not work overtime. The Department estimated the Year 1 adjustment and managerial costs for just this update would be $202.3 million and transfer payments would be $204.3 million. For the initial update to the HCE total annual compensation threshold, the Department estimated that just the update would result in 223,000 affected workers, $58.7 million in adjustment and managerial costs, and $164.5 million in transfer payments in Year 1.

ii. Future Updates

The Department is establishing future updates to the standard salary level and HCE total annual compensation threshold with current earnings data beginning 3 years after the date of the initial update, and every 3 years thereafter, using the methodologies in place at the time of the updates. For purposes of this analysis, the Department assumes that the future triennial updates to the standard salary level will be based on the same methodology that the Department used to set the new standard salary level in this rule: the 35th percentile of weekly earnings of full-time salaried workers in the lowest-wage Census Region (currently the South). Likewise, the Department assumes that future triennial updates to the HCE total annual compensation level will be based on the same methodology the Department used to set this earnings threshold in this rulemaking: the annualized weekly earnings of 85th percentile of full-time salaried workers nationally.

As previously discussed, future triennial updates will set the earnings thresholds using the most recent available 4 quarters of CPS data preceding the Department's notice with the updated thresholds. To estimate future thresholds in years when the salary and compensation levels will be updated, the Department used the historic geometric growth rate between 2012 and 2022 in (1) the 35th earnings percentile of full-time salaried workers in the South for the standard salary level and (2) the annualized weekly earnings of the 85th percentile of full-time salaried workers nationally for the HCE compensation level. For example, between 2012 and 2022, the annual growth rate in the 35th percentile of full-time salaried workers in the South has increased by 3.17 percent. To estimate the first future triennial update salary level of $1,239, the Department multiplied $1,128 by 1.0317 to the power of three. Figure 5 shows the projected future triennial

update levels for the first 10 years. Note that these projections are illustrative estimates based on past wage growth; the actual level at the time of the update will depend on the wage growth that occurs between now and the update date. Figure 6 shows the standard salary levels in both nominal and 2023 dollars.

Figure 5: Projected Future Salary and Compensation Levels, Nominal Dollars

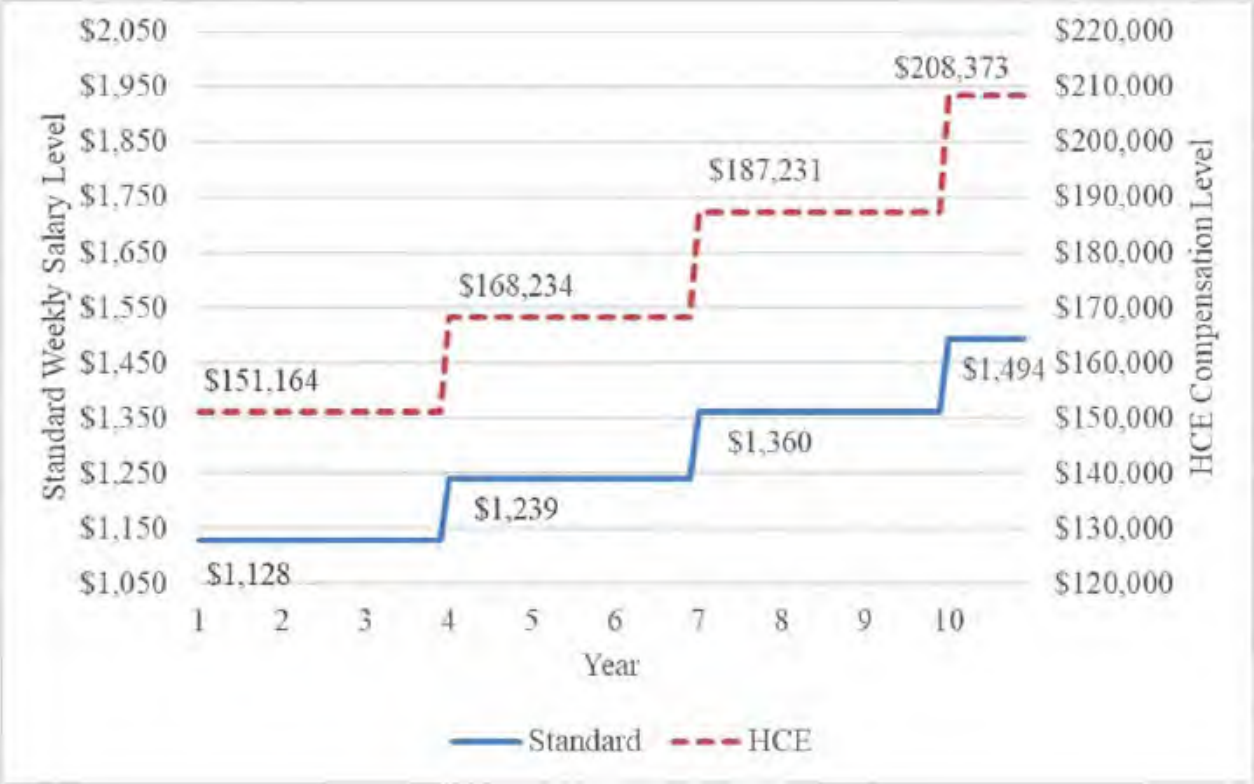
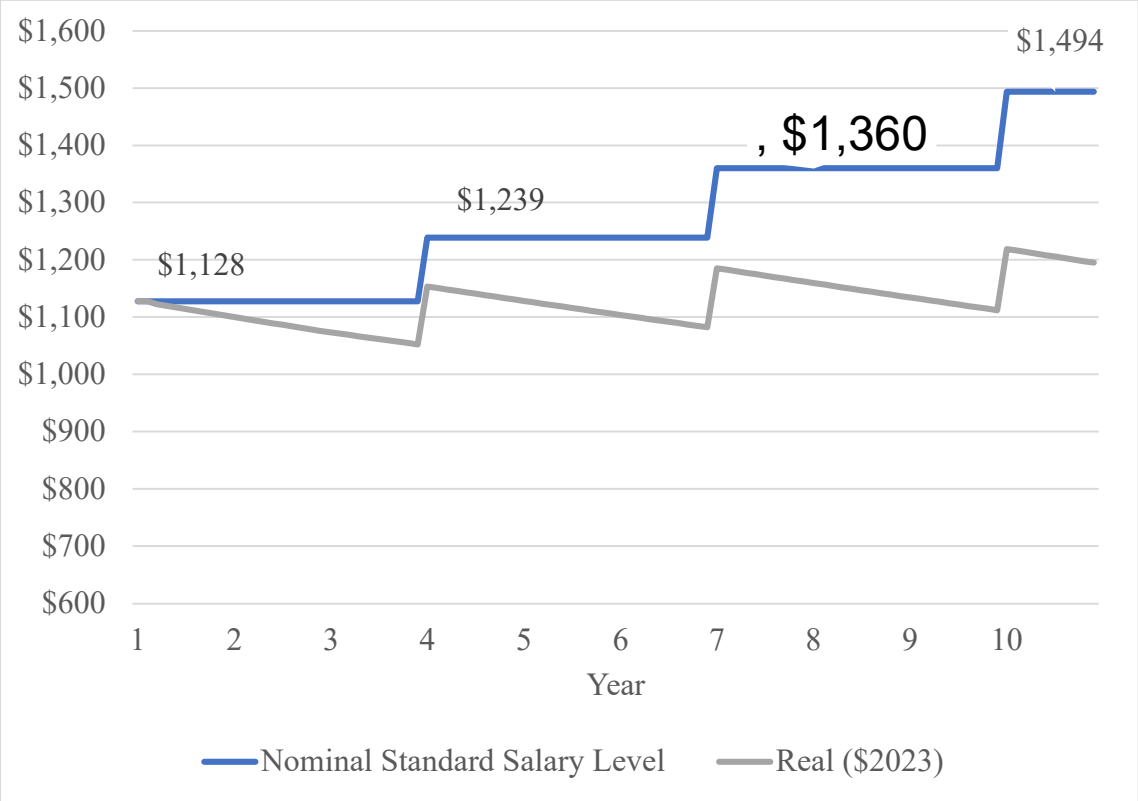


Figure 6: Projected Future Standard Salary Levels, Nominal and Real (Constant 2023 Dollars)



iii. Concerns with Use of Fixed Earnings Percentile as Updating Methodology

As discussed in detail in section V.A.3.iii, some commenters expressed concern that triennially updating the salary level using a fixed percentile of earnings would result in the salary levels growing at too quick a rate. *See, e.g.*, Chamber; National Lumber and Building Material Dealers Association; NRF; Seyfarth Shaw.

These commenters stated that updating the standard salary level using a fixed percentile of earnings of full-time salaried workers will cause some or all of the newly nonexempt workers to be converted to hourly status and thus removed from the data set, and earnings at the 35th percentile of salaried workers will quickly rise solely due to the exclusion of these hourly workers (an effect some commenters referred to as "ratcheting"). Commenters asserted that this

may cause growth in the 35th percentile of full-time salaried workers to no longer reflect prevailing economic conditions.

Claims that an updating mechanism using the fixed percentile approach will lead to the rapid escalation of the salary level are based primarily on the assumption that employers will respond to this rulemaking by converting newly nonexempt workers to hourly pay status. However, the Department believes these concerns are overstated because many affected EAP workers who are reclassified as nonexempt are likely to remain salaried as: (1) An analysis of the 2004 rule's salary level update did not indicate significant numbers of workers were converted to hourly pay; and (2) an analysis of updates in California's higher EAP exemption salary level (under state law) did not indicate significant numbers of workers were reclassified as hourly. In any event, the Department's modeling of the impact of updating shows that any potential "ratcheting" effect that may occur would be small, largely because newly nonexempt workers compose a small percentage of the pool of full-time nonhourly workers in the dataset used to establish the salary level.

The analyses discussed below are based on CPS MORG data. As acknowledged in the NPRM and above in section VII.B.5.i, salary status for CPS respondents cannot definitively be determined because workers who indicate they are paid on a salary basis or on some basis other than hourly are all classified as "nonhourly." To consider the possibility this biases our results, the Department looked at the Panel Study of Income Dynamics (PSID). The PSID provides additional information concerning salaried versus other nonhourly workers. In the PSID, respondents are asked how they are paid on their main job and are asked for more detail if their

response is in some way other than salaried or hourly.[423] The available responses include piecework, commission, self-employed/farmer/profits, and by the job/day/mile. None of these options are ones to which employers are likely to change their salaried workers. The share of workers who are not paid on either an hourly or salaried basis is relatively small, about 10 percent of workers in the PSID. Accordingly, grouping nonhourly workers with salaried workers does not negate the following comparisons and conclusions based on CPS data.

(a) Workers May Remain Salaried Even if Nonexempt

The Department disagrees with commenters that suggested that employers will likely (or automatically) convert large numbers of newly nonexempt employees to hourly pay status. In some instances such conversion may occur; for example, if an employee regularly works overtime and the employer is able to adjust his or her regular rate. However, for the majority of affected employees, there will be no incentive for employers to convert them to hourly pay because they do not work more than 40 hours in a workweek. Also, employers may have other incentives to maintain workers' salaried status; for example, they may offer salaried positions to attract talent. Some commenters representing employer interests highlighted that employees value job characteristics associated with salaried pay—such as earnings predictability—and so employers may pay nonexempt employees on a salary basis to preserve these benefits. Using the CPS MORG data pooled for 2021-2023 and projected to 2023, the Department estimated that 29.4 percent of white-collar workers earning below $684 per week are nonhourly; based on findings from the PSID, the Department believes most of these nonhourly workers are salaried.

[423] University of Michigan, Institute for Social Research. 2019 PSID. Data available at: https://simba.isr.umich.edu/data/data.aspx.

This data shows that even for some current nonexempt workers, employers are choosing to keep them as salaried instead of hourly. Furthermore, some nonhourly workers above the current salary threshold fail the duties test, and are therefore nonexempt, which is further evidence that employers already employ nonexempt workers who are paid on a salary basis.

(b) Previous Salary Level Updates Did Not Indicate a Significant Number of Workers Being Converted to Hourly

The "ratcheting" concerns raised in the comments are very similar to comments on this alleged effect that were received during the 2016 rulemaking. In that rule the Department analyzed employer responses to the 2004 rule and to a series of revisions to California's salary level test for exemption under state law in order to better estimate whether workers who become nonexempt are more likely to be paid on an hourly basis.[424] These analyses allow the identification of potential regulatory impact while controlling for time trends and a broad range of other relevant factors (education, occupation, industry, geographic location, etc.).

In the 2016 rule the Department analyzed the effect of the Federal 2004 salary level increase from $250 per week (short test salary level) to $455 (standard salary level) on the share of full-time, white-collar workers paid hourly. The analysis considered two types of differences: pre- versus post-rulemaking; and workers exempt before, but not after the rule compared to workers exempt both before and after the rule. As noted in the discussion of this analysis in the 2016 rule, if the salary level increase in the 2004 rule led employers to convert significant numbers of workers to hourly status (as commenters assert will result from the current rulemaking), then the Department would have expected to see a notable increase in the share of

[424] *See* 81 FR 32441, 32507.

workers earning just below the new threshold at the time ($455) who are paid hourly relative to the share of workers earning just above the new threshold who are paid hourly. Instead, the Department found that between the first quarter of 2004 and the first quarter of 2005, the share of full-time white-collar workers who are paid hourly decreased marginally in the group of potentially affected workers (those earning $250 to $455), whereas in the group earning above the salary level (those earning more than $455 but less than $600) it increased by 2.6 percentage points. These results do not suggest that the 2004 salary level increase caused an increase in the share of workers paid hourly below the new threshold, and thus provide no evidence that salary level increases due to triennial updates will result in employers converting significant numbers of affected EAP workers to hourly pay status.

The Department did not replicate this analysis for the salary level increase in the 2019 final rule, because it would require comparing a quarter in 2019 before the effective date of the rule with a quarter in 2020 after the effective date. The economic effects of the COVID-19 pandemic would make it impossible to isolate the impact of the 2019 rule.

In the 2016 rule the Department also analyzed the effect of changes to California statutes that set exempt salary levels at a level equal to twice the state minimum wage for 40 hours worked per week. The analysis considered two types of differences: pre- versus post-rulemaking; workers exempt before, but not after the rule compared to workers exempt both before and after the rule; and California workers versus workers in other states where the salary level was not increased. The analysis of two updates found that the share of full-time white-collar workers in California being paid hourly decreased from 73.4 percent to 73.1 percent compared to an increase of 66.2 percent to 67.5 percent in states where the salary level did not change after the

2007-2008 update, while there was an increase from 72.0 percent to 74.0 percent in California compared to an increase of 68.2 to 69.4 percent in other states after the 2014 update.

The Department found no evidence that changes in the salary level for exemption resulted in a statistically significant increase in the percent of full-time white-collar workers paid on an hourly basis following either the 2004 rule or the California salary level updates.

(c) The Department's Modeling of Possible "Ratcheting" Indicates Effect Would Be Negligible

In a study referenced by PPWO, Edgeworth Economics estimated the impact that an updating mechanism using the fixed percentile approach would have on the salary level. They found that "the DOL's automatic update mechanism would increase the salary threshold by approximately 9.1% to the current 40th percentile [which Edgeworth Economics estimated was equivalent to the 35th percentile of the resulting distribution after workers are reclassified] within three years even if there was not ANY wage growth." Their estimate was based on the assumption that all affected workers in the South Census Region who earn between $684 and $1,059 per week and who are expected to pass the duties test, which they estimate to be 1.4 million, would be reclassified to hourly employees, thus falling out of the distribution of workers that are part of the 35th percentile in the Census Region. However, as discussed above, the Department has found no evidence that previous changes in the salary level for exemption have resulted in a statistically significant increase in the percent of full-time white-collar workers paid on an hourly basis.

NRF submitted a 2023 study by Oxford Economics that also considered how converting salaried workers to hourly status could influence future triennial updates. The Oxford study states that DOL's updating methodology "suffers from the same technical flaw as its NPRM

analysis of the effects of the proposed regulation suffers from: the failure to model newly nonexempt affected workers losing salaried status." The study presents a visual analysis showing a share of workers who earn below the overtime threshold losing their salaried status, and a higher threshold for 2027 after this rule than in the scenario where there is no change to the standard salary level. Like Edgeworth Economics, Oxford Economics erroneously assumes that a large share of all affected workers will lose their salaried status. As discussed previously, the Department has found no evidence that previous changes in the salary level for exemption have resulted in a statistically significant increase in the percent of full-time white-collar workers paid on an hourly basis.

In 2016, the Department conducted a similar analysis, using what the Department believes are more realistic assumptions, and found a significantly smaller potential impact. The Department considered which affected workers are most likely to be converted from salaried to hourly pay as a result of that rulemaking. Type 4 workers, those whose salaries are increased to the new standard salary level, remain exempt and their method of pay will not change. Type 3 workers, who regularly work overtime and become nonexempt, and Type 2 workers, those who occasionally work overtime and become nonexempt, are the most likely to have their pay status changed. Type 1 workers (who, at the time, made up more than 60 percent of the affected workers) were assumed to not work overtime, and employers thus have little incentive to convert them to hourly pay. For this analysis, the Department assumed all Type 2 and Type 3 workers were converted to hourly status to generate a realistic upper bound of the magnitude of any possible ratcheting effect. The Department estimated that in 2026, after three updates over 10 years, the salary level as set in the final rule (based on weekly earnings of full-time salaried

workers in the South) could be approximately 2.5 percent higher than expected due to this effect. This figure is significantly smaller than the estimates provided by the commenters. Furthermore, the Department believes its estimate is an overestimate because it assumed employers convert all Type 2 and Type 3 workers to hourly status, which, for the reasons discussed above and in section V.A.3.iii of the preamble, the Department believes is a highly unlikely outcome. The Department did not replicate this analysis for the salary level increase in the 2019 final rule, because the economic effects of the COVID-19 pandemic make it difficult to compare periods before and after the effective date of the 2019 final rule and isolate the effect of the rule.

10. Projections

The Department estimated that in Year 1, 4.3 million EAP workers will be affected, with about 292,900 of these attributable to the revised HCE compensation level (Table 26). In Year 10, the number of affected EAP workers was estimated to equal 6.0 million with 1.0 million attributable to the updated HCE compensation level. Average annualized costs are $802.9 million and transfers are $1.5 billion using a 7 percent real discount rate. These projections involved several steps.

1. Use past growth in the earnings distribution to estimate future salary and compensation levels (*see* section VII.C.9).
2. Predict workers' earnings, absent a change in the salary levels.
3. Compare workers' predicted earnings to the predicted salary and compensation levels to estimate affected workers.
4. Project future employment levels.

5. Estimate employer adjustments to hours and pay.

6. Calculate costs and transfers.

Figure 7: 10-Year Projected Number of Affected Workers

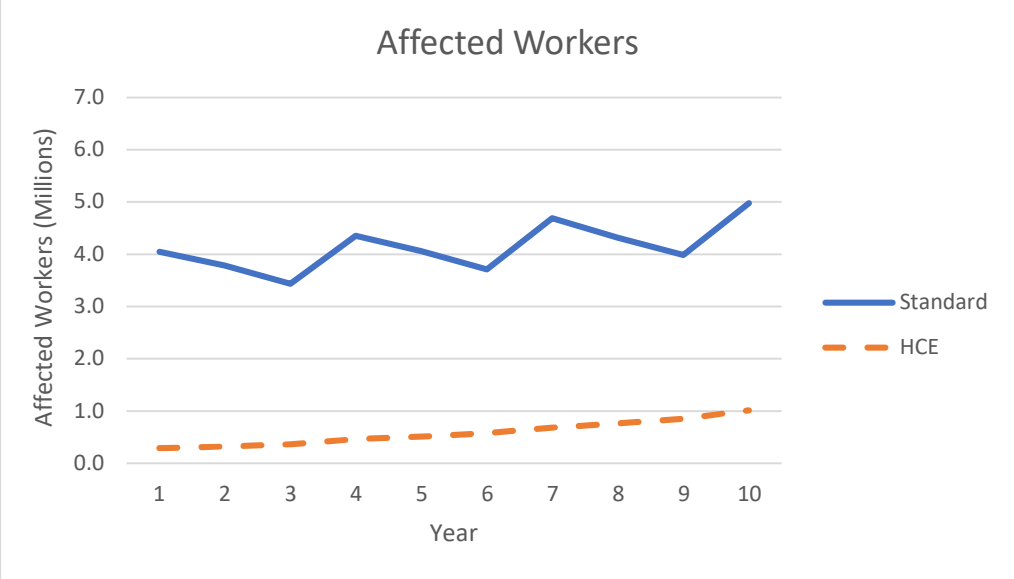


Figure 8: 10-Year Projected Costs and Transfers (Millions $2023)

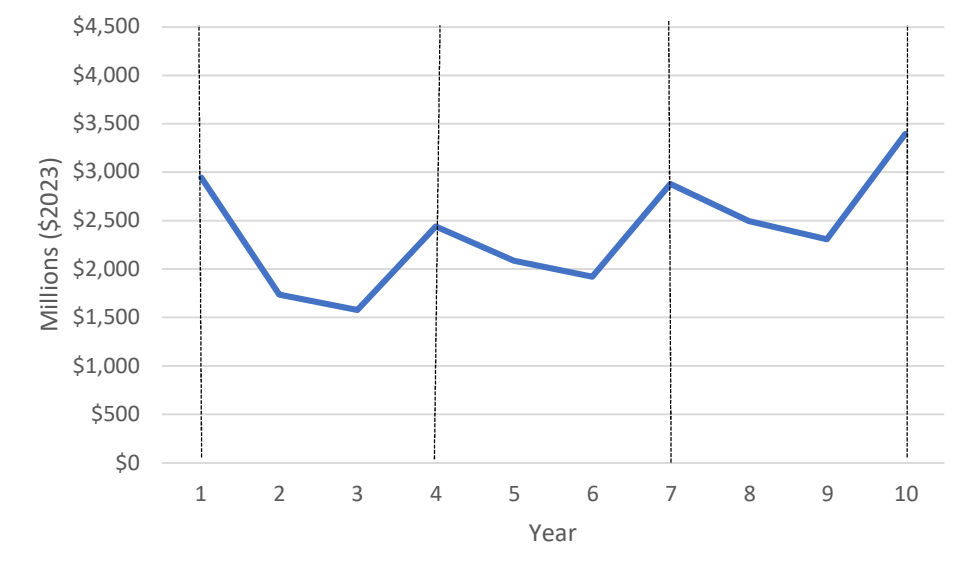


Table 26: Projected Costs and Transfers, Standard Salary and HCE Compensation Levels

Year	Affected EAP Workers (Millions)	Costs (Millions $2023)				Transfers (Millions $2023)		
		Regulatory Familiar-ization [a]	Adjust-ment [a]	Manag-erial	Total	Due to MW	Due to OT	Total
Year 1	4.3	$451.6	$299.1	$685.5	$1,436.2	$87.5	$1,421.7	$1,509.2
Year 2	4.1	$0.0	$9.4	$632.1	$641.5	$46.5	$1,047.8	$1,094.3
Year 3	3.8	$0.0	$8.9	$571.9	$580.8	$45.0	$953.7	$998.7
Year 4	4.8	$73.1	$14.2	$702.2	$789.5	$42.2	$1,609.4	$1,651.6
Year 5	4.6	$0.0	$8.7	$647.8	$656.5	$42.2	$1,386.5	$1,428.7
Year 6	4.3	$0.0	$9.5	$624.7	$634.2	$39.9	$1,246.0	$1,285.9
Year 7	5.4	$71.0	$18.6	$747.7	$837.2	$36.1	$2,005.6	$2,041.7
Year 8	5.1	$0.0	$9.6	$697.8	$707.4	$31.3	$1,757.3	$1,788.6
Year 9	4.8	$0.0	$9.0	$682.3	$691.3	$26.4	$1,590.1	$1,616.6
Year 10	6.0	$68.9	$20.9	$816.3	$906.1	$22.6	$2,467.5	$2,490.1
Annualized (3% real discount rate)	--	$71.8	$44.6	$677.6	$794.0	$43.2	$1,522.0	$1,565.2
Annualized (7% real discount rate)	--	$79.3	$50.0	$673.6	$802.9	$44.8	$1,489.3	$1,534.1

[a] Regulatory familiarization costs occur in years when the salary and compensation levels are updated. Adjustment costs occur in all years when there are newly affected workers.

The Department calculated workers' earnings in future years by applying the historical wage growth rate in the workers' industry-occupation to current earnings. The wage growth rate was calculated as the geometric growth rate in median wages using CPS MORG data for occupation-industry categories from 2011-2023.[425] The geometric growth rate is the constant annual growth rate that when compounded (applied to the first year's wage, then to the resulting second year's wage, etc.) yields the last historical year's wage. This rate only depends on the wage values in the first and last year.[426]

The geometric wage growth rates per industry-occupation combination were also calculated from the BLS' Occupational Employment and Wage Statistics (OEWS) survey for 2012 to 2022. In occupation-industry categories where the CPS MORG data had an insufficient number of observations to reliably calculate median wages, the Department used the growth rate in median wages calculated from the OEWS data.[427] Any remaining occupation-industry

[425] To maximize the number of observations used in calculating the median wage for each occupation-industry category, 3 years of data were pooled for each of the endpoint years. Specifically, data from 2011, 2012, and 2013 (converted to 2012 dollars) were used to calculate the 2012 median wage and data from 2021, 2022, and 2023 (converted to 2022 dollars) were used to calculate the 2022 median wage.

[426] The geometric growth rate may be a flawed measure if either or both of the endpoint years were atypical; however, in this instance these values seem typical. An alternative method would be to use the time series of median wage data to estimate the linear trend in the values and continue this to project future median wages. This method may be preferred if either or both of the endpoint years are outliers, since the trend will be less influenced by them. However, the linear trend may be flawed if there are outliers in the interim years. The Department chose to use the geometric mean because individual year fluctuations are difficult to predict and applying the geometric growth rate to each year provides a better estimate of the long-term growth in wages.

[427] To lessen small sample bias in the estimation of the median growth rate, this rate was only calculated using CPS MORG data when these data contained at least 10 observations in each time period.

combinations without sufficient data in either data source were assigned the median of the growth rates in median wages from the CPS MORG data.

The Department compared workers' counter-factual earnings (*i.e.*, absent the rulemaking) to the predicted salary levels. If the counter-factual earnings are below the relevant salary level (*i.e.*, standard or HCE) then the worker is considered affected. In other words, in each year affected EAP workers were identified as those who would be exempt absent the rule change (*e.g.*, would earn at least $684 if exempt under standard salary level) but have projected earnings in the future year that are less than the relevant salary level. The projected number of affected workers also includes workers who were not EAP exempt in the base year but will become exempt in the absence of this rule in Years 2 through 10. For example, a worker who passes the standard duties test may earn less than $684 in Year 1 but between $684 and the new salary level in subsequent years; such a worker will be counted as an affected worker in those subsequent years. Additionally, the number of affected workers is not limited to newly affected workers. Workers who are affected in a given year may remain affected in subsequent years (*e.g.*, because they earn between $684 and $1,128 in years 1, 2, and 3), and continue to be counted as affected.

The projected number of affected workers also accounts for anticipated employment growth. Employment growth was estimated as the geometric annual growth rate based on the 10-year employment projection from BLS' National Employment Matrix (NEM) for 2022 to 2032 within an occupation-industry category.[428, 429] The Department applied these growth rates to the

[428] Bureau of Labor Statistics, Employment Projections Program. 2022-32 National Employment Matrix. https://www.bls.gov/emp/ind-occ-matrix/matrix.xlsx.

[429] An alternative method is to spread the total change in the level of employment over the ten years evenly (constant change in the number employed). The Department believes that on

sample weights of the workers to estimate increased employment levels over time. This is because the Department cannot introduce new observations to the CPS MORG data to represent the newly employed.

For workers newly affected in Year 2 through Year 10, employers' wage and hour adjustments due to the rulemaking are generally estimated as described in section VII.C.4. The only difference is the hours adjustment now uses a long-run elasticity of labor demand of -0.4.[430] Employer adjustments are made in the first year the worker is affected and then applied to all future years in which the worker continues to be affected (unless the worker switches to a Type 4 worker). Workers' earnings in predicted years are earnings post employer adjustments, with overtime pay, and with ongoing wage growth based on historical growth rates (as described above).

The Department quantified three types of direct employer costs in the 10-year projections: (1) regulatory familiarization costs; (2) adjustment costs; and (3) managerial costs. Section VII.C.3 provides details on the methodology for estimating these costs. This section only discusses the aspects specific to projections. Projected costs and transfers were deflated to 2023 dollars using the Congressional Budget Office's projections for the CPI-U.[431]

Regulatory familiarization costs occur in years when the salary and compensation levels are updated. Thus, in addition to Year 1, some regulatory familiarization costs are expected to

---

average employment is more likely to grow at a constant percentage rate rather than by a constant level (a decreasing percentage rate).

[430] Based on the Department's analysis of the following paper:
Lichter, A., Peichl, A. & Siegloch, A. (2014). The Own-Wage Elasticity of Labor Demand: A Meta-Regression Analysis. IZA DP No. 7958.

[431] Congressional Budget Office. 2023. The Budget and Economic Outlook: 2023 To 2033. *See* https://www.cbo.gov/system/files/2023-02/58848-Outlook.pdf.

occur in Year 4, Year 7, and Year 10. The Department assumed 10 minutes per establishment for time to access and read the published notice in the *Federal Register* with the updated standard salary level and HCE compensation level. This average time estimate is low because the majority of establishments will not have newly affected workers, and while some firms may spend more than 10 minutes to read the new rule, many firms will spend no time. The time estimate has been increased from 5 minutes in the 2016 rulemaking. In each of these 3 years regulatory familiarization costs are between $68.9 and $73.1 million. Although start-up firms must become familiar with the FLSA, the difference between the time necessary for familiarization with the current part 541 exemptions and those exemptions as modified by this rulemaking is essentially zero. Therefore, projected regulatory familiarization costs for new entrants over the next 9 years are zero (although these new entrants will incur regulatory familiarization costs in years when the salary and compensation levels are updated).

Adjustment costs are a function of the number of newly affected EAP workers and would occur in any year in which workers are newly affected. Adjustment costs would be largest in Year 1, of moderate size in update years, and smaller in other years. Management costs would recur each year for all affected EAP workers whose hours are adjusted. Therefore, managerial costs increase in update years and then modestly decrease between updates since earnings growth will cause some workers to no longer be affected in those years.

The Department projected transfers from employers to employees due to the minimum wage provision and the overtime pay provision. Transfers to workers from employers due to the minimum wage provision would decline from $87.5 million in Year 1 to $22.6 million in Year 10

as increased earnings over time move workers' regular rates of pay above the minimum wage.[432] Transfers due to overtime pay should grow slightly over time because the number of affected workers would increase, although transfers fall in years between updates. Transfers to workers from employers due to the overtime pay provision would increase from $1.4 billion in Year 1 to $2.5 billion in Year 10.

The Department compared projected impacts with and without updating (Table 27). Projections without updating are shown so impacts of the initial increase and subsequent increases can be disaggregated. With triennial updating, the number of affected EAP workers would increase from 4.3 million to 6.0 million over 10 years. Conversely, in the absence of updating, the number of affected EAP workers is projected to decline from 4.3 million in Year 1 to 2.6 million in Year 10. As shown in Figure 9, the number of affected workers decreases from year to year between updates as the real value of the salary and compensation levels decrease, and then increases in update years.

Regarding costs, regulatory familiarization costs are lower without updating because, in the absence of updating, employers would not need to familiarize themselves with updated salary and compensation levels every 3 years. Adjustment costs and managerial costs are a function of the number of affected EAP workers and so will be higher with updating. Average annualized direct costs will be $802.9 million with updating and $615.6 million without updating. Transfers are also a function of the number of affected workers and hence are lower without updating.

[432] State minimum wages above the Federal level as of January 1, 2023 were incorporated and used for projected years. Increases in minimum wages were not projected. If state or Federal minimum wages increase over the next 10 years, then estimated projected minimum wage transfers would be underestimated.

Disclaimer: This final rule has been approved by the Office of Management and Budget's Office of Information and Regulatory Affairs and has been submitted to the Office of the Federal Register (OFR) for publication. It is currently pending placement on public inspection at the OFR and publication in the *Federal Register*. This version of the final rule may vary slightly from the published document if minor technical or formatting changes are made during the OFR review process. Only the version published in the *Federal Register* is the official version.

Average annualized transfers with a 7 percent real discount rate will be $1.5 billion with updating and $990 million without updating. Table 27 shows aggregated costs and transfers over the 10-year horizon.

Figure 9: 10-Year Projected Number of Affected Workers, with and without Updating

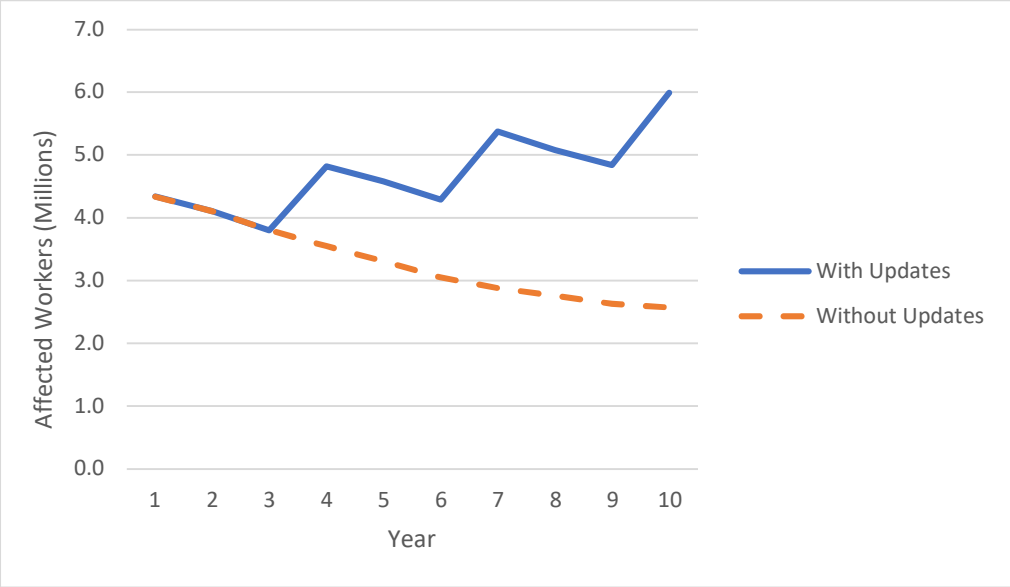


Table 27: Comparison of Projected Costs and Transfers with and without Updating

Year	Affected EAP Workers (Millions)		Costs (Millions $2023)		Transfers (Millions $2023)	
	With Updates	Without Updates	With Updates	Without Updates	With Updates	Without Updates
Year 1	4.3	4.3	$1,436.2	$1,436.2	$1,509.2	$1,509.2
Year 2	4.1	4.1	$641.5	$641.5	$1,094.3	$1,094.3
Year 3	3.8	3.8	$580.8	$580.8	$998.7	$998.7
Year 4	4.8	3.5	$789.5	$526.2	$1,651.6	$937.2
Year 5	4.6	3.3	$656.5	$483.6	$1,428.7	$885.9

Year 6	4.3	3.1	$634.2	$448.6	$1,285.9	$863.8
Year 7	5.4	2.9	$837.2	$420.8	$2,041.7	$847.6
Year 8	5.1	2.8	$707.4	$404.4	$1,788.6	$801.4
Year 9	4.8	2.6	$691.3	$388.8	$1,616.6	$809.9
Year 10	6.0	2.6	$906.1	$380.1	$2,490.1	$809.7
Annualized (3% real discount rate)	--	--	$794.0	$590.0	$1,565.2	$970.2
Annualized (7% real discount rate)	--	--	$802.9	$615.6	$1,534.1	$989.5

VIII. Final Regulatory Flexibility Analysis (FRFA)

The Regulatory Flexibility Act of 1980 (RFA) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), hereafter jointly referred to as the RFA, requires that an agency prepare an initial regulatory flexibility analysis (IRFA) when proposing, and a final regulatory flexibility analysis (FRFA) when issuing, regulations that will have a significant economic impact on a substantial number of small entities. The Department has determined that this rulemaking is economically significant. This section (1) provides an overview of the objectives of this rule; (2) estimates the number of affected small entities and employees; (3) discusses reporting, recordkeeping, and other compliance requirements; (4) presents the steps the Department took to minimize the significant economic impact on small entities; and (5) declares that it is unaware of any relevant Federal rules that may duplicate, overlap, or conflict with this rule.

A. Objectives of, and need for, the Final Rule

The FLSA requires covered employers to (1) pay employees who are covered and not exempt from the Act's requirements not less than the Federal minimum wage for all hours worked and overtime premium pay at a rate of not less than one and one-half times the

employee's regular rate of pay for all hours worked over 40 in a workweek, and (2) make, keep, and preserve records of the persons employed by the employer and of the wages, hours, and other conditions and practices of employment. The FLSA provides exemptions from the Act's minimum wage and overtime pay provisions, including one for bona fide executive, administrative, and professional (EAP) employees, as those terms are "defined and delimited" by the Department.[433] The Department's regulations implementing this white-collar exemption are codified at 29 CFR part 541.

To qualify for the EAP exemption under the Department's regulations, the employee generally must meet three criteria: (1) the employee must be paid a predetermined and fixed salary that is not subject to reduction because of variations in the quality or quantity of work performed (the salary basis test); (2) the amount of salary paid must meet a minimum specified amount (the salary level test); and (3) the employee's job duties must primarily involve executive, administrative, or professional duties as defined by the regulations (the duties test). In 2004, the Department revised its regulations to include a highly compensated employee test with a higher salary threshold and a minimal duties test.[434] The Department has periodically updated the regulations governing the white-collar exemptions since the FLSA's enactment in 1938. Most recently, the 2019 rule updated the standard salary level test to $684 per week and the HCE compensation level to $107,432 annually.

The goal of this rulemaking is to set effective earnings thresholds to help define and delimit the FLSA's EAP exemption. To this end, the Department is finalizing its proposed change

[433] 29 U.S.C. 213(a)(1).
[434] § 541.601.

to the salary level. Specifically, the Department is adjusting the salary level by setting it equal to the 35th percentile of weekly earnings of full-time salaried workers in the lowest-wage Census Region (currently the South), based on the most recent year (2023) of Current Population Survey (CPS) data at the time of drafting. Using BLS 2023 data on percentiles of usual weekly earnings of nonhourly full-time workers, the standard salary level will be set at $1,128 per week. Additionally, to maintain the effectiveness of this test, the Department is finalizing an updating mechanism that will update the earnings thresholds to reflect current wage data on July 1, 2024 and every 3 years thereafter.

The Department's new salary level will, in combination with the standard duties test, better define and delimit which employees are employed in a bona fide EAP capacity in a one-test system. As explained in greater detail in sections III and V.B, setting the standard salary level at or below the long test salary level, as the 2004 and 2019 rules did, results in the exemption of lower-salaried employees who traditionally were entitled to overtime protection under the long test either because of their low salary or because they perform large amounts of nonexempt work, in effect significantly broadening the exemption compared to the two-test system. Setting the salary level at the low end of the historic range of short test salary levels, as the 2016 rule did, would have restored overtime protections to those employees who perform substantial amounts of nonexempt work and earned between the long test salary level and the low end of the short test salary range. However, it would also have resulted in denying employers the use of the exemption for lower-salaried employees who traditionally were not entitled to overtime compensation under the long test, which raised concerns that the Department was in effect narrowing the exemption. By setting a salary level above the equivalent of the long test salary

level (using current data), the final rule will restore the right to overtime pay for salaried white-collar employees who prior to the 2019 rule were always considered nonexempt if they earned below the long test (or long test-equivalent) salary level. And it will ensure that fewer lower paid white-collar employees who perform significant amounts of nonexempt work are included in the exemption. At the same time, by setting it well below the equivalent of the short test salary level (using current data), the rule will allow employers to continue to use the exemption for many lower paid white-collar employees who were made exempt under the 2004 standard duties test. The new salary level will also more reasonably distribute between employees and their employers what the Department now understands to be the impact of the shift from a two-test to a one-test system on employees earning between the long and short test salary levels.

As the Department has previously noted, the amount paid to an employee is "a valuable and easily applied index to the 'bona fide' character of the employment for which the exemption is claimed," as well as the "principal[]" "delimiting requirement" "prevent[ing] abuse" of the exemption .[435] Additionally, the salary level test facilitates application of the exemption by saving employees and employers from having to apply the more time-consuming duties analysis to a large group of employees who will not pass it. For these reasons, the salary level test has been a key part of how the Department defines and delimits the EAP exemption since the beginning of its rulemaking on the EAP exemption.[436] At the same time, the salary test's role in defining and delimiting the scope of the EAP exemption must allow for appropriate examination of employee

[435] Stein Report at 19, 24; *see also* 81 FR 32422.
[436] *See* 84 FR 51237.

duties.[437] Under the final rule, duties will continue to determine the exemption status for most salaried white-collar employees.

The Department is also adjusting the HCE total annual compensation requirement to the annualized weekly earnings for the 85th percentile of full-time salaried workers nationally ($151,164 using 2023 data). Though not as high a percentile as the HCE threshold initially adopted in 2004, which covered 93.7 percent of all full-time salaried workers,[438] the Department's new HCE threshold will ensure it continues to serve its intended function, because the HCE total annual compensation level will be high enough to exclude all but those employees at the very top of the economic ladder.

In its three most recent part 541 rulemakings, the Department has expressed its commitment to keeping the earnings thresholds up to date to ensure that they remain effective in helping differentiate between exempt and nonexempt employees. Long intervals between rulemakings have resulted in eroded earnings thresholds based on outdated earnings data that were ill-equipped to help identify bona fide EAP employees. In contrast, routine updates to the part 541 earnings thresholds to reflect wage growth will bring certainty and stability to employers and employees alike. Based on its long experience with updating the salary levels, the Department has determined that adopting a regulatory provision for regularly updating the salary levels, with an exception for pausing future updates under certain conditions, is the most viable and efficient way to ensure the EAP exemption earnings thresholds keep pace with changes in employee pay and thus remain effective in helping determine exemption status. Accordingly, the

[437] *See id.* at 51238.
[438] *See* 69 FR 22169 (Table 3).

Department is including in this rule a mechanism for updating the salary and compensation levels, to reflect current wage data, on July 1, 2024 and every 3 years thereafter. As explained in greater detail in section V.A, employees and employers alike will benefit from the certainty and stability of regularly scheduled updates.

B. Response to Comment Filed by the Chief Counsel for Advocacy of the Small Business Administration

SBA Advocacy expressed similar concerns as those expressed by other small business commenters, based upon its meetings, roundtables, and other discussions regarding the NPRM. SBA Advocacy stated that it was concerned that the IRFA underestimated the compliance costs of the rule, the proposed rule would add to the current difficult business environment, the proposed rule would have significant impacts on small nonprofits, the IRFA did not account for non-financial costs to small entities and employees, and the IRFA did not consider less burdensome alternatives. SBA Advocacy recommended that the Department issue a supplemental RFA to reanalyze small entity impacts, adopt a lower standard salary level, update the standard salary level every four years through notice and comment rulemaking, publish a small entity compliance guide, provide more time for compliance, and add provisions to help small nonprofits comply. SBA Advocacy's comments and the Department's response to those comments are discussed in detail below.

SBA Advocacy reported that participants at its roundtables estimated first year costs would be much higher than the estimates in the IRFA, from $20,000 to over $200,000 in compliance costs per small entity. SBA Advocacy asserted that small businesses may have to hire outside staff to interpret and implement the rule and face high administrative and operational costs to schedule and track employee hours to minimize overtime costs. SBA Advocacy also

stated that participants at their roundtables reported much higher payroll costs than the estimates provided by the Department in the IRFA. Advocacy further stated that the IRFA failed to estimate compliance costs by small entity size and revenue by presenting average impacts by industry.

The assumptions small businesses used to estimate first-year compliance costs ranging from $20,000 to $200,000 per entity were not described. However, the Department clearly outlined its methodology and assumptions used to estimate regulatory familiarization, adjustment, and management costs that it expects businesses, including small businesses, might incur. The Department disagrees that it underestimated small entity costs in the IRFA. First, this rulemaking is narrow in scope as it only makes changes relating to earnings thresholds in the part 541 regulations. The Department published final rules changing the salary thresholds in 2016 and 2019. The Department therefore expects that most businesses will not require significant time to become familiar with these regulations, or that they will require significant time from outside consultants. Furthermore, the Department expects that small entities will rely upon compliance assistance materials provided by the Department, including the small entity compliance guide that will be published, or industry associations to become familiar with the final rule.

Second, the Department estimates businesses will require an average of 75 minutes per employee to choose how to make adjustments for affected employees. The Department expects that employers will most likely need to spend little to no time making adjustments for many affected workers, such as the almost 70 percent of the employees who do not work overtime (Type 1 employees) and those whose salaries are well below the new standard salary level or only occasionally work overtime. If, for example, decisions can be quickly made for half of a

business' affected employees, then that leaves two hours or more per employee for employers to consider how to respond with regard to employees requiring more consideration.

Third, the Department believes that most, if not all, entities have at least some nonexempt employees and, therefore, already have policies and systems in place for monitoring and recording their hours. The Department believes that applying those same policies and systems to the workers whose exemption status changes will, on average, not require more than 10 minutes per week per worker who works overtime in managerial time cost, as employers will rely on policies such as a policy against working overtime without express approval or a standard weekly schedule of assigned hours. The Department notes that nearly 70 percent of affected employees do not work overtime, and another 17 percent who do work overtime average about an hour of overtime per week; less than 15 percent of currently exempt employees average 10 or more hours of overtime per week. The Department therefore disagrees with SBA Advocacy that small entities will "face vast administrative and operational costs to schedule and track employee hours to minimize overtime costs." Consistent with the approach taken in calculating managerial costs in the 2019 rule,[439] the Department believes that an average of 10 additional minutes per week managing the hours of each newly exempt worker who works overtime is appropriate.

SBA Advocacy bases its claim that the Department underestimated payroll costs on reports from "[r]oundtable participants" of "much higher payroll costs," pointing to four businesses—"an Arkansas restaurant with four locations" and three "small amusement businesses"—which claimed they would need to increase manager salaries from $57,000 to $250,000 to comply with the rule. SBA Advocacy also provided hypothetical scenarios of

[439] *See* 84 FR 51267.

potential salary increases that restaurant employers with currently exempt employees would need to incur to comply with the proposed rule based on various assumptions. As discussed in section VII.C.4.iii.c, these anecdotal reports and hypothetical examples do not have any information on the actual amount of overtime work being performed by employees who could become newly nonexempt under the new salary level. The Department expects that businesses that would be faced with large increases in payroll costs if they were to increase salaries to the new threshold would instead find other responses more economically feasible, such as limiting the number of overtime hours worked by nonexempt workers.

Moreover, as explained above, the majority of affected workers who work no overtime or minimal overtime will likely receive little additional pay as a result of the rule. While some employers might have to pay the overtime premium, when combined with the 85 percent of affected employees who will receive little or no overtime pay premium because they work little or no overtime, the average pay raise over all affected employees and their employers will be much smaller than the examples presented in SBA Advocacy's comment.

SBA Advocacy stated that small firms have expressed the sentiment that they would have to fire and not promote employees and limit hours worked as a result of the rule, after recent inflation, supply chain disruptions, shutdowns and tight labor markets that followed the COVID-19 pandemic. The Department acknowledges that the economic climate has been difficult to navigate since the start of 2020. However, most indications are that the economy has been returning to long run growth patterns with subsiding inflation. For example, a report by Van

Nostrand and Sinclair (2023)[440] from the U.S. Department of the Treasury indicates that the United States has seen a strong GDP recovery and was on track during 2023 to recover to levels predicted before the pandemic. Similarly, reflecting improvements in inflation and personal incomes, the Survey of Consumers from the University of Michigan reported that consumer sentiment in January 2024 grew by 13 percent and reached its highest level since July 2021.[441] To the extent that labor markets remain tight, that might be a reflection of significant, potentially long-run changes in factors such as long run labor force participation rates.[442] Regardless, workers affected by this rule compose a relatively small part of the overall labor market and the increase in wages should be relatively small (*see e.g.*, estimated transfers per worker, Table 23). While small businesses may be more affected by labor market turmoil, the overall size of the impact of this rule on the economy would indicate that it is unlikely that the rule will have a significant impact on this market turmoil.

SBA Advocacy also stated that it believes that the Department underestimated the impact of the proposed rule on small nonprofit organizations, citing examples of small nonprofits that estimate costs above the one to three percent of revenue threshold, a measure for determining the economic impact on small entities from SBA Advocacy's RFA compliance guide. The Department disagrees that it underestimated the impact of this rule on small nonprofits. First,

---

[440] *Van Nostrand and Sinclair* (2023). The U.S. Economy in Global Context. U.S. Department of the Treasury. https://home.treasury.gov/news/featured-stories/the-us-economy-in-global-context
[441] University of Michigan (2024). Surveys of Consumers. http://www.sca.isr.umich.edu/
[442] Bognar et al. (2023) What Does Everything Besides the Unemployment Rate Tell Us About Labor Market Tightness?. Federal Reserve Bank of Chicago. https://www.chicagofed.org/publications/chicago-fed-letter/2023/491.
Hornstein and Kudlyak (2022). The Pandemic's Impact on Unemployment and Labor Force Participation Trends. Federal Reserve of Richmond Economic https://www.richmondfed.org/publications/research/economic_brief/2022/eb_22-12.

many nonprofits are non-covered enterprises because when determining enterprise coverage, only revenue derived from business operations, not charitable activities, is included. However, as discussed in section VII.B.3, the Department nonetheless included workers employed by enterprises that do not meet the enterprise coverage requirements in its estimate of workers subject to the FLSA, since there is no data set that would adequately inform an estimate of the size of this worker population in order to exclude them from these estimates. [443] Second, for the reasons stated above, the Department believes that expected costs and payroll impacts of the rule cited by SBA Advocacy and other commenters are overestimates, and that the Department's estimates are more accurate reflections of costs and impacts. The Department finds that even if all employees at a small entity, whether for-profit or nonprofit, are exempt—an unlikely scenario—then cost and increased payroll combined comprise about one percent of payroll per affected small entity, and therefore an even smaller percentage of revenues. *See* Table 32. SBA Advocacy cited concerns about the rule's effect on seasonal businesses raised by a representative from America Outdoors Association, which asserted that many affected employees in seasonal recreational businesses work nontraditional work schedules that would make it difficult to reclassify them as hourly workers, as well as a concern raised by a representative of the Independent Community Bankers Association of America that the rule could cause its members to reduce services in "rural or less profitable areas." The Department reiterates that employers do not need to reclassify nonexempt workers as hourly employees; they merely need to pay an

[443] Although not excluding such entities and associated workers only affects a small percentage of workers generally, it may have a larger effect (and result in a larger overestimate) for nonprofits, because revenue from charitable activities is not included when determining enterprise coverage. *See* section VII.B.3.

overtime premium for hours worked over 40 in a workweek. While there will be affected workers in the finance sector, the Department believes that costs and transfers for small entities in the finance sector will be manageable as a share of payroll and of total revenue.[444]

SBA Advocacy further stated that the IRFA "does not consider the non-financial consequences to reclassify workers, such as the effect on worker flexibility, worker morale, and loss of benefits and career advancement." The Department addresses these and other possible impacts that cannot be quantified in sections V.B.4.v and VII.C.3.v. In addition, the Department believes that while individual experiences vary, the rule will benefit employees in a variety of ways (*e.g.*, through increased earnings and an increase in personal time for some affected workers).

Exempt workers may enjoy more scheduling flexibility because their hours are less likely to be monitored than nonexempt workers. If so, the final rule could impose costs on newly nonexempt, overtime-eligible workers by, for example, limiting their ability to adjust their schedules to meet personal and family obligations. However, employers can continue to offer flexible schedules and require workers to monitor their own hours and to follow the employers' timekeeping rules. Additionally, some exempt workers already monitor their hours for billing purposes. For these reasons, and because there is little data or literature on these costs, the Department did not quantify potential costs regarding scheduling flexibility. Further, a study by Lonnie Golden[445] using data from the General Social Survey (GSS) found that "[i]n general, salaried workers at the lower (less than $50,000) income levels don't have noticeably greater

[444] *See* Table 32.

[445] Golden, L. (2014). Flexibility and Overtime Among Hourly and Salaried Workers. Economic Policy Institute. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2597174.

levels of work flexibility that they would 'lose' if they became more like their hourly counterparts."

Some of the workers who become nonexempt as a result of the final rule and whose pay is changed by their employer from salaried to hourly status may have preferred to remain salaried. As noted above in section VII.C.3.v, research has shown that salaried workers are more likely than hourly workers to receive benefits such as paid vacation time and health insurance,[446] and are more satisfied with their benefits.[447] Additionally, when employer demand for labor decreases, hourly workers tend to see their hours cut before salaried workers, making earnings for hourly workers less predictable.[448] However, this literature generally does not control for differences between salaried and hourly workers such as education, job title, or earnings; therefore, this correlation is not necessarily attributable to hourly status.

If workers are reclassified as hourly, and hourly workers have fewer benefits than salaried workers, reclassification could reduce workers' benefits. But the Department notes that these newly nonexempt workers may continue to be paid a salary, as long as that salary is equivalent to a base wage at least equal to the minimum wage rate for every hour worked, and the employee receives a 50 percent premium on that base wage for any overtime hours each week. Similarly,

---

[446] Lambert, S. J. (2007). Making a Difference for Hourly Employees. In A. Booth, & A. C. Crouter, Work-Life Policies that Make a Real Difference for Individuals, Families, and Communities. Washington, D.C.: Urban Institute Press.

[447] Balkin, D. B., & Griffeth, R. W. (1993). The Determinants of Employee Benefits Satisfaction. Journal of Business and Psychology, 7(3), 323-339.

[448] Lambert, S. J., & Henly, J. R. (2009). Scheduling in Hourly Jobs: Promising Practices for the Twenty-First Century Economy. The Mobility Agenda. Lambert, S. J. (2007). Making a Difference for Hourly Employees. In A. Booth, & A. C. Crouter, Work-Life Policies that Make a Real Difference for Individuals, Families, and Communities. Washington, D.C.: Urban Institute Press.

employers may continue to provide these workers with the same level of benefits as previously, whether paid on an hourly or salary basis. While reducing benefits may be one way for employers to offset payroll increases associated with this rule, as shown below, the Department estimates that costs and payroll increases for small, affected firms are less than 0.9 percent of payroll and less than 0.2 percent of estimated revenues. Therefore, the Department does anticipate that it will be necessarily for a significant number of employers to reduce employee benefits.

Finally, it is unclear why career advancement will be inhibited. As noted above, *see* section VII.C.3.v., nothing in this rule requires employers to limit advancement opportunities for newly nonexempt workers. The Department notes that if an employer believes that career advancement opportunities such as training are sufficiently important, it can ensure employees attend the trainings during their 40-hour workweek or pay the overtime premium where training attendance causes the employee to work over 40 hours in a workweek.

SBA Advocacy stated that the IRFA was incomplete "because it d[id] not analyze any regulatory alternatives that would minimize the impact of the rule for small businesses, such as lower salary levels." However, the Department considered several regulatory alternatives in the NPRM, describing both the alternatives it considered, which included lower (and higher) thresholds for the standard salary level and HCE total compensation requirement, and why it chose the earnings thresholds it proposed.[449] And it has considered and analyzed multiple

[449] *See* 88 FR 62217.

regulatory alternatives, including lower (and higher) thresholds for the standard salary and HCE total compensation requirement, in this final rule as well.[450]

SBA Advocacy recommended that the Department issue a Supplemental Regulatory Flexibility Analysis to be published in the *Federal Register* for public comment addressing compliance costs in and after the first year, compliance costs by different sized small entities, the current business environment, impacts to small nonprofits, the non-financial consequences of the rule, and the impacts of adopting alternative salary thresholds on different sizes of small businesses. The Department disagrees with SBA Advocacy that this rulemaking should be delayed for this reason. The Department provided a fully robust and transparent analysis of estimated impacts on small entities in its IRFA, relying on largely the same methods and assumptions the Department employed in drafting the IFRA in its 2019 rulemaking.

As the Department stated in the IRFA, it is difficult to directly evaluate compliance cost impacts by entity size due to lack of data concerning the distribution of affected workers by entity size. There are fewer affected workers than there are small entities. Therefore, many small entities will employ zero affected workers; small entities that do employ affected workers may employ one affected worker, or have nearly all workers affected, and anywhere in between. The number of small entities that employ affected workers will be inversely related to the number of affected employees per entity; if small entities only employ one affected worker, more entities will be affected, and vice versa.

Therefore, the Department evaluated a range of potential impacts from lowest to highest depending on whether one or all employees are affected. Furthermore, the Department evaluated

[450] *See* section VII.C.8.

the impact of regulatory compliance costs plus increased wages as a percent of payroll. Payroll is largely proportionate to the number of employees at the firm; if one entity has 10 times as many employees as another, its payroll is likely to be 10 times larger. Similarly, if an entity has 10 times more affected employees than another firm, then it will likely incur 10 times more compliance cost and wage impacts. Finally, firms hire more workers to increase production and sales, so entity revenues will be a multiple of payroll, although that multiple might vary by industry. If compliance costs and increased wages comprise 2 percent of payroll, those costs will comprise less than 2 percent of revenues. Thus, regardless of the size of the small entity, regulatory impacts should fall within the range calculated by the Department.

The Department shows in Table 34 that with the exception of the accommodation and the food services and drinking places industries, if all employees at an entity are affected by the rule, compliance cost and increased wages comprise less than 1.5 percent of payroll and substantially less than 1 percent of revenues per affected small entity. Although compliance costs and increased wages might comprise 3.55 percent of payroll in the food services and drinking places industry, that is about 1.10 percent of revenues. Performing this analysis for different sized firms should not appreciably change these results.

SBA Advocacy also recommended adopting a lower standard salary level that considers the significant small business impacts of the rule. The comment proposed two alternatives: retain the current standard salary threshold, or "adjust[] the standard salary threshold by a particular industry sector that will experience the greatest economic costs," noting that the 2019 standard salary level was based on earnings in both the lowest-wage Census region and the retail industry.

The comment also stated that small entities at SBA Advocacy's roundtable recommended a gradual or phased increase in the standard salary threshold.

Although SBA Advocacy disagreed with the standard salary level selected by the Department, the salary level accounts for regions and industries likely to be most affected by the rule. As discussed above,[451] the Department is setting the final rule standard salary level using the lowest-wage Census Region, instead of a national level, ensuring the salary level is not driven by earnings in high- or even middle-wage regions of the country. The Department believes that using earnings data from the lowest-wage Census Region produces a salary level that accounts for differences across industries and regional labor markets. The Department thus believes that the standard salary level is appropriate for small businesses.

Consistent with the history of the part 541 regulations, the Department also declines to create a lower salary level requirement for employees employed at small entities, or to exclude such employees from the salary level test. As the Department has previously noted, while "the FLSA itself does provide special treatment for small entities under some of its exemptions . . . the FLSA's statutory exemption for white-collar employees in section 13(a)(1) contains no special provision based on size of business."[452] In the 86-year history of the part 541 regulations defining the EAP exemption, the salary level requirements have never varied according to the size or revenue of the employer.[453]

---

[451] *See* sections V.B.4.iv, VII.C.2.
[452] *See* 81 FR 32526; 69 FR 22238.
[453] *See* Stein Report at 5–6 (rejecting proposals to set varying regional salary levels); *see also* 69 FR 22238 (stating that implementing differing salary levels based on business size industry-by-industry "would present the same insurmountable challenges" as adopting regional or population-based salary levels).

SBA Advocacy recommended that updates to the standard salary threshold be made once every 4 years through a proposed rule with a notice and comment process for each update, as opposed to updating the standard salary level every three years through the proposed updating mechanism. The comment conveyed skepticism regarding the lawfulness of the Department's proposed updating mechanism asserting that the FLSA requires the Department to periodically issue regulations to set the standard salary level. The comment also expressed concern that the updating provision would drive wage inflation for salaried workers because employers may raise the salaries of their newly nonexempt workers to keep them exempt or move them to hourly work to comply with the rule, thereby causing "a self-perpetuating threshold, as the salary level of the 35th percentile would grow each iteration or three years." The comment reported small businesses at Advocacy's roundtable opposed the proposed updating mechanism "because it creates steep and unpredictable changes to the EAP exemption and uncertainty for employers[,]" and asserted that small entities have highlighted the administrative burdens of reclassifying workers and tracking employee hours. The comment also mentioned the concern from small construction and professional services businesses about difficulties setting price structures on long term federal and private contracts.

The Department disagrees with SBA Advocacy's skepticism regarding the lawfulness of the updating mechanism. As explained in section V.A.3.i, the Department is adopting an updating mechanism in this rulemaking after publishing a notice of the proposed rule and providing opportunity for stakeholders to comment in accordance with the appropriate notice and comment requirements. The Department has received and considered numerous comments on the proposed updating mechanism. Future updates under the triennial updating mechanism would simply reset

the thresholds by applying current data to a standard already established by regulation. Therefore, the Department disagrees with the assertion that a notice and comment rulemaking must precede each future update made through the updating mechanism even where the methodology for setting the compensation levels and the mechanism for updating those levels would remain unchanged.

The Department also disagrees with the concern that the updating mechanism would result in rapid increases to the salary level solely because of employers' actions in response to the rule. This assertion is akin to the ones made by a number of other commenters that the updating mechanism tied to a fixed percentile would lead to the salary level being ratcheted upward over time due to the resulting actions of employers. As explained in detail in sections V.A.3.iii and VII.C.9, there is nothing to substantiate this assertion. On the contrary, the Department's analyses shows that employers' actions in response to the rule will not have the asserted impact on future updates. Rather, the updating mechanism will only ensure that the salary level continues to reflect prevailing economic conditions.

The Department also finds unpersuasive the assertion that the updating mechanism will lead to unpredictable changes and uncertainty for employers. Unlike irregular updates to the earnings thresholds, which may result in drastic changes to the thresholds, regular updates on a pre-determined interval and using an established methodology will produce more predictable and incremental changes. Through the updating mechanism, the Department will reset the standard salary level and total annual compensation threshold using the most recent, publicly available, BLS data on earnings for salaried workers. Therefore, employers will be able to track where the thresholds would fall on a quarterly basis by looking at the BLS data and can estimate the

changes in the thresholds even before the Department publishes the notice with the adjusted thresholds in the Federal Register. The Department believes that, compared to the irregular updates of the past, employers will be better positioned to anticipate and prepare for future updates under the updating mechanism.

SBA Advocacy also referenced that the Department must publish a small entity compliance guide for this rule. Pursuant to its obligations under section 212 of SBREFA, the Department will publish a small entity compliance guide for this rule.

SBA Advocacy recommended the Department add provisions to help small nonprofits comply with the rule, due to difficulties renegotiating government grants and contracts. As explained in section II.D, issues directly related to the public financing available for certain employers that might be affected by this final rule are beyond the Department's authority to address. However, the Department intends to issue technical assistance to help employers comply with the FLSA.

Finally, SBA Advocacy recommended an extended effective date for the rule of at least 1 year or 18 months, as small entities indicated needing "more time to understand and evaluate the rule, and possibly reclassify their workforce and budget for expenditures." As discussed in section IV, having considered commenter feedback in response to the NPRM, the Department has determined that a delayed applicability date is appropriate for the new standard salary level and the HCE total annual compensation threshold. Specifically, the new $1,128 per week standard salary level and $151,164 per year HCE total annual compensation threshold will not be applicable until approximately 8 months after publication of this final rule in the Federal Register. The Department will initially update those thresholds on July 1, 2024, by reapplying

the methodologies used to set those thresholds in the 2019 rule, resulting in an initial salary level of $844 per week and an initial HCE total annual compensation threshold of $132,964 per year. Those initial thresholds will remain in effect until the higher thresholds become applicable.

C. Significant Issues Raised by Public Comments in Response to the Initial Regulatory Flexibility Analysis

Many of the issues raised by small businesses in the public comments received on the proposed rule are described in the preamble and RIA above, which are incorporated herein. Nevertheless, significant issues raised by representatives of small businesses are also addressed here.

Most of the comments received concerning small businesses centered on the burden that the proposed salary level would impose on small entities. Many such commenters emphasized that rule-related costs would detrimentally impact small businesses. *See, e.g.*, Amusement and Music Operators Association; Independent Women's Forum; NSBA. Some commenters specifically asserted that the Department underestimated compliance costs for small entities under the proposed rule. *See, e.g.*, ABC; The 4A's. For example, NFIB contended that the rule could cost small businesses more than large businesses because, among other reasons, small businesses often have fewer resources (such as administrative staff members, experienced human resources personnel, or regular access to legal counsel). Sixteen Members of the U.S. House of Representatives cited rule-related costs, combined with burdens facing small businesses, in urging the Department to withdraw its proposal. A number of small businesses specifically raised concerns about the impact of the proposed salary level on small entities in low-wage regions and industries. *See, e.g.*, Nebraska Bankers Association; National Restaurant Association. Other commenters, including the Job Creators Network Foundation, expressed concern that the rule

would adversely impact small businesses by increasing inflation. Some small businesses, raising these and similar concerns, urged the Department to set a special salary level or create an exemption for small businesses. *See, e.g.*, Bowling Proprietors Association of America; WFCA. Opposition was not uniform, however, as some small businesses supported the proposed rule. *See, e.g.* A Few Cool Hardware Stores; BA Auto Care; Well-Paid Maids.

For the reasons previously discussed in detail, the Department believes its cost estimates are appropriate and do not provide a basis for changing the methodology used to set the salary level or for abandoning this rulemaking altogether. The Department does not agree with those commenters who asserted that the proposal would be ruinous for small businesses. As shown later in this section, Department's upper bound estimate of the impact of this rule per small establishment (which assumed all employees in a small firm are affected by the new rule) shows that costs and payroll increases for small affected firms were less than 0.9 percent of payroll and less than 0.2 percent of estimated revenues. While the affect in some industries will be somewhat larger, these figures reinforce that this rule will not be unduly burdensome for small businesses. In addition, the Department believes that most, if not all, small businesses, like larger businesses, employ a mix of exempt and overtime-protected workers. As such, to the extent cost concerns are tied in part to small businesses reclassifying some employees who become nonexempt as hourly as a result of this rule, many employers will already have policies and systems in place for scheduling workers and monitoring overtime hours worked and the corresponding overtime premium pay. Such established procedures, and experience gained through fairly recent rulemakings to increase the earnings thresholds, may help mitigate concerns related to small businesses requiring substantial assistance from outside professionals to comply with this final

rule. Additionally, the Department intends to publish compliance assistance materials, including a small entity compliance guide. Industry associations also typically become familiar with rulemakings such as this one and often provide compliance assistance to association members. As to inflationary concerns, as previously discussed, the Department does not expect its rule to lead to increased inflation on a national level.

The Department recognizes that many small employers operate in low-paying regions or industries, and the Department has historically accounted for small employers when setting the salary level.[454] This final rule is no exception, as the Department is setting the salary level using the lowest-wage Census Region. The Department declines to adopt special exceptions or lower salary levels for small businesses. As stated above and as the Department has emphasized in past rules, "'the FLSA's statutory exemption for white-collar employees in section 13(a)(1) contains no special provision based on size of business.'"[455] In the 86-year history of the part 541 regulations defining the EAP exemption, the Department has never adopted special salary levels for small businesses. The Department continues to believe that implementing differing salary levels based on business size industry-by-industry would be inadvisable because, among other reasons, it "would present the same insurmountable challenges" as adopting regional or population-based salary levels.[456]

The Department received many comments in response to its proposed mechanism to update the standard salary and HCE total annual compensation requirements. As discussed in

[454] *See, e.g.*, Weiss Report at 14–15 (setting the long test salary level for executive employees "slightly lower than might be indicated by the data" in part to avoid excluding "large numbers of the executives of small establishments from the exemption").
[455] *See* 81 FR 32526 (quoting 69 FR 22238).
[456] 69 FR 22238.

section V.A.3.i, some commenters asserted that the proposed updating mechanism would violate the RFA. Commenters, including Independent Electrical Contracts, RILA, and Seyfarth Shaw, commented that the RFA required the Department "to undertake a detailed economic and cost analysis" and that Department's proposed updating mechanism would bypass these requirements. The RFA requires a regulatory flexibility analysis to accompany any agency final rule promulgated under 5 U.S.C. 553.[457] In accordance with this requirement, this section estimates the costs of future triennial updates using the fixed percentile method. The RFA only requires that such analyses accompany rulemaking, and commenters did not cite any RFA provision that would require the Department to conduct a new regulatory flexibility analysis before each scheduled update to the salary and annual compensation thresholds.

Several commenters addressed the potential effects that the proposed updating mechanism could have on small entities. Small Business Majority expressed support for the proposed updating mechanism, asserting that "[s]maller, predictable increases that are known well in advance will allow small business owners to be better prepared for any staffing or compensation changes they need to make." Business for a Fair Minimum Wage—whose members include many small business owners—commented that the proposed updating mechanism would keep the thresholds up to date and predictable for employers. In contrast, NFIB asserted that "triennial updates would result in instability in labor and administrative costs for small businesses in perpetuity" as small businesses would have to reconsider the classifications given to their employees every 3 years. The 4As similarly asserted that the updating mechanism imposes substantial ongoing expense on small agencies noting that "[l]ike

[457] *See* 5 U.S.C. 603–604.

many small businesses, small agencies often outsource legal, payroll, and some HR functions to outside professionals." ASTA expressed concern that "small business owners with limited resources to engage outside help, would have difficulty keeping abreast of salary level increases and could inadvertently find themselves out of compliance."

As previously explained, the Department believes the updating mechanism adopted by this final rule will ensure greater certainty and predictability for the regulated community. For all future triennial updates, the Department will publish a notice with the revised salary and annual compensation thresholds not fewer than 150 days before the new thresholds are set to take effect. Moreover, businesses will be able to estimate the changes in the thresholds by looking at BLS data even before the Department publishes the notice with the adjusted thresholds. The Department believes that, compared to the irregular updates of the past, employers will be better positioned to anticipate and prepare for future updates under the updating mechanism. As noted in section V.A.3.ii, the alternative to Department's updating mechanism is not a permanent fixed earnings threshold, but instead larger changes to the threshold that would occur during irregular future updates. Since the updating mechanism will change the thresholds regularly and incrementally, and based on actual earnings of salaried workers, the Department predicts that employers will be in a better position to be able to adjust to the changes resulting from triennial updates.

The Department believes that the updating mechanism will ensure that the earnings thresholds for the EAP exemption will remain effective and up to date over time. The updating mechanism should benefit employers of all sizes going forward by avoiding the uncertainty and disruptiveness of larger increases that would likely occur as a result of irregular updates.

D. Estimate of the Number of Affected Small Entities

1. Definition of Small Entity

The RFA defines a "small entity" as (1) a small not-for-profit organization, (2) a small governmental jurisdiction, or (3) a small business. The Department used the entity size standards defined by SBA and in effect as of 2019, to classify entities as small or large.[458] The most recent size standards were released in 2022 and use the 2022 NAICS. However, because the data used by the Department to estimate the number of small entities uses the 2017 NAICS, the Department used the 2019 entity size standards instead of the 2022 standards.[459]

SBA establishes standards for 6-digit NAICS industry codes, and standard size cutoffs are typically based on either the average number of employees or average annual receipts. However, some exceptions exist, the most notable being that depository institutions (including credit unions, commercial banks, and non-commercial banks) are classified by total assets and small governmental jurisdictions are defined as areas with populations of less than 50,000.[460]

2. Number of Small Entities and Employees

The primary data source used to estimate the number of small entities and employment in these entities is the Statistics of U.S. Businesses (SUSB). Alternative sources were used for

[458] *See* https://data.sba.gov/dataset/small-business-size-standards/resource/d89a5f17-ab8e-4698-9031-dfeb34d0a773.
[459] The SBA size standard changes in 2022 primarily adjusted the standards to the 2022 NAICS, these changes were not substantive. https://www.govinfo.gov/content/pkg/FR-2022-09-29/pdf/2022-20513.pdf.
[460] *See* https://advocacy.sba.gov/resources/the-regulatory-flexibility-act/rfa-data-resources-for-federal-agencies/ for details.

industries with asset thresholds (credit unions,[461] commercial banks and savings institutions,[462] agriculture[463]), and public administration.[464] The Department used 2017 data, when possible, to align with the use of 2017 SUSB data. Private households are excluded from the analysis due to lack of data.

For each industry, the SUSB 2017 tabulates employment, establishment, and firm counts by both enterprise employment size (*e.g.*, 0-4 employees, 5-9 employees) and receipt size (*e.g.*, less than $100,000, $100,000-$499,999).[465] Although more recent SUSB data are available, these data do not disaggregate entities by revenue sizes. The Department combined these data with the SBA size standards to estimate the proportion of firms and establishments in each industry that are considered small, and the proportion of workers employed by a small entity. The Department classified all firms and establishments and their employees in categories below the SBA cutoff as small.[466] If a cutoff fell in the middle of a category, the Department assumed a uniform

[461] National Credit Union Association. (2018). 2018 Year End Statistics for Federally Insured Credit Unions. Available at: https://www.cuna.org/advocacy/credit-union---economic-data/data---statistics/credit-union-profile-reports.html.
[462] Federal Depository Insurance Corporation. (2018). Quarterly Financial Reports-Statistics On Depository Institutions (SDI). Available at: https://www.fdic.gov/foia/ris/id-sdi/index.html. Data are from 12/31/17.
[463] United States Department of Agriculture. (2019). 2017 Census of Agriculture: United States Summary and State Data: Volume 1, Geographic Area Series, Part 51. Available at: https://www.nass.usda.gov/Publications/AgCensus/2017/Full_Report/Volume_1,_Chapter_1_US/usv1.pdf.
[464] Census of Governments. 2017. Available at: https://www.census.gov/data/tables/2017/econ/gus/2017-governments.html.
[465] The SUSB defines employment as of March 12th.
[466] The Department's estimates of the numbers of affected small entities and affected workers who are employees of small entities includes entities not covered by the FLSA and thus are likely overestimates. The Department had no credible way to estimate which enterprises with annual revenues below $500,000 also did not engage in interstate commerce and hence are not subject to the FLSA.

distribution of employees across that bracket to determine what proportion of establishments should be classified as small.[467] The estimated share of establishments that were small in 2017 was applied to the more recent 2021 SUSB data on the number of small establishments to determine the number of small entities.[468]

The Department also estimated the number of small establishments and their employees by employer type (nonprofit, for-profit, government). This calculation is similar to the calculation of the number of establishments by industry but with different data. Instead of using data by industry, the Department used SUSB data by Legal Form of Organization for nonprofit and for-profit establishments. The estimated share of establishments that were calculated as small with the 2017 data was then applied to the 2021 SUSB counts. For governments, the Department used the number of governments reported in the 2017 Census of Governments.[469]

Table 28 presents the estimated number of establishments/governments and small establishments/governments in the U.S. (hereafter, referred to as "entities").[470] The numbers in the following tables are for Year 1; projected impacts are considered later. The Department found

[467] The Department assumed that the small entity share of credit card issuing and other depository credit intermediation institutions (which were not separately represented in FDIC asset data), is similar to that of commercial banking and savings institutions.
[468] Statistics of U.S. Businesses 2021, https://www.census.gov/programs-surveys/susb.html.
[469] Census of Governments 2017. Available at https://www.census.gov/programs-surveys/cog.html.
[470] SUSB reports data by "enterprise" size designations (a business organization consisting of one or more domestic establishments that were specified under common ownership or control). However, the number of enterprises is not reported for the size designations. Instead, SUSB reports the number of "establishments" (individual plants, regardless of ownership) and "firms" (a collection of establishments with a single owner within a given state and industry) associated with enterprises size categories. Therefore, numbers in this analysis are for the number of establishments associated with small enterprises, which may exceed the number of small enterprises. The Department based the analysis on the number of establishments rather than firms for a more conservative estimate (potential overestimate) of the number of small businesses.

that of the 8.2 million entities, 80 percent (6.6 million) are small by SBA standards. These small entities employ 55.3 million workers, about 37 percent of workers (excluding self-employed, unpaid workers, and members of the armed forces). They also account for roughly 35 percent of total payroll ($3.7 trillion of $10.7 trillion).[471]

Although the Department used 6-digit NAICS to determine the number of small entities and the associated number of employees, the following tables aggregate findings to 27 industry categories. This was the most detailed level available while maintaining adequate sample sizes.[472] The Department started with the 51-industry breakdown and aggregated where necessary to obtain adequate sample sizes.

Table 28: Number of Entities and Employees by SBA Size Standards, by Industry and Employer Type

Industry / Employer Type	Entities (1,000s)		Workers (1,000s) [a]		Annual Payroll (Billions)	
	Total	Small	Total	Small Business Employed	Total	Small
Total	8,238.7	6,588.6	147,798.7	55,279.6	$10,660.7	$3,743.6
Industry [b]						
Agriculture, forestry, fishing, and hunting	23.3	19.3	1,349.6	702.6	$66.0	$34.7
Mining	23.0	18.5	587.9	276.3	$62.3	$28.6
Construction	780.3	752.7	9,345.8	5,617.2	$646.7	$390.4
Manufacturing - durable goods	174.6	159.8	10,032.5	4,634.0	$824.9	$368.6
Manufacturing - non-durable goods	108.4	96.6	5,580.1	2,674.4	$435.0	$195.1

[471] Since information is not available on employer size in the CPS MORG, respondents were randomly assigned as working in a small business based on the SUSB probability of employment in a small business by detailed Census industry. Annual payroll was estimated based on the CPS weekly earnings of workers by industry size.

[472] The Department required at least 15 affected workers (*i.e.*, observations) in small entities in Year 1.

Wholesale trade	390.8	301.3	3,169.5	1,308.9	$250.8	$100.9
Retail trade	1,036.9	661.3	15,698.4	4,878.2	$815.6	$264.4
Transportation and warehousing	279.1	220.1	7,539.4	1,795.4	$476.5	$112.3
Utilities	19.9	8.0	1,463.3	309.9	$142.3	$27.2
Information	162.0	93.9	2,720.8	702.5	$283.3	$69.2
Finance	297.4	137.5	4,859.8	875.2	$533.1	$99.5
Insurance	181.5	139.9	2,801.6	641.1	$254.1	$58.0
Real estate and rental and leasing	456.2	353.3	2,359.8	1,212.3	$181.8	$93.5
Professional and technical services	962.5	858.7	12,003.4	5,320.8	$1,389.8	$598.3
Management, administrative and waste management services	499.5	411.0	5,622.8	2,406.6	$310.7	$121.8
Educational services	111.5	98.9	14,383.5	3,701.4	$998.1	$239.4
Hospitals	7.5	1.5	7,832.2	277.4	$649.1	$22.6
Health care services, except hospitals	751.4	579.3	10,476.2	4,565.8	$672.5	$288.7
Social assistance	188.7	152.8	3,121.3	1,739.0	$153.9	$82.7
Arts, entertainment, and recreation	156.1	142.3	2,656.0	1,296.1	$138.7	$66.7
Accommodation	70.8	59.4	1,190.0	466.8	$57.9	$22.6
Food services and drinking places	675.1	524.8	8,750.2	4,952.0	$294.8	$167.6
Repair and maintenance	220.0	202.3	1,736.5	1,253.6	$95.9	$68.8
Personal and laundry services	254.4	226.7	1,644.1	1,286.4	$71.7	$55.5
Membership associations and organizations	307.0	294.8	2,038.9	1,395.3	$143.6	$96.1

Public administration [c]	90.1	65.7	8,211.2	990.3	$692.2	$70.6
Employer Type						
Nonprofit, private	597.3	504.5	10,692.3	4,029.0	$796.6	$264.3
For profit, private	7,551.3	5,874.3	114,570.7	47,910.7	$8,169.1	$3,257.6
Government (state and local)	90.1	65.7	18,284.5	3,339.9	$1,296.3	$221.7

Note: Establishment data are from SUSB 2021; worker and payroll data from pooled CPS MORG data for 2021-2023 adjusted to reflect 2023.

[a] Excludes the self-employed, unpaid workers, and workers in private households.

[b] Summation across industries may not add to the totals reported due to suppressed values and some entities not reporting an industry.

[c] Entity number represents the total number of governments, including state and local. Data from Census of Governments, 2017.

Estimates are not limited to entities subject to the FLSA because the Department cannot estimate which enterprises do not meet the enterprise coverage requirements because of data limitations. Although not excluding such entities and associated workers only affects a small percentage of workers generally, it may have a larger effect (and result in a larger overestimate) for non-profits, because revenue from charitable activities is not included when determining enterprise coverage.

3. Number of Affected Small Entities and Employees

The calculation of the number of affected EAP workers was explained in detail in section VII.B. Here, the Department focuses on how these workers were allocated to either small or large entities. To estimate the probability that an exempt EAP worker in the CPS data is employed by a small entity, the Department assumed this probability is equal to the proportion of all workers employed by small entities in the corresponding industry. That is, if 50 percent of

workers in an industry are employed in small entities, then on average small entities are expected to employ one out of every two exempt EAP workers in this industry.[473] The Department applied these probabilities to the population of exempt EAP workers to find the number of workers (total exempt EAP workers and total affected by the rule) that small entities employ. No data are available to determine whether small businesses (or small businesses in specific industries) are more or less likely than non-small businesses to employ exempt EAP workers or affected EAP workers. Therefore, the best assumption available is to assign the same rates to all small and non-small businesses.[474, 475]

The Department estimated that small entities employ 1.6 million of the 4.3 million affected workers (36.3 percent) (Table 29). This composes 2.8 percent of the 55.3 million workers that small entities employ. The sectors with the highest total number of affected workers employed by small entities are professional and technical services (281,000); health care services, except hospitals (140,000); and retail trade (125,000). The sectors with the largest percent of workers employed by small entities who are affected include: insurance (7.0 percent);

[473] The Department used CPS microdata to estimate the number of affected workers. This was done individually for each observation in the relevant sample by randomly assigning them a small business status based on the best available estimate of the probability of a worker to be employed in a small business in their respective industry.

[474] A strand of literature indicates that small businesses tend to pay lower wages than larger businesses. This may imply that workers in small businesses are more likely to be affected than workers in large businesses; however, the literature does not make clear what the appropriate alternative rate for small businesses should be.

[475] Workers are designated as employed in a small business based on their industry of employment. The share of workers considered small in nonprofit, for profit, and government entities is therefore the weighted average of the shares for the industries that compose these categories.

membership associations and organizations (5.7 percent); and professional and technical services

(5.3 percent).

Table 29: Number of Affected Workers Employed by Small Entities, by Industry and Employer Type

Industry	Workers (1,000s)		Affected Workers (1,000s) [a]	
	Total	Small Business Employed	Total	Small Business Employed
Total	147,798.7	55,279.6	4,337.5	1,574.1
Industry				
Agriculture, forestry, fishing, and hunting	1,349.6	702.6	13.3	6.4
Mining	587.9	276.3	18.5	8.8
Construction	9,345.8	5,617.2	184.6	112.1
Manufacturing - durable goods	10,032.5	4,634.0	232.9	121.8
Manufacturing - non-durable goods	5,580.1	2,674.4	117.7	58.9
Wholesale trade	3,169.5	1,308.9	112.3	50.9
Retail trade	15,698.4	4,878.2	377.4	124.5
Transportation and warehousing	7,539.4	1,795.4	113.1	30.0
Utilities	1,463.3	309.9	39.8	7.5
Information	2,720.8	702.5	132.4	34.8
Finance	4,859.8	875.2	276.4	43.6
Insurance	2,801.6	641.1	198.6	45.1
Real estate and rental and leasing	2,359.8	1,212.3	89.4	51.3
Professional and technical services	12,003.4	5,320.8	676.3	280.7
Management, administrative and waste management services	5,622.8	2,406.6	151.1	47.5
Educational services	14,383.5	3,701.4	244.1	53.4
Hospitals	7,832.2	277.4	238.9	11.4
Health care services, except hospitals	10,476.2	4,565.8	347.0	140.1
Social assistance	3,121.3	1,739.0	154.2	91.4
Arts, entertainment, and recreation	2,656.0	1,296.1	118.3	64.6

Accommodation	1,190.0	466.8	26.6	12.3
Food services and drinking places	8,750.2	4,952.0	83.6	42.0
Repair and maintenance	1,736.5	1,253.6	21.5	16.1
Personal and laundry services	1,644.1	1,286.4	23.4	14.3
Membership associations and organizations	2,038.9	1,395.3	117.8	79.4
Public administration	8,211.2	990.3	227.2	25.2
Employer Type				
Nonprofit, private	10,692.3	4,029.0	461.3	201.3
For profit, private	114,570.7	47,910.7	3,392.5	1,310.8
Government (state and local)	18,284.5	3,339.9	483.6	62.1

Note: Worker data are from pooled CPS MORG data for 2021-2023 adjusted to reflect 2023.
[a] Estimation of affected workers employed by small entities was done at the most detailed industry level available. Therefore, at the more aggregated industry level shown in this table, the ratio of small business employed to total employed does not equal the ratio of affected small business employed to total affected for each industry, nor does it equal the ratio for the national total because relative industry size, employment, and small business employment differs from industry to industry.

Because no information is available on how affected workers would be distributed among small entities, the Department estimated a range of effects. At one end of this range, the Department assumed that each small entity employs no more than one affected worker, meaning that at most 1.6 million of the 6.6 million small entities will employ an affected worker. Thus, these assumptions provide an upper-end estimate of the number of affected small entities. (However, it provides a lower-end estimate of the effect per small entity because costs are spread over a larger number of entities; the impacts experienced by an entity would increase as the share of its workers that are affected increases.) For the purpose of estimating a lower-range number of affected small entities, the Department used the average size of a small entity as the typical size of an affected small entity, and assumed all workers are affected. This can be considered an

approximation of all employees at an entity affected.[476] The average number of employees in a small entity is the number of workers that small entities employ divided by the total number of small establishments in that industry. The number of affected employees at small businesses is then divided by this average number of employees to calculate 208,300 affected small entities.

Table 30 summarizes the estimated number of affected workers that small entities employ and the expected range for the number of affected small entities by industry. The Department estimated that the rule will affect 1.6 million workers who are employed by somewhere between 208,300 and 1.6 million small entities; this comprises from 3.2 percent to 23.9 percent of all small entities. It also means that from 5.0 million to 6.4 million small entities would incur no more than minimal regulatory familiarization costs (*i.e.*, 6.6 million minus 1.6 million equals 5.0 million; 6.6 million minus 208,300 equals 6.4 million, using rounded values). The table also presents the average number of affected employees per establishment using the method in which all employees at the establishment would be affected. For the other method, by definition, there would always be one affected employee per establishment. Also displayed is the average payroll per small establishment by industry (based on both affected and non-affected small entities), calculated by dividing total payroll of small businesses by the number of small businesses (Table 28) (applicable to both methods).

[476] This is not the true lower bound estimate of the number of affected entities. Strictly speaking, a true lower bound estimate of the number of affected small entities would be calculated by assuming all employees in the largest small entity are affected. For example, if the SBA standard is that entities with 500 employees are "small," and 1,350 affected workers are employed by small entities in that industry, then the smallest number of entities that could be affected in that industry (the true lower bound) would be three. However, because such an outcome appears implausible, the Department determined a more reasonable lower estimate would be based on average establishment size.

Table 30: Number of Small Affected Entities and Employees by Industry and Employer Type

Industry	Affected Workers in Small Entities (1,000s)	Number of Small Affected Entities (1,000s) [a]		Per Entity	
		One Affected Employee per Entity [b]	All Employees at Entity Affected [c]	Affected Employees [a]	Average Annual Payroll ($1,000s)
Total	1,574.1	1,574.1	208.3	7.6	$568.2
Industry					
Agriculture, forestry, fishing, and hunting	6.4	6.4	0.2	36.4	$1,796.9
Mining	8.8	8.8	0.6	15.0	$1,546.6
Construction	112.1	112.1	15.0	7.463	$518.6
Manufacturing - durable goods	121.8	121.8	4.2	29.0	$2,306.3
Manufacturing - non-durable goods	58.9	58.9	2.1	27.7	$2,020.1
Wholesale trade	50.9	50.9	11.7	4.3	$334.9
Retail trade	124.5	124.5	16.9	7.4	$399.7
Transportation and warehousing	30.0	30.0	3.7	8.2	$510.4
Utilities	7.5	7.5	0.2	38.9	$3,415.5
Information	34.8	34.8	4.7	7.5	$736.8
Finance	43.6	43.6	6.9	6.4	$723.6
Insurance	45.1	45.1	9.8	4.6	$415.0
Real estate and rental and leasing	51.3	51.3	15.0	3.4	$264.7
Professional and technical services	280.7	280.7	45.3	6.2	$696.8
Management, administrative and waste management services	47.5	47.5	8.1	5.9	$296.4
Educational services	53.4	53.4	1.4	37.4	$2,420.0
Hospitals	11.4	9.9 [d]	0.1	189.1	$15,377.1
Health care services, except hospitals	140.1	140.1	17.8	7.9	$498.4
Social assistance	91.4	91.4	8.0	11.4	$541.3

Arts, entertainment, and recreation	64.6	64.6	7.1	9.1	$468.5
Accommodation	12.3	12.3	1.6	7.9	$379.4
Food services and drinking places	42.0	42.0	4.5	9.4	$319.3
I Repair and maintenance	16.1	16.1	2.6	6.2	$340.1
Personal and laundry services	14.3	14.3	2.5	5.7	$244.8
Membership associations and organizations	79.4	79.4	16.8	4.7	$325.8
Public administration [e]	25.2	25.2	1.7	15.1	$1,075.1
Employer Type					
Nonprofit, private	201.3	201.3	25.2	8.0	$523.9
For profit, private	1,310.8	1,310.8	160.7	8.2	$554.5
Government (state and local)	62.1	62.1	1.2	50.8	$3,373.6

Note: Establishment data are from SUSB 2021; worker and payroll data from pooled CPS MORG data for 2021-2023 adjusted to reflect 2023.

[a] Estimation of both affected small entity employees and affected small entities was done at the most detailed industry level available. Therefore, the ratio of affected small entities employees to total small entity employees for each industry may not match the ratio of small affected entities to total small entities at the more aggregated industry level presented in the table, nor will it equal the ratio at the national level because relative industry size, employment, and small business employment differs from industry to industry.

[b] This method may overestimate the number of affected entities and therefore the ratio of affected workers to affected entities may be greater than 1-to-1. However, the Department addresses this issue by also calculating effects based on the assumption that 100 percent of workers at an entity are affected.

[c] For example, on average, a small entity in the construction industry employs 7.5 workers (5.6 million employees divided by 752,700 small entities). This method assumes if an entity is affected then all 7.5 workers are affected. Therefore, in the construction industry this method estimates there are 15,000 small affected entities (112,100 affected small entity workers divided by 7.5).

[d] Number of entities is smaller than number of affected employees; thus, total number of entities is ,reported.

[e] Entity number represents the total number of state and local governments.

4. Impacts to Affected Small Entities

For small entities, the Department estimated various types of effects, including regulatory familiarization costs, adjustment costs, managerial costs, and payroll increases borne by employers. The Department estimated a range for the number of affected small entities and the impacts they incur. While the upper and lower bounds are likely over- and under-estimates, respectively, of effects per small entity, the Department believes that this range of costs and payroll increases provides the most accurate characterization of the effects of the rule on small employers.[477] Furthermore, the smaller estimate of the number of affected entities (*i.e.*, where all employees at each affected employer are assumed to be affected) will result in the largest costs and payroll increases per entity as a percent of establishment payroll and revenue, and the Department expects that many, if not most, entities will incur smaller costs, payroll increases, and effects relative to entity size.

Parameters that are used in the small business cost analysis for Year 1 are provided in Table 31, along with summary data of the impacts.[478]

Table 31: Overview of Parameters used for Costs to Small Businesses and the Impacts on Small Businesses

Small Business Costs	Cost
Direct and Payroll Costs	
Average total cost per affected entity [a]	$4,544
Range of total costs per affected entity [a]	$1,767-$57,218
Average percent of revenue per affected entity	0.16%
Average percent of payroll per affected entity	0.80%
Direct Costs	

[477] As noted previously, these are not the true lower and upper bounds. The values presented are the highest and lowest estimates the Department believes are plausible.
[478] *See* section VII.C.3 for a more fulsome discussion on these costs.

Regulatory familiarization	
Time (first year)	1 hour per entity
Time (update years)	10 minutes per entity
Hourly wage	$54.82
Adjustment	
Time (first year affected)	75 minutes per newly affected worker
Hourly wage	$54.82
Managerial	
Time (weekly)	10 minutes per affected worker whose hours change
Hourly wage	$86.82
Payroll Increases	
Average payroll increase per affected entity [a]	$2,773
Range of payroll increases per affected entity [a]	$674-$15,532

[a] Using the methodology where all employees at an affected small firm are affected. This assumption generates upper-end estimates. Lower-end cost estimates are significantly smaller.

The Department expects total direct employer costs will range from $368.7 million to $443.6 million for affected small entities (*i.e.*, those with affected employees) in the first year (an average cost of between $282 to $1,771 per entity) (Table 32). Small entities that do not employ affected workers will incur $274.9 million to $349.7 million in regulatory familiarization costs (an average cost of $54.82 per entity). The three industries with the highest costs (professional and technical services; health care services, except hospitals; and retail trade) account for about 35 percent of the costs. Hospitals are expected to incur the largest cost per establishment ($42,900 using the method where all employees are affected), although the costs are not expected to exceed 0.3 percent of payroll. The food services and drinking places industry is expected to experience the largest effect as a share of payroll (estimated direct costs compose 0.69 percent of average entity payroll).

Table 32: Year 1 Small Establishment Direct Costs, Total and per Establishment, by Industry and Employer Type

Industry	Direct Cost to Small Entities in Year 1 [a]					
	One Affected Employee			All Employees Affected		
	Total (Millions) [a]	Cost per Affected Entity	Percent of Annual Payroll	Total (Millions) [b]	Cost per Affected Entity	Percent of Annual Payroll
Total	$443.6	$282	0.05%	$368.7	$1,771	0.31%
Industry						
Agriculture, forestry, fishing, and hunting	$1.8	$281	0.02%	$1.5	$8,292	0.46%
Mining	$2.5	$281	0.02%	$2.0	$3,443	0.22%
Construction	$31.6	$282	0.05%	$26.3	$1,751	0.34%
Manufacturing - durable goods	$34.3	$282	0.01%	$27.9	$6,631	0.29%
Manufacturing - non-durable goods	$16.7	$283	0.01%	$13.5	$6,367	0.32%
Wholesale trade	$14.3	$281	0.08%	$12.2	$1,039	0.31%
Retail trade	$35.1	$282	0.07%	$29.2	$1,731	0.43%
Transportation and warehousing	$8.5	$282	0.06%	$7.0	$1,912	0.37%
Utilities	$2.1	$281	0.01%	$1.7	$8,876	0.26%
Information	$9.8	$281	0.04%	$8.1	$1,750	0.24%
Finance	$12.3	$281	0.04%	$10.3	$1,496	0.21%
Insurance	$12.7	$281	0.07%	$10.8	$1,093	0.26%
Real estate and rental and leasing	$14.5	$283	0.11%	$12.5	$839	0.32%
Professional and technical services	$79.1	$282	0.04%	$66.2	$1,460	0.21%
Management, administrative and waste management services	$13.5	$284	0.10%	$11.3	$1,394	0.47%

Educational services	$15.0	$281	0.01%	$12.2	$8,531	0.35%
Hospitals	$3.2	$281	0.00%	$2.6	$42,885	0.28%
Health care services, except hospitals	$39.5	$282	0.06%	$32.8	$1,842	0.37%
Social assistance	$25.7	$281	0.05%	$21.1	$2,633	0.49%
Arts, entertainment, and recreation	$18.2	$282	0.06%	$15.0	$2,120	0.45%
Accommodation	$3.5	$281	0.07%	$2.9	$1,834	0.48%
Food services and drinking places	$11.9	$282	0.09%	$9.8	$2,203	0.69%
Repair and maintenance	$4.5	$281	0.08%	$3.8	$1,459	0.43%
Personal and laundry services	$4.0	$282	0.12%	$3.4	$1,343	0.55%
Membership associations and organizations	$22.4	$282	0.09%	$18.9	$1,129	0.35%
Public administration	$7.1	$281	0.03%	$5.8	$3,471	0.32%
Employer Type						
Nonprofit, private	$54.4	$270	0.05%	$44.8	$1,777	0.34%
For profit, private	$394.4	$301	0.05%	$331.4	$2,062	0.37%
Government (state and local)	$17.5	$283	0.01%	$14.2	$11,633	0.34%

Note: Pooled CPS data for 2021-2023 adjusted to reflect 2023.

[a] Direct costs include regulatory familiarization, adjustment, and managerial costs.

[b] The range of costs per entity depends on the number of affected entities. The minimum assumes that each affected entity has one affected worker (therefore, the number of affected entities is equal to the number of affected workers). The maximum assumes the share of workers in small entities who are affected is also the share of small entity entities that are affected.

It is possible that the costs of the rule may be disproportionately large for small entities, especially because small entities often have limited human resources personnel on staff. However, the Department expects that small entities would rely on compliance assistance

materials provided by the Department or industry associations to become familiar with the final rule. Additionally, the Department notes that the rule is narrow in scope because the changes all relate to the salary component of the part 541 regulations. Finally, the Department believes that most entities have at least some nonexempt employees and, therefore, already have policies and systems in place for monitoring and recording their hours. The Department believes that applying those same policies and systems to the workers whose exemption status changes will not be an unreasonable burden on small businesses.

Average weekly earnings for affected EAP workers in small entities are expected to increase by about $7.06 per week per affected worker, using the incomplete fixed-job model[479] described in section VII.C.4.iii.[480] This would lead to $577.5 million in additional annual wage payments to employees in small entities (less than 0.5 percent of aggregate affected establishment payroll; Table 33). The largest payroll increases per establishment are expected in utilities (up to $15,500 per entity); hospitals (up to $14,300 per entity); and manufacturing - durable goods (up to $13,000 per entity). However, average payroll increases per entity would exceed one percent of average annual payroll in only two sectors: food services and drinking places (2.9 percent) and accommodation (1.1 percent).

Table 33: Year 1 Small Establishment Payroll Increases, Total and per Establishment, by Industry and Employer Type

[479] The incomplete fixed-job model reflects the Department's determination that an appropriate estimate of the impact on the implicit hourly rate of pay for regular overtime workers should be determined using the average of Barkume's and Trejo's two estimates of the incomplete fixed-job model adjustments: a wage change that is 40 percent of the adjustment toward the amount predicted by the fixed-job model, assuming an initial zero overtime pay premium, and a wage change that is 80 percent of the adjustment assuming an initial 28 percent overtime pay premium.
[480] This is an average increase for all affected workers (both standard test and HCE), and reconciles to the weighted average of individual salary changes discussed in the Transfers section.

Industry	Increased Payroll for Small Entities in Year 1 [a]				
	Total (Millions)	One Affected Employee		All Employees Affected	
		Per Entity	Percent of Annual Payroll	Per Entity	Percent of Annual Payroll
Total	$577.5	$367	0.06%	$2,773	0.49%
Industry					
Agriculture, forestry, fishing, and hunting	$1.2	$195	0.01%	$7,088	0.39%
Mining	$2.2	$256	0.02%	$3,828	0.25%
Construction	$43.6	$389	0.08%	$2,904	0.56%
Manufacturing - durable goods	$54.7	$449	0.02%	$13,027	0.56%
Manufacturing - non-durable goods	$21.9	$372	0.02%	$10,291	0.51%
Wholesale trade	$24.9	$489	0.15%	$2,123	0.63%
Retail trade	$66.2	$532	0.13%	$3,922	0.98%
Transportation and warehousing	$14.0	$468	0.09%	$3,815	0.75%
Utilities	$3.0	$399	0.01%	$15,532	0.45%
Information	$4.1	$116	0.02%	$871	0.12%
Finance	$12.0	$274	0.04%	$1,746	0.24%
Insurance	$6.6	$147	0.04%	$674	0.16%
Real estate and rental and leasing	$25.7	$500	0.19%	$1,716	0.65%
Professional and technical services	$116.8	$416	0.06%	$2,577	0.37%
Management, administrative and waste management services	$14.1	$296	0.10%	$1,733	0.58%
Educational services	$12.0	$225	0.01%	$8,434	0.35%
Hospitals	$0.9	$76	0.00%	$14,333	0.09%
Health care services, except hospitals	$30.6	$218	0.04%	$1,721	0.35%
Social assistance	$12.3	$135	0.02%	$1,534	0.28%
Arts, entertainment, and recreation	$28.8	$446	0.10%	$4,059	0.87%
Accommodation	$6.6	$533	0.14%	$4,189	1.10%

Food services and drinking places	$40.7	$968	0.30%	$9,136	2.86%
Repair and maintenance	$8.7	$539	0.16%	$3,341	0.98%
Personal and laundry services	$2.1	$148	0.06%	$841	0.34%
Membership associations and organizations	$19.4	$244	0.07%	$1,155	0.35%
Public administration	$4.6	$181	0.02%	$2,730	0.25%
Employer Type					
Nonprofit, private	$47.3	$235	0.04%	$1,879	0.36%
For profit, private	$511.4	$390	0.07%	$3,182	0.57%
Government (state and local)	$18.8	$302	0.01%	$15,371	0.46%

Note: Pooled CPS data for 2021-2023 adjusted to reflect 2023.

[a] Aggregate change in total annual payroll experienced by small entities under the updated salary levels after labor market adjustments. This amount represents the total amount of (wage) transfers from employers to employees.

Table 34 presents estimated first year direct costs and payroll increases combined per entity and the costs and payroll increases as a percent of average entity payroll. The Department presents only the results for the upper bound scenario where all workers employed by the entity are affected. Combined costs and payroll increases per establishment range from $1,800 in insurance to $57,200 in hospitals. Combined costs and payroll increases compose more than two percent of average annual payroll in one sector, food services and drinking places (3.6 percent).

However, comparing costs and payroll increases to payrolls overstates the effects on entities because payroll represents only a fraction of the financial resources available to an establishment. The Department approximated revenue per affected small establishment by calculating the ratio of small business revenues to payroll by industry from the 2017 SUSB data

then multiplying that ratio by average small entity payroll.[481] Using this approximation of annual revenues as a benchmark, only one sector will have costs and payroll increases amounting to greater than one percent of revenues, food services and drinking places (1.1 percent).

Table 34: Year 1 Small Establishment Direct Costs and Payroll Increases, Total and per Entity, by Industry and Employer Type, Using All Employees in Entity Affected Method

Industry	Costs and Payroll Increases for Small Affected Entities, All Employees Affected			
	Total (Millions)	Per Entity [a]	Percent of Annual Payroll	Percent of Estimated Revenues [b]
Total	$946.3	$4,544	0.80%	0.16%
Industry				
Agriculture, forestry, fishing, and hunting	$2.7	$15,381	0.86%	0.17%
Mining	$4.3	$7,271	0.47%	0.07%
Construction	$69.9	$4,655	0.90%	0.21%
Manufacturing - durable goods	$82.6	$19,659	0.85%	0.18%
Manufacturing - non-durable goods	$35.4	$16,658	0.82%	0.11%
Wholesale trade	$37.1	$3,162	0.94%	0.07%
Retail trade	$95.4	$5,652	1.41%	0.14%
Transportation and warehousing	$21.1	$5,726	1.12%	0.26%
Utilities	$4.7	$24,409	0.71%	0.05%
Information	$12.2	$2,621	0.36%	0.11%
Finance	$22.2	$3,242	0.45%	0.13%
Insurance	$17.4	$1,767	0.43%	0.09%
Real estate and rental and leasing	$38.2	$2,554	0.97%	0.21%
Professional and technical services	$182.9	$4,038	0.58%	0.23%
Management, administrative and waste management services	$25.4	$3,127	1.06%	0.43%
Educational services	$24.2	$16,965	0.70%	0.29%
Hospitals	$3.5	$57,218	0.37%	0.16%

[481] The Department used this estimate of revenue, instead of small business revenue reported directly from the 2017 SUSB so revenue aligned with payrolls in 2023.

Health care services, except hospitals	$63.4	$3,564	0.72%	0.30%
Social assistance	$33.4	$4,167	0.77%	0.36%
Arts, entertainment, and recreation	$43.8	$6,179	1.32%	0.43%
Accommodation	$9.4	$6,023	1.59%	0.38%
Food services and drinking places	$50.5	$11,339	3.55%	1.11%
Repair and maintenance	$12.5	$4,800	1.41%	0.40%
Personal and laundry services	$5.5	$2,184	0.89%	0.31%
Membership associations and organizations	$38.3	$2,284	0.70%	0.17%
Public administration	$10.4	$6,201	0.58%	0.14%
Employer Type				
Nonprofit, private	$94.40	$3,570	1.00%	0.30%
For profit, private	$585.30	$3,532	1.00%	0.20%
Government (state and local)	$12.20	$9,264	0.60%	0.20%

Note: Pooled CPS data for 2021-2023 adjusted to reflect 2023.
[a] Total direct costs and transfers for small entities in which all employees are affected. Impacts to small entities in which one employee is affected will be a fraction of the impacts presented in this table.
[b] Revenues estimated by calculating the ratio of estimated small business revenues to payroll from the 2017 SUSB, and multiplying by payroll per small entity. For the public administration sector, the ratio was calculated using revenues and payroll from the 2017 Census of Governments.

5. Projected Effects to Affected Small Entities in Year 2 through Year 10

To determine how small businesses would be affected in future years, the Department projected costs to small businesses for 9 years after Year 1 of the rule. Projected employment and earnings were calculated using the same methodology described in section VII.B.3. Affected employees in small firms follow a similar pattern to affected workers in all entities: the number decreases gradually between automatic update years, and then increases. There are 1.6 million affected workers in small entities in Year 1 and 2.2 million in Year 10. Table 35 reports affected workers in these 2 years only.

Table 35: Projected Number of Affected Workers in Small Entities, by Industry

Industry	Affected Workers in Small entities (1,000s)	
	Year 1	Year 10
Total	1,574.1	2,171.7
Agriculture, forestry, fishing, and hunting	6.4	8.8
Mining	8.8	10.6
Construction	112.1	159.7
Manufacturing - durable goods	121.8	169.8
Manufacturing - non-durable goods	58.9	79.7
Wholesale trade	50.9	70.5
Retail trade	124.5	148.4
Transportation and warehousing	30.0	47.1
Utilities	7.5	13.3
Information	34.8	40.7
Finance	43.6	58.7
Insurance	45.1	58.6
Real estate and rental and leasing	51.3	81.0
Professional and technical services	280.7	394.5
Management, administrative and waste management services	47.5	56.8
Educational services	53.4	80.9
Hospitals	11.4	16.3
Health care services, except hospitals	140.1	205.0
Social assistance	91.4	136.0
Arts, entertainment, and recreation	64.6	99.6
Accommodation	12.3	12.4
Food services and drinking places	42.0	52.4
Repair and maintenance	16.1	20.5
Personal and laundry services	14.3	17.5
Membership associations and organizations	79.4	98.7
Public administration	25.2	34.2

Note: Worker data are from Pooled CPS data for 2021-2023 adjusted to reflect 2023.

Direct costs and payroll increases for small entities vary by year but generally decrease between updates as the real value of the salary and compensation levels decrease and the number

of affected workers consequently decreases. In updating years, costs will increase due to newly affected workers and some regulatory familiarization costs. Direct costs and payroll increases for small businesses will increase in Year 10 (an automatic update year) compared to Year 1, $946 million in Year 1 and $1.3 billion in Year 10 (Table 36 and Figure 10).

Table 36: Projected Direct Costs and Payroll Increases for Affected Small Entities, by Industry, Using All Employees in Entity Affected Method

Industry	Costs and Payroll Increases for Small Affected Entities, All Employees Affected (Millions $2023)	
	Year 1	Year 10
Total	$946.3	$1,263.5
Agriculture, forestry, fishing, and hunting	$2.7	$5.8
Mining	$4.3	$4.2
Construction	$69.9	$102.7
Manufacturing - durable goods	$82.6	$113.3
Manufacturing - non-durable goods	$35.4	$44.5
Wholesale trade	$37.1	$67.7
Retail trade	$95.4	$97.3
Transportation and warehousing	$21.1	$35.1
Utilities	$4.7	$5.5
Information	$12.2	$14.3
Finance	$22.2	$26.6
Insurance	$17.4	$16.7
Real estate and rental and leasing	$38.2	$54.7
Professional and technical services	$182.9	$236.7
Management, administrative and waste management services	$25.4	$41.1
Educational services	$24.2	$33.1
Hospitals	$3.5	$4.4
Health care services, except hospitals	$63.4	$94.0
Social assistance	$33.4	$41.3
Arts, entertainment, and recreation	$43.8	$65.3
Accommodation	$9.4	$7.9
Food services and drinking places	$50.5	$59.4
Repair and maintenance	$12.5	$16.9

Personal and laundry services	$5.5	$10.1
Membership associations and organizations	$38.3	$53.3
Public administration	$10.4	$11.7

Note: Pooled CPS data for 2021-2023 adjusted to reflect 2023.

Figure 10: 10-Year Projected Number of Affected Workers in Small Entities, and Associated Costs and Payroll Increases

E. Projected Reporting, Recordkeeping, and Other Compliance Requirements of the Rule

The FLSA sets minimum wage, overtime pay, and recordkeeping requirements for employment subject to its provisions. Unless exempt, covered employees must be paid at least the minimum wage and not less than one and one-half times their regular rates of pay for overtime hours worked.

Pursuant to section 11(c) of the FLSA, the Department's regulations at part 516 require covered employers to maintain certain records about their employees. Bona fide EAP workers

are subject to some of these recordkeeping requirements but are exempt from others related to pay and hours worked.[482] Thus, although this rulemaking does not introduce any new recordkeeping requirements, employers will need to keep some additional records for affected employees who become newly nonexempt if they do not presently record such information. As indicated in this analysis, this rule expands minimum wage and overtime pay coverage to 4.3 million affected EAP workers, of which 1.6 million are employed by a small entity. This will result in an increase in employer burden and was estimated in the PRA portion (section VI) of this rule.

F. Steps the Agency Has Taken to Minimize the Significant Economic Impact on Small Entities

This section describes the steps the agency has taken to minimize the economic impact on small entities, consistent with the stated objectives of the FLSA. It includes a statement of the factual, policy, and legal reasons for the selected standard and HCE levels adopted in the rule and why alternatives were rejected.

In this rule, the Department sets the standard salary level equal to the 35th percentile of earnings of full-time salaried workers in the lowest-wage Census Region (currently the South). Based on 2023 data, this results in a salary level of $1,128 per week. This approach will fully restore the salary level's screening function and, by setting the salary level above the long test salary level, ensure that fewer lower paid white-collar employees who perform significant amounts of nonexempt work are included in the exemption. At the same time, by setting it below the short test salary level, the new salary level allows employers to continue to use the exemption

[482] *See* 29 CFR 516.3 (providing that employers need not maintain the records required by 29 CFR 516.2(a)(6) through (10) for their EAP workers).

for many lower paid white-collar employees who were made exempt under the 2004 standard duties test. Thus, the Department believes that the new salary level will also more reasonably distribute between employees and their employers the impact of the shift from a two-test to a one-test system on employees earning between the long and short test salary levels. As in prior rulemakings, the Department is not establishing multiple salary levels based on region, industry, employer size, or any other factor, which stakeholders have generally agreed would significantly complicate the regulations.[483] Instead, the Department is setting the standard salary level using earnings data from the lowest-wage Census Region, in part to accommodate small employers and employers in low-wage industries.[484]

The Department is setting the HCE total annual compensation level equal to the 85th percentile of earnings of full-time salaried workers nationally ($151,164 annually based on 2023 data). The Department believes that this level avoids costs associated with evaluating, under the standard duties test, the exemption statuses of large numbers of highly-paid white-collar employees, many of whom would have remained exempt even under that test, while providing a meaningful and appropriate complement to the more lenient HCE duties test. While the threshold is higher than the HCE level adopted in the 2019 rule (which was set equal to the 80th percentile of earnings for salaried workers nationwide), the HCE threshold in this rule is lower than the HCE percentile adopted in the 2004 and 2016 rules, which covered 93.7 and 90 percent of salaried workers nationwide respectively. The Department further believes that nearly all of the highly-paid white-collar workers earning above this threshold "would satisfy any duties test."[485]

[483] *See* 84 FR 51239; 81 FR 32411; 69 FR 22171.
[484] *See* 84 FR 51238; 81 FR 32527; 69 FR 22237.
[485] *See* 84 FR 51250 (internal citation omitted).

1. Differing Compliance and Reporting Requirements for Small Entities

This rule provides no differing compliance requirements and reporting requirements for small entities. The Department strives to minimize respondent recordkeeping burden by requiring no specific form or order of records under the FLSA and its corresponding regulations. Moreover, employers normally maintain the records under usual or customary business practices.

2. Least Burdensome Option or Explanation Required

The Department believes it has chosen the most effective option that updates and clarifies the rule and results in the least burden. Among the options considered by the Department, the least restrictive option was using the 2004 methodology (the 20th percentile of weekly earnings of full-time nonhourly workers in the lowest-wage Census region, currently the South, and in retail nationally) to set the standard salary level, which was also the methodology used in the 2019 rule. As noted above, however, the salary level produced by the 2004 methodology is below the long test salary level, which the Department considers to be a key parameter for determining an appropriate salary level in a one-test system using the current standard duties test. Using the 2004 methodology thus does not address the Department's concerns discussed above under Objectives of, and Need for, the Rule.

Pursuant to section 603(c) of the RFA, the following alternatives are to be addressed:

i. Differing Compliance or Reporting Requirements That Take into Account the Resources Available to Small Entities.

The FLSA creates a level playing field for businesses by setting a floor below which employers may not pay their employees. To establish differing compliance or reporting requirements for small businesses would undermine this important purpose of the FLSA. The Department makes available a variety of resources to employers for understanding their

obligations and achieving compliance. Therefore, the Department is not implementing differing compliance or reporting requirements for small businesses.

ii. The Clarification, Consolidation, or Simplification of Compliance and Reporting Requirements for Small Entities.

This rule imposes no new reporting requirements. The Department makes available a variety of resources to employers for understanding their obligations and achieving compliance.

iii. The Use of Performance Rather than Design Standards.

Under this rule, employers may achieve compliance through a variety of means. Employers may elect to continue to claim the EAP exemption for affected employees by adjusting salary levels, hiring additional workers, spreading overtime hours to other employees, or compensating employees for overtime hours worked. The Department makes available a variety of resources to employers for understanding their obligations and achieving compliance.

iv. An Exemption from Coverage of the Rule, or any Part Thereof, for Such Small Entities.

Creating an exemption from coverage of this rulemaking for businesses with as many as 500 employees, those defined as small businesses under SBA's size standards, is inconsistent with the FLSA, which applies to all employers that satisfy the enterprise coverage threshold or employ individually covered employees, regardless of employer size.[486]

IX. Unfunded Mandates Reform Act Analysis

The Unfunded Mandates Reform Act of 1995 (UMRA),[487] requires agencies to prepare a written statement for rulemaking that includes any Federal mandate that may result in increased expenditures by state, local, and tribal governments, in the aggregate, or by the private sector, of

[486] *See* 29 U.S.C. 203(s).
[487] 2 U.S.C. 1501 *et seq.*

$200 million ($100 million in 1995 dollars adjusted for inflation to 2023) or more in at least one year. This statement must (1) identify the authorizing legislation; (2) present the estimated costs and benefits of the rule and, to the extent that such estimates are feasible and relevant, present its estimated effects on the national economy; (3) summarize and evaluate state, local, and tribal government input; and (4) identify reasonable alternatives and select, or explain the non-selection, of the least costly, most cost-effective, or least burdensome alternative. This rule contains unfunded mandates as described below.

A. Authorizing Legislation

This final rule is issued pursuant to section 13(a)(1) of the FLSA, 29 U.S.C. 213(a)(1). The section exempts from the FLSA's minimum wage and overtime pay requirements "any employee employed in a bona fide executive, administrative, or professional capacity (including any employee employed in the capacity of academic administrative personnel or teacher in elementary or secondary schools), or in the capacity of outside salesman (as such terms are defined and delimited from time to time by regulations of the Secretary, subject to the provisions of [the Administrative Procedure Act]. . .)."[488] The requirements of the exemption are contained in part 541 of the Department's regulations. Section 3(e) of the FLSA[489] defines "employee" to include most individuals employed by a state, political subdivision of a state, or interstate governmental agency. Section 3(x) of the FLSA[490] also defines public agencies to include the government of a state or political subdivision thereof, or any interstate governmental agency.

[488] 29 U.S.C. 213(a)(1).
[489] 29 U.S.C. 203(e).
[490] 29 U.S.C. 203(x).

B. Costs and Benefits

For purposes of the UMRA, this rule includes a Federal mandate that is expected to result in increased expenditures by the private sector of more than $200 million in at least one year and result in increased expenditures by state, local and tribal governments, in the aggregate, of $200 million or more in at least one year. Based on the economic impact analysis of this final rule, the Department determined that Year 1 costs for state and local governments would total $197.7 million, of which $98.9 million are direct employer costs and $98.8 million are payroll increases (Table 37). In subsequent years, state and local governments may experience payroll increases of as much as $183.7 million (in year 10 of the rule).

The Department estimates that the final rule will result in Year 1 costs to the private sector of approximately $2.7 billion, of which $1.3 billion are direct employer costs and $1.4 billion are payroll increases.

Table 37: Summary of Year 1 Impacts by Type of Employer

Impact	Total	Private	Government [a]
Affected EAP Workers (1,000s)			
Number	4,337	3,854	475
Direct Employer Costs (Millions)			
Regulatory familiarization	$451.6	$446.7	$4.9
Adjustment	$299.1	$265.9	$32.6
Managerial	$685.5	$622.8	$61.4
Total direct costs	$1,436.2	$1,335.3	$98.9
Payroll Increases (Millions)			
From employers to workers	$1,509.2	$1,402.7	$98.8
Direct Employer Costs & Payroll Increases (Millions)			
From employers	$2,945.4	$2,738.0	$197.7

[a] Includes only state, local, and tribal governments.

UMRA requires agencies to estimate the effect of a regulation on the national economy if, at its discretion, such estimates are reasonably feasible and the effect is relevant and material.[491] However, OMB guidance on this requirement notes that such macroeconomic effects tend to be measurable in nationwide econometric models only if the economic effect of the regulation reaches 0.25 percent to 0.5 percent of GDP, or in the range of $68.4 billion to $136.8 billion (using 2023 GDP). A regulation with a smaller aggregate effect is not likely to have a measurable effect in macro-economic terms unless it is highly focused on a particular geographic region or economic sector, which is not the case with this rule.

The Department's RIA estimates that the total first-year costs (direct employer costs and payroll increases from employers to workers) of the final rule would be approximately $2.7 billion for private employers and $197.7 million for state and local governments. Given OMB's guidance, the Department has determined that a full macro-economic analysis is not likely to show any measurable effect on the economy. Therefore, these costs are compared to payroll costs and revenue to demonstrate the feasibility of adapting to these new rules.

Total first-year state and local government costs compose 0.02 percent of state and local government payrolls.[492] First-year state and local government costs compose 0.004 percent of state and local government revenues (projected 2023 revenues were estimated to be $5.0 trillion).[493] Effects of this magnitude will not result in significant disruptions to typical state and

[491] 2 U.S.C. 1532(a)(4).
[492] 2020 state and local government payrolls were $1.1 trillion, inflated to 2023 payroll costs of $1.2 trillion using the GDP deflator. State and Local Government Finances 2020. Available at https://www.census.gov/data/datasets/2020/econ/local/public-use-datasets.html.
[493] 2020 state and local revenues were $4.3 trillion, inflated to 2023 dollars using the GDP deflator. State and Local Government Finances 2020. Available at https://www.census.gov/data/datasets/2020/econ/local/public-use-datasets.html.

local governments. The $197.7 million in state and local government costs constitutes an average of approximately $2,200 for each of the approximately 90,126 state and local entities. The Department considers these costs to be quite small both in absolute terms and in relation to payroll and revenue.

Total first-year private sector costs compose 0.034 percent of private sector payrolls nationwide.[494] Total private sector first-year costs compose 0.006 percent of national private sector revenues (revenues in 2023 are projected to be $45.3 trillion).[495] The Department concludes that effects of this magnitude are affordable and will not result in significant disruptions to typical firms in any of the major industry categories.

C. Summary of State, Local, and Tribal Government Input

Prior to issuing the NPRM, the Department held a series of stakeholder listening sessions between March 8, 2022, and June 3, 2022 to gather input on its part 541 regulations. Stakeholders invited to participate in these listening sessions included representatives from labor unions; worker advocate groups; industry associations; small business associations; state and local governments; tribal governments; non-profits; and representatives from specific industries such as K-12 education, higher education, healthcare, retail, restaurant, manufacturing, and wholesale. Stakeholders were invited to share their input on issues including the appropriate EAP salary level, the costs and benefits of increasing the salary level to employers and employees, the methodology for updating the salary level and frequency of updates, and whether changes to the

[494] Private sector payroll costs are projected to be $8.1 trillion in 2023 based on private sector payroll costs of $6.6 trillion in 2017, inflated to 2023 dollars using the GDP deflator. 2017 Economic Census of the United States.

[495] Private sector revenues in 2017 were $37.0 trillion using the 2017 Economic Census of the United States. This was inflated to 2023 dollars using the GDP deflator.

duties test are warranted. A listening session was held specifically for state and local governments on April 1, 2022, and a session for tribal governments was held on May 12, 2022. The input received at these listening sessions aided the Department in drafting its rule.

The Department received mixed feedback on the proposed rule from state, local, and tribal government commenters. Some state and local government stakeholders voiced strong support for the proposed rule. For example, the Coalition of State AGs supported the proposal, stating that the current salary level is too low and that the proposed updating mechanism "is important for employers in our respective states to have predictability in their labor costs." The Washington State Department of Labor & Industries noted that it implemented a state EAP salary level through administrative rulemaking which is currently $1,302.40 per week ($67,724.80 annually), stating that "the State of Washington considered many of the same factors" as the Department to set its salary level. Commenting on behalf of 1.4 million members who are state and local government employees, AFSCME described the proposed salary level as "a modest increase that will nevertheless benefit millions of workers."

Other state and local government stakeholders voiced opposition to the proposed rule. The National Association of Counties asserted that the proposed threshold increases would have a disproportionate impact on small and rural county governments, emphasizing that practical and legal constraints limit the ability of county governments to raise revenues to account for added labor costs. Similarly, Ohio Township Association commented that "[if] townships [do] not wish to raise taxes or residents reject a property tax levy for such purpose, the township will be forced to cut or eliminate services." *See also* Pennsylvania State Association of Township Supervisors (providing similar feedback). The Mississippi State Personnel Board asserted that the proposed

rule could jeopardize Mississippi's use of telework to recruit and retain certain employees for the state government.

The Department received one comment from a tribal government stakeholder—Ho-Chuck Inc., a subsidiary of the Winnebago Tribe of Nebraska. Explaining that it operates various establishments in the gaming and retail industries, Ho-Chuck Inc. expressed concern about the magnitude of the Department's proposed increase to the standard salary level and of the NPRM's proposed 60-day effective date. Ho-Chuck Inc. requested the Department to consider a smaller increase, such as a 25 percent increase to the current $684 per week salary level (i.e., $855 per week), with "staggered increases over a period of 3 to 5 years to the higher amount."

As discussed in this final rule,[496] the Department agrees with commenters such as the Coalition of State AGs that the updating mechanism's triennial updates to the earnings thresholds for exemption will provide greater certainty and predictability for the regulated community. The Department appreciates that some employers, such as state, local, and tribal governments, may have less flexibility than others to account for new labor costs, as well as that employers in low-wage industries, regions, and in non-metropolitan areas may be more affected because they typically pay lower wages and salaries. However, the Department believes that costs and transfers associated with this rule will be manageable for and will not result in significant disruptions to state, local, and tribal governments. The Department is setting the standard salary level using earnings data from the lowest-wage Census Region, in part to accommodate small employers and employers in low-wage sectors and regions. As discussed earlier in this section, the Department estimates that total first-year costs for state and local governments comprise 0.02

[496] *See* sections V.A.3, VII.C.

percent of state and local government payrolls and 0.004 percent of state and local government revenues. Moreover, as discussed in this final rule,[497] the Department has determined, upon consideration of commenter feedback, that a delayed applicability date is appropriate for the new standard salary level and the HCE total annual compensation threshold. Specifically, the new $1,128 per week standard salary level and $151,164 per year HCE total annual compensation threshold will not be applicable until January 1, 2025.

D. Least Burdensome Option or Explanation Required

This final rule has described the Department's consideration of various options throughout the preamble (*see* section V.B.4.iv) and economic impact analysis (*see* section VII.C.8). The Department believes that it has chosen the least burdensome but still cost-effective methodology to update the salary level consistent with the Department's statutory obligation to define and delimit the scope of the EAP exemption. Although some alternative options considered would set the standard salary level at a rate lower than the finalized level, that outcome would not necessarily be the most cost-effective or least-burdensome. A salary level equal to or below the long test level would result in the exemption of lower-salaried employees who traditionally were entitled to overtime protection under the long test either because of their low salary or because they perform large amounts of nonexempt work. This approach would also effectively place the burden of the move from a two-test system to a one-test system on employees who historically were nonexempt because they earned between the long and short test salary levels but did not meet the long duties test.

[497] *See* section IV.

Selecting a standard salary level in a one-test system inevitably affects the impact of providing overtime protection to employees paid between the long and short test salary levels. Too low of a salary level shifts the impact of the move to a one-test system to employees by exempting lower-salaried employees who perform large amounts of nonexempt work. However, too high a salary level shifts the impact of the move to a one-test system to employers by denying them the use of the exemption for lower-salaried employees who traditionally were exempt under the long duties test, thereby increasing their labor costs. The Department has determined that setting the standard salary level equivalent to the earnings of the 35th percentile of full-time salaried workers in the lowest-wage Census Region will more effectively identify in a one-test system who is employed in a bona fide EAP capacity in a manner that reasonably distributes among employees earning between the long and short test salary levels and their employers the impact of the Department's move from a two-test to a one-test system. The Department believes that the final rule reduces burden on employers of nonexempt workers who earn between the current and finalized standard salary level. Currently, employers must rely on the duties test to determine the exemption status of these workers. Under this final rule, the exemption status of these workers will be determined based on the simpler salary level test.

The Department is also adopting a mechanism to regularly update the standard salary level and HCE total compensation requirement for wage growth, which will ensure that the thresholds continue to work efficiently to help identify EAP employees. As noted above, the history of the part 541 regulations shows multiple, significant gaps during which the earnings thresholds were not updated and their effectiveness in helping to define the EAP exemption

decreased as wages increased. Routine updates of the earnings thresholds to reflect wage growth will bring certainty and stability to employers and employees alike.

X. Executive Order 13132, Federalism

The Department has reviewed this rule in accordance with Executive Order 13132 regarding federalism and determined that it does not have federalism implications. The proposed rule would not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

XI. Executive Order 13175, Indian Tribal Governments

This rule will not have tribal implications under Executive Order 13175 that would require a tribal summary impact statement. The rule would not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

List of Subjects

29 CFR Part 541

Labor, Minimum wages, Overtime pay, Salaries, Teachers, Wages.

For the reasons set out in the preamble, the Wage and Hour Division, Department of Labor amends Title 29 CFR chapter V, as follows:

PART 541—DEFINING AND DELIMITING THE EXEMPTIONS FOR EXECUTIVE, ADMINISTRATIVE, PROFESSIONAL, COMPUTER AND OUTSIDE SALES EMPLOYEES

1. The authority citation for part 541 continues to read as follows:

Authority: 29 U.S.C. 213; Pub. L. 101-583, 104 Stat. 2871; Reorganization Plan No. 6 of 1950 (3 CFR, 1945-53 Comp., p. 1004); Secretary's Order 01-2014 (Dec. 19, 2014), 79 FR 77527 (Dec. 24, 2014).

2. Add § 541.5 to read as follows:

§ 541.5 Severability.

The provisions of this part are separate and severable and operate independently from one another. If any provision of this part is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, the provision must be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding be one of utter invalidity or unenforceability, in which event the provision will be severable from part 541 and will not affect the remainder thereof.

3. Amend § 541.100, by revising paragraph (a)(1) to read as follows:

§ 541.100 General rule for executive employees.

(a) * * *

(1) Compensated on a salary basis at not less than the level set forth in § 541.600;

* * * * *

4. Amend § 541.200, by revising paragraph (a)(1) to read as follows:

§ 541.200 General rule for administrative employees.

(a) * * *

(1) Compensated on a salary or fee basis at not less than the level set forth in § 541.600;

* * * * *

5. Amend § 541.204, by revising paragraph (a)(1) to read as follows:

§ 541.204 Educational establishments.

(a) * * *

(1) Compensated on a salary or fee basis at not less than the level set forth in § 541.600; or on a salary basis which is at least equal to the entrance salary for teachers in the educational establishment by which employed; and

* * * * *

6. Amend § 541.300, by revising paragraph (a)(1) to read as follows:

§ 541.300 General rule for professional employees.

(a) * * *

(1) Compensated on a salary or fee basis at not less than the level set forth in § 541.600; and

* * * * *

7. Amend § 541.400, by revising the first sentence of paragraph (b) to read as follows:

§ 541.400 General rule for computer employees.

* * * * *

(b) The section 13(a)(1) exemption applies to any computer employee who is compensated on a salary or fee basis at not less than the level set forth in § 541.600. * * *

* * * * *

8. Revise § 541.600 to read as follows:

§ 541.600 Amount of salary required.

(a) *Standard salary level*. To qualify as an exempt executive, administrative, or professional employee under section 13(a)(1) of the Act, an employee must be compensated on a salary basis at a rate per week of not less than the amount set forth in paragraphs (a)(1) through (3) of this section, exclusive of board, lodging or other facilities, unless paragraph (b) or (c) of this section applies. Administrative and professional employees may also be paid on a fee basis, as defined in § 541.605.

(1) Beginning on July 1, 2024, $844 per week (the 20th percentile of weekly earnings of full-time nonhourly workers in the lowest-wage Census Region and/or retail industry nationally).

(2) Beginning on January 1, 2025, $1,128 per week (the 35th percentile of weekly earnings of full-time nonhourly workers in the lowest-wage Census Region).

(3) As of July 1, 2027, the level calculated pursuant to § 541.607(b)(1).

(b) *Commonwealth of the Northern Mariana Islands, Guam, Puerto Rico, U.S. Virgin Islands.* To qualify as an exempt executive, administrative, or professional employee under section 13(a)(1) of the Act, an employee in the Commonwealth of the Northern Mariana Islands, Guam, Puerto Rico, or the U.S. Virgin Islands employed by employers other than the Federal Government must be compensated on a salary basis at a rate of not less than $455 per week, exclusive of board, lodging or other facilities. Administrative and professional employees may also be paid on a fee basis, as defined in § 541.605.

(c) *American Samoa*. To qualify as an exempt executive, administrative, or professional employee under section 13(a)(1) of the Act, an employee in American Samoa employed by employers other than the Federal Government must be compensated on a salary basis at a rate of not less than $380 per week, exclusive of board, lodging or other facilities. Administrative and professional employees may also be paid on a fee basis, as defined in § 541.605.

(d) *Frequency of payment*. The salary level requirement may be translated into equivalent amounts for periods longer than one week. For example, the $1,128 per week requirement described in paragraph (a)(2) of this section would be met if the employee is compensated biweekly on a salary basis of not less than $2,256, semimonthly on a salary basis of not less than $2,444, or monthly on a salary basis of not less than $4,888. However, the shortest period of payment that will meet this compensation requirement is one week.

(e) *Alternative salary level for academic administrative employees*. In the case of academic administrative employees, the salary level requirement also may be met by compensation on a salary basis at a rate at least equal to the entrance salary for teachers in the educational establishment by which the employee is employed, as provided in § 541.204(a)(1).

(f) *Hourly rate for computer employees*. In the case of computer employees, the compensation requirement also may be met by compensation on an hourly basis at a rate not less than $27.63 an hour, as provided in § 541.400(b).

(g) *Exceptions to the standard salary criteria*. In the case of professional employees, the compensation requirements in this section shall not apply to employees engaged as teachers (*see* § 541.303); employees who hold a valid license or certificate permitting the practice of law or medicine or any of their branches and are actually engaged in the practice thereof (*see*

§ 541.304); or to employees who hold the requisite academic degree for the general practice of medicine and are engaged in an internship or resident program pursuant to the practice of the profession (*see* § 541.304). In the case of medical occupations, the exception from the salary or fee requirement does not apply to pharmacists, nurses, therapists, technologists, sanitarians, dietitians, social workers, psychologists, psychometrists, or other professions which service the medical profession.

9. Amend § 541.601 by revising paragraph (a), the first sentence of paragraph (b)(1), and paragraph (b)(2) to read as follows:

§ 541.601 Highly compensated employees.

(a) An employee shall be exempt under section 13(a)(1) of the Act if the employee receives total annual compensation of not less than the amount set forth in paragraph (a)(1) through (4) of this section, and the employee customarily and regularly performs any one or more of the exempt duties or responsibilities of an executive, administrative, or professional employee identified in subpart B, C, or D of this part:

(1) Beginning on July 1, 2024, $132,964 per year (the annualized earnings amount of the 80th percentile of full-time nonhourly workers nationally).

(2) Beginning on January 1, 2025, $151,164 per year (the annualized earnings amount of the 85th percentile of full-time nonhourly workers nationally).

(3) As of July 1, 2027, the total annual compensation level calculated pursuant to § 541.607(b)(2).

(4) Where the annual period covers periods during which multiple total annual compensation levels apply, the amount of total annual compensation due will be determined on a proportional basis.

(b)(1) Total annual compensation must include at least a weekly amount equal to that required by § 541.600(a)(1) through (3) paid on a salary or fee basis as set forth in §§ 541.602 and 541.605, except that § 541.602(a)(3) shall not apply to highly compensated employees. * * *

(2) If an employee's total annual compensation does not total at least the amount set forth in paragraph (a) of this section by the last pay period of the 52-week period, the employer may, during the last pay period or within one month after the end of the 52-week period, make one final payment sufficient to achieve the required level. For example, for a 52-week period beginning January 1, 2025, an employee may earn $135,000 in base salary, and the employer may anticipate based upon past sales that the employee also will earn $20,000 in commissions. However, due to poor sales in the final quarter of the year, the employee only earns $14,000 in commissions. In this situation, the employer may within one month after the end of the year make a payment of at least $2,164 to the employee. Any such final payment made after the end of the 52-week period may count only toward the prior year's total annual compensation and not toward the total annual compensation in the year it was paid. If the employer fails to make such a payment, the employee does not qualify as a highly compensated employee, but may still qualify as exempt under subpart B, C, or D of this part.

* * * * *

10. Amend § 541.602 by revising the first sentence of paragraph (a)(3) and the first sentence of paragraph (a)(3)(i) to read as follows:

§ 541.602 Salary basis.

* * * * *

(a)(3) Up to ten percent of the salary amount required by § 541.600(a) through (c) may be satisfied by the payment of nondiscretionary bonuses, incentives, and commissions, that are paid annually or more frequently. * * *

(i) If by the last pay period of the 52-week period the sum of the employee's weekly salary plus nondiscretionary bonus, incentive, and commission payments received is less than 52 times the weekly salary amount required by § 541.600(a) through (c), the employer may make one final payment sufficient to achieve the required level no later than the next pay period after the end of the year. * * *

* * * * *

11. Amend § 541.604 by

a. Revising the second, third, and fourth sentences of paragraph (a) and;

b. Revising the third sentence in paragraph (b).

The revisions and additions read as follows:

§ 541.604 Minimum guarantee plus extras.

(a) * * * Thus, for example under the salary requirement described in § 541.600(a)(2), an exempt employee guaranteed at least $1,128 each week paid on a salary basis may also receive additional compensation of a one percent commission on sales. An exempt employee also may receive a percentage of the sales or profits of the employer if the employment arrangement also includes a guarantee of at least $1,128 each week paid on a salary basis. Similarly, the exemption is not lost if an exempt employee who is guaranteed at least $1,128 each week paid on a salary

basis also receives additional compensation based on hours worked for work beyond the normal workweek. * * *

(b) * * * Thus, for example under the salary requirement described in § 541.600(a)(2), an exempt employee guaranteed compensation of at least $1,210 for any week in which the employee performs any work, and who normally works four or five shifts each week, may be paid $350 per shift without violating the $1,128 per week salary basis requirement. * * *

12. Amend § 541.605 by revising paragraph (b) to read as follows:

§ 541.605 Fee basis.

* * * * *

(b) To determine whether the fee payment meets the minimum amount of salary required for exemption under these regulations, the amount paid to the employee will be tested by determining the time worked on the job and whether the fee payment is at a rate that would amount to at least the minimum salary per week, as required by §§ 541.600(a) through (c) and 541.602(a), if the employee worked 40 hours. Thus, for example under the salary requirement described in § 541.600(a)(2), an artist paid $600 for a picture that took 20 hours to complete meets the $1,128 minimum salary requirement for exemption since earnings at this rate would yield the artist $1,200 if 40 hours were worked.

13. Add § 541.607 to read as follows:

§ 541.607 Regular updates to amounts of salary and compensation required.

(a) *Initial update*—(1) *Standard salary level*. Beginning on July 1, 2024, the amount required to be paid per week to an exempt employee on a salary or fee basis, as applicable, pursuant to § 541.600(a)(1) will be not less than $844.

(2) *Highly compensated employees*. Beginning on July 1, 2024, the amount required to be paid in total annual compensation to an exempt highly compensated employee pursuant to § 541.601(a)(1) will be not less than $132,964.

(b) *Future updates*—(1) *Standard salary level.* (i) As of July 1, 2027, and every 3 years thereafter, the amount required to be paid to an exempt employee on a salary or fee basis, as applicable, pursuant to § 541.600(a) will be updated to reflect current earnings data.

(ii) The Secretary will determine the future update amounts by applying the methodology in effect under § 541.600(a) at the time the Secretary issues the notice required by paragraph (b)(3) of this section to current earnings data.

(2) *Highly compensated employees.* (i) As of July 1, 2027, and every 3 years thereafter, the amount required to be paid in total annual compensation to an exempt highly compensated employee pursuant to § 541.601(a) will be updated to reflect current earnings data.

(ii) The Secretary will determine the future update amounts by applying the methodology used to determine the total annual compensation amount in effect under § 541.601(a) at the time the Secretary issues the notice required by paragraph (b)(3) of this section to current earnings data.

(3) *Notice.* (i) Not fewer than 150 days before each future update of the earnings requirements under paragraphs (b)(1) and (2) of this section, the Secretary will publish a notice in the *Federal Register* stating the updated amounts based on the most recent available 4 quarters of CPS MORG data, or its successor publication, as published by the Bureau of Labor Statistics.

(ii) No later than the effective date of the updated earnings requirements, the Wage and Hour Division will publish on its website the updated amounts for employees paid pursuant to this part.

(4) *Delay of updates.* A future update to the earnings thresholds under this section is delayed from taking effect for a period of 120 days if the Secretary has separately published a notice of proposed rulemaking in the *Federal Register*, not fewer than 150 days before the date the update is set to take effect, proposing changes to the earnings threshold(s) and/or updating mechanism due to unforeseen economic or other conditions. The Secretary must state in the notice issued pursuant to paragraph (b)(3)(i) of this section that the scheduled update is delayed in accordance with this paragraph (b)(4). If the Secretary does not issue a final rule affecting the scheduled update to the earnings thresholds by the end of the 120-day extension period, the updated amounts published in accordance with paragraph (b)(3) of this section will take effect upon the expiration of the 120-day period. The 120-day delay of a scheduled update under this paragraph will not change the effective dates for future updates of the earnings requirements under this section.

Signed this 11th day of April, 2024.

Jessica Looman
Administrator, Wage and Hour Division

WAGE AND HOUR DIVISION
UNITED STATES DEPARTMENT OF LABOR

Fact Sheet 13: Employee or Independent Contractor Classification Under the Fair Labor Standards Act (FLSA)

Revised March 2024

Is a Worker an Employee or an Independent Contractor?

The Department has issued regulations addressing how to analyze whether a worker is an employee or an independent contractor under the FLSA (29 CFR part 795, effective March 11, 2024). Employees receive the protections of the FLSA. Independent contractors are in business for themselves and therefore are not covered by the FLSA.

For a worker to be protected by the minimum wage and overtime pay requirements of the FLSA, the worker must be an "employee" of the employer, meaning that there is an employment relationship between the worker and employer. Independent contractors do not have these protections. Whether a worker is an employee or an independent contractor under the FLSA is determined by looking at the economic realities of the worker's relationship with the employer. If the economic realities show that the worker is economically dependent on the employer for work, then the worker is an employee. If the economic realities show that the worker is in business for themself, then the worker is an independent contractor. The economic realities of the entire working relationship are looked at to decide whether a worker is an employee or an independent contractor. Employment under the FLSA is not determined by technical concepts or common law standards of control; it is broader than the common law standard often applied to determine employment status under other Federal laws.

What Is the Economic Reality Test?

The economic reality test uses multiple factors to see if an employment relationship exists under the FLSA (29 CFR 795.110). The goal of the test is to decide if the worker is economically dependent on the employer for work or is instead in business for themse
All factors should be considered. No single factor determines a worker's status, and no one factor or combination of factors are more important than the other factors. Instead, the totality of the circumstances of the working relationship should be considere

The following factors, discussed more below, should guide the assessment of whether a worker is an employee under the FLSA or an independent contractor in business for themself:

1. Opportunity for profit or loss depending on managerial skill,
2. Investments by the worker and the employer,
3. Permanence of the work relationship,
4. Nature and degree of control,
5. Whether the work performed is integral to the employer's business, and
6. Skill and initiative.

Additional factors may be considered as well if they are relevant to whether the worker is in business for themself or is economically dependent on the employer for work. There are certain facts, however, that are not relevant to whether an employment relationship exists. What the worker is called is not relevant—a worker may be an employee under the FLSA regardless of the title or label they are given. A worker who is paid off the books or receives a 1099 is not necessarily an independent contractor and agreeing verbally or in writing to be classified as an independent contractor—including by signing an independent

contractor agreement—does not make a worker an independent contractor under the FLSA. Additionally, such facts as the place where work is performed, whether a worker is licensed by State/local government, and the time or mode of pay do not determine whether a worker is an employee or an independent contractor under the FLSA.

Economic Reality Test Factors

1. **Opportunity for profit or loss depending on managerial skill.** This factor primarily looks at whether a worker can earn profits or suffer losses through their own independent effort and decision making. Relevant facts include whether the worker negotiates their pay, decides to accept or decline work, hires their own workers, purchases material and equipment, or engages in other efforts to expand a business or secure more work, such as marketing or advertising. Taking such actions or having a real opportunity to take such actions but making a business decision not to (for example, because the potential profit to be gained may not justify the expense that would be incurred), indicates that the worker is an independent contractor. Not taking such actions or having only a theoretical opportunity to take such actions (for example, the worker must get approval from the employer), indicates that the worker is an employee. A worker who decides to work more hours or take on more jobs when paid a fixed rate per hour, day, or job is generally not exercising managerial skill like an independent contractor even if those decisions may lead to more earnings.

   Examples: Opportunity for Profit or Loss Depending on Managerial Skill

   - A worker for a landscaping company performs assignments only as decided by the company for its corporate clients. The worker does not independently choose assignments, ask for additional work from other clients, advertise the landscaping services, or try to reduce costs. The worker regularly agrees to work additional hours to earn more money. In this example, the worker does not exercise managerial skill that affects their profit or loss. Rather, their earnings may change based on the work available and their willingness to work more. Because of this lack of managerial skill affecting their opportunity for profit or loss, these facts indicate employee status under the opportunity for profit or loss factor.
   - In contrast, a worker provides landscaping services directly to corporate clients. The worker produces their own advertising, negotiates contracts, decides which jobs to perform and when to perform them, and decides when and whether to hire helpers to assist with the work. This worker exercises managerial skill that affects their opportunity for profit or loss. These facts indicate independent contractor status under the opportunity for profit or loss factor.
2. **Investments by the worker and the employer.** This factor primarily looks at whether the worker makes investments that are capital or entrepreneurial in nature. Investments by a worker that support the growth of a business, including by increasing the number of clients, reducing costs, extending market reach, or increasing sales, weigh in favor of independent contractor status. A lack of such capital or entrepreneurial investments weighs in favor of employee status. Costs to a worker of tools for a specific job and costs that the employer imposes on the worker are not capital or entrepreneurial investments that indicate independent contractor status. In addition to considering the nature of any investments by the worker, the worker's investments should be compared to the employer's investments in its overall business. The worker's investments do not need to be equal to the employer's and should not be compared only in dollar amounts or size. The focus should be on whether the worker makes similar types of investments as the employer (even if on a smaller scale) or investments of the type that would allow the worker to operate independently in the worker's industry or field. Such investments by the worke in comparison to the employer weigh in favor of independent contractor status, while a lack of investments that support an independent business indicate employee status.

   Examples: Investments by the Worker and the Employer

   - A graphic designer provides design services for a commercial design firm. The firm provides software, a computer, office space, and all the equipment and supplies for the worker. The company invests in marketing and finding clients and maintains a central office from which to manage services. The worker occasionally uses their own preferred drafting tools for certain jobs. In this scenario, the worker's relatively minor investment in supplies is not capital in nature and does little to further a business beyond completing specific jobs. These facts indicate employee status under the investment factor.
   - A graphic designer occasionally completes specialty design projects for the same commercial design firm. The graphic designer purchases their own design software, computer, drafting tools, and rents their own space. The graphic designer also spends money to market their services. These types of investments support an independent business and are capital in nature (e.g., they allow the worker to do more work and find new clients). These facts indicate independent contractor status under the investment factor.

3. **Degree of permanence of the work relationship.** This factor primarily looks at the nature and length of the work relationship. Work that is sporadic or project-based with a fixed ending date (or regularly occurring fixed periods of work), where the worker may make a business decision to take on multiple different jobs indicates independent contractor status. Work that is continuous, does not have a fixed ending date, or may be the worker's only work relationship indicates employee status. The lack of a long working relationship does not necessarily suggest that the worker is an independent contractor unless it is because of the worker's business decision. Short-term jobs for multiple employers may be due to the seasonal or temporary nature of the work or industry, and not the worker's business decision to market their services to multiple entities, and therefore may indicate employee status.

   Examples: Degree of Permanence of the Work Relationship

   - A cook has prepared meals for an entertainment venue continuously for several years. The cook prepares meals as decided by the venue, depending on the size and specifics of the event. The cook only prepares food for the entertainment venue, which has regularly scheduled events each week. The relationship between the cook and the venue is characterized by a high degree of permanence and exclusivity as the cook does not cook for other venues. These facts indicate employee status under the permanence factor.
   - A cook has prepared specialty meals occasionally for an entertainment venue over the past three years for certain events. The cook markets their meal preparation services to multiple venues and private individuals and turns down work from the entertainment venue for any reason, including because the cook is too busy with other meal preparation jobs. The cook has a sporadic or project-based nonexclusive relationship with the entertainment venue. These facts indicate independent contractor status under the permanence factor.

4. **Nature and degree of control.** This factor primarily looks at the level of control the potential employer has over the performance of the work and the economic aspects of the working relationship. Relevant facts include whether the potential employer: controls hiring, firing, scheduling, prices, or pay rates; supervises the performance of the work (including via technological means); has the right to supervise or discipline workers; and takes actions that limit the worker's ability to work for others. Where the potential employer maintains more control over these aspects of the work relationship, this factor weighs in favor of employee status, and where the potential employer maintains less control over these aspects of the work relationship, this factor weighs in favor of independent contractor status. Control that is for the sole purpose of complying with a specific, applicable federal, state, tribal, or local regulation, rather than the employer's own internal policies or customer standards, does not weigh in favor of an employment relationship.

   Examples: Nature and Degree of Control

   - A registered nurse provides nursing care for Alpha House, a nursing home. The nursing home sets the work schedule with input from staff regarding their preferences and determines the staff assignments. Alpha House's policies prohibit nurses from working for other nursing homes while employed with Alpha House to protect its residents. In addition, the nursing staff are supervised by regular check-ins with managers, but nurses generally perform their work without direct supervision. While nurses at Alpha House work without close supervision and can express preferences for their schedule, Alpha House maintains control over when and where a nurse can work and whether a nurse can work for another nursing home. These facts indicate employee status under the control factor.
   - Another registered nurse provides specialty movement therapy to residents at Beta House. The nurse maintains a website and was contacted by Beta House to assist its residents. The nurse provides the movement therapy for residents on a schedule agreed upon between the nurse and the resident, without direction or supervision from Beta House, and sets the price for services on the website. In addition, the nurse provides therapy sessions to residents at Beta House as well as other nursing homes in the community at the same time. These facts—that the nurse markets their specialized services to obtain work for multiple clients, is not supervised by Beta House, sets their own prices, and has the flexibility to select a work schedule—indicate independent contractor status under the control factor.

5. **Extent to which the work performed is an integral part of the employer's business.** This factor primarily looks at whether the work is critical, necessary, or central to the potential employer's principal business, which indicates employee status. Where the work performed by the worker is not critical, necessary, or central to the potential employer's principal business, this indicates independent contractor status. This factor does not depend on whether any individual worker in particular is an integral part of the business, but rather whether the work they perform is an integral part of the business.

   Examples: Extent to Which the Work Performed is an Integral Part of the Employer's Business

   - A large farm grows tomatoes that it sells to distributors. The farm pays workers to pick the tomatoes during the harvest season. Because a necessary part of a tomato farm is picking the tomatoes, the tomato pickers are integral to the

company's business. These facts indicate employee status under the integral factor.

- Alternatively, the same farm pays an accountant to provide non-payroll accounting support, including filing its annual tax return. This accounting support is not critical, necessary, or central to the principal business of the farm (farming tomatoes), thus the accountant's work is not integral to the business. Therefore, these facts indicate independent contractor status under the integral factor.

6. **Skill and initiative.** This factor primarily looks at whether the worker uses their own specialized skills together with business planning and effort to perform the work and support or grow a business. The fact that a worker does not use specialized skills (for example, the worker relies on the employer to provide training for the job) indicates that the worker is an employee. Additionally, both employees and independent contractors can be skilled, so the fact that a worker is skilled does not indicate one status or the other. The focus should be on whether the worker uses their skills in connection with business initiative. If the worker does, that indicates independent contractor status; if the worker does not, that indicates employee status.

   Examples: Skill and Initiative

   - A highly skilled welder provides welding services for a construction firm. The welder does not make any independent decisions at the job site beyond what it takes to do the work assigned. The welder does not determine the sequence of work, order additional materials, think about bidding for the next job, or use their welding skills to obtain additional jobs, and is told what work to perform and where to do it. In this scenario, the welder, although highly skilled technically, is not using those skills in a manner that evidences business-like initiative. These facts indicate employee status under the skill and initiative factor.
   - A highly skilled welder provides a specialty welding service, such as custom aluminum welding, for a variety of area construction companies. The welder uses these skills for marketing purposes, to generate new business, and to obtain work from multiple companies. The welder is not only technically skilled, but also uses and markets those skills in a manner that evidences business-like initiative. These facts indicate independent contractor status under the skill and initiative factor.

Additional factors may be considered if they assist in assessing whether the worker is in business for themself or is economically dependent on the employer for work.

Requirements

When an employer-employee relationship exists and the employee is performing work that is covered under the FLSA, the employee must be paid not less than the federal minimum wage ($7.25 per hour) and overtime pay that is not less than one and one-half the regular rate of pay for all hours worked over 40 per week unless a relevant exemption applies. The FLSA also has recordkeeping requirements, retaliation protections, and child labor provisions which regulate the employment of minors under the age of eighteen.

Where to Obtain Additional Information

For additional information, visit our Wage and Hour Division Website: http://www.dol.gov/agencies/whd and/or call our toll-free information and helpline, available 8 a.m. to 5 p.m. in your time zone, 1-866-4USWAGE (1-866-487-9243).

This publication is for general information and is not to be considered in the same light as official statements of position contained in the regulations.

Submit Feedback

WAGE AND HOUR DIVISION
UNITED STATES DEPARTMENT OF LABOR

Fact Sheet #22: Hours Worked Under the Fair Labor Standards Act (FLSA)

Revised July 2008

This fact sheet provides general information concerning what constitutes compensable time under the FLSA. The Act requires that employees must receive at least the minimum wage and may not be employed for more than 40 hours in a week without receiving at least one and one-half times their regular rates of pay for the overtime hours. The amount employees should receive cannot be determined without knowing the number of hours worked.

Definition of "Employ"

By statutory definition the term "employ" includes "to suffer or permit to work." The workweek ordinarily includes all time during which an employee is necessarily required to be on the employer's premises, on duty or at a prescribed work place. "Workday", in general, means the period between the time on any particular day when such employee commences his/her "principal activity" and the time on that day at which he/she ceases such principal activity or activities. The workday may therefore be longer than the employee's scheduled shift, hours, tour of duty, or production line time.

Application of Principles

Employees "Suffered or Permitted" to work: Work not requested but suffered or permitted to be performed is work time that must be paid for by the employer. For example, an employee may voluntarily continue to work at the end of the shift to finish an assigned task or to correct errors. The reason is immaterial. The hours are work time and are compensable.

Waiting Time:

Whether waiting time is hours worked under the Act depends upon the particular circumstances. Generally, the facts may show that the employee was engaged to wait (which is work time) or the facts may show that the employee was waiting to be engaged (which is not work time). For example, a secretary who reads a book while waiting for dictation or a fireman who plays checkers while waiting for an alarm is working during such periods of inactivity. These employees have been "engaged to wait."

On-Call Time:

An employee who is required to remain on call on the employer's premises is working while "on call." An employee who is required to remain on call at home, or who is allowed to leave a message where he/she can be reached, is not working (in most cases) while on call. Additional constraints on the employee's freedom could require this time to be compensated.

Rest and Meal Periods:

Rest periods of short duration, usually 20 minutes or less, are common in industry (and promote the efficiency of the employee) and are customarily paid for as working time. These short periods must be counted as hours worked. Unauthorized extensions of authorized work breaks need not be counted as hours worked when the employer has expressly and unambiguously communicated to the employee that the authorized break may only last for a specific length of time, that any extension of the break is contrary to the employer's rules, and any extension of the break will be punished. Bona fide meal periods (typically 30 minutes or more) generally need not be compensated as work time. The employee must be completely relieved from duty for the purpose of eating regular meals. The employee is not relieved if he/she is required to perform any duties, whether active or inactive, while eating.

Sleeping Time and Certain Other Activities:

An employee who is required to be on duty for less than 24 hours is working even though he/she is permitted to sleep or engage in other personal activities when not busy. An employee required to be on duty for 24 hours or more may agree with the employer to exclude from hours worked bona fide regularly scheduled sleeping periods of not more than 8 hours, provided adequate sleeping facilities are furnished by the employer and the employee can usually enjoy an uninterrupted night's sleep. No reduction is permitted unless at least 5 hours of sleep is taken.

Lectures, Meetings and Training Programs:

Attendance at lectures, meetings, training programs and similar activities need not be counted as working time only if four criteria are met, namely: it is outside normal hours, it is voluntary, not job related, and no other work is concurrently performed.

Travel Time:

The principles which apply in determining whether time spent in travel is compensable time depends upon the kind of travel involved.

Home to Work Travel:

An employee who travels from home before the regular workday and returns to his/her home at the end of the workday is engaged in ordinary home to work travel, which is not work time.

Home to Work on a Special One Day Assignment in Another City:

An employee who regularly works at a fixed location in one city is given a special one day assignment in another city and returns home the same day. The time spent in traveling to and returning from the other city is work time, except that the employer may deduct/not count that time the employee would normally spend commuting to the regular work site.

Travel That is All in a Day's Work:

Time spent by an employee in travel as part of their principal activity, such as travel from job site to job site during the workday, is work time and must be counted as hours worked.

Travel Away from Home Community:

Travel that keeps an employee away from home overnight is travel away from home. Travel away from home is clearly work time when it cuts across the employee's workday. The time is not only hours worked on regular working days during normal working hours but also during corresponding hours on nonworking days. As an enforcement policy the Division will not consider as work time that time spent in travel away from home outside of regular working hours as a passenger on an airplane, train, boat, bus, or automobile.

Typical Problems

Problems arise when employers fail to recognize and count certain hours worked as compensable hours. For example, an employee who remains at his/her desk while eating lunch and regularly answers the telephone and refers callers is working. This time must be counted and paid as compensable hours worked because the employee has not been completely relieved from duty.

Where to Obtain Additional Information

For additional information, visit our Wage and Hour Division Website: http://www.dol.gov/agencies/whd and/or call our toll-free information and helpline, available 8 a.m. to 5 p.m. in your time zone, 1-866-4USWAGE (1-866-487-9243).

This publication is for general information and is not to be considered in the same light as official statements of position contained in the regulations.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or agency policies.

WAGE AND HOUR DIVISION
UNITED STATES DEPARTMENT OF LABOR

Fact Sheet #53 – The Health Care Industry and Hours Worked

Revised July 2009

The Fair Labor Standards Act (FLSA) requires covered employers to pay non exempt employees at least the federal minimum wage of $7.25 per hour effective July 24, 2009, for all hours worked and overtime pay for hours worked over 40 in a workweek. The FLSA is administered by the Wage and Hour Division of the U.S. Department of Labor.

Hospitals and other institutions "primarily engaged in the care of the sick, the aged, or the mentally ill" are covered employers under Section 3(s)(1)(B) of the FLSA. Thus, hospitals, residential care establishments, skilled nursing facilities, nursing facilities, assisted living facilities, residential care facilities and intermediate care facilities for intellectually and developmentally disabled individuals must comply with the minimum wage, overtime and youth employment requirements of the FLSA.

Summary

This fact sheet provides guidance regarding common FLSA violations found by the Wage and Hour Division during investigations in the health care industry relating to the failure to pay employees for all hours worked. Nonexempt employees must be paid for all hours worked in a workweek. In general, " hours worked" includes all time an employee must be on duty, on the employer premises, or at any other prescribed place of work. Also included is any additional time the employee is "suffered or permitted" to work. The FLSA requires employers to pay for hours actually worked, but there is no requirement for payment of holidays, vacation, sick or personal time.

The failure to properly count and pay for all hours that an employee works may result in a minimum wage violation if the employee's hourly rate falls below the required federal minimum wage when his or her total compensation is divided by all hours worked. More likely, the failure to count all hours worked will result in an overtime violation because employers have not fully accounted for hours worked in excess of 40 during the workweek.

Rounding Hours Worked

Some employers track employee hours worked in 15 minute increments, and the FLSA allows an employer to round employee time to the nearest quarter hour. However, an employer may violate the FLSA minimum wage and overtime pay requirements if the employer always rounds down. Employee time from 1 to 7 minutes may be rounded down, and thus not counted as hours worked, but employee time from 8 to 14 minutes must be rounded up and counted as a quarter hour of work time. See Regulations 29 CFR 785.48(b).

Example #1:

An intermediate care facility docks employees by a full quarter hour (15 minutes) when they start work more than seven minutes after the start of their scheduled shift. Does this practice comply with the FLSA requirements? Yes, as long as the employees' time is rounded up a full quarter hour when the employee starts working from 8 to 14 minutes before their shift or if the employee works from 8 to 14 minutes beyond the scheduled end of their shift.

Example #2:

An employee's schedule is 7 a.m. to 3:30 p.m. with a thirty minute unpaid lunch break. The employee receives overtime compensation after 40 hours in a workweek. The employee clocks in 10 minutes early every day and clocks out 7 minutes late each day. The employer follows the standard rounding rules. Is the employee entitled to overtime compensation? Yes. If the employer rounds back a quarter hour each morning to 6:45 a.m. and rounds back each evening to 3:30 p.m., the employee will show a total of 41.25 hours worked during that workweek. The employee will be entitled to additional overtime compensation for the 1.25 hours over 40.

Example #3:

An employer only records and pays for time if employees work in full 15 minute increments. An employee paid $10 per hour is scheduled to work 8 hours a day Monday through Friday, for a total of 40 hours a week. The employee always clocks out 12 minutes after the end of her shift. The employee is paid $400 per week. Does this comply with the FLSA? No, the employer has violated the overtime requirements. The employee worked an hour each week (12 minutes times 5) that was not compensated. The employer has not violated the minimum wage requirement because the employee was paid $9.75 per hour ($400 divided by 41 hours). However, the employer owes the employee for one hour of overtime each week.

Travel Time

Time spent by an employee in travel as part of his principal activity, such as travel from jobsite to jobsite during the workday, must be considered as hours worked. An employee who travels from home before the regular workday and returns home at the end of the workday is engaged in ordinary home-to-work travel. This is not considered hours worked. See Regulations 29 CFR 785.33.

Example #4:

A licensed practical nurse (LPN) works at an assisted living facility which has a "sister facility" 20 miles away. There have been times that the LPN has been asked to fill in for someone at the other facility after she completes her shift at her normal work site. It takes her 30 minutes to drive to the other facility. The travel time is not recorded on her time sheet. Is this a violation of the FLSA? Yes. The travel time must be considered part of the hours worked.

Training and Seminars

Attendance at lectures, meetings, training programs and similar activities are viewed as working time ***unless all of the following criteria are met***:

- Attendance is outside of the employee's regular working hours;
- Attendance is in fact voluntary;
- The course, lecture, or meeting is not directly related to the employee's job; and
- The employee does not perform any productive work during such attendance.

See Regulations 29 CFR 785.27.

Example #5:

A residential care facility offers specialized training on caring for Alzheimer residents. There are two workshops: one in the evening for the day shift and one during the day for the evening shift. All employees are required to attend. Is this compensable time? Yes, because the training is not voluntary and is related to the employees' jobs.

Example #6:

The administrator of a nursing home says specialized patient care training is voluntary, but the nursing supervisors expect all employees on their units to attend and schedule times for each employee to go. Is the time considered hours worked? Yes, the time would be considered hours worked. When the nursing supervisors expect all unit employees to attend and schedule their times, it is not truly voluntary.

Example #7:

The dishwasher decides to go to the Alzheimer's training session after his shift. Must the administrator pay for the dishwasher's time spent at the training session? No, because all four criteria above are met. It is not considered hours worked.

Example #8:

The administrator provides a Tai Chi course to residents and allows employees to attend during their off-duty hours. Do employees have to be paid for the time they attend this course? No, the employees do not have to be paid because attendance is voluntary and the other three criteria are met.

Meal Breaks

Bona-fide meal periods (typically 30 minutes or more) are not work time, and an employer does not have to pay for them. However, the employees must be completely relieved from duty. When choosing to automatically deduct 30-minutes per shift, the employer must ensure that the employees are receiving the full meal break. See Regulations 29 CFR 785.19.

Example #9:

A skilled nursing facility automatically deducts one-half hour for meal breaks each shift. Upon hiring, the employer notifies employees of the policy and of their responsibility to take a meal break. Does this practice comply with the FLSA? Yes, but the employer is still responsible for ensuring that the employees take the 30-minute meal break without interruption.

Example #10:

An hourly paid registered nurse works at a nursing home which allows a 30-minute meal break. Residents frequently interrupt her meal break with requests for assistance. Must she be paid for these frequently interrupted meal breaks? Yes, if employees' meals are interrupted to the extent that meal period is predominately for the benefit of the employer, the employees should be paid for the full 30-minutes.

Other Breaks

Rest periods of short duration, generally running from 5 minutes to about 20 minutes, are common in industry. They promote the efficiency of the employee and are customarily paid for as work time. It is immaterial with respect to compensability of such breaks whether the employee drinks coffee, smokes, goes to the rest room, etc. See Regulations 29 CFR 785.18.

Example #11:

Many third shift nursing home employees who smoke prefer to take three ten-minute unpaid smoke breaks instead of their 30-minute unpaid meal break. Is it okay for them to substitute the smoke breaks for their meal break? No, the employee must be compensated for the smoke breaks.

On-Call Time An employee who is required to remain on call on the employer's premises or so close to the premises that the employee cannot use the time effectively for his or her own purpose is considered working while on-call. An employee who is required to carry a cell phone, or a beeper, or who is allowed to leave a message where he or she can be reached is not working (in most cases) while on-call. Additional constraints on the employee's freedom could require this time to be compensated. See Regulations 29 CFR 785.17.

Example #12:

An assisted living facility has four LPN wellness coordinators who are paid hourly. They rotate being on-call each week. They are required to carry a cell phone and be within 45 minutes of the facility when they are on-call. They are not paid for all time spent carrying the cell phone but are paid for time spent responding to calls and time when they have returned to work at the assisted living facility. Does this comply with the FLSA? Yes.

Unauthorized Hours Worked

Employees must be paid for work “suffered or permitted” by the employer even if the employer does not specifically authorize the work. If the employer knows or has reason to believe that the employee is continuing to work, the time is considered hours worked. See Regulation 29 CFR 785.11.

Example #13:

A residential care facility pays its nurses an hourly rate. Sometimes the residential care facility is short staffed and the nurses stay beyond their scheduled shift to work on patients’ charts. This results in the nurses working overtime. The director of nursing knows additional time is being worked, but believes no overtime is due because the nurses did not obtain prior authorization to work the additional hours as required by company policy. Is this correct? No. The nurses must be paid time-and-one-half for all FLSA overtime hours worked.

Example #14:

An hourly paid office clerk is working on a skilled nursing home’s quarterly budget reports. Rather than stay late in the office, she takes work home and finishes the work in the evening. She does not record the hours she works at home. The office manager knows the clerk is working at home, but since she does not ask for pay, assumes she is doing it “on her own.” Should the clerk’s time working at home be counted? Yes. The clerk was “suffered and permitted” to work, so her time must be considered hours worked even thought she worked at home and the time was unscheduled. See Regulations 29 CFR 785.12.

Where to Obtain Additional Information

For additional information, visit our Wage and Hour Division Website: http://www.dol.gov/agencies/whd and/or call our toll-free information and helpline, available 8 a.m. to 5 p.m. in your time zone, 1-866-4USWAGE (1-866-487-9243).

This publication is for general information and is not to be considered in the same light as official statements of position contained in the regulations.

FEDERAL TRADE COMMISSION

16 CFR Parts 910 and 912

RIN 3084–AB74

Non-Compete Clause Rule

AGENCY: Federal Trade Commission.

ACTION: Final rule.

SUMMARY: Pursuant to the Federal Trade Commission Act (''FTC Act''), the Federal Trade Commission (''Commission'') is issuing the Non-Compete Clause Rule (''the final rule''). The final rule provides that it is an unfair method of competition for persons to, among other things, enter into non-compete clauses (''non-competes'') with workers on or after the final rule's effective date. With respect to existing non-competes—*i.e.,* non-competes entered into before the effective date—the final rule adopts a different approach for senior executives than for other workers. For senior executives, existing non-competes can remain in force, while existing non-competes with other workers are not enforceable after the effective date.

DATES: The final rule is effective September 4, 2024.

FOR FURTHER INFORMATION CONTACT: Benjamin Cady or Karuna Patel, Office of Policy Planning, 202–326–2939 (Cady), 202–326–2510 (Patel), Federal Trade Commission, 600 Pennsylvania Avenue NW, Mail Stop CC–6316, Washington, DC 20580.

SUPPLEMENTARY INFORMATION:

I. Background

A. Summary of the Final Rule's Provisions

The Commission proposed the Non-Compete Clause Rule on January 19, 2023 pursuant to sections 5 and 6(g) of the FTC Act.[1] Based on the Commission's expertise and after careful review and consideration of the entire rulemaking record—including empirical research on how non-competes affect competition and over 26,000 public comments—the Commission adopts this final rule addressing non-competes.

The final rule provides that it is an unfair method of competition—and therefore a violation of section 5—for employers to, *inter alia,* enter into non-compete clauses with workers on or after the final rule's effective date.[2] The Commission thus adopts a comprehensive ban on new non-competes with all workers.

With respect to existing non-competes, *i.e.,* non-competes entered into before the final rule's effective date, the Commission adopts a different approach for senior executives[3] than for other workers. Existing non-competes with senior executives can remain in force; the final rule does not cover such agreements.[4] The final rule allows existing non-competes with senior executives to remain in force because this subset of workers is less likely to be subject to the kind of acute, ongoing harms currently being suffered by other workers subject to existing non-competes and because commenters raised credible concerns about the practical impacts of extinguishing existing non-competes for senior executives. For workers who are not senior executives, existing non-competes are no longer enforceable after the final rule's effective date.[5] Employers must provide such workers with existing non-competes notice that they are no longer enforceable.[6] To facilitate compliance and minimize burden, the final rule includes model language that satisfies this notice requirement.[7]

The final rule contains separate provisions defining unfair methods of competition for the two subcategories of workers. Specifically, the final rule provides that, with respect to a worker other than a senior executive, it is an unfair method of competition for a person to enter into or attempt to enter into a non-compete clause; to enforce or attempt to enforce a non-compete clause; or to represent that the worker is subject to a non-compete clause.[8] The Commission describes the basis for its finding that these practices are unfair methods of competition in Parts IV.B.1 through IV.B.3.

The final rule provides that, with respect to a senior executive, it is an unfair method of competition for a person to enter into or attempt to enter into a non-compete clause; to enforce or attempt to enforce a non-compete clause entered into after the effective date; or to represent that the senior executive is subject to a non-compete clause, where the non-compete clause was entered into after the effective date.[9] The Commission describes the basis for its finding that these practices are unfair methods of competition in Part IV.C.2.

The final rule defines ''non-compete clause'' as ''a term or condition of employment that prohibits a worker from, penalizes a worker for, or functions to prevent a worker from (1) seeking or accepting work in the United States with a different person where such work would begin after the conclusion of the employment that includes the term or condition; or (2) operating a business in the United States after the conclusion of the employment that includes the term or condition.'' [10] The final rule further provides that, for purposes of the final rule, ''term or condition of employment'' includes, but is not limited to, a contractual term or workplace policy, whether written or oral.[11] The final rule further defines ''employment'' as ''work for a person.'' [12]

The final rule defines ''worker'' as ''a natural person who works or who previously worked, whether paid or unpaid, without regard to the worker's title or the worker's status under any other State or Federal laws, including, but not limited to, whether the worker is an employee, independent contractor, extern, intern, volunteer, apprentice, or a sole proprietor who provides a service to a person.'' [13] The definition further states that the term ''worker'' includes a natural person who works for a franchisee or franchisor, but does not include a franchisee in the context of a franchisee-franchisor relationship.[14]

The final rule does not apply to non-competes entered into by a person pursuant to a bona fide sale of a business entity.[15] In addition, the final rule does not apply where a cause of action related to a non-compete accrued prior to the effective date.[16] The final rule further provides that it is not an unfair method of competition to enforce or attempt to enforce a non-compete or to make representations about a non-compete where a person has a good-faith basis to believe that the final rule is inapplicable.[17]

The final rule does not limit or affect enforcement of State laws that restrict non-competes where the State laws do not conflict with the final rule, but it preempts State laws that conflict with the final rule.[18] Furthermore, the final

[1] Non-Compete Clause Rule, NPRM, 88 FR 3482 (Jan. 19, 2023) (hereinafter ''NPRM'').

[2] § 910.2(a)(1)(i) and § 910.2(a)(2)(i).

[3] *See* § 910.1 (defining ''senior executive'').

[4] *See* Part IV.C.3.

[5] § 910.2(a)(1)(ii).

[6] § 910.2(b)(1).

[7] § 910.2(b)(4).

[8] § 910.2(a)(1).

[9] § 910.2(a)(2).

[10] § 910.1.

[11] *Id.*

[12] *Id.*

[13] *Id.*

[14] *Id.*

[15] § 910.3(a).

[16] § 910.3(b).

[17] § 910.3(c); *see also* Part V.C.

[18] § 910.4.

rule includes a severability clause clarifying the Commission's intent that, if a reviewing court were to hold any part of any provision or application of the final rule invalid or unenforceable—including, for example, an aspect of the terms or conditions defined as non-competes, one or more of the particular restrictions on non-competes, or the standards for or application to one or more category of workers—the remainder of the final rule shall remain in effect.[19] The final rule has an effective date of September 4, 2024.[20]

B. Context for the Rulemaking

1. Growing Concerns Regarding the Harmful Effects of Non-Competes

The purpose of this rulemaking is to address conduct that harms fair competition. Concern about non-competes dates back centuries, and the evidence of harms has increased substantially in recent years. However, the existing case-by-case and State-by-State approaches to non-competes have proven insufficient to address the tendency of non-competes to harm competitive conditions in labor, product, and service markets.

The ability of employers[21] to enforce non-competes has always been restricted, based on public policy concerns that courts have recognized for centuries. For example, in *Mitchel* v. *Reynolds* (1711), an English case that provided the foundation for American common law on non-competes,[22] the court noted that workers were vulnerable to exploitation through non-competes and that non-competes threatened a worker's ability to practice a trade and earn a living.[23] These concerns have persisted. Today, non-competes between employers and workers are generally subject to greater scrutiny under State common law than other employment terms ''because they are often the product of unequal bargaining power and because the employee is likely to give scant attention to the hardship he may later suffer through loss of his livelihood.''[24] For these reasons, State courts often characterize non-competes as ''disfavored.''[25]

Furthermore, as ''contract[s] . . . in restraint of trade,''[26] non-competes have always been subject to our nation's antitrust laws.[27] As early as 1911, in the formative antitrust case of *United States* v. *American Tobacco Co.,* the Supreme Court held that several tobacco companies violated both section 1 and section 2 of the Sherman Act because of the ''constantly recurring'' use of non-competes, among other practices.[28]

Concerns about non-competes have increased substantially in recent years in light of empirical research showing that they tend to harm competitive conditions in labor, product, and service markets. Changes in State laws governing non-competes[29] in recent decades have allowed researchers to better isolate the effects of non-competes, giving rise to a body of empirical research documenting these harms. This research has shown that the use of non-competes by employers tends to negatively affect competition in labor markets, suppressing earnings for workers across the labor force—including even workers not subject to non-competes.[30] This research has also shown that non-competes tend to negatively affect competition in product and service markets, suppressing new business formation and innovation.[31]

Alongside this large body of empirical work, news reports revealed that employers subject even middle-income and low-wage workers to non-competes on a widespread basis.[32] Workers came forward to recount how—by blocking them from taking a better job or starting their own business, and subjecting them to threats and litigation from their employers—non-competes derailed their careers, destroyed their finances, and upended their lives.[33]

Yet despite the mounting empirical and qualitative evidence confirming these harms and the efforts of many States to ban them, non-competes remain prevalent in the U.S. economy. Based on the available evidence, the Commission estimates that approximately one in five American workers—or approximately 30 million workers—is subject to a non-compete.[34] The evidence also indicates that employers frequently use non-competes even when they are unenforceable under State law.[35] This suggests that employers may believe workers are unaware of their legal rights; that employers may be seeking to take advantage of workers' lack of knowledge of their legal rights; or that workers are unable to enforce their rights through case-by-case litigation.[36] In addition, the ability of States to regulate non-competes effectively is constrained by employers' use of choice-of-law provisions, significant variation in how courts apply choice-of-law rules in disputes over non-competes, and the increasingly interstate nature of work. As the public comments attest, this patchwork of laws and legal uncertainty has become extremely burdensome for both employers and workers.[37]

As concern about the harmful effects of non-competes increased, the Commission began exploring the potential for Federal rulemaking on non-competes. In 2018 and 2019, the Commission held several hearings on twenty-first century competition and consumer protection issues, including ''the use of non-competition agreements

[19] § 910.5.

[20] § 910.6.

[21] For ease of reference, the Commission uses the term ''employer'' in this Supplementary Information to refer to a person for whom a worker works. The text of part 910 does not use the term ''employer.''

[22] Harlan Blake, *Employee Agreements Not to Compete,* 73 Harv. L. Rev. 625, 629–31 (1960).

[23] The *Mitchel* court expressed concern that non-competes threaten ''the loss of [the worker's] livelihood, and the subsistence of his family.'' *Mitchel* v. *Reynolds,* 1 P. Wms. 181, 190 (Q.B. 1711). The court likewise emphasized ''the great abuses these voluntary restraints'' are subject to—for example, ''from masters, who are apt to give their apprentices much vexation'' by using ''many indirect practices to procure such bonds from them, lest they should prejudice them in their custom, when they come to set up for themselves.'' *Id.*

[24] Restatement (Second) of Contracts sec. 188, cmt. g (1981).

[25] *See, e.g., Navarre Chevrolet, Inc.* v. *Begnaud,* 205 So. 3d 973, 975 (La. Ct. App. 3d 2016); *Eastman Kodak Co.* v. *Carmosino,* 77 A.D.3d 1434, 1435 (N.Y. App. Div. 4th 2010); *Access Organics, Inc.* v. *Hernandez,* 175 P.3d 899, 904 (Mont. 2008); *Bybee* v. *Isaac,* 178 P.3d 616, 621 (Idaho 2008); *Softchoice, Inc.* v. *Schmidt,* 763 NW2d 660, 666 (Minn. Ct. App. 2009).

[26] 15 U.S.C. 1.

[27] *See, e.g., Newburger, Loeb & Co., Inc.* v. *Gross,* 563 F.2d 1057, 1082 (2d Cir. 1977) (''Although such issues have not often been raised in the federal courts, employee agreements not to compete are proper subjects for scrutiny under section 1 of the Sherman Act. When a company interferes with free competition for one of its former employee's services, the market's ability to achieve the most economically efficient allocation of labor is impaired. Moreover, employee-noncompetition clauses can tie up industry expertise and experience and thereby forestall new entry.'') (internal citation omitted).

[28] 221 U.S. 106, 181–83 (1911).

[29] *See* NPRM at 3494 (describing recent legislative activity at the State level).

[30] *See* Parts IV.B.3.a and IV.C.2.c.ii.

[31] *See* Parts IV.B.3.b and IV.C.2.c.i.

[32] *See, e.g.,* Dave Jamieson, *Jimmy John's Makes Low-Wage Workers Sign 'Oppressive' Noncompete Agreements,* HuffPost, Oct. 13, 2014, *https://www.huffpost.com/entry/jimmy-johns-non-compete_n_5978180;* Spencer Woodman, *Exclusive: Amazon Makes Even Temporary Warehouse Workers Sign 18-Month Non-Competes,* The Verge, Mar. 26, 2015, *https://www.theverge.com/2015/3/26/8280309/amazon-warehouse-jobs-exclusive-noncompete-contracts.*

[33] *See, e.g.,* Conor Dougherty, *How Noncompete Clauses Keep Workers Locked In,* N.Y. Times, May 13, 2017, *https://www.nytimes.com/2017/05/13/business/noncompete-clauses.html;* Lauren Weber, *The Noncompete Clause Gets a Closer Look,* Wall St. J., Jul. 21, 2021, *https://www.wsj.com/articles/the-noncompete-clause-gets-a-closer-look-11626872430.*

[34] *See* Part I.B.2. As described therein, this is likely a conservative estimate.

[35] *See* Part IV.B.2.b.i.

[36] *See id.*

[37] *See* Part IX.C.2.

and the conditions under which their use may be inconsistent with the antitrust laws.'' [38] In January 2020, the Commission held a public workshop on non-competes. The speakers and panelists who participated in the workshop—and the hundreds of public comments the Commission received in response to the workshop—addressed a wide range of issues, including statutory and judicial treatment of non-competes; the economic literature regarding the effects of non-competes; and whether the Commission should initiate a Federal rulemaking on non-competes.[39] The Commission also sought public comment on non-competes as part of an August 2021 solicitation for public comment on contract terms that may harm competition and a December 2021 public workshop on competition in labor markets.[40] The Commission has also addressed non-competes in connection with its merger review work.[41]

In 2021, the Commission initiated investigations into the use of non-competes. In 2023, the Commission secured final consent orders settling charges that certain firms engaged in an unfair method of competition in violation of section 5 because their use of non-competes tended to impede rivals' access to the restricted employees' labor, harming workers, consumers, and competitive conditions.[42]

The Commission also secured a final consent order settling charges that another firm violated section 5 by using non-competes with its employees.[43] The Commission's complaint alleged the firm's imposition of non-competes took advantage of the unequal bargaining power between the firm and its employees, including low-wage security guard employees, and thus reduced workers' job mobility; limited competition for workers' services; and ultimately deprived workers of higher wages and more favorable working conditions.[44]

Based on the feedback obtained from years of extensive public outreach and fact-gathering, in January 2023, the Commission published a notice of proposed rulemaking (NPRM) concerning non-competes.[45] The proposed rule would have categorically banned employers from using non-competes with all workers and required rescission of all existing non-competes.[46]

In response to the NPRM, the Commission received over 26,000 public comments.[47] The comments reflected a diverse cross-section of the U.S. The Commission received comments from employers and workers in a wide range of industries and from every State; [48] from small, medium, and large businesses; and from workers with wide-ranging income levels.[49] The Commission also received comments from representatives of different industries through trade and professional groups as well as from academics and researchers. Federal, State, and local governmental representatives also submitted public comments.

Among these comments, over 25,000 expressed support for the Commission's proposal to categorically ban non-competes. Among the public commenters were thousands of workers who described how non-competes prevented them from taking a better job or starting a competing business, as well as numerous small businesses who struggled to hire talented workers. Commenters stated that non-competes have suppressed their wages, harmed working conditions, negatively affected their quality of life, reduced the quality of the product or service their company provided, prevented their business from growing and thriving, and created a climate of fear that deters competitive activity. The following examples are illustrative of the comments the Commission received: [50]

- I currently work in sales for an asphalt company in Michigan. The company had me sign a two year non-compete agreement to not work for any other asphalt company within 50 miles if I decide to resign. After two years with the company I have been disheartened at how poorly customers are being treated and how often product quality is sub-par. I would love to start my own business because I see this as an opportunity to provide a better service at a lower cost. However, the non-compete agreement stands in the way even though there are no trade secrets and too many customers in this market.[51]
- [I] signed a non-compete clause for power-washing out of duress. My boss said that if I didn't sign before the end of the week, not to come in the next week. . . . I'd like to start my own business but I would have to find another job and wait 5 years. All I know is power-washing and these business owners all want me to sign a non-compete clause. It's one big circle of wealthy business owners keeping the little man down. Essentially, non-compete clauses limit an employee's opportunity to excel in whatever skill or trade they're familiar with. In the land of the free, we should be free to start a business not limited by greedy business owners.[52]
- In October 2020, I started working as a bartender at a company called [REDACTED] for $10 an hour. On my first day, I

[38] Hearings on Competition and Consumer Protection in the 21st Century, Notice, 83 FR 38307, 38309 (Aug. 6, 2018).

[39] FTC, *Non-Competes in the Workplace: Examining Antitrust and Consumer Protection Issues* (Jan. 9, 2020), *https://www.ftc.gov/news-events/events/2020/01/non-competes-workplace-examining-antitrust-consumer-protection-issues.*

[40] FTC, *Solicitation for Public Comments on Contract Terms that May Harm Competition* (Aug 5, 2021), *https://www.regulations.gov/document/FTC-2021-0036-0022;* FTC, *Making Competition Work: Promoting Competition in Labor Markets* (Dec. 6–7, 2021), *https://www.regulations.gov/docket/FTC-2021-0057/comments.*

[41] *See* NPRM at 3498–99.

[42] FTC, Press Release, *FTC Approves Final Orders Requiring Two Glass Container Manufacturers to Drop Noncompete Restrictions That They Imposed on Workers* (Feb. 23, 2023), *https://www.ftc.gov/news-events/news/press-releases/2023/02/ftc-approves-final-orders-requiring-two-glass-container-manufacturers-drop-noncompete-restrictions;* FTC, Press Release, *FTC Approves Final Order Requiring Anchor Glass Container Corp. to Drop Noncompete Restrictions That It Imposed on Workers* (June 2, 2023), *https://www.ftc.gov/news-events/news/press-releases/2023/06/ftc-approves-final-order-requiring-anchor-glass-container-corp-drop-noncompete-restrictions-it.*

[43] FTC, Press Release, *FTC Approves Final Order Requiring Michigan-Based Security Companies to Drop Noncompete Restrictions That They Imposed on Workers* (Mar. 8, 2023), *https://www.ftc.gov/news-events/news/press-releases/2023/03/ftc-approves-final-order-requiring-michigan-based-security-companies-drop-noncompete-restrictions.*

[44] FTC, Analysis of Agreement Containing Consent Order to Aid Public Comment, *In re Prudential Sec., Inc. et al.* at 1 (Jan. 4, 2023).

[45] NPRM, *supra* note 1.

[46] *Id.* at 3482–83.

[47] The public comments are available online. *See Regulations.gov,* Non-Compete Clause Rule (NPRM), FTC–2023–0007, *https://www.regulations.gov/docket/FTC-2023-0007/comments.* The Commission cannot quantify the number of individuals or entities represented by the comments. The number of comments undercounts the number of individuals or entities represented by the comments because many comments, including comments from different types of organizations, jointly represent the opinions or interests of many.

[48] This reflects information provided by commenters. Commenters self-identify their State and are not required to include geographic information.

[49] Though most commenters identifying as workers did not provide information regarding their income or compensation levels, many provided information about their particular jobs or industries from which the Commission was able to infer a broad range of income levels based on occupational data from the Bureau of Labor Statistics (''BLS''). BLS wage data for each year can be found at Occupational Employment and Wage Statistics, *Tables Created by BLS, https://www.bls.gov/oes/tables.htm* (hereinafter ''BLS Occupational Employment and Wage Statistics''). The Commission used data from the May 2022 National XLS table, generally for private ownership.

[50] To be clear, the Commission does not rely on any particular individual comment submission for its findings, but rather provides here (and throughout this final rule) examples of comments that were illustrative of themes that spanned many comments. The Commission's findings are based on consideration of the totality of the evidence, including its review of the empirical literature, its review of the full comment record, and its expertise in identifying practices that harm competition.

[51] Individual commenter, FTC–2023–0007–2215. Comment excerpts have been cleaned up for grammar, spelling, and punctuation.

[52] Individual commenter, FTC–2023–0007–12689.

unknowingly signed a 2-year non-compete, slipped between other paperwork while my boss rushed me, and downplayed its importance. . . . At [REDACTED], I was sexually harassed and emotionally abused. I needed money, so I searched for a new job while remaining at [REDACTED] for one year. I was eventually offered a bartending job at a family-owned bar with better wages, conditions, and opportunities. Upon resigning, I was threatened with a non-compete I didn't know existed. Still, I couldn't take it anymore, so believing it was an unenforceable scare tactic, I took the new job, thinking our legal system wouldn't allow a massive company with over 20 locations to sue a young entry-level worker with no degree. In December 2021, I was sued for $30,000 in ''considerable and irreparable damages'' for violating the non-compete. . . .[53]

• I am a physician in a rural underserved area of Appalachia. . . . ''[N]on-compete'' clauses have become ubiquitous in the healthcare industry. With hospital systems merging, providers with aggressive non compete clauses must abandon the community that they serve if they chose to leave their employer. . . . Healthcare providers feel trapped in their current employment situation, leading to significant burnout that can shorten their career longevity. Many are forced to retire early or take a prolonged pause in their career when they have no other recourse to combat their employer.[54]

• I am a practicing physician who signed an employment contract containing a noncompete agreement in 2012, entering into this agreement with an organization that no longer exists. My original employer merged with, and was made subsidiary to, a new organization that is run under religious principles in conflict with my own. . . . I would have never signed such an agreement with my new employer, yet I am bound to this organization under threat of legal coercion. To be clear, the forced compromise of my religious principles does direct harm to me. My only recourse to this coercion is to give up medical practice anywhere covered by my current medical license, which is injurious to the patients in my care, and to myself.[55]

• I am the owner of a small-midsize freight brokerage, and non-competes of large brokerages have time and time again constrained talent from my business. Countless employees of [a] mega brokerage . . . have left and applied for our company and we must turn them away. These are skilled brokers that are serving the market and their clients well due to THEIR skillsets. . . . These non-competes affect not just me but the clients they work with as these skilled brokers are forced out of the entire logistics market for an entire year and possibly a lifetime when they pick up a new career in a different field because of these aggressive non-competes. . . .[56]

• I was laid off from my company in 2008 due to the economy, not to any fault of my own. However, when I was offered a job at another company, my former company threatened them and my offer was rescinded. I was unable to find gainful employment for months, despite opportunities in my field, and had to utilize unemployment when I otherwise would not have needed it. To find work, I ultimately had to switch fields, start part time somewhere, and just continue to work my way up. All of this because I was laid off to no fault of my own.[57]

• I was terminated by a large hospital organization suddenly with a thriving, full Pediatric practice. . . . My lawyer and I believe the non-compete does not apply in my circumstances and that the noncompete is overly broad, restrictive and harmful to the public (my patients). I started seeing my patients mostly gratuitously in their homes so they would not go without the care they wanted and needed . . . The judge awarded the order and I was told I cannot talk to patients on the phone, text patients, zoom visits or provide any pediatric care within my non-compete area. Patients are angry and panicked. I'm worried every day about my patients and how I can continue to care for them. . . . Patients have a right to choose and keep their doctor. The trust built between a patient and his doctor is crucial to keeping a patient healthy. It's not a relationship that can or should be replaced. . . . Patients should always come first and that is not happening.[58]

• When I first graduated veterinary school I signed a noncompete clause that was for 7 years. I tried to negotiate it to a more reasonable time period but the employer wouldn't budge. There weren't many job openings for new graduates at the time and I had student loans to pay back so I signed it. . . . I moved back home to a small town and took a job that required a 10-radial-mile, 2-year noncompete (this is currently considered ''reasonable/standard'' in my industry). Unfortunately since it's a rural area the 10 miles blocked me out of the locations of all other veterinary clinics in the county and I had to commute an hour each way to work in the next metropolitan area. This put a lot of stress on my family since I have young children. Some days I didn't even get to see them when they were awake.[59]

• I work for a large electronic health records company . . . that is known for hiring staff right out of college, myself included. I was impressed with their starting salary and well-advertised benefits, so I was quick to accept their offer. After accepting their offer, I was surprised to receive a contract outlining a strict non-compete agreement . . . I feel disappointed that this information was not made apparent to me prior to my acceptance of the position, and now I feel stuck in a job that I've quickly discovered is not a good long-term fit for me. I am certain that many other recent graduates often find themselves in a similar position—they accept shiny offers from a workplace, not knowing whether the company and position will be the right fit for them, and find themselves trapped by such contracts as mine.[60]

• Non competes are awful. I am being sued right now for going into business on my own in Boston, Massachusetts, by my former employer who says I signed a non-compete in 2003, 20 years ago. . . . I am fighting them in court. Hopefully I will prevail. . . . [The] corporation I worked for is a billion-dollar corporation. And they just keep trying scare tactics to make me back down. They went as far as trying to get a preliminary injunction ordered against me. And the judge refused but I still have to spend $1,000 an hour to defend myself.[61]

• I have been working in the field of multi-media in the DC/Baltimore region since the early 2000s. . . . I was 26 when I first became employed, and at that time a requirement was that I sign a non-compete agreement. . . . This means I can't be an entrepreneur- which kills any opportunities for me to grow something of my own- which could potentially provide jobs for others in the future. So what this non-compete does is basically enables businesses to be small monopolies. I could literally have a new lease on my career if non competes were abolished. As of now, when I think of working someplace else I have to consider changing careers altogether.[62]

• A former employer had me sign a non-compete when I started employment at an internship in college. It was a part-time position of 20 hours of work as an electrical engineer, while I finished university. After university, I worked for this employer another 4 years full time, but then found a better job in another state. It was not a competitor, but a customer of my former employer. My former employer waited till the day after my 4-week notice to tell me that I had signed a non-compete agreement and that it [barred] me from working for any competitor, customer or any potential customer up to 5 years after leaving the company with no geographic limitations. This was effectively the entire semi-conductor industry and put my entire career at risk.[63]

• Non-competes serve little more purpose than to codify and entrench inefficiencies. I have seen this firsthand in the context of a sophisticated management consulting environment where company owners provided ever less support in terms of contributing to projects or even to sales of new business while still feeling secure through agreements that substantially limited anyone from working in the relevant industry for two years on a global basis after leaving. . . . The reality is that there are innumerable retention mechanisms (such as good working conditions, compensation, culture, management, growth trajectory and/or strategy) that can contribute to loyal employees without the need for non-competes.[64]

The Commission has undertaken careful review of the public comments

[53] Individual commenter, FTC–2023–0007–8852.
[54] Individual commenter, FTC–2023–0007–0026.
[55] Individual commenter, FTC–2023–0007–9671.
[56] Individual commenter, FTC–2023–0007–6142.
[57] Individual commenter, FTC–2023–0007–15497.
[58] Individual commenter, FTC–2023–0007–14956.
[59] Individual commenter, FTC–2023–0007–0922.
[60] Individual commenter, FTC–2023–0007–10729.
[61] Individual commenter, FTC–2023–0007–10871.
[62] Individual commenter, FTC–2023–0007–10968.
[63] Individual commenter, FTC–2023–0007–16347.
[64] Individual commenter, FTC–2023–0007–3963.

and the entirety of the rulemaking record. Based on this record and the Commission's experience and expertise in competition matters, the Commission issues this final rule pursuant to its authority under sections 5 and 6(g) of the FTC Act.

2. Prevalence of Non-Competes

Based on its own data analysis, studies published by economists, and the comment record, the Commission finds that non-competes are in widespread use throughout the economy and pervasive across industries and demographic groups, albeit with some differences in the magnitude of the prevalence based on industries and demographics. The Commission estimates that approximately one in five American workers—or approximately 30 million workers—is subject to a non-compete.[65]

As described in Part II.F, the inquiry as to whether conduct is an unfair method of competition under section 5 focuses on the nature and tendency of the conduct, not whether or to what degree the conduct caused actual harm.[66] Although a finding that non-competes are prevalent is not necessary to support the Commission's determination that the use of non-competes by employers is an unfair method of competition, the Commission finds that non-competes are prevalent and in widespread use throughout the economy, which is why researchers have observed such significant negative actual effects from non-competes on competitive conditions in labor markets and markets for products and services.[67]

A 2014 survey of workers finds that 18% of respondents work under a non-compete and 38% of respondents have worked under one at some point in their lives.[68] This study has the broadest and likely the most representative coverage of the U.S. labor force among the prevalence studies discussed here.[69] This study reports robust results contradicting the prior assumptions of some that non-competes were, in most cases, bespoke agreements with sophisticated and highly-paid workers. It finds that, among workers without a bachelor's degree, 14% of respondents reported working under a non-compete at the time surveyed and 35% reported having worked under one at some point in their lives.[70] For workers earning less than $40,000 per year, 13% of respondents were working under a non-compete and 33% worked under one at some point in their lives.[71] Furthermore, this survey finds that 53% of workers covered by non-competes are hourly workers.[72] The survey suggests that a large share of workers subject to non-competes are relatively low-earning workers. In addition, a survey from the Federal Reserve Board of Governors found that 11.4% of workers have non-competes, including workers with relatively low earnings and low levels of education. The survey finds some degree of geographic heterogeneity, though it finds that large numbers of workers in all regions of the country have non-competes (including 7.0% of workers in States which broadly do not enforce non-competes).[73]

Furthermore, a survey of workers conducted in 2017 estimates that 24.2% of workers are subject to a non-compete.[74] This survey also finds that non-competes are often used together with other restrictive employment agreements, including non-disclosure agreements (''NDAs'') and non-recruitment and non-solicitation agreements.[75] A methodological limitation of this survey is that it is a convenience sample of individuals who visited *Payscale.com* during the time period of the survey and is therefore unlikely to be fully representative of the U.S. working population. While weighting based on demographics helps, it does not fully mitigate this concern.

Additionally, a 2017 survey of business establishments with 50 or more employees estimates that 49% of such establishments use non-competes for at least some of their employees, and 32% of such establishments use non-competes for all of their employees.[76]

Other estimates of non-compete use cover subsets of the U.S. labor force. One 2022 study is based on National Longitudinal Survey of Youth (NLSY) data.[77] The NLSY is an often-used labor survey conducted by the Bureau of Labor Statistics (''BLS'') that consists of a nationally representative sample of 8,984 men and women born from 1980–84 and living in the U.S. at the time of the initial survey in 1997; it is a subset of the workforce by age of worker.[78] The 2022 study using NLSY data reports prevalence of non-competes to be 18%, in line with the number estimated based on the 2014 survey of workers directed solely at calculating the prevalence of non-competes.[79]

Non-competes are pervasive across occupations. For example, a survey of independent hair salon owners finds that 30% of hair stylists worked under a non-compete in 2015.[80] A survey of electrical and electronic engineers finds that 43% of respondents signed a non-compete.[81] A different study finds that 45% of physicians worked under a non-compete in 2007.[82] One study published in 2021 finds that 62% of CEOs worked under a non-compete between 1992 and 2014.[83] Another, published in 2023, supports that finding and reflects an upward trend in the use of non-competes among executives—specifically, the proportion of executives working under a non-compete rose from ''57% in the early 1990s to 67% in the mid-2010s.'' [84] The 2014 survey reports industry-specific rates ranging from 9% in the Agriculture and Hunting category to 32% in the

[65] This is likely a conservative estimate. Surveys of workers likely underreport the share of workers subject to non-competes, since many workers may not know they are subject to a non-compete. *See, e.g.,* Alexander J.S. Colvin & Heidi Shierholz, Econ. Policy Inst., *Noncompete Agreements,* Report (Dec. 10, 2019) at 3.

[66] *See infra* note 288 and accompanying text.

[67] *See* Parts IV.A through IV.C (describing this evidence).

[68] Evan P. Starr, J.J. Prescott, & Norman D. Bishara, *Noncompete Agreements in the US Labor Force,* 64 J. L. & Econ. 53, 53 (2021).

[69] The final survey sample of 11,505 responses represented individuals from nearly every demographic in the labor force. *Id.* at 58.

[70] *Id.* at 63.

[71] *Id.*

[72] Michael Lipsitz & Evan Starr, *Low-Wage Workers and the Enforceability of Noncompete Agreements,* 68 Mgmt. Sci. 143, 144 (2022) (analyzing data from the Starr, Prescott, & Bishara survey).

[73] Tyler Boesch, Jacob Lockwood, Ryan Nunn, & Mike Zabek, *New Data on Non-Compete Contracts and What They Mean for Workers* (2023), *https://www.minneapolisfed.org/article/2023/new-data-on-non-compete-contracts-and-what-they-mean-for-workers.*

[74] Natarajan Balasubramanian, Evan Starr, & Shotaro Yamaguchi, *Employment Restrictions on Resource Transferability and Value Appropriation from Employees* (Jan. 18, 2024), *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3814403.*

[75] *Id.* at 11 (reporting that if a worker has a non-compete, there is a 70%–75% chance that all three restrictive covenants are present).

[76] Colvin & Shierholz, *supra* note 65 at 1.

[77] Donna S. Rothstein & Evan Starr, *Noncompete Agreements, Bargaining, and Wages: Evidence from the National Longitudinal Survey of Youth 1997,* June 2022 Mthly. Lab. Rev. (2022).

[78] BLS, *NLSY97 Data Overview, https://www.bls.gov/nls/nlsy97.htm.*

[79] Rothstein & Starr, *supra* note 77 at 1.

[80] Matthew S. Johnson & Michael Lipsitz, *Why Are Low-Wage Workers Signing Noncompete Agreements?,* 57 J. Hum. Res. 689, 700 (2022).

[81] Matt Marx, *The Firm Strikes Back: Non-Compete Agreements and the Mobility of Technical Professionals,* 76 a.m. Socio. Rev. 695, 702 (2011). Calculated as 92.60% who signed a non-compete of the 46.80% who were asked to sign a non-compete.

[82] Kurt Lavetti, Carol Simon, & William D. White, *The Impacts of Restricting Mobility of Skilled Service Workers: Evidence from Physicians,* 55 J. Hum. Res. 1025, 1042 (2020).

[83] Omesh Kini, Ryan Williams, & Sirui Yin, *CEO Noncompete Agreements, Job Risk, and Compensation,* 34 Rev. Fin. Stud. 4701, 4707 (2021).

[84] Liyan Shi, *Optimal Regulation of Noncompete Contracts,* 91 Econometrica 425, 447 (2023).

Information category.[85] The Balasubramaian et al. survey reports industry-specific rates ranging from 12% in the Arts, Entertainment, and Recreation category to 30% in the Professional, Scientific, and Technical category.[86] The same survey also reports occupation-specific rates ranging from 8% in the Community and Social Services category to 32% in the Computer and Mathematical category.[87]

In addition, commenters presented survey data on the prevalence of non-competes in various occupations and industries. The Commission does not rely on these surveys to support its finding that non-competes are in widespread use throughout the economy. Because the Commission lacked access to a detailed description of the methodology for these surveys (unlike for the surveys described previously), the Commission cannot evaluate how credible their research designs are. However, they generally confirm the Commission's finding that non-competes are in widespread use throughout the economy and pervasive across industries and demographic groups.

For example, commenters reported that 33% of practitioners in the applied behavioral analysis field reported being subject to a non-compete,[88] along with 68% of cardiologists,[89] 42% of colorectal surgeons,[90] 72% of members of the American Association of Hip and Knee Surgeons,[91] and 31% of wireless telecommunications retail workers.[92] Other commenters cited a 2019 study finding that 29% of businesses where the average wage is below $13 per hour use non-competes for all their workers.[93]

Several trade organizations included information in their comments about the percentage of their members that use non-competes for at least some of their workers, based on surveys of their membership. For the National Association of Wholesaler-Distributors, this figure was 80%;[94] for the Independent Lubricant Manufacturing Association, 69%;[95] for the Michigan Chamber of Commerce, 73%;[96] for the Gas and Welding Distributors Association, 80%;[97] and for the National Association of Manufacturers, 70%.[98] One industry organization said its survey found that 57% of respondents require workers earning over $150,000 to sign non-competes.[99] A survey by the Authors Guild finds that 19.2% of respondents reported that non-competes prevented them from publishing a similar or competing book.[100] The HR Policy Association stated that 75% of respondents indicated they use non-competes for less than 10% of their workers, and nearly one third indicated they use non-competes for less than 1% of their workers.[101] The association stated that its survey covered 3 million workers and argued that its survey finding less usage of non-competes was more representative than studies cited in the NPRM.[102] However, the commenter did not provide the data underlying its claims. The Retail Industry Leaders Association stated that a recent survey of its members indicated that, among members that use non-competes, the majority do so with less than 1% of their workforce and an additional quarter use non-competes with less than 10% of their workforce.[103] Additionally, a commenter referenced a survey of small business owners finding that 48% use non-competes for their own business.[104]

Several commenters misrepresented the Commission's finding related to prevalence as based on ''a single study from 2021'' (Starr, Prescott, and Bishara, 2021), which relied on survey data from 2014. The Commission's finding is not based on a single study. The NLSY study reaches similar conclusions about the prevalence of non-competes across the economy,[105] and the occupation-specific studies indicate that non-competes are pervasive in various occupations.[106] Furthermore, despite its methodological limitations, the data submitted by commenters generally comport with the estimates reported in the academic literature. One commenter stated the respondents to the Starr, Prescott, and Bishara survey were not necessarily representative of the population. The Commission believes that the weighting of the data sufficiently addresses this concern.

Another commenter argued that individuals may misunderstand contracts that they have signed, leading them to mistakenly believe they are bound by a non-compete. The Commission does not find this to be a plausible explanation for the high numbers of workers, businesses, and trade associations that report that non-competes are prevalent.

The Commission appreciates the additional estimates provided by commenters. The comments broadly corroborate the Commission's finding that non-competes are used across the workforce, with some heterogeneity in the magnitude of the prevalence. The

[85] Starr, Prescott, & Bishara, *supra* note 68 at 67.

[86] Balasubramanian et al., *supra* note 74 at 47.

[87] *Id.*

[88] Kristopher J. Brown, Stephen R. Flora, & Mary K. Brown, *Noncompete Clauses in Applied Behavior Analysis: A Prevalence and Practice Impact Survey,* 13 Behavioral Analysis Practice 924 (2020) (survey of 610 workers).

[89] Comment of Am. Coll. of Cardiology, FTC–2023–0007–18077, at 2. The comment did not provide a citation to the survey or the underlying data, including the number of respondents or the time period.

[90] William C. Cirocco. *Restrictive Covenants in Physician Contracts: An American Society of Colon and Rectal Surgeons' Survey,* 54 Diseases of the Colon and Rectum 482 (2011). The survey examined 157 colorectal surgeons who had completed their residency in the prior decade.

[91] Comment of Am. Ass'n of Hip and Knee Surgeons, FTC–2023–0007–21076, at 4. The comment said the internal poll was conducted in early 2023, but the comment did not provide a citation to the survey or the underlying data, including the number of respondents.

[92] Comm. Workers of Am. and Nat'l Employment L. Project, *Broken Network: Workers Expose Harms of Wireless Telecom Carriers' Outsourcing to 'Authorized Retailers'* (Feb. 2023), *https://cwa-union.org/sites/default/files/2023-02/20230206_BrokenNetwork.pdf,* at 12. The survey had 204 respondents.

[93] Colvin & Shierholz, *supra* note 65 at 13.

[94] Comment of Nat'l Assoc. of Wholesaler-Distribs., FTC–2023–0007–19347, at 2. The comment did not provide a citation to the survey or the underlying data, including the number of respondents.

[95] Comment of Indep. Lubricant Mfrs. Ass'n, FTC–2023–0007–19445, at 3. The comment did not provide a citation to the survey or the underlying data, including the number of respondents.

[96] Calculated as 77%*95% (assuming that the 95% reported in their comment applies to the 77% who reported using restrictive covenants). Comment of Mich. Chamber of Com., FTC–2023–0007–20855. The comment did not provide a citation to the survey or the underlying data, including the number of respondents.

[97] Comment of Gas and Welding Distribs. Ass'n, FTC–2023–0007–20934, at 2–3. The comment did not provide a citation to the survey or the underlying data. The comment said the survey took place after the NPRM was proposed and had 161 respondents.

[98] Comment of Nat'l Ass'n of Mfrs., FTC–2023–0007–20939, at 2 (citing Nat'l Ass'n of Mfrs., Noncompete Survey Data Report, *https://www.nam.org/wp-content/uploads/2023/03/Noncompete_Survey_Data_Report.pdf*). The survey had 150 respondents.

[99] Comment of Soc. for Hum. Res. Mgmt., FTC–2023–0007–20903, at 5 n.2. The comment did not provide a citation to the survey or the underlying data, including the number of respondents.

[100] Comment of The Authors Guild, FTC–2023–0007–20854, at 7. The comment did not provide a citation to the survey or the underlying data, but said it had 630 respondents.

[101] Comment of HR Policy Ass'n, FTC–2023–0007–20998, at 8.

[102] *Id.*

[103] Comment of Retail Indus. Leaders Ass'n, FTC–2023–0007–20989, at 6. The comment did not provide a citation to the survey or the underlying data, including the number of respondents or the time period.

[104] Comment of Sm. Bus. Majority, FTC–2023–0007–21093 (citing Small Business Majority, Opinion Poll: Small Business Owners Support Banning Non-Compete Agreements (Apr. 13, 2013), *https://smallbusinessmajority.org/sites/default/files/research-reports/2023-non-compete-poll-report.pdf*).

[105] *See* Rothstein & Starr, *supra* note 77 and accompanying text.

[106] *See supra* notes 80–87 and accompanying text.

Commission finds that this heterogeneity is insufficient to warrant industry-specific exclusions from coverage under the final rule in part because employers' use of non-competes is prevalent across labor markets and for the reasons discussed in Part V.D regarding requests for exclusions.

II. Legal Authority

A. The History of the Commission and Section 5 of the FTC Act

The FTC Act was enacted in 1914.[107] Section 5 of that Act ''declared'' that ''unfair methods of competition in commerce'' are ''unlawful,'' and it ''empowered and directed'' the Commission ''to prevent'' entities subject to its jurisdiction from ''using'' such methods.[108] Congress removed certain enumerated industries, activities, or entities—such as banks [109]—from the Commission's jurisdiction but otherwise envisioned a Commission whose purview would cover commerce across the national economy.

The term '''unfair methods of competition' . . . was an expression new in the law'' when it first appeared in the FTC Act.[110] Congress purposely introduced this phrase to distinguish the Commission's authority from the definition of ''unfair competition'' at common law. Because the ''meaning which the common law had given to ['unfair competition'] was . . . too narrow,'' Congress adopted ''the broader and more flexible phrase 'unfair methods of competition.' '' [111] Using this new phrase also made clear that Congress designed section 5 to extend beyond the reach of other antitrust laws—most notably, the Sherman Act—whose text did not include the term ''unfair methods of competition.'' [112] In particular, Congress wanted the Commission to apply a standard that would reach conduct not captured by other antitrust laws and the rule of reason, which courts applied when interpreting the Sherman Act, making it ''impossible to predict with any certainty'' whether courts would condemn the many ''practices that seriously interfere with competition.'' [113] Allowing the Commission to prevent unfair methods of competition would also help the Commission achieve a core purpose of the Act: to stop ''trade restraints in their incipiency'' before they grew into violations of other antitrust laws.[114]

By design, the new phrase ''unfair methods of competition'' did ''not 'admit of precise definition.' '' [115] Congress intentionally gave the Commission flexibility to adapt to changing circumstances.[116] The Supreme Court has affirmed the more inclusive scope of section 5 on numerous occasions [117] and has affirmed the Commission's power under the Act to condemn coercive and otherwise unfair practices that have a tendency to stifle or impair competition.[118] Federal appellate courts have likewise consistently held that the Commission's authority under section 5 extends beyond ''the letter'' of other antitrust laws.[119]

Congress further expanded the Commission's jurisdiction over time. Congress extended the Commission's authority in 1938 by adding the further prohibition on ''unfair or deceptive acts or practices.'' [120] And in 1975, Congress amended the phrase ''in commerce'' in section 5 to ''in or affecting commerce,'' a change that was ''specifically designed to expand the Commission's jurisdiction . . . to make it coextensive with the constitutional power of Congress under the Commerce Clause.'' [121]

Congress gave careful thought to the structure of the FTC as an independent agency entrusted with this considerable responsibility. The Commission would consist of five members, no more than three of whom could be part of the same political party, who would serve for terms of seven years.[122] The Commission would draw on trained expert staff to develop the body of law regarding what constitutes unfair methods of competition (and, later, unfair and deceptive practices),[123] both through acting as ''a quasi judicial body'' [124] that determines whether conduct is an unfair method of competition in adjudications and through authority to promulgate legislative rules delineating conduct that constitutes an unfair method of competition. Recognizing that the Commission is an expert agency in making such determinations about anticompetitive conduct, courts reviewing Commission determinations as to what practices constitute an unfair method of competition have given the Commission's decisions ''great weight.'' [125]

The FTC Act today reflects a careful balance from Congress. Congress has directed the Commission to proceed

---

[107] Federal Trade Commission Act of 1914, Public Law 63–203, 38 Stat. 717, 719 (hereinafter ''FTC Act of 1914'').

[108] FTC Act of 1914, 38 Stat. at 719. Section 5 is codified as amended at 15 U.S.C. 45. Congress later amended the term ''in commerce'' to ''in or affecting commerce.'' The Supreme Court has explained that this amended phrase makes section 5 of the FTC Act ''coextensive with the constitutional power of Congress under the Commerce Clause.'' *United States* v. *Am. Bldg. Maintenance Indus.,* 422 U.S. 271, 277 n.6 (1975). For simplicity, this statement of basis and purpose often refers to ''unfair methods of competition'' without the commerce requirement, but the Commission acknowledges that it has power to prevent only such methods that are in or affect commerce as that term is defined in the Act. *See* 15 U.S.C. 44.

[109] *See* 15 U.S.C. 45(a)(2).

[110] *A.L.A. Schechter Poultry Corp.* v. *United States,* 295 U.S. 495, 532 (1935).

[111] *See FTC* v. *R. F. Keppel & Bro., Inc.,* 291 U.S. 304, 310–11 (1934); *see also Schechter Poultry,* 295 U.S. at 532.

[112] *See E.I. du Pont de Nemours* v. *FTC* (*Ethyl),* 729 F.2d 128, 136 (2d Cir. 1984) (''Congress' aim was to protect society against oppressive anti-competitive conduct and thus assure that the conduct prohibited by the Sherman and Clayton Acts would be supplemented as necessary and any interstices filled.'').

[113] S. Rep. No. 62–1326, at 14 (1913) (hereinafter ''Cummins Report''). After analyzing a series of Supreme Court decisions interpreting the Sherman Act—*e.g., Standard Oil Co. of New Jersey* v. *United States,* 221 U.S. 1, 60 (1911)—the Senate committee feared that the rule of reason meant that ''in each instance it [would be] for the court to determine whether the established restraint of trade is a due restraint or an undue restraint'' and that this made it ''imperative to enact additional legislation.'' Cummins Report at 11–12.

[114] *FTC* v. *Brown Shoe Co.,* 384 U.S. 316, 322 (1966); *see also FTC* v. *Motion Picture Advert. Serv. Co.,* 344 U.S. 392, 394–95 (1953).

[115] *R.F. Keppel & Bro.,* 291 U.S. at 312.

[116] *Id.* at 311 n.2.

[117] *See, e.g., id.* at 311; *A.L.A. Schechter Poultry Corp.* v. *United States,* 295 U.S. 495, 532 (1935); *Brown Shoe Co.,* 384 U.S. at 320–22.

[118] *FTC* v. *Texaco,* 393 U.S. 223, 225–26 (1968) (citing *Atl. Refin. Co.* v. *FTC,* 381 U.S. 357, 376 (1965)).

[119] *Spiegel, Inc.* v. *FTC,* 540 F.2d 287, 292 (7th Cir. 1976) (quoting *FTC* v. *Sperry & Hutchinson Co.,* 405 U.S. 233, 244 (1972)); *cf., Chuck's Feed & Seed Co.* v. *Ralston Purina Co.,* 810 F.2d 1289, 1292–93 (4th Cir. 1987).

[120] Federal Trade Commission Act, Public Law 447, 75th Cong., 3d Sess. (March 21, 1938) c. 49; 52 Stat. 111 (1938).

[121] *United States* v. *Am. Bldg. Maintenance Indus.,* 422 U.S. 271, 277 n.6 (1975). As noted, the Commission's authority does not reach certain enumerated industries or activities—a list that has also grown over time. *See* 15 U.S.C. 45(a)(2); *see also* Part II.E.1. Some of these industries are statutorily prohibited from engaging in unfair or deceptive practices or unfair methods of competition under different laws overseen by other agencies. *See, e.g.,* 49 U.S.C. 41712(a) (allowing the Secretary of Transportation to ''decide whether an air carrier, foreign air carrier, or ticket agent'' has engaged in such conduct).

[122] 15 U.S.C. 41.

[123] *Id.* (anticipating that the Commission would ''build up a comprehensive body of information for the use and advantage of the Government and the business world''); *id.* at 11,092 (''[W]e want trained experts; we want precedents; we want a body of administrative law built up.'').

[124] *A.L.A. Schechter Poultry Corp.* v. *United States,* 295 U.S. 495, 533 (1935).

[125] *FTC* v. *Cement Inst.,* 333 U.S. 683, 720 (1948); *Atl. Ref. Co.* v. *FTC,* 381 U.S. 357, 368 (1965); *FTC* v. *Texaco,* 393 U.S. 223, 226 (1968); *Official Airline Guides, Inc.* v. *FTC,* 630 F.2d 920, 927 (2d. Cir. 1980) (quoting *Cement Inst.,* 333 U.S. at 720); *see also FTC* v. *Motion Picture Advert. Serv. Co.,* 344 U.S. 392, 396 (1953); *FTC* v. *Ind. Fed'n of Dentists,* 476 U.S. 447, 454 (1986).

against a broader range of anticompetitive conduct than other antitrust laws like the Sherman and Clayton Acts can reach. On the other hand, Congress has never established a private right of action under section 5,[126] nor has it authorized the Commission to recover civil penalties or other monetary relief from parties who engage in unfair methods of competition.[127] Instead, the Commission may either pursue an adjudication under section 5(b) or seek an injunction in Federal court under section 13(b) against a party that has engaged in an unfair method of competition.[128] As explained below, it may also promulgate rules prohibiting unfair methods of competition. The Commission cannot obtain civil penalties or other monetary relief against parties for using an unfair method of competition, although it can obtain civil penalties in court if a party is ordered to cease and desist from a violation and fails to do so.[129]

B. The Commission's Authority To Promulgate the Rule

Alongside section 5, Congress adopted section 6(g) of the Act, in which it authorized the Commission to ''make rules and regulations for the purpose of carrying out the provisions of'' the FTC Act, which include the Act's prohibition of unfair methods of competition.[130] The plain text of section 5 and section 6(g), taken together, empower the Commission to promulgate rules for the purpose of preventing unfair methods of competition. That includes legislative rules defining certain conduct as an unfair method of competition.

The Commission has exercised its authority under section 6(g) to promulgate legislative rules on many occasions stretching back more than half a century. Between 1963 and 1978,[131] the Commission relied on section 6(g) to promulgate the following rules: (1) a rule declaring it an unfair method of competition (''UMC'') and an unfair or deceptive act or practice (''UDAP'') to mislead consumers about the size of sleeping bags by representing that the ''cut size'' represents the finished size; [132] (2) a rule declaring it a UMC and UDAP to use the word ''automatic'' or similar words to describe household electric sewing machines; [133] (3) a rule declaring it a UMC and UDAP to misrepresent nonprismatic instruments as prismatic; [134] (4) a rule declaring it a UMC and UDAP to advertise or market dry cell batteries as ''leakproof;'' [135] (5) a rule declaring it a UMC and UDAP to misrepresent the ''cut size'' as the finished size of tablecloths and similar products; [136] (6) a rule declaring it a UMC and UDAP to misrepresent that belts are made of leather if they are made of other materials; [137] (7) a rule declaring it a UMC and UDAP to represent used lubricating oil as new; [138] (8) a rule declaring it a UDAP to fail to disclose certain health warnings in cigarette advertising and on cigarette packaging (''Cigarette Rule''); [139] (9) a rule declaring it a UMC and UDAP to fail to disclose certain features of light bulbs on packaging; [140] (10) a rule declaring it a UMC and UDAP to misrepresent the actual size of the viewable picture area on a TV; [141] (11) a rule declaring a presumption of a violation of section 2(d) and (e) of the amended Clayton Act for certain advertising and promotional practices in the men's and boy's clothing industry; [142] (12) a rule declaring it a UMC and UDAP to fail to make certain disclosures about the handling of glass fiber products and contact with certain products containing glass fiber; [143] (13) a rule declaring it a UMC and UDAP to make certain misrepresentations about transistors in radios; [144] (14) a rule declaring it a UDAP to fail to disclose certain effects about inhaling certain aerosol sprays; [145] (15) a rule declaring it a UMC and UDAP to misrepresent the length or size of extension ladders; [146] (16) a rule declaring it a UDAP to make certain misrepresentations, or fail to disclose certain information, about games of chance; [147] (17) a rule declaring it a UMC and UDAP to mail unsolicited credit cards; [148] (18) a rule declaring it a UMC and UDAP to fail to disclose the minimum octane number on gasoline pumps (''Octane Rule''); [149] (19) a rule declaring it a UMC and UDAP to sell finished articles of clothing without a permanent tag or label disclosing care and maintenance

[126] *See, e.g., Holloway* v. *Bristol-Myers Corp.,* 485 F.2d 986, 988–89 (D.C. Cir. 1973); *Liu* v. *Amerco,* 677 F.3d 489, 492 (1st Cir. 2012).

[127] Congress has authorized the FTC to seek civil monetary remedies against parties who engage in unfair or deceptive acts or practices under some circumstances. *See* 15 U.S.C. 45(m); 15 U.S.C. 57b.

[128] *See* 15 U.S.C. 45(b); 15 U.S.C. 53(b).

[129] *See* 15 U.S.C. 45(l).

[130] 15 U.S.C. 46(g).

[131] As explained in more detail later in this Part, Congress added section 18 to the FTC Act in 1975, and that section provides the process the Commission must go through to promulgate rules defining unfair or deceptive acts or practices. *See* Magnuson-Moss Warranty—Federal Trade Commission Improvement Act, Public Law 93–637, 88 Stat. 2183 (Jan. 4, 1975) (hereinafter ''Magnuson-Moss Act''); 15 U.S.C. 57a. Congress provided, however, that ''[a]ny proposed rule under section 6(g) . . . with respect to which presentation of data, views, and arguments was substantially completed before'' section 18 was enacted ''may be promulgated in the same manner and with the same validity as such rule could have been promulgated had'' section 18 ''not been enacted.'' 88 Stat. 2198; 15 U.S.C. 57a note. This list therefore includes a handful of rules promulgated under section 6(g) but after 1975 because those rules were substantially completed before section 18's enactment.

[132] Advertising and Labeling as to Size of Sleeping Bags, 28 FR 10900 (Oct. 11, 1963), *repealed by* 60 FR 65528 (Dec. 20, 1995).

[133] Misuse of ''Automatic'' or Terms of Similar Import as Descriptive of Household Electric Sewing Machines, 30 FR 8900 (Jul. 15, 1965), *repealed by* 55 FR 23900 (June 13, 1990).

[134] Deception as to Nonprismatic and Partially Prismatic Instruments Being Prismatic Binoculars, 29 FR 7316 (Jun. 5, 1964), *repealed by* 60 FR 65529 (Dec. 20, 1995).

[135] Deceptive Use of ''Leakproof,'' ''Guaranteed Leakproof,'' etc., as Descriptive of Dry Cell Batteries, 29 FR 6535 (May 20, 1964), *repealed by* 62 FR 61225 (Nov. 17, 1997).

[136] Deceptive Advertising and Labeling as to Size of Tablecloths and Related Products, 29 FR 11261 (Aug. 5, 1964), *repealed by* 60 FR 65530 (Dec. 20, 1995).

[137] Misbranding and Deception as to Leather Content of Waist Belts, 29 FR 8166 (Jun. 27, 1964), *repealed by* 61 FR 25560 (May 22, 1996).

[138] Deceptive Advertising and Labeling of Previously Used Lubricating Oil, 29 FR 11650 (Aug. 14, 1964), *repealed by* 61 FR 55095 (Oct. 24, 1996).

[139] Unfair or Deceptive Advertising and Labeling of Cigarettes in Relation to the Health Hazards of Smoking, 29 FR 8324 (July 2, 1964), *repealed by* 30 FR 9485 (July 29, 1965). As explained in more detail herein, Congress superseded this rule with legislation.

[140] Incandescent Lamp (Light Bulb) Industry, 35 FR 11784 (Jul. 23, 1970), *repealed by* 61 FR 33308 (Jun. 27, 1996).

[141] Deceptive Advertising as to Sizes of Viewable Pictures Shown by Television Receiving Sets, 31 FR 3342 (Mar. 3, 1966), *repealed by* 83 FR 50484 (Oct. 9, 2018).

[142] Discriminatory Practices in Men's and Boys' Tailored Clothing Industry, 32 FR 15584 (Nov. 9, 1967), *repealed by* 59 FR 8527 (Feb. 23, 1994).

[143] Failure to Disclose that Skin Irritation May Result from Washing or Handling Glass Fiber Curtains and Draperies and Glass Fiber Curtain and Drapery Fabrics, 32 FR 11023 (Jul. 28, 1967), *repealed by* 60 FR 65532 (Dec. 20, 1995).

[144] Deception as to Transistor Count of Radio Receiving Sets, Including Transceivers, 33 FR 8446 (Jun. 7, 1968), *repealed by* 55 FR 25090 (Jun. 20, 1990).

[145] Failure to Disclose the Lethal Effects of Inhaling Quick-Freeze Aerosol Spray Products Used for Frosting Cocktail Glasses, 34 FR 2417 (Feb. 20, 1969), *repealed by* 60 FR 66071 (Dec. 21, 1995).

[146] Deceptive Advertising and Labeling as to Length of Extension Ladders, 34 FR 929 (Jan. 22, 1969), *repealed by* 60 FR 65533 (Dec. 20, 1995).

[147] Games of Chance in the Food Retailing and Gasoline Industries, 34 FR 13302 (Aug. 16, 1969), *repealed by* 61 FR 68143 (Dec. 27, 1996).

[148] Unsolicited Mailing of Credit Cards, 35 FR 4614 (Mar. 17, 1970), *repealed by* 36 FR 45 (Jan. 5, 1971). This rule was rescinded in response to an amendment to the Truth in Lending Act that prohibited similar conduct. *See* Public Law 91–508, 84 Stat. 1126 (1970).

[149] Posting of Minimum Octane Numbers on Gasoline Dispensing Pumps, 36 FR 23871 (Dec. 16, 1971), *repealed by* 43 FR 43022 (Sept. 22, 1978). This rule was superseded by the Petroleum Marketing Practices Act, Public Law 95–297, 92 Stat. 333 (June 19, 1978). A similar regulation was promulgated under that law at 16 CFR part 306.

instructions;[150] (20) a rule declaring a UMC and UDAP for a grocery store to offer products for sale at a stated price if those products will not be readily available to consumers (''Unavailability Rule'');[151] (21) a rule declaring it a UMC and UDAP for a seller to fail to make certain disclosures in connection with a negative option plan (''Negative Options Rule'');[152] (22) a rule declaring it a UDAP for door-to-door sellers to fail to furnish certain information to buyers;[153] (23) a rule declaring it a UMC and UDAP to fail to make certain disclosures about sound power amplification for home entertainment products;[154] (24) a rule declaring it a UDAP for sellers failing to include certain contract provisions preserving claims and defenses in consumer credit contracts (''Holder Rule'');[155] (25) a rule declaring it a UMC or UDAP to solicit mail order merchandise from a buyer unless the seller can ship the merchandise within 30 days (''Mail Order Rule'');[156] and (26) a rule declaring it a UDAP for a franchisor to fail to furnish a franchisee with certain information.[157]

Some of these rules attracted significant attention. For instance, the Commission began the rulemaking process to require warnings on cigarette packages just one week after the Surgeon General's ''landmark report'' that determined smoking is a health hazard,[158] and that rule was front-page news.[159] Following a lobbying campaign by the tobacco industry,[160] Congress supplanted the Commission's regulation with the Cigarette Labeling and Advertising Act but did not disturb the Commission's rulemaking authority.[161] The Unavailability Rule was likewise front-page news upon its release in 1971, and Congress left it intact.[162]

In *National Petroleum Refiners Association* v. *FTC* (''*Petroleum Refiners*''), the D.C. Circuit expressly upheld the Octane Rule as a proper exercise of the Commission's power under section 6(g) to make rules regulating both unfair methods of competition and unfair or deceptive acts or practices.[163] After construing ''the words of the statute creating the Commission and delineating its powers,'' the court held ''that under the terms of its governing statute . . . and under Section 6(g) . . . the Federal Trade Commission is authorized to promulgate rules defining the meaning of the statutory standards of the illegality the Commission is empowered to prevent.''[164] That interpretation was also ''reinforced by the construction courts have given similar provisions in the authorizing statutes of other administrative agencies.''[165] The Seventh Circuit later agreed with the D.C. Circuit's decision and ''incorporate[d] [it] by reference'' when rejecting a challenge to the Mail Order Rule.[166]

Following such rulemakings and the D.C. Circuit's confirmation of the Commission's rulemaking power in *Petroleum Refiners,* Congress in 1975 enacted a new section 18 of the FTC Act. This new section introduced special procedures, beyond those required under the Administrative Procedure Act, for promulgating rules for unfair or deceptive acts or practices, and it eliminated the Commission's authority to issue such rules under section 6(g).[167] But Congress pointedly chose not to restrict the Commission's authority to promulgate rules regulating unfair methods of competition under section 6(g). That choice was deliberate. While considering this legislation, Congress knew that the Commission had promulgated rules regulating unfair methods of competition and that the D.C. Circuit in *Petroleum Refiners* had confirmed the Commission's authority to do so.[168] And Congress expressly considered—but rejected—an amendment to the FTC Act under which ''[t]he FTC would have been prohibited from prescribing rules with respect to unfair competitive practices.''[169]

Instead, the enacted section 18 confirmed the Commission's authority to make rules under section 6(g). The law expressly preserved ''any authority of the Commission to prescribe rules (including interpretive rules), and general statements of policy, with respect to unfair methods of competition in or affecting commerce.''[170] Congress also made clear that Section 18 ''shall not affect the validity of any rule which was promulgated under section 6(g).''[171] And it provided that ''[a]ny proposed rule under section 6(g)'' with certain components that were ''substantially completed before'' section 18's enactment ''may be promulgated in the same manner and with the same validity as such rule could have been promulgated had this section not been enacted.''[172] Among the substantially completed rules at the time was the Mail Order Rule, which proposed to define—and upon promulgation did define—certain conduct as both an unfair method of competition and an unfair or deceptive act or practice.[173] The 1975 legislation thus expressly permitted the Commission to promulgate a rule under section 6(g) that defined an unfair method of competition and evinces Congress's

[150] Care Labeling of Textile Wearing Apparel, 36 FR 23883 (Dec. 16, 1971).

[151] Retail Food Store Advertising and Marketing Practices, 36 FR 8777 (May 13, 1971).

[152] Use of Negative Option Plans by Sellers in Commerce, 38 FR 4896 (Feb. 22, 1973).

[153] Cooling-off Period for Door-to-Door Sales, 37 FR 22934 (Oct. 26, 1972).

[154] Power Output Claims for Amplifiers Used in Home Entertainment Products, 39 FR 15387 (May 3, 1974).

[155] Preservation of Consumers' Claims and Defenses, 40 FR 53506 (Nov. 18, 1975).

[156] Mail Order Merchandise, 40 FR 49492 (Oct. 22, 1975) (regulatory text), 40 FR 51582 (Nov. 5, 1975) (statement of basis and purpose). The Mail Order Rule has since been updated to become the Mail, internet, or Telephone Order Merchandise Rule, or MITOR. *See* 79 FR 55619 (Sept. 17, 2014). The updates to the rule were based on the Commission's authority to regulate unfair or deceptive acts or practices.

[157] Disclosure Requirements and Prohibitions Concerning Franchising and Business Opportunity Ventures, 43 FR 59614 (Dec. 21, 1978).

[158] Teresa Moran Schwartz & Alice Saker Hrdy, *FTC Rulemaking: Three Bold Initiatives and Their Legal Impact,* 2–3 (Sept. 22, 2004).

[159] *U.S. to Require Health Warning for Cigarettes,* N.Y. Times (June 25, 1964) at 1, 15 (tobacco industry indicating plans to immediately challenge the Commission's authority to issue the regulation), *https://www.nytimes.com/1964/06/25/archives/us-to-require-health-warning-for-cigarettes-trade-commission-orders.html.*

[160] Tobacco Inst., *Tobacco—A Vital U.S. Industry* (1965), *https://acsc.lib.udel.edu/exhibits/show/legislation/cigarette-labeling.*

[161] Public Law 89–92, 79 Stat. 282 (July 27, 1965); *see* 15 U.S.C. 1331 *et seq.*

[162] *FTC Bars Grocery Ads for Unavailable Specials,* N.Y. Times (May 13, 1971) at 1, *https://www.nytimes.com/1971/05/13/archives/f-t-c-bars-grocery-ads-for-unavailable-specials-bars-grocery;* 16 CFR 424.1 and 424.2. The rule was amended after its enactment in 1971 to add an exception and defenses but otherwise remains intact as promulgated. Amendment to Trade Regulation Rule Concerning Retail Food Store Advertising and Marketing Practices, 54 FR 35456–08 (Aug. 28, 1989); *see also* Retail Food Store Advertising and Marketing Practices Rule, 79 FR 70053–01 (Nov. 25, 2014).

[163] *Nat'l Petroleum Refiners Ass'n* v. *FTC,* 482 F.2d 672 (D.C. Cir. 1973).

[164] *Nat'l Petroleum Refiners,* 482 F.2d at 674, 698; *see also Am. Fin. Servs. Ass'n* v. *FTC,* 767 F.2d 957, 967 (D.C. Cir. 1985) (concluding, after extensive review of the legislative history related to the FTC's rulemaking authority originating in 1914 and extending through amendments to the FTC Act in 1980, that ''Congress has not at any time withdrawn the broad discretionary authority originally granted the Commission in 1914 to define unfair practices on a flexible, incremental basis.'').

[165] *Nat'l Petroleum Refiners,* 482 F.2d at 678.

[166] *United States* v. *JS & A Grp., Inc.,* 716 F.2d 451, 454 (7th Cir. 1983).

[167] Magnuson-Moss Act, 88 Stat. 2183; *see* 15 U.S.C. 57a.

[168] S. Rep. No. 93–151, at 32 (1973).

[169] H.R. Conf. Rep. No. 93–1606, at 30 (1974).

[170] 15 U.S.C. 57a(a)(2).

[171] Magnuson-Moss Act, 88 Stat. 2183.

[172] Magnuson-Moss Act, 88 Stat. 2183.

[173] *See* Undelivered Mail Order Merchandise and Services, 36 FR 19092 (Sept. 28, 1971) (initial NPRM); 39 FR 9201 (Mar. 8, 1974) (amended NPRM); 40 FR 49492 (Oct. 22, 1975) (final regulatory text).

intent to leave in place the Commission's authority to promulgate such rules under section 6(g). As the Seventh Circuit later put it, ''Congress . . . considered the controversy surrounding the Commission's substantive rulemaking power under Section 6(g) to have been settled by the *Octane Rating* case.'' [174]

Congress again confirmed the Commission's authority to promulgate rules regulating unfair methods of competition under section 6(g) when it enacted section 22 of the FTC Act as part of the Federal Trade Commission Improvements Act of 1980.[175] Section 22 imposes certain procedural requirements the Commission must follow when it promulgates any ''rule.'' Section 22(a) defines ''rule'' as ''any rule promulgated by the Commission under section 6 or section 18'' while *excluding* from that definition ''interpretive rules, rules involving Commission management or personnel, general statements of policy, or rules relating to Commission organization, procedure, or practice.'' [176] Thus, by its terms, section 22(a) demonstrates the 1980 Congress's understanding that the Commission maintained authority to promulgate rules under section 6 that are not merely ''interpretive rules, rules involving Commission management or personnel, general statements of policy, or rules relating to Commission organization, procedure, or practice.'' [177] Section 22 envisions rules that will have the force of law as legislative rules and defines ''rule'' based on whether it may ''have an annual effect on the national economy of $100,000,000 or more,'' ''cause a substantial change in the cost or price of goods or services,'' or ''have a significant impact upon'' persons and consumers.[178] Section 22(b) of the Act similarly contemplates authority to make legislative rules by imposing regulatory analysis obligations on any rules that the Commission promulgates under section 6.[179] The specific obligations in section 22(b), such as the requirement for the Commission to conduct a cost-benefit analysis, assume that section 6(g) authorizes substantive and economically significant rules.

Both the 1975 and 1980 amendments to the FTC Act thus indicate that Congress understood the Commission possessed rulemaking power under section 6(g) and chose to leave that authority in place.[180] As the Supreme Court has observed, ''[t]he long time failure of Congress to alter'' a statutory provision, like section 6(g) here, ''after it had been judicially construed, and the enactment by Congress of legislation which implicitly recognizes the judicial construction as effective, is persuasive of legislative recognition that the judicial construction is the correct one.'' [181] That is especially true when, as here, ''the matter has been fully brought to the attention of the public and the Congress, the latter has not seen fit to change the statute.'' [182] Were there any doubt that the 1914 Congress granted the Commission the authority to make rules under section 6(g) to prevent unfair methods of competition, the Congresses of 1975 and 1980 eliminated such doubt by ratifying the D.C. Circuit's decision holding that the Commission has such authority.

C. Comments and Responses Regarding the Commission's Legal Authority

The Commission received many comments supporting, discussing, or questioning its authority to promulgate the final rule. Numerous commenters supported that the Commission has such authority, including, among others, legal scholars and businesses.[183] In addition, hundreds of small businesses—hailing from 45 States and the District of Columbia—joined a comment by the Small Business Majority supporting the final rule.[184]

Commenters questioning the Commission's authority typically advanced one of three arguments. First, some commenters claimed the FTC Act does not grant the Commission authority to promulgate the rule. Second, some commenters contended that the validity of non-competes is a major question that Congress has not given the Commission the authority to address. And third, some commenters argued that Congress had impermissibly delegated to the Commission authority to promulgate nationwide rules governing methods of competition. A smaller number of comments asserted other, miscellaneous reasons the Commission allegedly lacked authority to promulgate the rule. The Commission has considered these comments and disagrees for the reasons explained below.

1. The Commission's Authority Under the FTC Act

The Commission received numerous comments claiming that it lacks authority under the FTC Act to promulgate rules prohibiting unfair methods of competition. The Commission disagrees. Congress expressly granted the Commission authority to promulgate such rules in the original FTC Act of 1914, Congress enacted legislation in 1975 expressly preserving that authority,[185] and it imposed requirements in 1980 that presumed that authority.

The Commission is not persuaded by commenters' arguments in opposition to its authority. For instance, some commenters argued that Congress's choice to exclude certain industries from the Commission's jurisdiction indicates that Congress did not intend to give the Commission power to pass rules that affect commerce across the national economy.[186] But Congress expressly ''empowered and directed'' the Commission to prevent unfair methods of competition throughout the economy,[187] in any activities ''in or affecting commerce,'' subject only to limited exceptions. The final rule will apply only to the extent that the Commission has jurisdiction under the FTC Act. The Act does not limit the Commission's authority to pursue, for example, industry-specific rulemaking. Where Congress wished to limit the scope of the Commission's authority over particular entities or activities, it did so expressly, demonstrating its intent to give the Commission broad enforcement authority over activities in or affecting commerce outside the scope of the enumerated exceptions.[188] That section 22 of the FTC Act requires the Commission to perform a regulatory analysis for amendments to rules based on, *inter alia,* ''their annual effect on the

[174] *United States* v. *JS & A Grp.,* 716 F.2d 451, 454 (7th Cir. 1983).

[175] Public Law 96–252, 94 Stat. 374 (1980).

[176] *Id.; see* 15 U.S.C. 57b–3(a)(1).

[177] 15 U.S.C. 57b–3(a)(1).

[178] *Id.*

[179] 15 U.S.C. 57b–3(b).

[180] Congress has also amended section 6 since the D.C. Circuit decided *Petroleum Refiners,* but it left section 6(g) untouched. *See* Public Law 109–455, 120 Stat. 3372 (2006).

[181] *Apex Hosiery Co.* v. *Leader,* 310 U.S. 469, 488 (1940).

[182] *Id.* at 489.

[183] *See, e.g.,* Comment of Lev Menand et al., FTC–2023–0007–20871; Comment of Peter Shane et al., FTC–2023–0007–21024; Comment of Yelp, FTC–2023–0007–20974; Comment of Veeva Systems, FTC–2023–0007–18078.

[184] Comment of Sm. Bus. Majority, FTC–2023–0007–21022.

[185] Some commenters argued that the 1975 Magnuson-Moss Act, which created additional procedures the Commission must use to promulgate rules regulating unfair or deceptive acts or practices, implies that the Commission entirely lacks authority to promulgate rules regulating unfair methods of competition. The Commission disagrees with these comments and notes the effect of the 1975 legislation, which preserved the Commission's existing rulemaking authority.

[186] *E.g.,* Comment of Fed'n of Am. Hosps., FTC–2023–0007–21034.

[187] 15 U.S.C. 45(a)(2).

[188] 15 U.S.C. 45(a)(2), (3).

national economy'' confirms the same.[189]

Other commenters argued that the Commission is relying on vague or ancillary provisions for its authority and invoked the familiar refrain that Congress ''does not . . . hide elephants in mouseholes.'' [190] None of the provisions on which the Commission is relying are either vague or ancillary. As explained earlier, preventing unfair methods of competition is at the core of the Commission's mandate, the plain text of the Act gives the Commission rulemaking authority to carry out that mandate, and the Commission has exercised this rulemaking authority before.[191] The D.C. Circuit and Seventh Circuits have upheld that exercise of authority, and Congress preserved this authority in subsequent amendments to the Act following the D.C. Circuit's decision.[192]

Additional commenters cited select legislative history from the 1914 FTC Act to suggest the Commission lacks authority to promulgate rules regulating competition.[193] ''[T]here is no reason to resort to legislative history'' when, as here, the text of the statute speaks plainly.[194] Even if that were not the case, however, the legislative history does not unambiguously compel a different conclusion. Faced with similar arguments to those raised by commenters here, in *National Petroleum Refiners,* the D.C. Circuit conducted an exhaustive review of the 1914 FTC Act and concluded ''the legislative history of section 5 and Section 6(g) is ambiguous'' and ''certainly does not compel the conclusion that the Commission was not meant to exercise the power to make substantive rules with binding effect[.]'' [195] As the D.C. Circuit explained, even individual statements by some Congresspeople that might suggest otherwise,[196] when properly contextualized, ''can be read to support substantive rule-making of the kind asserted by the'' Commission.[197]

Statements from the enactment of the 1975 Magnuson Moss Act, which added section 18 to the FTC Act, confirm the Commission's authority to promulgate rules under section 6(g). That legislative history reveals Congress in 1975 made a considered decision to reject an effort to overturn the D.C. Circuit's interpretation of the FTC Act and instead confirmed that section 6(g) authorizes the Commission to promulgate legislative rules concerning unfair methods of competition.[198] More importantly, these sorts of individual statements cannot trump the plain text of the Act that Congress passed,[199] which gave the Commission the authority ''to make rules and regulations for the purpose of carrying out the provisions'' of the FTC Act. Indeed, even if the legislative history were to be selectively read to cut against the Commission's authority, the Commission would still conclude that section 6(g) confers authority to promulgate this final rule because the plain text of the statute (including both the original 1914 Act and subsequent enacted amendments to the FTC Act) unambiguously confers that authority.

In short, neither the legislative history of the FTC Act, nor any of the other arguments commenters raised about the Commission's rulemaking authority overcome the plain meaning of the Act or Congress's ratification of the Commission's power to make rules preventing unfair methods of competition, as discussed in Part II.B.[200]

The Commission acknowledges that individual members of the Commission have, at times, disclaimed the Commission's authority to promulgate rules regulating unfair methods of competition.[201] The statement of an individual Commissioner does not reflect the views of or bind ''[t]he Commission itself,'' which has concluded—just as it did when it issued such rules in the past—that it does possess such authority.[202] In any event, the Commission has reviewed these statements, along with the many comments it received, and does not believe any of the arguments raised in support of that position overcome the plain meaning of the FTC Act provisions.

2. Major Questions Doctrine

Many commenters assert that the Commission lacks the authority to adopt the final rule based on the major questions doctrine. That doctrine, as the Supreme Court recently explained in *West Virginia* v. *EPA,* ''teaches that there are extraordinary cases . . . in which the history and the breadth of the authority that the agency has asserted, and the economic and political significance of that assertion, provide a reason to hesitate before concluding that Congress meant to confer such authority.'' [203] In such cases, ''something more than a merely plausible textual basis for the agency action is necessary. The agency instead must point to clear congressional authorization for the power it claims.'' [204] Having considered the factors that the Supreme Court has used to identify major questions, the Commission concludes that the final rule does not implicate the major questions doctrine. And even if that doctrine did apply, the Commission concludes that Congress provided clear authorization for the Commission to promulgate this rule.[205]

[189] 15 U.S.C. 57b–3 (outlining requirements of the Commission's rulemaking process for new rules and amendments); *see also* Part II.E (discussing the Commission's jurisdiction).

[190] *Whitman* v. *Am. Trucking Ass'ns,* 531 U.S. 457, 468 (2001); *see, e.g.,* Comment of La. And 12 Other States, FTC–2023–0007–21094.

[191] *See* Part II.B (discussing the Commission's history of using section 6(g) to promulgate rules).

[192] *Id.*

[193] *E.g.,* Comment of Nat'l Ass'n of Mfrs., FTC–2023–0007–20939; Comment of La. And 12 Other States, FTC–2023–0007–21094.

[194] *United States* v. *Gonzales,* 520 U.S. 1, 6 (1997).

[195] *Nat'l Petroleum Refiners Ass'n* v. *FTC,* 482 F.2d 672, 686 (D.C. Cir. 1973).

[196] *Id.* at 704; *see also, e.g.,* Comment from La. and 12 Other States, FTC–2023–0007–21094 (identifying statements and failed bills that, the commenters say, show the Commission was not intended to possess rulemaking authority).

[197] *Nat'l Petroleum Refiners,* 482 F.2d at 709.

[198] For example, while the Senate was considering amendments to the FTC Act, Senator Hart read excerpts of *Nat'l Petroleum Refiners* into the record. *See* 120 Cong. Rec. 40712 (Dec. 18, 1974). These short excerpts included the court acknowledging that it was considering whether the Commission ''is empowered to promulgate substantive rules'' that would ''give greater specificity and clarity to the broad standard of illegality—'unfair methods of competition' . . .—which the agency is empowered to prevent.'' *Id.* (quoting *Nat'l Petroleum Refiners,* 482 F.2d at 673). Senator Hart then explained that the ''procedural requirements . . . respecting FTC rulemaking'' in the bill under consideration ''are limited to unfair or deceptive acts or practices rules.'' *Id.* ''These provisions and limitations,'' he explained, ''are not intended to affect the Commission's authority to prescribe and enforce rules respecting unfair methods of competition.'' *Id.* ''Rules respecting unfair methods of competition,'' Senator Hart said, ''should continue to be prescribed in accordance with'' the APA. *Id.; see also* Comment of Lev Menand et al., FTC–2023–0007–20871 at 3–6 (recounting legislative history that preceded the 1975 amendments to the FTC Act).

[199] *See Barnhart* v. *Sigmon Coal Co.,* 534 U.S. 438, 457 (2002) (''Floor statements from two Senators [who were sponsors of the bill] cannot amend the clear and unambiguous language of a statute.'').

[200] This includes arguments about the legislative intent, structure, or post-enactment history of the 1914 FTC Act.

[201] *See, e.g., Nat'l Petroleum Refiners,* 482 F.2d at 695–96 & n. 32, 38–39; NPRM at 3544 (dissenting statement of Commissioner Wilson).

[202] *Nat'l Petroleum Refiners,* 482 F.2d at 694; *see also* 16 CFR 4.14(c) (''Commission action'' requires ''the affirmative concurrence of a majority of the participating Commissioners'').

[203] *W. Va.* v. *EPA,* 597 U.S. 697, 721 (2022) (cleaned up).

[204] *Id.* at 723 (cleaned up).

[205] The Commission notes that some commenters either implicitly or explicitly focused on the Commission's rulemaking authority, as opposed to the Commission's authority to define non-competes as an unfair method of competition, as a major question. The Commission has already addressed

The agency authority underlying this final rule rests on firm historical footing. There is nothing novel about the Commission's assertion of authority to promulgate legislative rules under section 6(g).[206] As explained in Part II.B, the Commission has used this authority for more than 60 years to promulgate many rules defining unfair methods of competition and/or unfair or deceptive acts or practices.[207] The Commission's use of this power sometimes garnered significant attention, such as when it made national news by requiring cigarette warnings in the immediate wake of the Surgeon General's groundbreaking report on the health effects of smoking.[208] And the Commission's rulemaking authority was long ago ''addressed''—and affirmed—''by a court.'' [209] Moreover, after that high-profile rulemaking and judicial affirmation, Congress considered—and twice reaffirmed—the Commission's authority to issue legislative rules defining unfair methods of competition under section 6(g).[210] Indeed, even when Congress decided to displace the FTC's Cigarette Rule with legislation, it left the Commission's rulemaking authority in place.[211] Likewise, when Congress added procedural steps the Commission must take when promulgating rules concerning unfair or deceptive acts or practices, it expressly allowed the Commission to complete certain ongoing rulemakings, including one that relied on section 6(g) to define an unfair method of competition.[212] This is not a situation where Congress ''conspicuously and repeatedly'' declined to grant the agency the claimed power.[213]

Nor does the substance of the rule represent any departure from the Commission's past practices. Since its establishment in 1914, the Commission has had the authority to determine whether given practices constitute unfair methods of competition. Rather than trying to define all the many and varied practices that are unfair, Congress empowered the Commission to respond to changing market conditions and to bring specialized expertise to bear when making unfairness determinations.[214] As noted in Part I.B, the Commission has previously secured consent orders premised on the use of non-competes being an unfair method of competition,[215] and there is little question that the Commission has the authority to determine that non-competes are unfair methods of competition through adjudication.[216] Indeed, one commenter who asserted the rule would violate the major questions doctrine expressly agreed that the Commission could determine that a specific non-compete is an unfair method of competition through case-by-case adjudication.[217] The Commission is making the same kind of determination here through rulemaking rather than adjudication.[218] And because the rulemaking process allows all interested parties a chance to weigh in, this process ''may actually be fairer to parties than total reliance on case-by-case adjudication.'' [219] This is thus not a situation where the agency's action would fundamentally change the nature of the regulatory scheme. Determining whether a practice is an ''unfair method of competition'' under section 5 has been a core task of the Commission for more than a century—and, indeed, goes to the heart of its mandate.

Additionally, non-competes have already been the subject of FTC scrutiny and enforcement actions, so subjecting them to rulemaking is a more incremental—and thus less significant—step than it would be for an agency to wade into an area not currently subject to its enforcement authority. And the present rulemaking is consistent with both Congress's intent for the Commission and the Commission's prior practice. Congress ''empowered and directed'' the Commission ''to prevent persons, partnerships, or corporations'' within the Commission's jurisdiction ''from using unfair methods of competition in or affecting commerce.'' [220] Following that directive, the Commission has previously used its section 6(g) authority to promulgate rules that reach industries across the economy. For example, the Mail Order Rule placed restrictions on any sale conducted by mail,[221] and the Negative Option Rule requires certain disclosures for some negative option plans. These rules—promulgated nearly 50 or more years ago—applied across the industries within the FTC's jurisdiction, yet no court has held that they exceeded the Commission's authority.[222] Indeed, the Seventh Circuit upheld the Mail Order Rule as a valid exercise of that authority.[223]

Congress itself recognized that the Commission's authority will sometimes affect firms across the economy. Indeed, addressing unfair methods of competition and unfair and deceptive practices across industries (other than the industries, activities, or entities Congress expressly exempted) is the core of the Commission's mandate—and the Commission has long pursued that mandate through both rulemaking [224] and adjudication.[225] Congress imposed

the source of its rulemaking authority, *see* Part II.B. But to be clear, the Commission concludes that neither its rulemaking authority under section 6(g) nor its authority to use that power to define non-competes as an unfair method of competition implicates the major questions doctrine, and that even assuming either did, Congress has provided express statutory authority for both.

[206] *W. Va.* v. *EPA,* 597 U.S. at 725.

[207] *See* Part II.B (discussing the Commission's history of promulgating rules under section 6(g)).

[208] *See* Part II.B (discussing Cigarette Rule and Holder Rule); *see also* ''U.S. to Require Health Warning for Cigarettes,'' N.Y. Times (June 25, 1964) at 1, 15 (tobacco industry indicating plans to immediately challenge the Commission's authority to issue the regulation).

[209] *W. Va.* v. *EPA,* 597 U.S. at 725; *see* Part II.B (discussing decisions from the D.C. Circuit and Seventh Circuit affirming the Commission's rulemaking power under section 6(g)).

[210] *See* Part II.B (discussing the history and content of sections 18 and 22 of the FTC Act).

[211] *See* Federal Cigarette Labeling and Advertising Act, Public Law 89–92, 79 Stat. 282 (July 27, 1965).

[212] 15 U.S.C. 57a(a)(2); *see* Part II.B (discussing the Mail Order Rule).

[213] *W. Va.* v. *EPA,* 597 U.S. at 724.

[214] *See, e.g., FTC* v. *R.F. Keppel & Bro.,* 291 U.S. 304, 311 n.2, 314 (1934).

[215] In those orders, the party agreed, *inter alia,* to cease and desist from enforcing or attempting to enforce existing non-competes and from entering into or attempting to enter into new ones, and also agreed to provide notice to affected employees that they are no longer subject to a non-compete. *See* Part I.B n.42–44 (citing recent Commission investigations and consent orders involving non-competes).

[216] To the extent that any commenters argued the Commission lacked authority over the entire subject matter of non-compete agreements, the Commission did not see any compelling explanation that an agreement not to compete falls outside the meaning of a ''method of competition.''

[217] Comment of Int'l Ctr. For L. & Econs., FTC–2023–0007–20753, at 75–76.

[218] *Nat'l Petroleum Refiners Ass'n* v. *FTC,* 482 F.2d 672 at 685 (D.C. Cir. 1973) (recognizing that the Commission may ''choose[ ]to elaborate'' section 5's ''comprehensive statutory standards through rule-making or through case-by-case adjudication'').

[219] *Id.* at 681; *see generally* Part IX.C.2 (discussing the value of rulemaking).

[220] 15 U.S.C. 45(a)(2).

[221] *Mail Order Merchandise,* 40 FR 49492 (Oct. 22, 1975); *see* 16 CFR part 435.

[222] *See* Part II.B (listing rules promulgated by the FTC exercising authority under sections 5 and 6(g)).

[223] *United States* v. *JS & A Grp.,* 716 F.2d 451, 454 (7th Cir. 1983).

[224] *See* Part II.B.

[225] The Commission's adjudicatory power, like its rulemaking power, stretches across the national economy. For instance, the Commission has found companies in a variety of industries participated in price-fixing conspiracies that violated section 5 and ordered them to cease and desist from such practices following an adjudication. *See, e.g., Eugene Dietzgen Co.* v. *FTC,* 142 F.2d 321 (7th Cir. 1944) (scientific instruments); *U.S. Maltsters Ass'n* v. *FTC,* 152 F.2d 161 (7th Cir. 1945) (malt manufacturers); *Keasbey & Mattison Co.* v. *FTC,* 159 F.2d 940 (6th Cir. 1947) (asbestos insulation); *Allied Paper Mills* v. *FTC,* 168 F.2d 600 (7th Cir. 1948) (book paper manufacturers); *Bond Crown & Cork. Co.* v. *FTC,* 176 F.2d 974 (4th Cir. 1949) (bottle cap manufacturers). Price-fixing is just one example. The Commission's adjudicatory power also supported a cease-and-desist order concerning a food manufacturer's resale practices more than 100 years ago. *FTC* v. *Beech-Nut Packing,* 257 U.S. 441 (1922). And it supported a cease-and-desist order

Continued

certain requirements in section 22 on any amendment to a Commission rule promulgated under section 6 (or section 18) that would have certain substantial effects on the national economy, the price of goods or services, or regulated entities and consumers.[226] Congress thus anticipated—and intended—that the Commission's rulemaking power carried the potential to affect the economy in considerable ways, and Congress already considered and specified the necessary steps and checks to ensure the Commission's exercise of that power is appropriate. For all these reasons, the final rule does not involve a ''major question'' as the Supreme Court has used that term.

Even if the final rule does present a major question, the final rule passes muster because the FTC Act provides clear authorization for the Commission's action. In cases involving major questions, courts expect Congress to ''speak clearly'' if it wishes to assign the disputed power.[227] Congress did so when it ''declared unlawful'' in the FTC Act ''[u]nfair methods of competition'' and empowered the Commission ''to make rules and regulations for the purpose of carrying out the provisions of th[e] Act.'' [228] Congress ''[i]n large measure'' left ''the task of defining 'unfair methods of competition' . . . to the Commission.'' [229] That is precisely what the Commission has done here, for the reasons elaborated in Part IV. Finally, there is no doubt that the Commission has expertise in the field (competition) it is regulating here.[230] For these reasons, even if the final rule involves a major question, Congress has clearly delegated to the Commission the authority to address that question.

3. Non-Delegation Doctrine

Some commenters also objected that Congress violated the non-delegation doctrine by empowering the Commission to promulgate rules regulating unfair methods of competition. The Commission disagrees. The non-delegation doctrine provides that ''Congress generally cannot delegate its legislative power to another Branch.'' [231] But the Constitution does not ''prevent Congress from obtaining the assistance of its coordinate Branches.'' [232] ''So long as Congress shall lay down by legislative act an intelligible principle to which the person or body authorized to [exercise the delegated authority] is directed to conform, such legislative action is not a forbidden delegation of legislative power.'' [233] Applying this rule, the Supreme Court has ''over and over upheld even very broad delegations'' including those directing agencies ''to regulate in 'the public interest,' . . . to set 'fair and equitable' prices and 'just and reasonable' rates,'' and ''to issue whatever air quality standards are 'requisite to protect the public health.' '' [234] ''The Supreme Court has'' also ''explained that the general policy and boundaries of a delegation 'need not be tested in isolation' '' and ''[i]nstead, the statutory language may derive content from the 'purpose of the Act, its factual background and the statutory context in which they appear.' '' [235]

Here, Congress ''declared unlawful'' any ''unfair methods of competition in or affecting commerce'' and ''empowered and directed'' the Commission ''to prevent'' entities within its jurisdiction ''from using unfair methods of competition.'' [236] Congress also instructed the Commission to ''make rules and regulations for the purpose of carrying out the provisions'' of the FTC Act.[237] Congress's stated purpose and policy in section 5 provides the Commission with an intelligible principle to guide its section 6(g) rulemaking authority.[238]

Were there any doubt, the Supreme Court has laid it to rest in *A.L.A. Schechter Poultry Corp.* v. *United States.*[239] *Schechter Poultry* marked one of two occasions ''in this country's history'' that the Supreme Court ''found a delegation excessive,'' and ''in each case . . . Congress had failed to articulate *any* policy or standard to confine discretion.'' [240] The Court offered the FTC Act, however, as a counterexample of proper Congressional delegation. The Court recognized that the phrase ''unfair methods of competition'' in the FTC Act was ''an expression new in the law'' without ''precise definition,'' but that Congress had empowered the Commission to ''determine[ ] in particular instances, upon evidence, in the light of particular competitive conditions and of what is found to be a specific and substantial public interest'' whether a method of competition is unfair.[241] The FTC Act stood in contrast, the Court explained, to the National Industrial Recovery Act (''NIRA''), which the Court held included an unconstitutional delegation.[242]

The Commission recognizes that *Schechter Poultry* approved of the FTC Act's adjudicatory process for determining unfair methods of competition without commenting on the Act's rulemaking provision. But the ''unfair method of competition'' authority the Court approvingly cited in *Schechter Poultry* is the same intelligible principle the Commission is applying in this rulemaking. And just as the adjudication process provides for a ''formal complaint, for notice and hearing, for appropriate findings of fact supported by adequate evidence, and for judicial review,'' [243] the APA rulemaking process provides for a public notice of proposed rulemaking, the opportunity to ''submi[t] . . . written data, views, or arguments,'' agency consideration of those comments, and judicial review.[244] If Congress may permissibly delegate the

within the past few years enjoining a pharmaceutical company from entering into reverse payment settlement schemes. *Impax Labs., Inc.* v. *FTC,* 994 F.3d 484 (5th Cir. 2021). In the century between, the Commission has found section 5 violations based on false advertising, monopoly maintenance, exclusive dealing, and more in diverse sectors throughout the country.

[226] 15 U.S.C. 57b–3; *see also* Part II.B.

[227] *W. Va.* v. *EPA,* 597 U.S. 697, 716, 723 (2002).

[228] FTC Act of 1914, 38 Stat. at 721–22; *see* 15 U.S.C. 45(a), 46(g); *see also* Part II.A (discussing the Commission's rulemaking authority).

[229] *FTC* v. *Texaco, Inc.,* 393 U.S. 223, 225 (1968).

[230] *Cf. W. Va.* v. *EPA,* 597 U.S. at 729 (noting the Court's view that the EPA had traditionally lacked the expertise needed to develop the rule at issue); *Ala. Ass'n of Realtors* v. *HHS,* 594 U.S. 758, at 764–65 (2021) (questioning the link between the Center for Disease Control and an eviction moratorium); *see also* Part II.A (discussing Congress's creation of the Commission as an expert body); Parts IV.B and IV.C (discussing the rationale for the rule and explaining the negative effects non-competes have on competition). The Commission also notes that through, *inter alia,* the roundtables and enforcement actions described in Part I.B, and through this rulemaking process, it has acquired expertise on non-competes specifically. The Commission further notes that non-competes are, inherently, a method of competition.

[231] *Mistretta* v. *United States,* 488 U.S. 361, 372 (1989).

[232] *Id.*

[233] *Id.* (alteration in original).

[234] *Gundy* v. *United States,* 139 S. Ct. 2116, 2121 (2019) (citing *Nat'l Broadcasting Co.* v. *United States,* 319 U.S. 190, 216 (1943); *N.Y. Cent. Secs. Corp.* v. *United States,* 287 U.S. 12, 24 (1932); *Yakus* v. *United States,* 321 U.S. 414, 422 (1944); *Fed. Power Comm'n* v. *Hope Natural Gas Co.,* 320 U.S. 591 (1944); and *Whitman* v. *Am. Trucking Ass'ns,* 531 U.S. 457, 472 (2001)).

[235] *TOMAC, Taxpayers of Mich. Against Casinos* v. *Norton,* 433 F.3d 852, 866 (D.C. Cir. 2006) (quoting *Am. Power & Light Co.* v. *SEC,* 329 U.S. 90, 104 (1946)).

[236] 15 U.S.C. 45(a)(1)–(2).

[237] 15 U.S.C. 46(g).

[238] As the D.C. Circuit noted in *Nat'l Petroleum Refiners Ass'n* v. *FTC,* ''the Supreme Court has ruled that the powers specified in Section 6 do not stand isolated from the Commission's enforcement and law applying role laid out in Section 5.'' 482 F.2d 672, 677 (D.C. Cir. 1973) (citing *United States* v. *Morton Salt Co.,* 338 U.S. 632 (1950)).

[239] *A.L.A. Schechter Poultry Corp.* v. *United States,* 295 U.S. 495 (1935).

[240] *Gundy,* 588 U.S. at 2129 (internal quotation omitted); *cf. also Panama Refin. Co.* v. *Ryan,* 293 U.S. 388 (1935) (finding impermissible delegation).

[241] *Schechter Poultry,* 295 U.S. at 532–33.

[242] *Id.* at 529–42.

[243] *Id.* at 533.

[244] 5 U.S.C. 553, 702.

authority to determine through adjudication whether a given practice is an unfair method of competition, it may also permit the Commission to do the same through rulemaking.[245]

For these reasons, the Commission concludes that its authority to promulgate rules regulating unfair methods of competition is not an impermissible delegation of legislative authority.

4. Other Challenges to the Commission's Authority

Finally, a handful of comments raised other, miscellaneous arguments contending that the Commission lacks authority to promulgate the rule. The Commission has reviewed and considered these comments and concludes they do not undercut the Commission's authority to promulgate the final rule.

The Commission received several comments about the Commerce Clause. That clause allows Congress ''to regulate Commerce with foreign Nations, and among the several States, and with the Indian tribes.'' [246] Consistent with that clause, the FTC Act empowers the Commission to prevent unfair methods of competition ''in or affecting commerce,'' which the Act also defines consistently with the Constitution.[247] One commenter wrote to support the rule and emphasized that non-competes restrict the free flow of interstate commerce. Others argued that the proposed rule would violate the Commerce Clause by regulating local commerce. The Commission has considered these comments and concludes that it may promulgate the final rule consistent with the Commerce Clause. The final rule extends to the full extent of the FTC's jurisdiction, which in turn extends no further than the Commerce Clause permits. As the Supreme Court has explained, the phrase ''in or affecting commerce'' in section 5 of the FTC Act is ''coextensive with the constitutional power of Congress under the Commerce Clause.'' [248] In this final rule, the Commission finds the use of non-competes by employers substantially affects commerce as that term is defined in the FTC Act. The final rule is therefore a lawful exercise of Congress's delegated power.[249]

Relatedly, one commenter objected that the rule would violate the Tenth Amendment, which provides that ''[t]he powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.'' [250] But as just explained, the Constitution grants Congress the power to regulate interstate commerce, and pursuant to that power Congress granted the Commission authority to prevent unfair methods of competition in or affecting commerce. The Commission is not intruding on any power reserved to the States.

Some commenters objected that the rule infringes on the right to contract. One of these commenters acknowledged that the Constitution's Contracts Clause does not apply to the Federal government.[251] Regardless, even assuming the Constitution protects a right to contract that can be asserted against a Federal regulation, that right sounds in substantive due process, and the Commission must offer only a rational basis for the rule.[252] As relevant here, the final rule advances the Commission's congressional mandate to prevent unfair methods of competition and will promote competition and further innovation among its many benefits.[253] There is a rational relationship between regulating non-competes and these legitimate government purposes.

One commenter argued that the proposed rule was unconstitutionally vague. This commenter's objection focused on the proposed provision governing *de facto* non-competes. The Commission is not adopting that proposed language in the final rule. Instead, the Commission has clarified the scope of its definition of non-compete clause. Whether a specific clause falls within the scope of the final rule will necessarily depend on the precise language of the agreement at issue, but the text of the final rule provides regulated parties with sufficient notice of what the law demands to satisfy any due process vagueness concerns.

D. Compliance With the Administrative Procedure Act (''APA'')

Some commenters also contended that the Commission has not complied with the Administrative Procedure Act (''APA'').[254] At a high level, the APA requires prior public notice, an opportunity to comment, and consideration of those comments before an agency can promulgate a legislative rule.[255] The Commission has engaged in that process, which has led to this final rule and the accompanying explanation. Some comments failed to recognize the NPRM was a preliminary step that did not fossilize the Commission's consideration of arguments or weighing of evidence. Moreover, the APA ''limits causes of action under the APA to final agency action.'' [256] It is this final rule, not the NPRM, that constitutes final agency action. Before adopting this final rule, the Commission reviewed and considered all comments received. In many instances, the Commission has made changes relative to the proposed rule to address concerns that commenters raised. In all cases, however, the Commission has complied with the APA.

E. The Commission's Jurisdiction Under the FTC Act

The Commission's jurisdiction derives from the FTC Act. Employers that are outside the Commission's jurisdiction under the FTC Act are not subject to the final rule. The Commission clarifies in the definition of person in § 910.1, that the rule applies only to those within the Commission's jurisdiction. Some commenters sought a more detailed accounting of the

[245] *Nat'l Petroleum Refiners Ass'n* v. *FTC,* 482 F.2d 672, 685 (D.C. Cir. 1973); *cf. SEC* v. *Chenery Corp.,* 332 U.S. 194, 202–03 (1947) (''Some principles must await their own development, while others must be adjusted to meet particular, unforeseeable situations. In performing its important functions in these respects, therefore, an administrative agency must be equipped to act either by general rule or by individual order. To insist upon one form of action to the exclusion of the other is to exalt form over necessity.'').

[246] U.S. Const. art. I, sec. 8, cl. 3.

[247] 15 U.S.C. 44, 45(a)(1).

[248] *United States* v. *Am. Bldg. Maintenance Indus.,* 422 U.S. 271, 277, n.6 (1975).

[249] *See Nat'l Fed'n of Indep. Bus.* v. *Sebelius,* 567 U.S. 519, 549 (2012) (''Congress's power'' under the Commerce Clause ''is not limited to regulation of an activity that by itself substantially affects interstate commerce, but also extends to activities that do so only when aggregated with similar activities of others.''); *see also* Part I.B.2 (discussing prevalence of non-competes) and Part IX.C.2 (addressing the need for a nationwide regulation prohibiting non-competes).

[250] U.S. Const. amend. X.

[251] *See* U.S. Const. art. I, sec. 10, cl. 1.

[252] *See, e.g., L & H Sanitation, Inc.* v. *Lake City Sanitation, Inc.,* 769 F.2d 517, 522 (8th Cir. 1985).

[253] *See* Parts IV.B and IV.C, Part X.F.6.

[254] This includes, for example, a commenter who argued that the NPRM was not the product of reasoned decision-making, asserting that the Commission had failed to consider key aspects of the rule or misconstrued evidence; commenters who argued that the rule was arbitrary and capricious for failing to consider less restrictive alternatives; commenters who argued that the NPRM failed to consider State policy or that the Commission would be acting arbitrarily by not passing a uniform rule; and commenters who argued that the Commission had failed to consider reliance interests. The Commission has addressed the concerns underlying these comments in other parts of this statement of basis and purpose.

[255] 5 U.S.C. 553; *see also Elec. Priv. Info. Ctr.* v. *DHS,* 653 F.3d 1, 5 (D.C. Cir. 2011) (APA ''generally require[s] an agency to publish notice of a proposed rule in the **Federal Register** and to solicit and consider public comments upon its proposal.'').

[256] *Trudeau* v. *FTC,* 456 F.3d 178, 188–89 (D.C. Cir. 2006) (internal quotation marks omitted); *see* 5 U.S.C. 704.

Commission's jurisdiction under the FTC Act. The Commission addresses those comments in this section. Comments seeking an exclusion for entities within the Commission's jurisdiction are addressed in Parts V.D.3 and V.D.4.

1. Generally

Certain entities that would otherwise be subject to the final rule may fall outside the FTC's jurisdiction under the FTC Act. The FTC Act exempts certain entities or activities from the Commission's enforcement jurisdiction, which otherwise applies to ''persons, partnerships, or corporations.'' [257] For example, the Act exempts ''banks'' and ''persons, partnerships, or corporations insofar as they are subject to the Packers and Stockyards Act.'' [258] And the Act excludes from its definition of ''corporation'' any entity that is not ''organized to carry on business for its own profit or that of its members.'' [259] The NPRM explained that, where an employer is exempt from coverage under the FTC Act, the employer would not be subject to the rule.[260] The NPRM also explained State and local government entities—as well as some private entities—may not be subject to the rule when engaging in activity protected by the State action doctrine.[261] Some commenters stated that the Commission should restate, clarify, interpret, or limit the reach of its authority under the FTC Act in the rule.

In response, the Commission explains that the final rule extends to covered persons that are within the Commission's jurisdiction. The Commission does not believe restating or further specifying each jurisdictional limit in the final rule's text is necessary; the FTC Act defines the limits of the Commission's jurisdiction and those limits govern this rule. Moreover, the Commission cannot here provide guidance that applies to every fact and circumstance. Whether an entity falls under the Commission's jurisdiction can be a fact-specific determination. An attempt by the Commission to capture all potential interpretations of the laws governing exclusions from the FTC Act may create confusion rather than clarity. In response to commenters who asked the Commission to affirm that the final rule does not bind agencies that regulate firms outside the Commission's jurisdiction under the FTC Act, the Commission affirms that the Commission applies the final rule only to entities that are covered by the FTC Act.[262]

A State government agency commenter suggested that the Commission explicitly exempt State and local governments from the rule. The commenter pointed to conflicts-of-interest policies used by some State agencies to preclude former employees from working on related projects or jobs in the private sector, which the commenter stated do not implicate the policy concerns the FTC seeks to address in the rule. The commenter also noted the complexity of when the Commission's jurisdiction might extend to State and local governments. The Commission clarifies in the definition of ''person'' in § 910.1 that the final rule applies only to a legal entity within the Commission's jurisdiction. The Commission also explains in Part III.E that the definition of ''person'' is coextensive with the Commission's authority to issue civil investigative demands. Nothing in this rule changes the extent of the Commission's jurisdiction over State and local governments. The Commission declines to specify all circumstances under which a governmental entity or quasi-governmental entity would or would not be subject to the Commission's jurisdiction and, thus, this final rule. In any event, with respect to the government ethics policies referenced by the commenter, to the extent the commenter is referring to traditional ''cooling off'' policies that preclude former government employees from working on discrete, specific projects that fell within the scope of their former official governmental position to address ethical concerns, such policies would not meet the definition of ''non-compete clause'' in § 910.1 because they do not prohibit, penalize or function to prevent a worker from switching jobs or starting a new business.

2. Jurisdiction Over Entities Claiming Nonprofit Status Under the FTC Act or the Internal Revenue Code

Commenters from the healthcare industry argued that the Commission should restate, clarify, interpret, or limit the reach of its authority under the FTC Act specifically for the healthcare industry. They pointed to the prevalence of healthcare organizations registered under section 501(c) of the Internal Revenue Code claiming tax-exempt status as nonprofits. Commenters contended that these organizations are categorically outside the Commission's authority under the FTC Act. In fact, under existing law, these organizations are not categorically beyond the Commission's jurisdiction. To dispel this misunderstanding, the Commission summarizes the existing law pertaining to its jurisdiction over non-profits.

a. Comments Received

Business and trade industry commenters from the healthcare industry, including, for example, hospitals, physician practices, and surgery centers, focused on whether the Commission has jurisdiction over nonprofit organizations registered under section 501(c)(3) of the Internal Revenue Code in light of the FTC Act's definition of ''corporation.'' Section 501(c)(3) exempts from taxation certain religious, charitable, scientific, educational, and other corporations, ''no part of the net earnings of which inure[] to the benefit of any private shareholder or individual.'' [263] An entity is a ''corporation'' under the FTC Act only if it is ''organized to carry on business for its own profit or that of its members.'' [264] Several industry commenters argued the Commission does not have jurisdiction over entities that claim tax-exempt status as nonprofits because they are, by definition, not ''organized to carry on business for [their] own profit or that of [their] members.'' The Commission presumes that commenters self-identifying as or referring to ''nonprofits,'' ''not-for-profits,'' or other similar terms without further explanation are referencing entities claiming tax-exempt status under section 501(c)(3) or other provisions of the Internal Revenue Code. Some commenters contended that, to avoid confusion, the rule should state it does

[257] 15 U.S.C. 45(a)(2); *see also FTC* v. *AT&T Mobility LLC,* 883 F.3d 848, 853–56 (9th Cir. 2018) (*en banc*).

[258] 15 U.S.C. 45(a)(2).

[259] 15 U.S.C. 44.

[260] NPRM at 3510.

[261] *Id.* (citing *Parker* v. *Brown,* 317 U.S. 341, 350–51 (1943)).

[262] For example, a few community bank commenters expressed concern that because the Federal Deposit Insurance Corporation (''FDIC'') can enforce the FTC Act against banks, the rule could be applied by the FDIC to banks. The FTC Act is the Commission's organic statute, and interpretive authority of the FTC Act rests with the Commission. Whether other agencies enforce section 5 or apply the rule to entities under their own jurisdiction is a question for those agencies. At the same time, as discussed in this Part II.E.1, the Commission applies and enforces the rule only to the extent of its jurisdiction.

[263] 26 U.S.C. 501(c)(3). Other, less frequently invoked paragraphs of section 501(c) also identify corporations and organizations that qualify for tax-exempt status. The distinctions between these entities and those claiming tax-exempt status under 501(c)(3) are analyzed under the same standard.

[264] 15 U.S.C. 44.

not apply to entities claiming tax-exempt status as non-profits. At least one commenter stated that the Commission should clarify whether and how the rule would apply to healthcare entities claiming tax-exempt status as nonprofits and then reopen the comment period. One commenter sought clarification on how ownership interest in a for-profit entity or joint venture with a for-profit partner by an entity that claims tax-exempt status as a nonprofit would affect the rule's applicability.

b. The Final Rule

The final rule applies to the full scope of the Commission's jurisdiction. Many of the comments about nonprofits erroneously assume that the FTC's jurisdiction does not capture any entity claiming tax-exempt status as a nonprofit. Given these comments, the Commission summarizes Commission precedent and judicial decisions construing the scope of the Commission's jurisdiction as it relates to entities that claim tax-exempt status as nonprofits and to other entities that may or may not be organized to carry on business for their own profit or the profit of their members.

Congress empowered the Commission to ''prevent persons, partnerships, or corporations'' from engaging in unfair methods of competition.[265] To fall within the definition of ''corporation'' under the FTC Act, an entity must be ''organized to carry on business for its own profit or that of its members.'' [266] These FTC Act provisions, taken together, have been interpreted in Commission precedent [267] and judicial decisions [268] to mean that the Commission lacks jurisdiction to prevent section 5 violations by a corporation not organized to carry on business for its own profit or that of its members.

The Commission stresses, however, that both judicial decisions and Commission precedent recognize that not all entities claiming tax-exempt status as nonprofits fall outside the Commission's jurisdiction. As the Eighth Circuit has explained, ''Congress took pains in drafting § 4 [15 U.S.C. 44] to authorize the Commission to regulate so-called nonprofit corporations, associations and all other entities if they are in fact profit-making enterprises.'' [269] The Commission applies a two-part test to determine whether a corporation is organized for profit and thus within the Commission's jurisdiction. As the Commission has explained, ''[t]he not-for profit jurisdictional exemption under Section 4 requires both that there be an adequate nexus between an organization's activities and its alleged public purposes and that its net proceeds be properly devoted to recognized public, rather than private, interests.'' [270] Alternatively stated, the Commission looks to both ''the source of the income, *i.e.,* to whether the corporation is organized for and actually engaged in business for only charitable purposes, and to the destination of the income, *i.e.,* to whether either the corporation or its members derive a profit.'' [271] This test reflects the Eighth Circuit's analysis in *Community Blood Bank of Kansas City Area, Inc.* v. *FTC* and ''the analogous body of federal law which governs treatment of not-for-profit organizations under the Internal Revenue Code.'' [272] Under this test, a corporation's ''tax-exempt status is certainly one factor to be considered,'' but that status ''does not obviate the relevance of further inquiry into a [corporation's] operations and goals.'' [273]

Merely claiming tax-exempt status in tax filings is not dispositive. At the same time, if the Internal Revenue Service (''IRS'') concludes that an entity does not qualify for tax-exempt status, such a finding would be meaningful to the Commission's analysis of whether the same entity is a corporation under the FTC Act. Administrative proceedings and judicial decisions involving the Commission or the IRS [274] have identified numerous private benefits that, if offered, could render an entity a corporation organized for its own profit or that of its members under the FTC Act, bringing it within the Commission's jurisdiction. For instance, the Commission has exercised jurisdiction in a section 5 enforcement action over a physician-hospital organization because the organization engaged in business on behalf of for-profit physician members.[275] That organization, which consisted of over 100 private physicians and one non-profit hospital, claimed tax-exempt status as a nonprofit.[276] Similarly, the Commission has exercised jurisdiction over an independent physician association claiming tax-exempt status as a nonprofit. The association consisted of private, independent physicians and private, small group practices.[277] That association was organized for the pecuniary benefit of its for-profit members because it ''contract[ed] with payers, on behalf of its [for-profit] physician members, for the provision of physician services for a fee.'' [278] Under IRS precedent in the context of purportedly tax-exempt nonprofit hospitals and other related entities that partner with for-profit entities, where the purportedly nonprofit entity ''has ceded effective control'' to a for-profit partner, ''conferring impermissible private benefit,'' the entity loses tax-exempt status.[279] The IRS has also rejected claims of nonprofit tax-exempt status for entities that pay unreasonable compensation, including percentage-based compensation, to founders, board members, their families, or other insiders.[280]

These examples are illustrative. As has been the case for decades, under Commission precedent and judicial

[265] 15 U.S.C. 45(a)(2). The Commission focuses on coverage as ''corporations'' in this section.

[266] 15 U.S.C. 44.

[267] *In the Matter of Coll. Football Ass'n,* 117 F.T.C. 971, 992–999 (1990).

[268] *California Dental Ass'n* v. *FTC,* 526 U.S. 756, 766 (1999); *Cmty. Blood Bank of Kansas City Area, Inc.* v. *FTC,* 405 F.2d 1011, 1016 (8th Cir. 1969); *FTC* v. *Univ. Health, Inc.,* 938 F.2d 1206, 1214 (11th Cir. 1991).

[269] *Blood Bank,* 405 F.2d at 1018; *see also, e.g., FTC* v. *Nat'l Comm'n on Egg Nutrition,* 517 F.2d 485, 488 (7th Cir. 1975).

[270] *Coll. Football Ass'n,* 117 F.T.C. at 998.

[271] *Id.* at 994 (internal quotation and citation omitted).

[272] *Id.* at 994.

[273] *In the Matter of the Am. Med. Assoc.,* 94 F.T.C. 701, 1979 WL 199033, at *221 (FTC Oct. 12, 1979).

[274] The Commission offers examples of decisions from the IRS and Tax Court as examples that the Commission may deem persuasive. Although ''[r]ulings of the Internal Revenue Services are not binding upon the Commission,'' the Commission has recognized that ''a determination by another Federal agency that a respondent is or is not organized and operated exclusively for eleemosynary purposes should not be disregarded.'' *Am. Med. Assoc.,* 1979 WL 199033 at *221.

[275] *In the Matter of Preferred Health Servs., Inc.,* FTC No. 41–0099, 2005 WL 593181, at *1 (Mar. 2, 2005).

[276] *Id.* at *1.

[277] *In the Matter of Boulder Valley Individual Prac. Assoc.,* 149 F.T.C. 1147, 2010 WL 9434809, at *2 (Apr. 2, 2010).

[278] *Boulder Valley,* 2010 WL 9434809, at *2. The Commission has similarly exercised jurisdiction where an entity claiming nonprofit tax-exempt status provides pecuniary benefit to for-profit entities or individuals. *See, e.g., In the Matter of Mem'l Hermann Health Network Providers,* 137 F.T.C. 90, 92 (2004); *Preferred Health,* 2005 WL 593181, at *1–*2; *Advoc. Health Partners,* F.T.C. No. 31–0021, 2007 WL 643035, at *3–*4 (Feb. 7, 2007); *Conn. Chiropractic Ass'n,* F.T.C. No. 71–0074, 2008 WL 625339, at *2 (Mar. 5, 2008); *Am. Med. Ass'n* v. *FTC,* 638 F.2d 443 (2d Cir. 1980), aff'd, 455 U.S. 676 (1982).

[279] *Redlands Surgical Servs.* v. *Comm'r,* 242 F.3d 904, 904–05 (9th Cir. 2001); *see also St. David's Health Care Sys.* v. *United States,* 349 F.3d 232, 239 (5th Cir. 2003).

[280] *See Fam. Tr. of Mass., Inc.* v. *United States,* 892 F. Supp. 2d 149, 155–156 (D.D.C. 2012); I.R.S. G.C.M. 39,674 (Oct. 23, 1987); *Bubbling Well Church of Universal Love, Inc.* v. *Comm'r,* No. 5717–79X, 1980 WL 4453 (T.C. June 9, 1980) (''[E]xcessive payments made purportedly as compensation constitute benefit inurement in contravention of section 501(c)(3).'').

decisions construing the scope of the Commission's jurisdiction, any entity satisfying the two-prong test falls within the Commission's jurisdiction. Such entities would thus be bound by the final rule.[281]

F. The Legal Standard for Unfair Methods of Competition Under Section 5

In section 5 of the FTC Act, ''unfair methods of competition in or affecting commerce'' are ''declared unlawful.'' [282] In enacting section 5, Congress intentionally did not mirror either the common law or the text or judicial interpretations of the Sherman Act, but instead adopted this new term.[283] As the Supreme Court has confirmed, this different term reflects a distinct standard.[284] Under section 5, the Commission assesses two elements: (1) whether the conduct is a method of competition, as opposed to a condition of the marketplace, and (2) whether it is unfair, meaning that it goes beyond competition on the merits. The latter inquiry has two components: (a) whether the conduct has indicia of unfairness and (b) whether the conduct tends to negatively affect competitive conditions. These two components are weighed according to a sliding scale.

Indicia of unfairness include the extent to which the conduct may be coercive, exploitative, collusive, abusive, deceptive, predatory, or involve the use of economic power of a similar nature.[285] Indicia of unfairness may also be present if the conduct is otherwise restrictive or exclusionary, depending on the circumstances, such as the nature of the commercial setting and the current and potential future effects of the conduct.[286] Notably, section 5 does not limit indicia of unfairness to conduct that benefits one or more firms and necessarily disadvantages others. Instead, restrictive and exclusionary conduct may also be unlawful where it benefits specific firms while tending to negatively affect competitive conditions.[287]

The second prong, whether conduct tends to negatively affect competitive conditions, focuses on the nature and tendency of the conduct. It does not turn on whether the conduct directly caused actual harm in the specific instance at issue and therefore does not require a detailed economic analysis or current anticompetitive effects.[288] Instead, the inquiry examines whether the conduct has a tendency to negatively affect competitive conditions, including by raising prices, reducing output, limiting choice, lowering quality, reducing innovation, impairing or excluding other market participants, reducing the likelihood of potential or nascent competition, reducing labor mobility, suppressing worker compensation or degrading working conditions for workers. These concerns may arise when the conduct is examined in the aggregate along with the conduct of others engaging in the same or similar conduct.[289] Section 5 does not require a separate showing of market power or market definition.[290] Nor does section 5 import the rule-of-reason analysis applied under other antitrust laws, including in some Sherman Act cases.[291]

The Commission weighs the two elements—indicia of unfairness and tendency to negatively affect competitive conditions—on a sliding scale. Where the indicia of unfairness are clear, conduct may be an unfair method of competition with only a limited showing of a tendency to negatively affect competitive conditions.[292] For example, conduct that is coercive and exploitative evinces facial unfairness and weighs heavily as clear indicia of unfairness.[293] Where indicia of unfairness are less clear, conduct may still violate section 5 where it tends to negatively affect

---

[281] The Commission cannot predict precisely how many entities claiming nonprofit tax-exempt status may be subject to the final rule. The Commission finds that the benefits of the final rule justify implementing it no matter how many nonprofit entities claiming tax-exempt status it ultimately reaches—including under the unlikely assumption that it does not reach any of them.

[282] 15 U.S.C. 45(a)(1).

[283] The Clayton Antitrust Act (38 Stat. 730, ch. 323, Pub. L. 63–212, Oct. 15, 1914) was signed into law weeks after the FTC Act of 1914, 38 Stat. 717.

[284] *See FTC* v. *Ind. Fed'n of Dentists,* 476 U.S. 447, 454 (1986); *FTC* v. *Sperry & Hutchinson,* 405 U.S. 233, 243–44 (1972); *FTC* v. *Brown Shoe Co.,* 384 U.S. 316, 321 (1966); *FTC* v. *Motion Picture Advert. Serv.,* 344 U.S. 392, 394–95 (1953); *FTC* v. *R.F. Keppel & Bro.,* 291 U.S. 304, 309–10 (1934). While some commenters argued the Commission should apply the rule of reason in this rule, as outlined in Parts II.A, II.B, II.C, and II.F, neither the text of section 5, the Supreme Court and other courts' interpretation of section 5, nor the legislative history support the conclusion that the Commission should apply the rule of reason to determine whether conduct violates section 5 as an unfair method of competition. The Commission outlines the legal standard for finding certain uses of non-competes to be unfair methods of competition in the final rule in this Part II.F.

[285] *See e.g., Sperry & Hutchinson Co.,* 405 U.S. at 243 (holding section 5 reaches conduct shown to exploit consumers, citing *R.F. Keppel & Bro.,* 291 U.S. at 313); *Atl. Refin. Co.* v. *FTC,* 381 U.S. 357, 369 (1965) (holding that the ''utilization of economic power in one market to curtail competition in another . . . . bolstered by actual threats and coercive practices'' was an unfair method of competition); *FTC* v. *Texaco,* 393 U.S. 223, 228–29 (1968) (finding that use of ''dominant economic power . . . in a manner which tended to foreclose competition'' is an unfair method of competition); *E.I. du Pont de Nemours* v. *FTC (Ethyl),* 729 F.2d 128, 137, 140 (2d Cir. 1984) (finding that unfair methods of competition includes practices that are ''collusive, coercive, predatory, restrictive or deceitful'' as well as ''exclusionary'').

[286] *See, e.g., Motion Picture Advert. Serv. Co.,* 344 U.S. at 395–96; *Luria Bros. & Co.* v. *FTC,* 389 F.2d 847, 860–61 (3d Cir. 1968). As the Supreme Court has made clear, the inquiry into the nature of the commercial setting does not, however, require market definition or proof of market power. *See, e.g., Atl. Refin. Co.,* 381 U.S. at 371 (finding it ''unnecessary to embark upon a full scale economic analysis of competitive effect''). On November 10, 2022, the Commission issued a policy statement describing the key principles of general applicability concerning whether conduct is an unfair method of competition under section 5. FTC, *Policy Statement Regarding the Scope of Unfair Methods of Competition Under Section 5 of the Federal Trade Commission Act* (Nov. 10, 2022) (hereinafter ''FTC Policy Statement''). The FTC Policy Statement cites a number of cases explaining that section 5 does not require market definition or proof of market power. *Id.* at 10.

[287] *See, e.g., Brown Shoe Co.,* 384 U.S. at 320 (''Thus the question . . . is whether the Federal Trade Commission can declare it to be an unfair practice for Brown, the second largest manufacturer of shoes in the Nation, to pay a valuable consideration to hundreds of retail shoe purchasers in order to secure a contractual promise from them that they will deal primarily with Brown and will not purchase conflicting lines of shoes from Brown's competitors. We hold that the Commission has power to find, on the record here, such an anticompetitive practice unfair . . . .'')

[288] *Atl. Refin. Co.,* 381 U.S. at 371 (It is ''unnecessary to embark upon a full scale economic analysis of competitive effect.''); *Texaco,* 393 U.S. at 230 (''It is enough that the Commission found that the practice in question unfairly burdened competition for a not insignificant volume of commerce.''); *Union Circulation Co.* v. *FTC,* 241 F.2d 652, 657 (2d Cir. 1957) (''The agreements should be struck down if their reasonable tendency, as distinguished from actual past effect, is to injure or obstruct competition. Under the Federal Trade Commission Act, industry agreements and practices have been enjoined without an actual showing of injury to competition . . . .''). *See also Sperry & Hutchinson Co.,* 405 U.S. at 244 (''[U]nfair competitive practices [are] not limited to those likely to have anticompetitive consequences after the manner of the antitrust laws.''); *Ethyl,* 729 F.2d at 138 (finding that evidence of actual harm is not required); *In re Coca-Cola Co.,* 117 F.T.C. 795, 915 n.25 (1994) (rejecting argument that section 5 violation requires showing of ''anticompetitive effects'').

[289] *Motion Picture Advert. Serv. Co.,* 344 U.S. at 395; *Union Circulation Co.,* 241 F.2d at 658 (''The tendency of the 'no-switching' agreements is to discourage labor mobility, and thereby the magazine-selling industry may well become static in its composition to the obvious advantage of the large, well-established signatory agencies and to the disadvantage of infant organizations.'').

[290] *Atl. Refin. Co.,* 381 U.S. at 371; *Texaco,* 393 U.S. at 230; *L.G. Balfour Co.* v. *FTC,* 442 F.2d 1, 19–20 (7th Cir. 1971) (no proof of foreclosure of a relevant market necessary in an exclusive dealing contract case under section 5 (citing *Brown Shoe*)).

[291] *See* Part II.A.

[292] *See, e.g., Ethyl,* 729 F.2d at 137–39; FTC Policy Statement, *supra* note 286, at 9.

[293] *See e.g., Sperry & Hutchinson Co.,* 405 U.S. at 243; *Ethyl,* 729 F.2d at 139, 140 (finding that unfair methods of competition include practices that are ''collusive, coercive, predatory, restrictive, or deceitful'' as well as ''exclusionary''); FTC Policy Statement, *supra* note 286, at 7, 9.

competitive conditions, but a stronger showing of such tendency is required.

In many cases the Commission (and courts) have held conduct to constitute an unfair method of competition by pointing to clear indicia of unfairness, including coercive or exploitative conduct, without conducting a detailed economic analysis of its effects. In *Atlantic Refining Co.* v. *FTC* and *FTC* v. *Texaco, Inc.,* the Supreme Court held that the Commission established an unfair method of competition where an oil company used its economic power over its gas stations to coerce them into buying certain tires, batteries, or accessories only from firms that paid the oil company a commission.[294] The Court determined in *Atlantic Refining* that ''a full-scale economic analysis of competitive effect'' was not required and the Commission needed only to show that the conduct burdened ''a not insubstantial portion of commerce.'' [295] The Court reiterated this standard in *Texaco* holding that, even though the impact was less harmful than the conduct in *Atlantic Refining,* ''the anticompetitive tendencies of [the challenged] system are clear, and . . . the Commission was properly fulfilling the task that Congress assigned it in halting this practice in its incipiency.'' [296] As the Court observed, ''[t]he Commission is not required to show that a practice it condemns has totally eliminated competition.'' [297] In *FTC* v. *R.F. Keppel & Brother, Inc.,* the Supreme Court held that the Commission established an unfair method of competition where a manufacturer exploited the inability of children to protect themselves in the marketplace by marketing inferior goods to them through use of a gambling scheme.[298] The Court considered the extent of the practice and concluded ''[the practice] is successful in diverting trade from competitors'' without engaging in a full-scale economic analysis.[299]

In other cases, the Commission (and courts) have held exclusionary or restrictive conduct was an unfair method of competition based on evidence of the conduct's tendency to negatively affect competitive conditions without focusing on the indicia of unfairness, including whether the conduct is coercive or exploitative. But an evidentiary showing or detailed economic analysis that such conduct generated actual anticompetitive effects or would do so in the future still was not required. For example, in *Union Circulation Company* v. *FTC,* the Second Circuit held the Commission established an unfair method of competition where a group of door-to-door subscription solicitation agencies agreed not to hire workers who were previously employed by another signatory agency.[300] The court looked to whether the ''reasonably foreseeable effect'' of the agencies' conduct would be to ''impair or diminish competition between existing [competitors]'' or prevent potential new rivals.[301] In finding the conduct was an unfair method of competition, the court concluded that ''[t]he tendency of the . . . agreements is to discourage labor mobility, and thereby the magazine-selling industry may well become static in its composition to the obvious advantage of the large, well established signatory agencies and to the disadvantage of infant organizations.'' [302] In *FTC* v. *Brown Shoe Co.,* the Supreme Court held that an exclusive dealing arrangement under which the Brown Shoe Company offered shoe retailers ''a valuable consideration . . . to secure a contractual promise from them that they will deal primarily with Brown and will not purchase conflicting lines of shoes from Brown's competitors'' violated section 5 consistent with the Commission's authority ''to arrest trade restraints in their incipiency.'' [303] Of course, evidence of actual adverse effects on competition meets the requirement to show a tendency to negatively affect competitive conditions. For example, in *FTC* v. *Motion Picture Advertising Service Co.,* the Supreme Court held that an exclusive dealing arrangement violated section 5 where there was ''substantial evidence'' that the contracts ''unreasonably restrain competition.'' [304]

Respondents in unfair method of competition cases sometimes assert purported justifications as an affirmative defense. Some courts have declined to consider justifications altogether. However, where defendants raise justifications as an affirmative defense, the Commission and courts have consistently held that pecuniary benefit to the party responsible for the conduct in question is not cognizable as a justification.[305] Additionally, to the extent justifications are asserted, they must be legally cognizable,[306] non-pretextual,[307] and any restriction used to bring about the benefit must be narrowly tailored to limit any adverse impact on competitive conditions.[308]

[294] *Atl. Refin. Co.,* 381 U.S. at 369–70; *Texaco,* 393 U.S. at 228–29.

[295] *Atl. Refin. Co.,* 381 U.S. at 371. *See also Texaco,* 393 U.S. at 230 (finding that the practice unfairly burdened competition for a not insignificant volume of commerce); *FTC* v. *R.F. Keppel & Bro.,* 291 U.S. 304, 309 (1934) (''A practice so widespread and so far reaching in its consequences is of public concern if in other respects within the purview of the statute.'').

[296] *Texaco,* 393 U.S. at 230 (further noting that ''[i]t is enough that the Commission found that the practice in question unfairly burdened competition for a not insignificant volume of commerce.'').

[297] *Id.* at 230. *See also Shell Oil Co.* v. *FTC,* 360 F.2d 470, 487 (5th Cir. 1966) (''A man operating a gas station is bound to be overawed by the great corporation that is his supplier, his banker, and his landlord.'').

[298] 291 U.S. 304, 313.

[299] 291 U.S. at 308–09.

[300] 241 F.2d 652, 655 (2d Cir. 1957).

[301] *Id.* at 658. Notably, the court also considered facially coercive conduct by which the door-to-door subscription agencies coerced magazine publishers into not doing business with one of their competitors because the competitor hired their former workers. *Id.* at 655–56. The court upheld the Commission's order concluding this conduct was an unfair method of competition under section 5. The court did not conduct any related economic analysis and simply concluded that the ''illegal scheme of coercion . . . is clearly unjustified.'' *Id.*

[302] *Id.* at 658; *see also Nichols* v. *Spencer Intern. Press, Inc.,* 371 F.2d 332, 334 (7th Cir. 1967) (''Granting that the antitrust laws were not enacted for the purpose of preserving freedom in the labor market, nor of regulating employment practices as such, nevertheless it seems clear that agreements among supposed competitors not to employ each other's employees not only restrict freedom to enter into employment relationships, but may also, depending upon the circumstances, impair full and free competition in the supply of a service or commodity to the public.'')

[303] *FTC* v. *Brown Shoe Co.,* 384 U.S. 316, 320, 322 (1966).

[304] *FTC* v. *Motion Picture Advert. Serv. Co.,* 344 U.S. 392, 395–96 (1953); *see also L.G. Balfour Co.* v. *FTC,* 442 F.2d 1, 14 (7th Cir. 1971) (holding that a firm's exclusive dealing contracts violated section 5 where such contracts were 'anti-competitive' '').

[305] *Atl. Refin. Co.* v. *FTC,* 381 U.S. 357, 371 (1965) (considering that defendant's distribution contracts at issue ''may well provide Atlantic with an economical method of assuring efficient product distribution among its dealers'' and holding that the ''Commission was clearly justified in refusing the participants an opportunity to offset these evils by a showing of economic benefit to themselves''); *FTC* v. *Texaco,* 393 U.S. 223, 230 (1968) (following the same reasoning as *Atlantic Refining* and finding that the ''anticompetitive tendencies of such system [were] clear''); *Balfour,* 442 F.2d at 15 (while relevant to consider the advantages of a trade practice on individual companies, this cannot excuse an otherwise illegal business practice). For provisions of the antitrust laws where courts have not accepted justifications as part of the legal analysis, the Commission will similarly not accept justifications when these claims are pursued through section 5.

[306] *See, e.g., FTC* v. *Ind. Fed. Dentists,* 476 U.S. 447, 463 (1986); *Fashion Originators' Guild of Am.* v. *FTC,* 312 U.S. 457, 468 (1941); *FTC* v. *Superior Ct. Trial Lawyers Ass'n,* 493 U.S. 411, 423–24 (1990).

[307] *See, e.g., Ind. Fed'n of Dentists,* 476 U.S. at 464. *See also United States* v. *Microsoft Corp.,* 253 F.3d 35, 62–64, 72, 74, 76–77 (D.C. Cir. 2001); *Eastman Kodak Co.* v. *Image Technical Tech. Svcs,* 504 U.S. 541, 472, 484–85 (1992); *Aspen Skiing Co.* v. *Aspen Highlands Skiing Corp.,* 472 U.S. 585, 608–10 (1985).

[308] *NCAA* v. *Alston,* 594 U.S. 69, 100–101 (2021); *Polygram Holding, Inc.* v. *FTC,* 416 F.3d 29, 38

Continued

III. Section 910.1: Definitions

Section 910.1 sets forth definitions of several terms used in the final rule.

A. Definition of ''Business Entity''

The Commission adopts the definition of ''business entity'' as proposed.

1. Proposed Definition

The Commission proposed to define ''business entity'' as ''a partnership, corporation, association, limited liability company, or other legal entity, or a division or subsidiary thereof.'' [309] The term ''business entity'' was used in two places: (1) in proposed § 910.3, which contained an exception for certain non-competes entered into in the context of a sale of a business by a substantial owner of, or substantial member or substantial partner in, the business entity,[310] and (2) in proposed § 910.1(e), which defined ''substantial owner, substantial member, or substantial partner'' as an owner, member, or partner holding at least a 25% ownership interest in a business entity.

The Commission explained in the NPRM that it proposed including divisions and subsidiaries in the definition of ''business entity'' to apply the sale-of-a-business exception where a person is selling a division or subsidiary of a business entity.[311] The Commission stated the primary rationale for the sale-of-business exception—to help protect the value of a business acquired by a buyer—also applies where a person is selling a division or subsidiary of a business entity.[312]

2. Comments Received

Two commenters specifically addressed the definition of business entity. One commenter suggested a new definition using a functional test that the commenter asserted would prevent employers from structuring their businesses as several smaller legal entities in order to fall within the sale-of-a-business exception. Another commenter also suggested that the definition be amended to explicitly include ''general partnerships'' and trusts.

3. The Final Rule

The Commission adopts the definition of ''business entity'' as proposed. The Commission declines to adopt a functional test for the definition of ''business entity.'' As described in greater detail in Part V.A, the sale-of-a-business exception in the final rule does not contain a 25% ownership threshold, so employers will not have an incentive to structure their businesses as several smaller legal entities in order to fall within the sale-of-a-business exception. The Commission also believes replacing the current bright-line definition of ''business entity'' with a functional test would make it more difficult for workers and employers to know whether a given non-compete is enforceable in the context of the sale of a business. The Commission concludes adding the terms ''general partnerships'' and ''trusts'' to the definition is unnecessary, because the phrase ''other legal entity'' already includes those entity types.

B. Definition of ''Employment''

The Commission proposed to define ''employment'' as ''work for an employer, as the term employer is defined in § 910.1(c).'' [313] That provision defined ''employer'' as ''a person, as defined in 15 U.S.C. 57b–1(a)(6) [section 20 of the FTC Act], that hires or contracts with a worker to work for the person.'' [314] Section 20 defines ''person'' as ''any natural person, partnership, corporation, association, or other legal entity, including any person acting under color or authority of State law.'' The Commission intended the proposed definition of ''employer'' to clarify that an employment relationship exists, for purposes of the final rule, regardless of whether an employment relationship exists under another law, such as a Federal or State labor law.[315] The final rule clarifies the definitions to better reflect that intent.

While commenters generally did not address the proposed definition of ''employment,'' many commenters expressed concern that the proposed definition of ''employer'' would exclude workers hired by one entity to work for another, such as workers hired through a staffing agency. To avoid excluding such workers, and consistent with the Commission's intent to cover workers irrespective of whether they are classified as in an ''employer-employee'' relationship under other State and Federal laws, the final rule defines ''employment'' as ''work for a person'' and makes corresponding changes to the definition of ''employer,'' described in Part III.C. This definition of ''employment'' better clarifies that an employment relationship exists, for purposes of the final rule, regardless of whether an employment relationship exists under another law, such as a Federal or State labor law.

C. Proposed Definition of ''Employer''

The Commission proposed to define employer as a ''person, as defined in 15 U.S.C. 57b–1(a)(6) [section 20 of the FTC Act], that hires or contracts with a worker to work for the person.'' [316] Section 20 defines ''person'' as ''any natural person, partnership, corporation, association, or other legal entity, including any person acting under color or authority of State law.'' [317] The Commission clarified in the NPRM that a person meeting the definition of an employer under proposed § 910.1(c) would be an employer regardless of whether the person meets another legal definition of employer, such as a definition in Federal or State labor law.[318] In response to concerns raised by commenters, the final rule does not adopt a definition of ''employer.''

1. Comments Received

Several commenters expressed support for the proposed definition of ''employer.'' A few commenters suggested changes to the definition of ''employer'' to maximize the final rule's coverage and close potential loopholes. Worker and employer advocates noted the proposed definition appeared to exclude certain persons who are commonly understood to be a worker's employer because it assumed that a worker's employer is the same legal entity that hired or contracted with the worker. These commenters contended the proposed definition would not cover arrangements such as when a worker is employed through a contractual relationship with a professional employer organization or staffing agency; under a short-term ''loan-out arrangement,'' during which a worker hired by one employer may work for another employer; under contract with a parent, subsidiary, or affiliate of the business who hired them; or by persons or entities who share common control over the worker's work. A few of these commenters also stated that the proposed definition creates a loophole allowing evasion of the rule through third-party hiring. Most commenters that addressed this issue suggested listing one or more such arrangements in the definition of ''employer'' to

(D.C. Cir. 2005); 2000 Collaboration Guidelines, sec. 3.36b. *See also Union Circulation Co.* v. *FTC,* 241 F.2d 652, 658 (2d Cir. 1957) (''The agreements here went beyond what was necessary to curtail and eliminate fraudulent practices.'').

[309] NPRM, proposed § 910.1(a).

[310] *Id.* at 3508.

[311] *Id.* at 3509.

[312] *Id.*

[313] *Id.,* proposed § 910.1(d).

[314] *Id.,* proposed § 910.1(c).

[315] *Id.* at 3510.

[316] *Id.,* proposed § 910.1(c).

[317] 15 U.S.C. 57b–1(a)(6).

[318] NPRM at 3510.

ensure these kinds of arrangements are covered.

One worker advocacy group argued the term ''hires or contracts'' in the proposed definition of ''employer'' is in tension with the Commission's stated intent to broadly cover all workers, including externs, interns, and volunteers. This commenter suggested the definition of ''employer'' incorporate language from the Fair Labor Standards Act (''FLSA'') definition of ''employ,'' which includes to ''suffer or permit to work.'' [319] The commenter suggested this language because of its breadth, noting the language originated in State laws designed to reach businesses that use third parties to illegally hire and supervise children.

One industry trade organization argued that, to minimize inconsistencies with the FLSA, the Commission should incorporate the FLSA's definition of ''employer.''

2. Final Rule

After considering the comments, the Commission has revised the definitions of ''non-compete clause'' and ''worker'' as described in Parts III.D and III.G. These revisions make the definition of ''employer'' unnecessary, so the Commission is not finalizing a definition of ''employer.''

These revisions clarify that the final rule covers all workers regardless of whether they work for the same person that hired or contracted with them to work. As explained in Part III.D, in the definition of ''non-compete clause,'' the Commission has revised the phrase ''contractual term between an employer and a worker'' to read ''term or condition of employment'' and has revised the phrase ''after the conclusion of the worker's employment with the employer'' to read ''after the conclusion of the employment that includes the term or condition.'' Furthermore, as explained in Part III.G, in the definition of ''worker,'' the Commission has revised the phrase ''a natural person who works, whether paid or unpaid, for an employer'' to read ''a natural person who works or who previously worked, whether paid or unpaid.''

The Commission is adopting this more general language, rather than listing the exact kinds of contractual arrangements and entities (*e.g.,* staffing agencies, affiliates, joint employers, etc.) to avoid unnecessary or confusing terminology, evasion of the final rule through complex employment relationships, and the need to specify myriad fact-specific scenarios. The language is designed to capture indirect employment relationships as a general matter without regard to the label used.

D. Definition of ''Non-Compete Clause''

Based on the comments received, the Commission adopts a slightly modified definition of ''non-compete clause'' in § 910.1. Section 910.1 defines a ''non-compete clause'' as a term or condition of employment that prohibits a worker from, penalizes a worker for, or functions to prevent a worker from (A) seeking or accepting work in the United States with a different person where such work would begin after the conclusion of the employment that includes the term or condition; or (B) operating a business in the United States after the conclusion of the employment that includes the term or condition. Section 910.1 further provides that, for purposes of the final rule, ''term or condition of employment ''includes, but is not limited to, a contractual term or workplace policy, whether written or oral.'' Similar to the proposed rule, the final rule applies to terms and conditions that expressly prohibit a worker from seeking or accepting other work or starting a business after their employment ends, as well as agreements that penalize or effectively prevent a worker from doing the same.

1. Proposed Definition

The Commission's proposed definition of ''non-compete clause'' consisted of proposed § 910.1(b)(1) and (b)(2). Proposed § 910.1(b)(1) would have defined ''non-compete clause'' as ''a contractual term between an employer and a worker that prevents the worker from seeking or accepting employment with a person, or operating a business, after the conclusion of the worker's employment with the employer.'' Proposed § 910.1(b)(2) would have provided that the definition in proposed § 910.1(b)(1) includes ''a contractual term that is a *de facto* non-compete clause because it has the effect of prohibiting the worker from seeking or accepting employment with a person or operating a business after the conclusion of the worker's employment with the employer.''

The Commission explained that the proposed definition of non-compete clause would be limited to non-competes between employers and workers and would not apply to other types of non-competes, for example, non-competes between two businesses.[320] The Commission further explained the definition would be limited to post-employment restraints (*i.e.,* restrictions on what the worker may do after the conclusion of the worker's employment) and would not apply to concurrent-employment restraints (*i.e.,* restrictions on what the worker may do during the worker's employment).[321]

In the NPRM, the Commission noted that, rather than expressly prohibiting a worker from competing against their employer, some non-competes require workers to pay damages if they compete against their employer. The Commission explained that courts generally view these contractual terms as non-competes and that proposed § 910.1(b)(1) encompassed them.[322]

The Commission also expressed concern that workplace policies—for example, a term in an employee handbook stating that workers are prohibited from working for certain types of firms or in certain fields after their employment ends—could have the same effects as a contractual non-compete even if they are not enforceable, because workers may believe they are bound by the policy. The Commission sought comment on whether the term ''non-compete clause'' should expressly include a provision in a workplace policy.[323]

The Commission stated that proposed § 910.1(b)(1) was a generally accepted definition of non-compete clause that covers both express non-competes and terms purporting to bind a worker that have the same functional effect as non-competes.[324] The Commission stated that the definition would generally not apply to other types of restrictive employment agreements that do not altogether prevent a worker from seeking or accepting other work or starting a business after their employment ends and do not generally prevent other employers from competing for that worker's labor.[325] At the same time, the Commission expressed concern about unusually restrictive employment agreements that, while not formally triggered by seeking or accepting other work or starting a business after their employment ends, nevertheless restrain such an unusually large scope of activity that they have the same functional effect as non-competes.[326] The Commission noted judicial opinions finding some such

[319] 29 U.S.C. 203(g).

[320] NPRM at 3509.

[321] *Id.*

[322] *Id.*

[323] *Id.* at 3510.

[324] *Id.* at 3509.

[325] *Id.*

[326] *Id.*

restrictive employment agreements to be *de facto* non-competes.[327]

Proposed § 910.1(b)(2) accordingly sought to clarify that the definition in proposed § 910.1(b)(1) includes contractual terms that are *de facto* non-competes because they have the effect of prohibiting the worker from seeking or accepting employment with a person or operating a business after the conclusion of the worker's employment with the employer. It then provided two illustrative, non-exhaustive examples of contractual terms that may be such functional non-competes: (1) an NDA between an employer and a worker written so broadly that it effectively precludes the worker from working in the same field after the conclusion of the worker's employment with the employer; and (2) a training-repayment agreement (''TRAP'') that requires the worker to pay the employer or a third-party entity for training costs if the worker's employment terminates within a specified time period, where the required payment is not reasonably related to the costs the employer incurred to train the worker.[328]

2. Coverage of the Definition

a. Comments Received

Most of the comments on the definition of ''non-compete clause'' addressed whether, and under what circumstances, the rule should apply to functional non-competes.[329] Many commenters that generally supported the NPRM agreed the definition of non-compete clause should cover other restrictive employment agreements when they function as non-competes. These commenters argued that, when restraints on labor mobility are banned, companies switch to functionally equivalent restraints. Some commenters asked the Commission to adopt a broader definition of functional non-competes or to expand the rule to ban additional types of restrictive employment agreements altogether. A few commenters asked the Commission to broaden proposed § 910.1(b)(1) and (2) by replacing the terms ''prevent'' and ''prohibit'' with ''restrains'' and ''limits.''

In contrast, many commenters who generally opposed the NPRM stated that proposed § 910.1(b)(2) was overinclusive. Many such commenters also asserted the definition was vague and could lead to confusion and significant litigation. Several comments suggested clarifications, such as including additional examples of functional non-competes; creating safe harbors for certain restrictive employment covenants; replacing proposed § 910.1(b)(2) with a standard based on antitrust law's ''quick look'' test; [330] or revising the provision to focus on the ''primary purpose'' of a restrictive employment covenant. Several commenters argued the Commission failed to cite evidence that functional non-competes are anti-competitive. Other commenters expressed concern that prohibiting functional non-competes would undermine the rule's intent to permit less restrictive alternatives to non-competes.

At least one commenter argued that proposed § 910.1(b)(2) should be removed because it was redundant, as the proposed definition of non-compete clause in proposed § 910.1(b)(1) already captured any term that prevents an employee from seeking alternative employment, without regard to how the term is labeled. Some commenters who generally supported the NPRM also expressed concern that ambiguity in proposed § 910.1(b)(2) could enable employers to intimidate workers by suggesting that restrictive employment agreements used to evade a final rule are not non-competes under the functional test. Other commenters who generally supported the rule asked for greater specificity in proposed § 910.1(b)(2) to prevent adverse judicial interpretations that could undermine the effectiveness of the rule.

Many commenters addressed issues specific to other types of restrictive employment agreements, including NDAs (also sometimes referred to as confidentiality agreements), TRAPs, non-solicitation agreements, and garden leave and severance agreements.

With respect to NDAs, some commenters stated that the Commission rightly identified overbroad NDAs as a potential method of evasion of the rule and supported the Commission's recognition of overbroad NDAs as functional non-competes. In contrast, some commenters contended that by covering functional non-competes, the proposed rule would limit their ability to use NDAs. Some commenters argued that providing that overbroad NDAs may be functional non-competes would be inconsistent with the proposed rule's separate preliminary finding that NDAs are less restrictive alternatives to non-competes. Similarly, some commenters contended that a functional test may frustrate employers' ability to use NDAs to protect legitimate trade secrets or to enjoin a former worker employed with a competitor under the Defend Trade Secrets Act of 2016, in part because they would be concerned about potential legal liability. Some commenters contended that the example of an overbroad NDA in proposed § 910.1(b)(2) would discourage the use of NDAs, including the use of narrowly tailored NDAs, and undermine confidence in their enforceability. Some commenters stated that reference to cases, including *Brown* v. *TGS Management Co.*[331] and similar cases, represent outliers that are likely to cause more confusion than clarity.

Other commenters addressed the proposed definition's application to TRAPs, which are agreements in which the worker agrees to pay the employer for purported training expenses if the worker leaves their job before a certain date. Several commenters asked the Commission to ban all forms of TRAPs. These commenters argued that employers are increasingly adopting TRAPs and that abusive TRAPs are pervasive throughout the economy. Some commenters asserted millions of workers are likely bound by TRAPs. Commenters stated TRAPs may impose penalties that are disproportionate to the value of training workers received or require the worker to pay alleged training expenses for on-the-job training. Some commenters contended TRAPs may be even more harmful than non-competes, because while non-competes prohibit or prevent workers from seeking or accepting other work or starting a business after they leave their job, TRAPs can prevent workers from leaving their job for any reason.

Some commenters expressed concern that the example in proposed § 910.1(b)(2)(ii) of a TRAP that was a functional non-compete was too narrow, and that the Commission should not imply that TRAPs with penalties that *are* reasonably related to an employer's training expenses cannot be functional

[327] *Wegmann* v. *London,* 648 F.2d 1072, 1073 (5th Cir. 1981) (holding that liquidated damages provisions in a partnership agreement were *de facto* non-compete clauses ''given the prohibitive magnitudes of liquidated damages they specify''); *Brown* v. *TGS Mgmt. Co., LLC,* 57 Cal. App. 5th 303, 306, 319 (Cal. Ct. App. 2020) (holding that an NDA that defined ''confidential information'' ''so broadly as to prevent [the plaintiff] in perpetuity from doing any work in the securities field'' operated as a *de facto* non-compete clause and therefore could not be enforced under California law, which generally prohibits enforcement of non-compete clauses).

[328] NPRM, proposed § 910.1(b)(2).

[329] While the NPRM generally used the term ''*de facto* non-competes,'' the final rule uses the term ''functional non-competes.'' The Commission believes this term more clearly conveys that certain terms are considered non-competes under the final rule where they function to prevent workers from seeking or accepting other work or starting a business after their employment ends.

[330] *See, e.g., Cal. Dental Ass'n* v. *FTC,* 526 U.S. 756, 770–71 (1999).

[331] *See supra* note 327 and accompanying text.

non-competes. One commenter asked the Commission to adopt the standard for TRAPs in the Uniform Restrictive Employment Agreement Act.[332] Another commenter suggested that the Commission ban TRAPs below an income threshold of $75,000. Another commenter asked the Commission to clarify that costs that are inherent in any employer-employee relationship—such as time spent by a supervisor training a new employee how to perform routine business procedures typical for their position or role—should not be considered costs that are ''reasonably related to the costs'' of training.

At least one commenter urged the Commission to treat as functional non-competes other employment terms similar to TRAPs such as equipment loans, where employers provide employees with a loan to purchase equipment that the worker needs in order to perform their job, and damages provisions containing open-ended costs related to the employee's departure—including hiring and training replacements or vague harms such as reputational damages, loss of good will or lost profits. In contrast, some commenters argued that TRAPs should be excluded from coverage under proposed § 910.1(b)(2) because they are not unfair or anti-competitive.

Regarding non-solicitation agreements—which prohibit a worker from soliciting former clients or customers of the employer—a few commenters expressed concern that overbroad non-solicitation agreements may be permitted because they were not listed in the regulatory text for proposed § 910.1(b)(2) as examples of functional non-competes (although the Commission described them in the preamble to the proposed rule as restrictive employment agreements that may fall within the definition of non-compete clause if they restrain such an unusually large scope of activity that they are *de facto* non-compete clauses).[333] These commenters asked the Commission to revise proposed § 910.1(b)(2) to expressly cover non-solicitation agreements that prohibit workers from doing business with prospective or actual customers to an extent that would effectively preclude them from continuing to work in the same field or that prevent a worker from doing business with their former employer's client where the client solicits the worker directly. Other commenters, however, expressed concern that the proposed rule could undermine employers' confidence in the enforceability of non-solicitation agreements and asked that the final rule clarify that non-solicitation agreements are generally not prohibited, or exclude them altogether.

Some comments addressed no-hire clauses, which bar former workers from hiring their former colleagues. One employment lawyer stated that these are less restrictive than non-compete clauses. Other commenters stated that no-hire clauses can still limit careers or make it hard for new businesses to find staff. Some commenters expressed concerns with no-business or non-dealing clauses, which bar former workers from doing business with former clients or customers even if the clients or customers sought them out. These commenters stated such agreements limit the options of clients and customers.

Many commenters raised questions about forfeiture-for-competition clauses, which they stated are often a component of deferred compensation arrangements for executives. Commenters stated that deferred compensation plans often include forfeiture clauses, or contingencies on receiving the promised compensation, to incentivize their recipients to act in ways that benefit the employer. These commenters stated that agreements not to compete for a period of time after employment ends are a common feature of forfeiture clauses. Some commenters stated that such forfeiture-for-competition clauses are non-competes and have the same negative effects as non-competes because they are contingent on competition—they require workers to give up bonus pay or other post-employment benefits if they work for a competing employer or start a competing business, and they keep other employers from being able to hire those workers. Other commenters stated forfeiture-for-competition clauses are a common and important component of deferred compensation arrangements for highly compensated employees and senior executives.[334] Other commenters argued the clauses allow workers to choose between receiving the deferred compensation and forfeiting it if they choose to work for a competitor, and thus they are not non-competes. Other commenters urged the Commission to either clarify that forfeiture-for-competition clauses are not non-competes or to carve them out explicitly.

Many commenters also addressed the application of the rule to garden leave agreements. In using the term ''garden leave,'' commenters seemed to be referring to a number of different types of agreements. Some commenters referred to garden leave agreements as those in which, before a worker left their job, they remained employed and received full pay for a specified period of time but their access to co-workers and company facilities was restricted. In contrast, other commenters considered ''garden leave'' an arrangement to make payments to a worker after their employment concluded. Commenters used different terminology to refer to these kinds of agreements, including severance pay, partial pay, and full pay akin to administrative leave, in exchange for an agreement not to compete. Some commenters argued it is coercive for a worker to sign a non-compete in exchange for severance pay and argued garden leave arrangements are non-competes because they limit a worker's options to work for a competitor. Some commenters asked the Commission to adopt a durational limit for garden leave. At least one commenter also urged the Commission to clarify that an employer cannot unilaterally terminate garden leave.

Other commenters requested clarification that garden leave was not a non-compete on the basis that garden leave does not create a legal obligation on the part of the worker to refrain from competing. Some commenters requested a specific exclusion for garden-leave arrangements. They argued that by forcing employers to pay workers, garden leave would reduce the overuse of non-competes. One talent industry commenter argued that the rule should expressly allow for ''fee tails,'' which require talent agents to pay a portion of future commissions to former employers.

b. The Final Rule

After considering the comments, the Commission has slightly modified the definition of non-compete clause to clarify its scope. In the final rule, § 910.1 defines ''non-compete clause'' as a term or condition of employment that either ''prohibits'' a worker from, ''penalizes'' a worker for, or ''functions to prevent'' a worker from (A) seeking or accepting work in the United States with a different person where such work would begin after the conclusion of the employment that includes the term or condition; or (B) operating a business in the United States after the conclusion of the employment that includes the term or condition.

[332] *See* ULC, *Uniform Restrictive Employment Agreement Act* (2021), sec. 14.

[333] NPRM at 3509.

[334] Commenters also provided purported business justifications for forfeiture-for-competition clauses, which are addressed in Part IV.D.2.

Pursuant to the term ''prohibits,'' the definition applies to terms and conditions that expressly prohibit a worker from seeking or accepting other work or starting a business after their employment ends. Examples of such agreements would be a contractual term between a national sandwich shop chain and its workers stating that, for two years after the worker leaves their job, they cannot work for another sandwich shop within three miles of any of the chain's locations,[335] or a contractual term between a steelmaker and one of its executives prohibiting the executive from working for any competing business anywhere in the world for one year after the end of the executive's employment.[336] The vast majority of existing agreements covered by the final rule fall into this category of agreements that expressly prohibit a worker from seeking or accepting other work or starting a business after their employment ends.

Pursuant to the term ''penalizes,'' the definition also applies to terms and conditions that require a worker to pay a penalty for seeking or accepting other work or starting a business after their employment ends. One example of such a term is a term providing that, for two years after the worker's employment ends, the worker may not engage in any business within a certain geographic area that competes with the employer unless the worker pays the employer liquidated damages of $50,000.[337] Because such an agreement penalizes the worker for seeking or accepting other work or for starting a business after the worker leaves their job, it would be a non-compete clause under § 910.1. Indeed, where an agreement restricts who a worker can work for or their ability to start a business after they leave their job, State courts generally characterize the agreement as a non-compete, regardless of whether the agreement contains an express prohibition or requires the worker to pay liquidated damages.[338]

Another example of a term that ''penalizes'' a worker, under § 910.1, is an agreement that extinguishes a person's obligation to provide promised compensation or to pay benefits as a result of a worker seeking or accepting other work or starting a business after they leave their job. One example of such an agreement is a forfeiture-for-competition clause, which, similar to the agreement with liquidated damages described previously, imposes adverse financial consequences on a former employee as a result of the termination of an employment relationship, expressly conditioned on the employee seeking or accepting other work or starting a business after their employment ends. An additional example of a term that ''penalizes'' a worker under § 910.1 is a severance arrangement in which the worker is paid only if they refrain from competing. The Commission also notes that a payment to a prospective competitor to stay out of the market may also violate the antitrust laws even if it is not a non-compete under this rule.[339]

The common thread that makes each of these types of agreements non-compete clauses, whether they ''prohibit'' or ''penalize'' a worker, is that on their face, they are triggered where a worker seeks to work for another person or start a business after they leave their job—*i.e.,* they prohibit or penalize post-employment work for another employer or business. As elaborated in Part IV, such non-competes are inherently restrictive and exclusionary conduct, and they tend to negatively affect competitive conditions in both labor and product and service markets by restricting the mobility of workers and preventing competitors from gaining access to those workers.

Pursuant to the term ''functions to prevent,'' the definition of non-compete clause also applies to terms and conditions that restrain such a large scope of activity that they function to prevent a worker from seeking or accepting other work or starting a new business after their employment ends, although they are not expressly triggered by these specific undertakings. This prong of the definition does not categorically prohibit other types of restrictive employment agreements, for example, NDAs, TRAPs, and non-solicitation agreements. These types of agreements do not by their terms prohibit a worker from or penalize a worker for seeking or accepting other work or starting a business after they leave their job, and in many instances may not have that functional effect, either. However, the term ''functions to prevent'' clarifies that, if an employer adopts a term or condition that is so broad or onerous that it has the same functional effect as a term or condition prohibiting or penalizing a worker from seeking or accepting other work or starting a business after their employment ends, such a term is a non-compete clause under the final rule.

In response to the comments alleging that covering ''de facto'' or ''functional'' non-competes is overinclusive or vague, the Commission notes that the definition's three prongs—''prohibit,'' ''penalize,'' and ''function to prevent''—are consistent with the current legal landscape governing whether a particular agreement is a non-compete. In addition to generally accepted definitions of non-competes encompassing the ''prohibits'' prong of the definition, terms that ''penalize'' workers for seeking or accepting other work or starting a business after they leave their job (for example, by requiring them to pay liquidated damages) are typically considered non-competes under State law.[340] And the ''functions to prevent'' prong of the definition is likewise consistent with legal decisions holding that restrictive employment agreements other than non-competes may be analyzed under the State law test applicable to non-competes where they function similarly to non-competes.[341] As the First Circuit stated in a recent opinion, ''[O]verly broad nondisclosure agreements, while not specifically prohibiting an employee from entering into competition with the former employer, raise the same policy concerns about restraining competition as noncompete clauses where, as here, they have the effect of preventing the defendant from competing with the plaintiff.'' [342] The fact that whether a given restrictive covenant rises to the level of being a functional non-compete will turn on the facts and circumstances

[335] This example is based on the agreements described in Jamieson, *supra* note 32. The company agreed to remove the non-competes in 2016 as part of a settlement. Office of the Att'y Gen. of the State of N.Y., Press Release, *A.G. Schneiderman Announces Settlement With Jimmy John's To Stop Including Non-Compete Agreements In Hiring Packets* (June 22, 2016), *https://ag.ny.gov/press-release/2016/ag-schneiderman-announces-settlement-jimmy-johns-stop-including-non-compete.*

[336] This example is based on *AK Steel Corp.* v. *ArcelorMittal USA, LLC,* 55 NE3d 1152, 1156 (Ohio Ct. App. 2016).

[337] This example is based on *Press-A-Dent, Inc.* v. *Weigel,* 849 NE2d 661, 668–70 (Ind. Ct. App. 2006) (holding that the agreement was an unlawful non-compete).

[338] *See, e.g., Wichita Clinic, P.A.* v. *Louis,* 185 P.3d 946, 951 (Kan. Ct. App. 2008); *Grayhawk Homes, Inc.* v. *Addison,* 845 SE2d 356 (Ga. Ct. App. 2020); *Salewski* v. *Pilchuck Veterinary Hosp., Inc.,* 359 P.3d 884 (Wash. Ct. App. 2015).

[339] *See., e.g., Palmer* v. *BRG of Ga., Inc.,* 498 U.S. 46, 49–50 (1990) (''[A]greements between competitors to allocate territories to minimize competition are illegal'' (citing *United States* v. *Topco Assocs., Inc.,* 405 U.S. 596 (1972)); *FTC* v. *Actavis, Inc.,* 570 U.S. 136, 154 (2013) (''payment in return for staying out of the market'' may violate the antitrust laws).

[340] *See supra* note 338 and accompanying text.

[341] *See, e.g., Brown* v. *TGS Mgmt. Co., LLC,* 57 Cal. App. 5th 303, 306, 316–19 (Cal. Ct. App. 2020); *Wegmann* v. *London,* 648 F.2d 1072, 1073 (5th Cir. 1981); *TLS Mgmt. & Mktg. Servs.* v. *Rodriguez-Toledo,* 966 F.3d 46, 59–60 (1st Cir. 2020).

[342] *TLS Mgmt. & Mktg. Servs.,* 966 F.3d at 57.

of particular covenants and the surrounding market context does not render this aspect of the final rule overinclusive or vague. Such covenants would be subject to case-by-case adjudication for whether they constitute an unfair method of competition even in the absence of the final rule.

In response to the comments alleging the Commission failed to cite evidence that functional non-competes harm competition, the Commission disagrees. This final rule is based on a robust evidentiary record that includes significant empirical evidence and thousands of public comments, as well as the Commission's longstanding expertise in evaluating competition issues. Based on this record, the Commission finds that non-competes are restrictive and exclusionary conduct that tends to negatively affect competitive conditions in labor markets and markets for products and services.[343] In addition, the Commission finds that, with respect to workers other than senior executives, non-competes are exploitative and coercive.[344] The Commission finds that the functional equivalents of non-competes—because they prevent workers from engaging in the same types of activity—are likewise restrictive and exclusionary conduct that tends to negatively affect competitive conditions in a similar way. In response to the commenters who expressed concern that prohibiting functional non-competes would undermine the rule's intent to permit reasonable substitutes, the Commission stresses that, as described throughout this Part III.D, the ''functions to prevent'' prong of the definition of non-compete clause captures only agreements that function to prevent a worker from seeking or accepting other work or starting a business after they leave their job—not appropriately tailored NDAs or TRAPs that do not have that functional effect.

While many commenters requested the Commission state expressly in the final rule whether various specific restrictive employment agreements satisfy the definition of non-compete clause, the Commission declines to adopt a definition that attempts to capture or carve out every edge case. Rather, the final rule focuses on providing a clear, understandable, and generally applicable definition of non-compete clause that reflects the need for case-by-case consideration of whether certain restrictive covenants rise to the level of being functional non-competes—which is fully consonant with the legal landscape employers generally face today. The Commission nevertheless here responds to comments regarding the restrictive clauses that commenters contended should be expressly addressed in the final rule.

As noted in this Part III.D, restrictive employment agreements other than non-competes—such as NDAs, non-solicitation agreements, and TRAPs—do not by their terms or necessarily in their effect prevent a worker from seeking or accepting work with a person or operating a business after the worker leaves their job. For example, a garden-variety NDA in which the worker agrees not to disclose certain confidential information to a competitor would not prevent a worker from seeking work with a competitor or from accepting such work after the worker leaves their job. Put another way, an NDA would not be a non-compete under § 910.1 where the NDA's prohibitions on disclosure do not apply to information that (1) arises from the worker's general training, knowledge, skill or experience, gained on the job or otherwise; or (2) is readily ascertainable to other employers or the general public.[345]

However, NDAs may be non-competes under the ''functions to prevent'' prong of the definition where they span such a large scope of information that they function to prevent workers from seeking or accepting other work or starting a business after they leave their job. Examples of such an agreement may include an NDA that bars a worker from disclosing, in a future job, any information that is ''usable in'' or ''relates to'' the industry in which they work.[346] Such an agreement would effectively prevent the worker from working for another employer in that industry. A second example would be an NDA that bars a worker from disclosing any information or knowledge the worker may obtain during their employment whatsoever, including publicly available information.[347] These agreements are so broadly written that, for practical purposes, they function to prevent a worker from working for another employer in the same field and are therefore non-competes under § 910.1.

Under the final rule's definition of non-compete clause, the same inquiry applies to non-solicitation agreements. Non-solicitation agreements are generally not non-compete clauses under the final rule because, while they restrict who a worker may contact after they leave their job, they do not by their terms or necessarily in their effect prevent a worker from seeking or accepting other work or starting a business. However, non-solicitation agreements can satisfy the definition of non-compete clause in § 910.1 where they function to prevent a worker from seeking or accepting other work or starting a business after their employment ends. Whether a non-solicitation agreement—or a no-hire agreement or a no-business agreement, both of which were referenced by commenters, as discussed previously—meets this threshold is a fact-specific inquiry. The Commission further notes that—like all the restrictive employment agreements described in this Part III.D—non-solicitation agreements, no-hire, and no-business agreements are subject to section 5's prohibition of unfair methods of competition, irrespective of whether they are covered by the final rule.

Depending on the facts and circumstances, a TRAP can also function to prevent a worker from working for another firm or starting a business. For example, one commenter cited a TRAP that required entry-level workers at an IT staffing agency who were earning minimum wage or nothing at all during their training periods to pay over $20,000 if they failed to complete a certain number of billable hours.[348] The commenter also cited a TRAP requiring nurses to work for three years or else repay all they have earned, plus paying the company's ''future profits,'' attorney's fees, and arbitration costs.[349] These types of TRAPs may be functional non-competes because when faced with significant out-of-pocket costs for leaving their employment—dependent on the context of the facts and circumstances—workers may be forced to remain in their current jobs, effectively prevented from seeking or accepting other work or starting a business.

In response to the comments, the Commission declines at this time to either categorically prohibit all TRAPs related to leaving employment, or to exempt such provisions altogether. The Commission agrees with comments raising substantial concerns about the

[343] *See* Parts IV.B and IV.C.

[344] *See* Part IV.B.2.b.

[345] This example is based on sec. 9 of the Uniform Restrictive Employment Agreement Act, *supra* note 332.

[346] This example is based on *Brown* v. *TGS Mgmt.,* 57 Cal. App. 5th at 316–19 (''Collectively, these overly restrictive provisions [in the NDA at issue] operate as a de facto noncompete provision; they plainly bar Brown in perpetuity from doing any work in the securities field.'').

[347] This example is based on *TLS Mgmt. & Mktg. Servs.,* 966 F.3d at 57 (holding that the NDA was unenforceable).

[348] Comment of Jonathan F. Harris, Dalié Jiménez, & Jonathan Glater, FTC–2023–0007–20873 at 4.

[349] *Id.* at 6–7.

potential effects of such agreements on competitive conditions. As noted in the summary of the comments, commenters cited TRAPs that impose penalties disproportionate to the value of training workers received and/or that claimed training expenses for on-the-job training. However, the evidentiary record before the Commission principally relates to non-competes, meaning on the present record the Commission cannot ascertain whether there are any legitimate uses of TRAPs that do not tend to negatively affect competitive conditions. When TRAPs function to prevent a worker from seeking or accepting other work or starting a business after the employment associated with the TRAP, they are non-competes under § 910.1.

The Commission notes that clauses requiring repayment of a bonus when a worker leaves their job would not be non-competes under § 910.1 where they do not penalize or function to prevent a worker from seeking or accepting work with a person or operating a business after the worker leaves their job. For example, a provision requiring the repayment of a bonus if the worker leaves before a certain period of time would not be a non-compete under § 910.1 where the repayment amount is no more than the bonus that was received, and the agreement is not tied to who the worker can work for, or their ability to start a business, after they leave their job. Similarly, a term or condition under which a worker loses accrued sick leave when their employment ends would not function to prevent a worker from seeking or accepting work with a person or operating a business after the worker leaves their job.

With respect to garden leave agreements, as noted previously, commenters used the term ''garden leave'' to refer to a wide variety of agreements. The Commission declines to opine on how the definition of non-compete clause in § 910.1 would apply in every potential factual scenario. However, the Commission notes that an agreement whereby the worker is still employed and receiving the same total annual compensation and benefits on a *pro rata* basis would not be a non-compete clause under the definition,[350] because such an agreement is not a post-employment restriction. Instead, the worker continues to be employed, even though the worker's job duties or access to colleagues or the workplace may be significantly or entirely curtailed. Furthermore, where a worker does not meet a condition to earn a particular aspect of their expected compensation, like a prerequisite for a bonus, the Commission would still consider the arrangement ''garden leave'' that is not a non-compete clause under this final rule even if the employer did not pay the bonus or other expected compensation. Similarly, a severance agreement that imposes no restrictions on where the worker may work following the employment associated with the severance agreement is not a non-compete clause under § 910.1, because it does not impose a post-employment restriction.

The Commission declines a commenter's request to replace the term ''prevent'' with ''restrains'' or ''limits.'' Commenters generally did not express concern about the term ''prevent'' and the Commission is concerned that different language could greatly expand the scope of the definition and reduce its clarity.

The Commission also declines to adopt alternative *de facto* tests raised by commenters, such as a version of the ''quick look'' test. As described in Part II.F, the legal standard under section 5 of the FTC Act is distinct from that of the Sherman Act. The Commission also declines to adopt a test that would consider the primary purpose of a restrictive employment agreement. The Commission believes that it can be difficult to establish an employer's subjective ''purpose'' in entering into an agreement. In addition, such a test could allow extremely overbroad agreements that dramatically restrict a worker's ability to compete against the employer—and have the negative effects described in Parts IV.B and IV.C—as long as the employer entered into the agreement without the subjective intent to restrict competition.

The Commission agrees with the commenter who stated that proposed § 910.1(b)(2) was redundant because proposed § 910.1(b)(1) was already a functional definition. In the final rule, the Commission has revised the text of the definition of non-compete clause to address confusion among commenters about whether proposed § 910.1(b)(2) clarified the definition or extended it.

In response to the commenters requesting that the Commission clarify the circumstances under which the definition would apply to various other types of restrictive employment agreements, the Commission declines at this time to enumerate every circumstance that may arise. As noted, a restrictive employment covenant may be a non-compete clause under § 910.1 if it expressly prohibits a worker from, or penalizes a worker for, seeking or accepting other work or starting a business, or if it does not do so expressly but is so broad or onerous in scope that it functionally has the same effect of preventing a worker from doing the same.

3. International Application of the Rule

a. Comments Received

The Commission received several comments expressing concern about whether the final rule would apply to non-competes that restrict work outside the U.S. In response, the final rule's definition of non-compete clause clarifies that it applies only to work in the U.S. or operating a business in the U.S.

Some commenters raised concerns about the cross-border movement of workers. A research center commenter asserted there is a global shortage of science and technology workers and stated that the final rule's adoption could exacerbate the U.S. shortage by allowing other countries to more easily poach U.S. workers. An academic commenter argued that banning non-competes might deter foreign investors from sending workers to the U.S. if the final rule would invalidate their non-competes.

Some commenters argued that legal systems in the People's Republic of China or other jurisdictions provide insufficient protection for U.S. companies' trade secrets, confidential information, or patent rights, and contended employers need non-competes as *ex ante* protection. These commenters generally say that trade secrets litigation is more challenging in some jurisdictions outside the U.S., for example because of less extensive discovery processes, less frequent use of preliminary injunctions, insufficient remedies, and a lower propensity to prosecute criminal intellectual property cases. An academic commenter argued that some courts may have fewer protections for confidential information compared to the U.S., so a suit concerning only a non-compete is less likely to reveal trade secrets through the course of litigation and thus more effectively prevent technologies from leaking to other governments and protecting U.S. national security interests. However, the comments provided limited evidence on non-competes and trade secret protection outside the U.S., and collectively only

[350] The term and practice of ''garden leave'' appears to have a British origin and is recognized by the Government of the United Kingdom. *See Gov.UK, Handing in your notice, https://www.gov.uk/handing-in-your-notice/gardening-leave* (''Your employer may ask you not to come into work, or to work at home or another location during your notice period. This is called 'gardening leave'.'').

discussed evidence from a few jurisdictions. One commenter noted that legal information and data from some jurisdictions may not be fully accurate because not all court decisions are public.

Two commenters highlighted the domestic semiconductor industry and the CHIPS Act of 2022, arguing the Chinese government seeks to acquire IP related to semiconductors and semiconductor experts with relevant knowledge and information. Those comments expressed concern that a ban on non-competes would damage the semiconductor industry, which relies on skilled workers and trade secrets, by weakening trade secrets protection and disincentivizing investment. Another commenter argued the proposed rule would undermine export controls designed to prevent foreign countries from acquiring U.S. technology and knowledge by allowing workers to move to foreign competitors. One commenter argued the proposed rule conflicts with an October 2022 Bureau of Industry and Security (''BIS'') export control rulemaking, stating that the rulemaking limits worker mobility in certain industries from the U.S. to the People's Republic of China. Another commenter suggested the proposed rule would violate the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which requires that persons ''shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent . . . .'' [351] Finally, one commenter argued that by making it more difficult for businesses to protect against international theft of their intellectual property, the rule is at odds with the purposes of the Protecting American Intellectual Property Act of 2022.[352]

Some of these commenters made recommendations for the final rule. A law firm suggested that the final rule prevent evasion by barring employers from selecting the law of non-U.S. jurisdictions to govern employment contracts with U.S.-based workers. A trade association requested that the final rule cover only agreements subject to the law of a U.S. State. An academic commenter suggested revisions to the text of the proposed rule to ensure the final rule applies only within the U.S. The commenter also recommended stating that a non-compete restricting work outside the U.S. is not a *per se* unfair method of competition and providing guidance on how employers should evaluate international non-competes, using factors such as the business justification for the non-compete and the impact on the worker. The commenter recommended applying the law of the jurisdiction where the worker seeks to be employed.

b. The Final Rule

In response to commenters' concerns, in this final rule the Commission adopts changes to the definition of ''non-compete clause'' that expressly limit the definition of non-compete to terms or conditions that prevent workers from seeking or accepting work in the U.S. or operating a business in the U.S. The final rule does not apply to non-competes if they restrict only work outside the U.S. or starting a business outside the U.S.

This revision clarifies for stakeholders the scope of the final rule and confirms it does not prohibit employers from using non-competes that restrict work outside the U.S., in compliance with those jurisdictions' own laws. The Commission understands that, as a commenter noted, some companies operating or competing globally already draft non-competes that comply with the laws of multiple jurisdictions and, thus, amending their non-competes to reflect this application of the final rule would not pose a significant challenge for those entities.

The Commission's revision clarifying the final rule's application to work or starting a business only in the U.S. also addresses the concerns from some commenters about key U.S. workers and technology flowing overseas, because the final rule does not ban non-competes that restrict workers from working or starting a business outside the U.S. It also clarifies that the final rule would not invalidate non-competes entered into by foreign companies with foreign workers unless they restrict a worker's ability to work or start a business inside the U.S. Other questions about the final rule's application to cross-border or non-U.S. employment are also addressed by the Foreign Trade Antitrust Improvements Act, codified at 15 U.S.C. 45(a)(3).

The Commission agrees with the academic commenter that, for non-competes that apply outside the U.S., the law of the relevant jurisdiction should govern any issue other than restricting work or starting a business in the U.S. However, the Commission declines to adopt a balancing test for non-competes restricting a worker's ability to work or start a business outside the U.S., as a bright-line rule that applies only to work or starting a business in the U.S. is more administrable. In addition, the Commission declines to add language in the final rule stating that it does not apply to overseas employers or to non-competes not subject to U.S. State law. The final rule may apply to overseas employers if the non-compete purports to restrict work or starting a business in the U.S. and the reviewing court applies U.S. law.

The empirical evidence cited in the NPRM focused on the U.S., primarily consisting of studies based on the effects of changes in State laws in the U.S. The comments provided limited evidence on non-competes and trade secret protection outside the U.S., leaving many issues and most jurisdictions unaddressed. The Commission also notes, as one commenter did, that legal information and data from some jurisdictions may not be fully accurate because not all court decisions are public. On the current record, the Commission cannot reach conclusions on whether other jurisdictions have sufficient alternatives to non-competes, the scope of any potential risk, and many of the other issues raised. As a result, the Commission limits application of the final rule to work in the U.S., where the Commission has ample evidence on non-competes' negative effects.

One commenter argued the rule conflicts with BIS's October 2022 export control rulemaking, which restricts the ability of U.S. persons to support development or production at certain semiconductor facilities in the People's Republic of China without a license from BIS.[353] While the revision addresses the commenter's underlying concern about protection of sensitive technology from other governments by not banning non-competes that restrict the movement of workers to and in other jurisdictions, neither the NPRM nor the final rule is inconsistent with the BIS rule. The final rule will not affect BIS's ability to grant or decline to grant a license. With respect to the commenter that suggested the rule would violate TRIPS, the Commission has found that U.S. law provides alternative means of protecting trade secrets,[354] and TRIPS does not require enforcement of non-competes.

With respect to the commenter that stated that the final rule should include

[351] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, sec. 7, art. 39, para. 2, 33 I.L.M. 81 (as amended Jan. 23, 2017).

[352] 50 U.S.C. 1709.

[353] Implementation of Additional Export Controls: Certain Advanced Computing and Semiconductor Manufacturing Items; Supercomputer and Semiconductor End Use; Entity List Modification, Interim Final Rule, 87 FR 62186 (Oct. 13, 2022).

[354] *See* Part IV.D.2.

a choice-of-law provision to prevent evasion, there is an existing body of law in the U.S. governing choice of law and conflict of law issues. Accordingly, the Commission declines to add any provisions concerning choice of law or conflict of law to the final rule. Rather, such questions are left to the relevant jurisdiction, whether that is a U.S. State, the Federal government, or another jurisdiction, as determined by applicable law.

4. Other Issues Relating to the Definition

a. Comments Received

While most commenters focused on the proposed definition's application to functional non-competes or international application, some commenters addressed other issues relating to the proposed definition. Several commenters stated that the definition should cover workplace policies or handbooks, to minimize confusion and make clear that employers are prohibited from including non-competes in workplace policies or handbooks, even if such clauses are unenforceable because they are not formal binding contracts. Some commenters stated that such policies or handbooks can affect a worker's decision to leave their job to work with a competitor or start their own businesses. Others stated the same about oral agreements. One commenter stated that the definition should not cover workplace policies because they apply only during, not after, employment.

A few commenters said the Commission should state explicitly in the definition of ''non-compete clause'' that restrictions on concurrent employment, such as prohibitions on ''moonlighting'' with competitors, are excluded. Other commenters urged the Commission to expand the definition to include restraints on concurrent employment because workers often need to take additional jobs during economic downturns, and low-wage workers generally need to take on additional jobs.

An organized labor commenter argued that no-raid agreements, which the commenter described as agreements between labor organizations not to attempt to organize workers already under representation by another union, should be exempted from the definition. An industry trade organization asked the Commission to clarify whether the definition would apply to non-competes in agreements between motor carriers and brokers in the trucking industry. In addition, a few commenters stated that proposed § 910.1(b)(1) was too broad or potentially ambiguous without pointing to any specific features of the definition.

b. The Final Rule

To address the concerns raised by commenters about workplace policies and handbooks, the definition of non-compete clause in § 910.1 uses the phrase ''a term or condition of employment'' instead of ''contractual term.'' The definition further clarifies that term or condition of employment includes ''a contractual term or workplace policy, whether written or oral.'' The Commission finds that employers have used restrictions in handbooks, workplace policies, or other vehicles that are not formal written contracts to successfully prevent workers from seeking or accepting other employment or starting a new business. The Commission finds, consistent with the views expressed by commenters, that such restrictions in handbooks, workplace policies, or other such vehicles have the same tendency to negatively affect competitive conditions as a formal binding contract term. To provide that such conduct is covered by the definition of non-compete clause, this language clarifies that the definition of non-compete clause is not limited to clauses in written, legally enforceable contracts and applies to all forms a non-compete might take, including workplace policies or handbooks and informal contracts. Given the comments expressing concern about oral representations, the Commission clarifies in the definition of non-compete clause that clauses that purport to bind a worker are covered, whether written or oral, and provides in § 910.2(a)(1) and (2) that it is an unfair method of competition to make representations that a worker is subject to a non-compete. (However, as explained in Part V.C, such representations are not prohibited where the person has a good-faith basis to believe that the final rule is inapplicable.)

The Commission declines to extend the reach of the final rule to restraints on concurrent employment. Although several commenters raised this issue, the evidentiary record before the Commission at this time principally relates to post-employment restraints, not concurrent-employment restraints. The fact that the Commission is not covering concurrent-employment restraints in this final rule does not represent a finding or determination as to whether these terms are beneficial or harmful to competition. The Commission relatedly clarifies that fixed-duration employment contracts, *i.e.,* contracts between employers and workers whereby a worker agrees to remain employed with an employer for a fixed term and the employer agrees to employ the worker for that period, are not non-compete clauses under the final rule because they do not restrain post-employment conduct.

While the final rule does not extend to restraints on concurrent employment, the Commission has made a technical edit to the definition of non-compete to clarify how it relates to seeking and accepting employment. Proposed § 910.1(b) defined non-compete clause as a contractual term that ''prevents the worker from seeking or accepting employment with a person . . . after the conclusion of the worker's employment with the employer.'' Because, as a technical matter, non-competes can also prevent workers from seeking or accepting future employment with another person before their work for their previous employer has concluded, the Commission has clarified the relevant language to read ''that prevents a worker from seeking or accepting work in the United States with a different person *where such work would begin after* the conclusion of the employment that includes the term or condition'' and ''that prevents a worker from operating a business in the United States *after the conclusion of the employment* that includes the term or condition'' (emphases added).

In addition, in response to comments expressing concern about evasion of the rule through third-party hiring,[355] the Commission has revised the phrase ''after the conclusion of the worker's employment with the employer'' to read ''after the conclusion of the employment that includes the term or condition.'' The Commission recognizes that non-competes can cover workers who are hired by one party but work for another, such as workers hired through staffing agencies. The Commission intends for the final rule to apply to such non-competes, and for this revision to eliminate any ambiguity as to whether such clauses are covered by the definition of non-compete clause in § 910.1.

With respect to the comment about union no-raid agreements, the Commission notes that the definition would apply only to the extent the agreement is a ''term or condition of employment'' and only if the agreement ''prevents a worker from seeking or accepting work in the United States with a different person where such work would begin after the conclusion of the employment that includes the term or

[355] These comments are described in greater detail in Part III.G.

condition'' or ''operating a business in the United States after the conclusion of the employment that includes the term or condition.'' [356] The Commission's understanding is that union no-raid agreements are not terms and conditions of employment that prevent workers from seeking or accepting work or operating a business.

With respect to the comment asking whether the definition would apply to non-competes in agreements between motor carriers and brokers in the trucking industry, the Commission notes as a general matter that the definition would not apply to non-competes between businesses, but the Commission declines to opine on specific factual circumstances.

E. Definition of ''Person''

The proposed rule did not separately define the term ''person.'' Instead, proposed § 910.1(c)—the proposed definition of ''employer''—stated that an employer ''means a person, as defined in 15 U.S.C. 57b–1(a)(6), that hires or contracts with a worker to work for the person.'' The statutory provision cross-referenced in proposed § 910.1(c) is section 20(a)(6) of the FTC Act, which defines ''person'' for purposes of the Commission's authority to issue civil investigative demands. Section 20(a)(6) defines ''person'' as ''any natural person, partnership, corporation, association, or other legal entity, including any person acting under color or authority of State law.'' No comments were received concerning the use of ''person'' in proposed § 910.1(c).

As explained in Part III.C, the Commission has removed the defined term ''employer'' from the regulatory text of the final rule. However, the regulatory text still uses the term ''person.'' For example, § 910.2(a)(1) prohibits a ''person'' from, among other things, entering into a non-compete clause. As a result, the Commission has adopted a separate definition of the term ''person.'' Section 910.1 defines ''person'' as ''any natural person, partnership, corporation, association, or other legal entity within the Commission's jurisdiction, including any person acting under color or authority of State law.'' This text consists of the proposed definition from section 20(a)(6), plus the phrase ''within the Commission's jurisdiction,'' which clarifies that only persons within the Commission's jurisdiction are subject to the final rule.

[356] § 910.1.

F. Definitions Related to Senior Executives

With respect to existing non-competes, *i.e.,* non-competes entered into before the final rule's effective date, the Commission adopts a different approach for ''senior executives'' than for other workers. Existing non-competes with senior executives can remain in force; the final rule does not cover such agreements.[357] For workers who are not senior executives, existing non-competes are no longer enforceable after the final rule's effective date.[358] The Commission describes its rationale for the final rule's differential treatment of senior executives in Part IV.C.

Section 910.1 defines the term ''senior executive'' as well as related terms. Because the Commission's rationale for the final rule's differential treatment of senior executives provides important context for these definitions, the Commission describes these definitions in Part IV.C.4.

G. Definition of ''Worker''

1. Proposed Definition

In the NPRM, the Commission proposed to define ''worker'' in proposed § 910.1(f) as ''a natural person who works, whether paid or unpaid, for an employer.'' [359] Proposed § 910.1(f) also stated that ''the term [worker] includes, without limitation, an employee, individual classified as an independent contractor, extern, intern, volunteer, apprentice, or sole proprietor who provides a service to a client or customer.'' [360]

In the NPRM, the Commission explained it intended the term ''worker'' to include not only employees, but also individuals classified as independent contractors, as well as other kinds of workers.[361] The Commission explained that, under proposed § 910.1(f), the term ''worker'' would include any natural person who works, whether paid or unpaid, for an employer, without regard to whether the worker is classified as an ''employee'' under the FLSA or any other statute that draws a distinction between ''employees'' and other types of workers.[362]

The Commission stated in the NPRM that it was concerned that if the rule were to define workers as ''employees'' according to, for example, the FLSA definition, employers may misclassify employees as independent contractors to evade the rule's requirements.[363] The Commission explained it had no reason to believe non-competes that apply to workers who are treated as independent contractors under the FLSA or interns tend to negatively affect competitive conditions to a lesser degree than non-competes that apply to employees, and that such non-competes may, in fact, be more harmful to competition, given that these other types of workers tend to have shorter working relationships.[364] In addition, the Commission explained that the purported business justifications for applying non-competes to independent contractors would not be different or more cognizable from those related to employees.[365]

Proposed § 910.1(f) also stated the term worker ''does not include a franchisee in the context of a franchisee-franchisor relationship.'' [366] The Commission explained that the relationship between a franchisor and franchisee may in some cases be more analogous to the relationship between two businesses than the relationship between an employer and a worker, and that the evidentiary record before the Commission related primarily to non-competes arising solely out of employment.[367] The Commission therefore stated that it believed it would be appropriate to clarify that a franchisee—in the context of a franchisor-franchisee relationship—is not a ''worker'' for purposes of proposed § 910.1(f).[368]

Proposed § 910.1(f) further clarified, however, that the term worker ''includes a natural person who works for the franchisee or franchisor,'' and that ''non-competes between franchisors and franchisees remain subject to [F]ederal antitrust law as well as all other applicable law.'' [369] The Commission explained that these laws include State laws that apply to non-competes in the franchise context.[370] The Commission also clarified that it was not proposing to find that non-competes between franchisors and franchisees are beneficial to competition.[371]

2. Comments Received

Several commenters stated that they agreed with the proposed definition of ''worker'' because it applies to all workers without regard to their classification. Many of these

[357] *See* Part IV.C.3.
[358] *See* § 910.2(a)(1)(i).
[359] NPRM, proposed § 910.1(f).
[360] *Id.*
[361] *Id.* at 3511.
[362] *Id.*
[363] *Id.*
[364] *Id.*
[365] *Id.*
[366] *Id.* at 3511, 3520.
[367] *Id.*
[368] *Id.*
[369] *Id.* at 3511.
[370] *Id.*
[371] *Id.*

commenters specifically urged the Commission to adopt a final definition that includes all categories of workers regardless of whether they are classified as employees, including independent contractors, ''gig'' workers, and others. These commenters pointed to the Commission's preliminary finding that non-competes are widely used across the economy. They cited employers' frequent misclassification of workers as independent contractors, agreeing with concerns raised in the NPRM that, if ''worker'' excludes independent contractors, employers may misclassify workers as independent contractors to avoid complying with the rule. Many commenters stated that millions of workers are misclassified as independent contractors, including a disproportionate number of women, people of color, and low-income workers. These commenters expressed concern that, if the rule excluded independent contractors from coverage, it would fail to benefit these groups, for whom non-competes may be particularly exploitative and coercive.

On the other hand, several commenters suggested removing bona fide independent contractors and sole proprietors from the definition of ''worker.'' Two industry groups contended that there is a lack of data regarding the prevalence and effects of non-competes among independent contractors as opposed to other kinds of workers and that, as a legal matter, the evidence is insufficient to justify including independent contractors as ''workers'' under the rule. A few industry organizations also contended that, because they have more control over their work and generally work for more than one employer, independent contractors have greater bargaining power than other workers. One academic commenter suggested that non-competes between employers and independent contractors are more akin to agreements between businesses than agreements between employers and workers. A few of these industry organizations also contended that non-competes are justified because independent contractors provide services outside the scope of their employers' expertise and thus have greater access to sensitive information than other workers. Other industry organizations contended that small businesses employ more independent contractors than their larger rivals. These commenters stated that, to protect small businesses from being impacted disproportionately by the rule, the definition of ''worker'' should exclude independent contractors. Finally, a few industry trade organizations and an academic commenter stated that independent contractors should be excluded from coverage under the rule to avoid ''free riding,'' in which a contractor working for one firm can use that firm's assets—like tools or databases—to benefit another firm.

Several commenters suggested changes to the definition of ''worker'' to maximize the rule's coverage and close potential loopholes. One worker advocacy group noted that, combined with the proposed definition of ''employer,'' the proposed definition of ''worker''—a natural person who works ''for an employer''—appeared to exclude workers who work for a person other than the person who hired or contracted with them to work. The commenter noted that workers are often employed indirectly—by way of a contractual relationship with a staffing agency, an affiliate of their common-law employer, or some entity other than their common-law employer—and that non-competes are often imposed on workers by the non-hiring party. In order to ensure these workers are covered by the rule, the commenter suggested that the definition of ''worker'' should also cover a person who works ''directly or indirectly'' for an employer and that the definition specifically include ''a person who works for the employer under an arrangement with a professional employer organization, statutory employer, wholly owned entity of which the person is the sole or principal employee or service provider, loan-out arrangement or similar arrangement.''

The same commenter also argued that employers often impose non-competes on workers who own a portion of the business while not applying the same restriction to outside investors who do not work for the company, and that such worker-owner non-competes should be treated as employment-related non-competes. In order to ensure these workers are covered by the rule, the commenter suggested that ''worker'' should also include ''a person who holds direct or indirect equity or other interest in the employer and who provides services to or for the benefit of the employer.'' Another commenter suggested that, for clarity, ''worker'' should specifically exclude a ''substantial owner, member or partner'' as defined in the sale-of-business exception.

Several State attorneys general, local government commenters, academic commenters, and a worker advocacy group warned that categorically excluding franchisees from the definition of ''worker'' would lead employers to misclassify workers as franchisees to evade the rule's requirements. Some commenters suggested incorporating the ''ABC'' test—a common law test designed to determine whether a worker is an employee based on fact-specific conditions—into the definition of ''worker'' to prevent evasion.[372]

Some commenters requested that the Commission revise the definition of ''worker'' to exclude or include certain workers from coverage under the rule. These comments are addressed in Part IV.C (comments requesting an exclusion for senior executives) and in Part V.D (comments requesting exclusions for other categories of workers).

3. The Final Rule

After considering the comments, the Commission revised the definition of ''worker'' in three ways to clarify that the term covers all current and former workers, regardless of which entity hired or contracted with them to work, and regardless of a worker's title or status under any other applicable law.

First, the Commission added ''or who previously worked'' to the basic definition of ''worker'' as ''a natural person who works.'' This revision is designed to clarify that former workers are considered ''workers'' under the final rule, such as where an employer is required to notify a former worker that their non-compete is no longer enforceable.[373]

Second, the Commission removed ''for an employer'' from the definition. This revision is designed to ensure that the final rule covers workers who are hired by one party but work for another, closing the unintended loophole identified by commenters regarding third-party hiring.

Third, the Commission added ''without regard to the worker's title or the worker's status under any other State or Federal laws'' prior to the list of examples of different categories of workers that the definition covers. This change is designed to make more explicit that the term ''worker'' includes all workers regardless of their titles, status under other laws, or the details of the contractual relationship with their employer.

The Commission has made two additional changes to the definition for clarity. First, the Commission has revised the phrase ''individual classified as an independent contractor'' to ''independent contractor.'' Second, the Commission has added ''a natural person who works for a franchisee or

[372] *See, e.g., Dynamex Operations W.* v. *Superior Ct.,* 4 Cal. 5th 903, 955–957 (Cal. 2018).

[373] *See* § 910.2(b).

franchisor'' to the non-exclusive list of examples of types of workers that would be covered by the definition. This language is simply moved from elsewhere in the definition. Third, the Commission has removed the sentence reading ''[n]on-competes between franchisors and franchisees would remain subject to Federal antitrust law as well as all other applicable law'' from the definition to avoid the implication that only such non-competes remain subject to Federal antitrust law and other applicable law.

The Commission declines to specify that a ''worker'' includes an owner who provides services to or for the benefit of their business because the definition already encompasses the same.

The Commission is not persuaded by commenters' arguments that independent contractors or sole proprietors are inherently different from other kinds of workers with respect to non-competes, and therefore declines to exclude them from the definition of ''worker.'' Commenters did not present persuasive evidence that non-competes that apply to independent contractors or sole proprietors tend to negatively affect competitive conditions to a lesser degree—or are restrictive, exclusionary, exploitative, or coercive to a lesser degree—than non-competes that apply to other workers. As noted by commenters who supported including independent contractors, non-competes' tendency to negatively affect competitive conditions by restricting workers' ability to change jobs or start businesses is not contingent on whether the worker is an employee or an independent contractor. While some commenters contended that independent contractors have more independence and more access to intellectual property than other workers, commenters did not provide evidence that this is the case. Moreover, even were this to be true, it would not justify an exclusion, because the Commission generally declines to exclude workers based on their access to intellectual capital or their independence for the reasons explained in Part V.D.

Furthermore, whether a worker is an employee or an independent contractor does not impact employers' ability to exploit imbalances of bargaining power or limit employers' ability to use less restrictive alternatives to non-competes to protect their intellectual property. While commenters who supported excluding independent contractors contended that independent contractors have more bargaining power than other workers, this contention is not backed by evidence. While some economists hypothesize that, theoretically, independent contractors may have more bargaining power vis-à-vis employers than employees do, they do not provide empirical evidence to support that assertion. Furthermore, as described by a report from the Treasury Department that was based on an extensive literature review, independent contractors may have less bargaining power than employees in many respects.[374]

The Commission is also not persuaded that non-competes are necessary to prevent ''free riding'' by independent contractors who use one firm's assets to benefit another. The final rule prohibits agreements that restrain a worker from working after the scope of employment has ended and does not prohibit agreements which prevent a worker from working for two firms simultaneously. In addition, any ''free riding'' may be addressed through less restrictive means, including through agreements prohibiting an independent contractor from using assets provided by one firm to benefit another.

Nor is the Commission persuaded that small businesses will be disproportionately harmed by a rule which prohibits non-competes for independent contractors. Commenters did not provide evidence to support their assertion that small businesses employ more independent contractors than larger ones.

The Commission agrees with the commenters who contended that excluding independent contractors may have the effect of excluding misclassified workers, who may be among the most vulnerable to exploitation and coercion. The recent overview by the U.S. Department of Labor (''DOL'') of the evidence on misclassification led it to conclude that although the prevalence of misclassification of employees as independent contractors is unclear, there is evidence that it is nonetheless ''substantial'' and has a disproportionate effect on workers who are people of color or immigrants because of the disparity in occupations most affected by misclassification, which include jobs in construction, trucking, delivery, home care, agriculture, personal care, ride-hailing services, and janitorial and building services.[375] The Commission also agrees with commenters' contentions that excluding independent contractors from the definition of ''worker'' could increase employers' incentive to misclassify workers as independent contractors. Indeed, misclassification is often motivated by attempts to evade the application of laws.

Because there is no reason to believe non-competes that apply to independent contractors or sole proprietors tend to negatively affect competitive conditions to a lesser degree, or are restrictive, exclusionary, exploitative, or coercive to a lesser degree, than non-competes that apply to employees—and in light of substantial evidence of widespread employee misclassification—the Commission declines to exclude independent contractors from the definition of ''worker.'' For this reason, the Commission also declines to incorporate the ''ABC'' test or other tests designed to differentiate between independent contractors and employees.

IV. Section 910.2: Unfair Methods of Competition

A. Introduction

1. Overview of the Commission's Findings and Determinations

In the NPRM, the Commission proposed to categorically ban employers from using non-competes with all workers, including existing agreements. However, the Commission sought comment on whether it should adopt different standards for non-competes with senior executives, and, if so, how it should define senior executives.[376] Based on the totality of the evidence, including its review of the empirical literature, its review of the full comment record, and its expertise in identifying practices that harm competition, the Commission in this final rule finds that non-competes with all workers are an unfair method of competition—although its rationale differs with respect to workers who are and are not senior executives.

The final rule provides that it is an unfair method of competition—and therefore a violation of section 5—for employers to, *inter alia,* enter into non-competes with workers on or after the final rule's effective date.[377] The Commission thus adopts a comprehensive ban on new non-competes with all workers. With respect to existing non-competes, *i.e.,* non-competes entered into before the final rule's effective date, the Commission adopts a different approach for senior executives[378] than for other workers.

[374] U.S. Treasury Dep't, Report, *The State of Labor Market Competition* (Mar. 7, 2022) (hereinafter ''Treasury Labor Market Competition Report'').

[375] Employee or Independent Contractor Classification Under the Fair Labor Standards Act, 89 FR 1638, 1735 (Jan. 10, 2024).

[376] NPRM at 3519.

[377] *See* § 910.2(a)(1)(i) and § 910.2(a)(2)(i).

[378] *See* § 910.1 (defining ''senior executive'').

Existing non-competes with senior executives can remain in force; the final rule does not cover them.[379] For workers who are not senior executives, existing non-competes are no longer enforceable after the final rule's effective date.[380] Employers must provide such workers with existing non-competes notice that the non-competes will not be enforced after the final rule's effective date.[381]

Specifically, with respect to workers who are not senior executives, the Commission determines that it is an unfair method of competition for a person to enter into or attempt to enter into a non-compete clause; enforce or attempt to enforce a non-compete clause; or represent to the worker that the worker is subject to a non-compete clause.[382] The Commission finds that with respect to these workers, these practices are unfair methods of competition in several independent ways:

- The use of non-competes is restrictive and exclusionary conduct that tends to negatively affect competitive conditions in labor markets.
- The use of non-competes is restrictive and exclusionary conduct that tends to negatively affect competitive conditions in product and service markets.
- The use of non-competes is exploitative and coercive conduct that tends to negatively affect competitive conditions in labor markets.
- The use of non-competes is exploitative and coercive conduct that tends to negatively affect competitive conditions in product and service markets.

In contrast, with respect to senior executives, the Commission determines that it is an unfair method of competition for a person to enter into or attempt to enter into a non-compete clause; enforce or attempt to enforce a non-compete clause entered into after the effective date; or represent that the senior executive is subject to a non-compete clause, where the non-compete clause was entered into after the effective date. The Commission does not find that non-competes with senior executives are exploitative and coercive. With respect to senior executives, the Commission finds that non-competes are unfair methods of competition in two independent ways:

- The use of non-competes is restrictive and exclusionary conduct that tends to negatively affect competitive conditions in product and service markets.
- The use of non-competes is restrictive and exclusionary conduct that tends to negatively affect competitive conditions in labor markets.

The final rule allows existing non-competes with senior executives to remain in force. Because the harm of these non-competes is principally that they tend to negatively affect competitive conditions (rather than exploiting or coercing the executives themselves), and due to practical concerns with extinguishing existing non-competes for such executives, the final rule prohibits employers only from entering into or enforcing new non-competes with senior executives.

Parts IV.B and IV.C set forth the findings that provide the basis for the Commission's determinations that the foregoing practices are unfair methods of competition under section 5 for these two categories of workers, respectively.[383] In these sections, the Commission also describes and responds to comments regarding the preliminary findings in the NPRM that informed its preliminary determinations related to unfair methods of competition.

2. Analytical Framework for Assessing Empirical Evidence

Before turning to the basis for its findings, the Commission describes the analytical framework it has applied in assessing the empirical evidence on non-competes. In the NPRM, the Commission discussed the existing empirical literature on non-competes and its assessment of those studies, including its preliminary view of which studies were more robust and thus should be given more weight.[384] In response, some commenters argued the Commission gave too much weight to certain studies or too little weight to others.[385]

The Commission notes that the methodologies of empirical studies on the effects of non-competes vary widely. In this final rule, based on the Commission's longstanding expertise assessing empirical evidence relating to the effects of various practices on competition, the Commission gives more weight to studies with methodologies that it finds are more likely to yield accurate, reliable, and precise results. In evaluating studies, the Commission utilized the following five principles that reflect best practices in the economic literature.

First, the Commission gives more weight to studies examining the effects of a change in legal status or a change in the enforceability of non-competes, and less weight to studies that simply compare differences between workers who are subject to non-competes and those who are not. Studies that look at what happens before and after a change in State law that affects the enforceability of non-competes provide a reliable way to study the effects of the change. This is especially true when only the enforceability of non-competes changes, and not other factors affecting firms and workers. If other substantial changes do not also occur around the same time, this study design often allows the researcher to infer that the change caused the effects—since the likelihood that confounding variables are driving the effects or outcomes is minimal.[386]

In contrast, other studies of the use of non-competes compare a sample of workers who are subject to non-competes with a sample of workers who are not subject to non-competes. The shortcoming of these studies is that they cannot easily differentiate between correlation and causation. For example, if such a study shows that workers with non-competes earn more, there could be many confounding reasons for this result. For example, employers may be more likely to enter into non-competes with workers who earn more. In contrast, a study showing that workers' earnings increase or decrease when non-

[379] *See* Part IV.C.3.

[380] *See* § 910.2(a)(1)(ii) and § 910.2(a)(1)(iii).

[381] *See* § 910.2(b).

[382] *See* § 910.2(a)(1).

[383] In addition to the findings described in Parts IV.B and C, the Commission finds that the use of non-competes by employers substantially affects commerce as that term is defined in section 5 and burdens a not insubstantial portion of commerce. The findings in Parts IV.B and C apply with respect to senior executives and other workers, whether considered together or respectively. The evidence establishes that non-competes affect labor mobility, workers' earnings, new business formation, and innovation, including empirical evidence specifically identifying cross-border effects with respect to earnings, *see infra* notes 464–468 and accompanying text, and innovation, *see infra* note 563 and accompanying text.

[384] *See* NPRM at 3484–93.

[385] The Commission discusses comments addressing specific studies in Parts IV.B, IV.C, and IV.D.

[386] In Parts IV.B and C, the Commission describes how these ''enforceability'' studies show that increased enforceability of non-competes results in various harms, such as reduced earnings, new business formation, and innovation. Notably, the available evidence also shows that workers are chilled from engaging in competitive activity even where a non-compete is likely unenforceable—for example, because they are unaware of the law or unable to afford a legal battle against the employer. *See* Part IV.B.3.a.i. The fact that many workers may not adjust their behavior in response to changes in State-level enforceability of non-competes suggests that the final rule could result in even greater effects than those observed in the research, particularly because it would require employers to provide workers with notice that their non-compete is no longer in effect, which would help correct for workers' lack of knowledge of the law. *See* § 910.2(b).

competes are made more or less enforceable provides much stronger evidence regarding the effect of non-competes, in isolation. Researchers studying non-competes are aware of this bias and frequently caution that estimates of the correlation between outcomes and the use of non-competes should not be misinterpreted as causal.[387]

Second, the Commission gives more weight to studies examining the effects of changes in non-compete enforceability and less weight to studies that simply compare economic outcomes between States where non-competes are more enforceable and States where non-competes are less enforceable. This latter category of studies is known as ''cross-sectional studies of enforceability.'' Like studies based on the use of non-competes, these cross-sectional studies of enforceability cannot easily differentiate between correlation and causation. This is because differences between States that are unrelated to non-competes and their enforceability can easily pollute comparisons. For example, non-competes are less enforceable in California than in Mississippi, and the cost of living is higher in California than in Mississippi. However, the difference in the cost of living is likely to be due to underlying differences between the economies and geographies of the two States, rather than being attributable to non-competes. In contrast, studies examining how changes in enforceability of non-competes affect various outcomes—studies that look at what happens within States before and after a change in State law that affects the enforceability of non-competes—allow researchers to infer that the change caused the effects.[388]

Despite having this limitation, the Commission believes that cross-sectional studies of enforceability are still superior to the ''use'' studies described under the first principle. This is because although comparisons of different States may have unreliable results due to confounding variables—depending on which States are compared—''use'' studies are inherently unreliable due to confounding effects. For example, because employers enter into non-competes more often with highly paid workers, all ''use'' studies related to worker earnings are inherently unreliable, although studies that utilize data on the use of non-competes but employ a design that plausibly identifies a causal effect may be less unreliable.

Third, the Commission gives more weight to studies assessing changes in the enforceability of non-competes in multiple States. This reduces the possibility that the observed change in economic outcomes was driven by an idiosyncratic factor unique to a particular State. For example, assume State X changed its laws to make non-competes less enforceable, and new business formation subsequently increased compared with other States. However, around the same time it changed its non-compete law, State X also enacted legislation to provide attractive tax incentives to entrepreneurs. It would be difficult to isolate the effect of the change in non-compete law from the effect of the tax law change. For this reason, the Commission gives more weight to studies that analyze the effects of multiple changes in enforceability. For example, if a study shows that, compared with other States that did not change their non-compete laws, new business formation rose not only in State X, but also in several other States that changed their laws to make non-competes less enforceable, the Commission would be more confident inferring that changes in non-compete law caused these effects.

Fourth, the Commission gives more weight to studies that use sophisticated, nuanced measures of enforceability, such as non-binary measures of non-compete enforceability that capture multiple dimensions of non-compete enforceability. This fourth guiding principle ensures accuracy and granularity in the measurement of non-compete enforceability.

A variety of different factors affect the enforceability of non-competes from State to State, including (among others) the permissible geographic scope and duration of non-competes and how high the employer's burden of proof is to establish that a non-compete is enforceable. Given the different factors involved, the overall level of non-compete enforceability from State to State falls along a spectrum; it is not as simple as whether non-competes are enforceable or not. Thus, scales which use binary measures miss nuance between States. This is true for enforceability overall (*e.g.,* scales which simply assign States to ''enforcing'' or ''non-enforcing'' categories) and for elements of enforceability (*e.g.,* scales which assess whether a non-compete is enforceable if a worker is fired with a yes or no answer). While no scale is perfect, scales which allow for multidimensionality and granularity measure non-compete enforceability (and thus the effects that stem from it) with a higher degree of accuracy.[389]

Fifth, the Commission gives more weight to studies in which the outcome studied by the researchers is the same as the outcome the Commission is interested in or is an effective proxy for the outcome the Commission is interested in. It gives less weight to studies that use ineffective proxies. For example, some outcomes are relatively easy to study. There is extensive data on workers' earnings at the State level, so researchers can simply use this data to study how changes in non-compete enforceability affect workers' earnings in a State. Other outcomes, however, may be more challenging to quantify directly, and thus researchers may use proxies for understanding the effect they are studying. For example, there is no single metric that measures innovation in the economy. For this reason, to learn about how non-competes affect innovation, a researcher might study the effect of changes in non-compete enforceability on the number of patents issued in the State as a proxy for innovation. However, proxies can sometimes be ineffective or inapt. For example, a study that analyzes the effect of non-compete enforceability on the number of patents issued is generally a weaker proxy for innovation than a study that also takes into account the quality of patents issued. For this reason, the Commission gives more weight to studies that measure the exact outcome of interest or studies that use effective proxies.

While these five guiding principles are important indicators of the relative strength of empirical studies evaluated by the Commission for the purpose of this final rule, the Commission's assessment of empirical studies was holistic and relied on its economic expertise. In addition to the guiding principles described in this Part IV.A.2, the Commission's holistic, expert assessment of the empirical evidence also included considering characteristics of studies important in any context, such as data quality, statistical precision, and other factors.

[387] *See, e.g.,* Starr, Prescott, & Bishara, *supra* note 68 at 73 (''Our analysis of the relationships between noncompete use and labor market outcomes . . . is best taken as descriptive and should not be interpreted causally.''); Johnson & Lipsitz, *supra* note 80 at 711 (''These regressions [of firm investment on non-compete use] should be interpreted as correlations rather than causation, since the decisions to make these investments and use [non-competes] are made jointly.'').

[388] Matthew S. Johnson, Kurt J. Lavetti, & Michael Lipsitz, *The Labor Market Effects of Legal Restrictions on Worker Mobility,* Nat'l Bureau of Econ. Rsch. 2 (2023) (''. . . cross-sectional variation in enforceability might be correlated with other unobserved differences across states.'').

[389] Jonathan M. Barnett & Ted Sichelman, *The Case for Noncompetes,* 87 U. Chi. L. Rev. 953 (2020).

In some instances, the Commission cites studies beyond those discussed in the NPRM. The Commission cites such studies only where they check or confirm analyses discussed in the NPRM, or where the Commission is responding to comments raising them. The Commission's findings do not rest on these studies, however, and they are not necessary to support its findings.

B. Section 910.2(a)(1): Unfair Methods of Competition—Non-Competes With Workers Other Than Senior Executives

The Commission now turns to the basis for its findings that non-competes with workers other than senior executives are an unfair method of competition. As explained in Part II.F, under section 5, the Commission assesses two elements: (1) whether the conduct is a method of competition, as opposed to a condition of the marketplace, and (2) whether it is unfair, meaning that it goes beyond competition on the merits. The latter inquiry has two components: (a) whether the conduct has indicia of unfairness, and (b) whether the conduct tends to negatively affect competitive conditions. These two components are weighed according to a sliding scale.

Non-competes with workers other than senior executives satisfy all the elements of the section 5 inquiry.[390] As described in Part IV.B.2, such non-competes are facially unfair because they are restrictive and exclusionary, and because they are exploitative and coercive. And as described in Part IV.B.3, such non-competes tend to negatively affect competitive conditions in labor markets and markets for products and services. As explained in Part II.F, the legal standard for an unfair method of competition under section 5 requires only a tendency to negatively affect competitive conditions. The inquiry does not turn on whether the conduct directly caused actual harm in a specific instance. Here, the tendency of non-competes to impair competition is obvious from their nature and function. And even if this tendency were not facially obvious, the evidence confirms that non-competes do in fact have a negative effect on competitive conditions.

The Commission finds that the empirical research described in this Part IV.B supports findings related to workers other than senior executives.[391]

1. The Commission Finds That Non-Competes Are a Method of Competition, Not a Condition of the Marketplace

With respect to the first element, whether the conduct is a method of competition, the Commission preliminarily found in the NPRM that non-competes are a method of competition under section 5 because they are specific conduct undertaken by an actor in a marketplace, as opposed to merely a condition of the marketplace.[392] No commenters disagreed with this finding, and the Commission reaffirms its preliminary finding that non-competes are a method of competition.

2. The Commission Finds That Non-Competes Are Facially Unfair Conduct

The Commission finds that non-competes are facially unfair conduct under section 5 because they are restrictive and exclusionary. The Commission further finds that non-competes are facially unfair under section 5 because they are exploitative and coercive.

a. Non-Competes Are Restrictive and Exclusionary Conduct

Under section 5, indicia of unfairness may be present where conduct is restrictive or exclusionary, provided that the conduct also tends to negatively affect competitive conditions.[393] In the NPRM, the Commission explained that non-competes are restrictive conduct.[394] No commenters disputed this analysis, and the Commission reaffirms its preliminary finding that non-competes are restrictive.

The restrictive nature of non-competes is evident from their name and function: non-competes restrict competitive activity. They do so by restricting a worker's ability to seek or accept other work or start a business after the worker leaves their job, and by restricting competitors from hiring that worker. Because non-competes facially restrict competitive activity, courts have long held they are restraints of trade and proper subjects for scrutiny under the antitrust laws.[395]

The restrictions that non-competes impose on workers are often substantial. Non-competes can severely restrict a worker's ability to compete against a former employer. For most workers, the most natural alternative employment options are jobs in the same geographic area and in the same field. These are the very jobs that non-competes typically prevent workers from taking. Furthermore, for most workers, the most practical entrepreneurship option is starting a business in the same field. This is the very opportunity that non-competes typically prevent workers from pursuing. Moreover, the record before the Commission reflects that non-competes are often so broad as to force a worker to sit out of the labor market altogether.

In the NPRM, the Commission used the term ''restrictive'' to encompass both restrictive and exclusionary conduct.[396] In this final rule, in addition to finding that they are restrictive conduct, the Commission separately finds that non-competes are exclusionary conduct because they tend to impair the opportunities of rivals. Where a worker is subject to a non-compete, the ability of a rival firm to hire that worker is impaired. In addition, where many workers in a market are subject to non-competes, the ability of firms to expand into that market, or entrepreneurs to start new businesses in that market, is impaired.

For the foregoing reasons, the Commission finds that the use of non-competes with workers other than senior executives is facially unfair under section 5 because it is conduct that is restrictive or exclusionary.

b. Non-Competes Are Exploitative and Coercive Conduct

Conduct may violate section 5 where it is exploitative or coercive and tends to negatively affect competitive conditions.[397] Indeed, where conduct is exploitative or coercive, it evidences

[390] For the sake of readability, in this Part IV.B, the Commission refers to non-competes with workers other than senior executives as ''non-competes.''

[391] Some of the studies described in Part IV.B analyze non-competes between employers and workers across the labor force. Other studies analyze non-competes with particular populations of workers. In each of the studies described in Part IV.B, non-competes with workers other than senior executives represented a large enough segment of the sample that the study supports findings related to the effects of non-competes for such workers. Studies that focus primarily on non-competes for senior executives are described in Part IV.C, which explains the Commission's findings related to non-competes with senior executives.

[392] NPRM at 3504.

[393] *See* Part II.F.

[394] NPRM at 3500.

[395] *See, e.g., Am. Tobacco Co.,* 221 U.S. 106, 181–83 (1911) (holding that several tobacco companies violated Sections 1 and 2 of the Sherman Act due to the collective effect of six of the companies' practices, one of which was the ''constantly recurring'' use of non-competes); *Newburger, Loeb & Co., Inc.,* 563 F.2d 1057, 1082 (2d Cir.) (''Although such issues have not often been raised in the federal courts, employee agreements not to compete are proper subjects for scrutiny under section 1 of the Sherman Act. When a company interferes with free competition for one of its former employee's services, the market's ability to achieve the most economically efficient allocation of labor is impaired. Moreover, employee-noncompetition clauses can tie up industry expertise and experience and thereby forestall new entry.'') (internal citation omitted).

[396] NPRM at 3500 (''Non-competes also restrict rivals from competing against the employer to attract their workers.'').

[397] *See* Part II.F.

clear indicia of unfairness, and less may be necessary to show a tendency to negatively affect competitive conditions.[398]

In the NPRM, the Commission preliminarily found that non-competes with workers other than senior executives were exploitative and coercive because in imposing them on workers, employers take advantage of their unequal bargaining power.[399] The Commission also preliminarily found that non-competes are exploitative and coercive at the time of the worker's potential departure, because they force a worker to either stay in a job the worker wants to leave or force the worker to bear other significant harms and costs, such as leaving the workforce or their field for a period of time; relocating to a different area; violating the non-compete and facing the risk of expensive and protracted litigation; or attempting to pay the employer to waive the non-compete.[400]

The Commission received an outpouring of comments on the question of whether non-competes were exploitative or coercive. Thousands of workers described non-competes as pernicious forces in their lives that took advantage of their lack of bargaining power and forced them to make choices detrimental to their finances, their careers, and their families. Above all, the predominant themes that emerged from the comments were powerlessness and fear.

Thousands of workers reported feeling powerless to avoid non-competes, either because the worker needed the job or because non-competes were pervasive in the worker's field. Hundreds of workers reported non-competes were unilaterally imposed on them. Workers overwhelmingly reported that they did not bargain over non-competes, did not receive compensation for non-competes, and were not represented by counsel in connection with non-competes, with only rare exceptions.

And hundreds of workers reported that even where they wanted a job with better pay or working conditions, or to strike out on their own, the fear of litigation from a deep-pocketed employer or the fear of being without work prevented them from doing so. Hundreds of workers described how this fear coerced them into remaining in jobs with poor conditions or pay, including dangerous or toxic work environments; into leaving an industry or profession that they invested, trained, studied, or were experienced in, damaging or derailing their careers; into moving away from their home, uprooting or separating their families; or into enduring long-distance commutes, which made it harder to care for and spend precious time with their loved ones. Many workers described how this fear hung above them even if they thought the non-compete was overbroad and probably unenforceable under State law, because having to defend a lawsuit from an employer for any length of time would devastate their finances.

Based on the entirety of the record, for the following reasons, the Commission finds non-competes with workers other than senior executives are exploitative and coercive because they are unilaterally imposed by a party with superior bargaining power, typically without meaningful negotiation or compensation, and because they trap workers in worse jobs or otherwise force workers to bear significant harms and costs.

i. Non-Competes With Workers Other Than Senior Executives Are Unilaterally Imposed

The Commission finds that employers almost always unilaterally impose non-competes, exploiting their superior bargaining power to impose—without any meaningful negotiation or compensation—significant restrictions on workers' abilities to leave for better jobs or to engage in competitive activity.

The Commission finds that employers have significantly more bargaining power than workers. Most workers, especially workers other than senior executives, depend on income from their jobs to get by—to pay their rent or mortgage, pay their bills, and put food on the table. The loss of a job or a job opportunity can severely damage workers' finances and is far more likely to have serious financial consequences for a worker than the loss of a worker or a job candidate would have for most employers.

The Treasury Department, in a report based on an extensive literature review, finds that firms generally have considerable labor market power.[401] The report states that concentration in particular industries and locations can increase employers' labor market power.[402] However, the report explains that, even in the absence of concentration, firms have significant labor market power due to a variety of factors.

As the report notes, some of these factors are inherent in the firm-worker relationship. The report states that workers are at an informational disadvantage relative to firms, often not knowing what other workers earn or the competitive wages for their labor.[403] The report states further that workers often have limited or no ability to switch locations and occupations quickly and may lack the financial resources to support themselves while they search for jobs that pay more and better match their skills and abilities.[404] According to the report, these conditions often enable firms to exert market power even in labor markets that are not highly concentrated.[405]

In addition to factors inherent to the employer-worker relationship, the report concludes that firms use a wide range of practices to restrain competition for workers, including sharing wage information and conspiring to fix wages with other firms; agreeing not to hire other firms' workers; and adopting non-competes, mandatory arbitration agreements, and overbroad NDAs.[406] The report also states that practices such as outsourcing and worker misclassification have further diminished workers' market power.[407] Overall, the report finds that employers' labor market power has resulted in a 20% decrease in wages relative to the level in a fully competitive market.[408]

The Commission finds that employers are able to exploit their considerable labor market power—and indeed routinely do so—with respect to non-competes imposed on workers other than senior executives. Employers are repeat players likely to have greater experience and skill at bargaining than individual workers in the context of negotiating employment terms such as non-competes.[409] Research has found that employers present non-competes in standard-form contracts,[410] which workers are unlikely to read,[411] and that

[398] *See id.*

[399] NPRM at 3502–04.

[400] *Id.* at 3504.

[401] Treasury Labor Market Competition Report, *supra* note 374 at i–ii.

[402] *Id.* at i.

[403] *Id.*

[404] *Id.*

[405] *Id.*

[406] *Id.*

[407] *Id.* at ii.

[408] *Id.*

[409] *See, e.g., Samuel Stores, Inc.* v. *Abrams,* 108 A. 541, 543 (Conn. 1919); *Sunder Energy, LLC* v. *Jackson,* 305 A.3d 723, 753 (Del. Ct. Chancery 2023).

[410] Starr, Prescott, & Bishara, *supra* note 68 at 72 (''Taken together, the evidence in this section indicates that employers present (or employees receive) noncompete proposals as take-it-or-leave-it propositions.'').

[411] *See, e.g.,* Todd D. Rakoff, *Contracts of Adhesion: An Essay in Reconstruction,* 96 Harv. L. Rev. 1173 (1983); Russell Korobkin, *Bounded Rationality, Standard-Form Contracts, and*

Continued

workers rarely bargain over non-competes and rarely seek the assistance of counsel in reviewing non-competes.[412] Many workers also lack the legal training or legal knowledge necessary to understand whether a particular non-compete is enforceable or the consequences of entering into a non-compete. The available evidence indicates that many workers are not aware of the applicable law governing non-competes or their rights under those laws.[413] Research has also found that employers exploit their power over workers by providing them with non-competes after they have accepted the job offer—and in many cases, on or after their first day of work—when the worker's negotiating power is at its weakest, since the worker may have turned down other job offers or left their previous job.[414]

The comment record provides strong support for the Commission's finding that non-competes are coercive and exploitative because they are typically unilaterally imposed by employers on workers other than senior executives. Illustrative examples of the comments the Commission received include the following:

- I am a practicing OB/GYN physician in Shreveport, LA. . . . I was put into a non-negotiable, vague non-compete with NO expiration date. . . . I needed a job. I was in a large amount of debt with accumulating interest during my four years of residency with a minimal salary. Honestly, I could not afford an attorney. So naively I trusted that the people that had been training me for the past 4 years would not take advantage of me in a contract. I did not have the ability to seek advice on ''how'' to negotiate a contract with my mentors since my mentors were the ones who wrote the contract.[415]
- As [a] physician who recently negotiated a new contract, I support FTC changes to the non-compete rules. . . . All three institutions [I considered working for] had unreasonable and onerous non-competes. Essentially making it impossible to get another job in the entire state of NJ—not just a few mile radius but two thirds of the state. . . . Non-competes are never negotiable even when hiring a lawyer to review and negotiate the contract. Hospitals refused to negotiate on the majority of the contract citing it is [an] across the board provision that cannot be altered.[416]
- I'm a worker that has had to consider whether to take a job that requires signing a no-compete agreement . . . . Several times in my career, after weeks of interviewing and salary negotiation, I've found myself facing a required no-compete agreement that would drastically limit my future career options and negotiating power. Several times I've accepted these agreements because I had already turned down competing offers and found myself with limited options.[417]
- I'm a project manager at an Interior Design & Home Staging company in Manhattan; we're the largest staging company on the East Coast. After I accepted my job offer and went in to file paperwork, I was very briefly walked through what this non-compete means (the details were not made entirely clear; I believe they left it intentionally murky) and it was buried deep in the new employee rules and regulations packet I needed to read and sign at my onboarding. I personally am very against these agreements because, as mine states, I cannot work with ''a competing staging company'' or for any of the clients of my current company. Again, we're the largest staging firm on the east coast and have a lot of clients (we do over 100 stagings per year). Essentially, I am completely shut out of working in the industry in NYC as there are only a handful of other staging companies that can pay me a living wage to do so.[418]
- You might say that we might be able to negotiate out of a non-compete in our contract, but that is simply not true. In my hospital, I was already established, owning a house and having kids in school in a spouse in a career when the Hospital came forward and sit on my next contract renewal that I had no choice, but to sign a noncompete. They had me over a barrel. At my next contract negotiation, I try to negotiate out of the noncompete, with less salary or less benefits, and it was a nonstarter. There is zero tolerance for negotiating out of the noncompete.[419]
- At the end of 2018, as a Manager at a small business (150 employees) in a niche technology industry, I was offered shares in our company as we were acquired by a Private Equity firm. . . . I worked with a company-provided attorney on an Employment Agreement. This agreement offered a 6-month severance with a 1-year non-compete period, which I negotiated down to a 6-month non-compete to match the severance period. Later that month, I was sent an additional, previously unseen 120-page Share Agreement that governed how I would vest the shares I had earned. I didn't realize it at the time, but buried toward the end of this document was another non-compete that had a much longer timeframe dictated—1 year from when I no longer held any shares. As it would potentially take up to 6 years for the company to sell again, that meant an incredibly long and indefinite sounding time period. I was given only one business day to review this agreement, and was sent a signature packet the following day. I honestly thought I was signing my Employment Agreement negotiated with a company attorney, not the share agreement that neither myself nor the attorney had reviewed, and which I had only received the day prior.[420]
- Desperate to obtain an entry level job in the Accounting field in which I am currently obtaining my Associate's degree, I was presented with an offer of employment and a non-compete agreement contract to sign. Because I needed to pay rent, I signed it.[421]
- On the first day of my husband's employment, without prior notice, an extensive 2 year non-compete clause was put in his employment contract and while it was noted within the clause he could seek counsel, when you are in the middle of your first day of work it's not practical. In addition, for most people, if it is your first experience with a non-compete, you likely do not have the funds to pay a $750 per hour lawyer to advise and negotiate on your behalf, nor realize the possible long-term consequences.[422]

Many commenters agreed with the Commission's preliminarily finding that employers generally have considerable labor market power. Even commenters opposing the NPRM did not generally dispute the notion that there is unequal bargaining power between employers and workers. Many workers stated that non-competes are pervasive in their industry, meaning they could not find a job without one. Many commenters stated that high wages or skills do not automatically translate into more bargaining power or sufficiently mitigate the harms from non-competes, especially in concentrated markets or markets where so many employers use non-competes that workers effectively have no choice but to sign them. Commenters also said that underrepresented groups may have even less bargaining power to negotiate non-competes and are less likely to have the resources for litigation, which could have an increased deterrent effect on worker mobility.

Hundreds of commenters stated that workers are rarely, if ever, able to negotiate their non-competes because non-competes are typically presented in a take-it-or-leave-it fashion. These comments spanned both lower-wage workers and workers in high-wage industries.[423] Workers often stated that they were ''forced'' to sign a non-

Unconscionability, 70 U. Chi. L. Rev. 1203, 1217 (2003).

[412] Starr, Prescott, & Bishara, *supra* note 68 at 72.

[413] J.J. Prescott & Evan Starr, *Subjective Beliefs About Contract Enforceability,* Forthcoming, J. L. Stud. 10–11 (2022).

[414] Marx (2011), *supra* note 81 at 706.

[415] Individual commenter, FTC–2023–0007–4414.

[416] Individual commenter, FTC–2023–0007–10547.

[417] Individual commenter, FTC–2023–0007–12428.

[418] Individual commenter, FTC–2023–0007–12480.

[419] Individual commenter, FTC–2023–0007–14706.

[420] Individual commenter, FTC–2023–0007–2347.

[421] Individual commenter, FTC–2023–0007–2600.

[422] Individual commenter, FTC–2023–0007–5933.

[423] Industries that the Commission considered as higher wage industries included but were not limited to engineers, entertainment (namely on-air talent), entrepreneurs, financial services, dentists, physicians, sales workers, tech industry workers, and veterinarians. Industries were assessed as high wage based on BLS occupational wage data. BLS, *Occupational Employment and Wage Statistics, https://www.bls.gov/oes/tables.htm* (based on the May 2022 National XLS table).

compete. Very few workers said they were able to decline signing a non-compete and still be hired or employed. An employment law firm also agreed with the Commission and stated that non-competes are rarely subject to negotiation.

Confirming the research described in this Part IV.B.2.b.i, many workers—including highly paid and highly skilled workers—stated that they did not receive notice that they would be required to sign a non-compete until after accepting a job offer. Some workers said they were told of the non-compete after accepting the job but before starting work. Many workers who described when they were notified of a non-compete said it was on their first day of work or even later. Many workers stated that they were required to sign their non-compete after a merger or acquisition—*i.e.,* after they were already on the job but there was a change in ownership of the company. For example, a trade organization stated that it is common for the purchaser of a business to impose non-competes on its workers, which may trap workers in an organization different from the one they originally agreed to work for. An employment law firm commented that even highly paid or highly skilled workers do not always receive notice of non-competes with the employment offer.

Many workers also stated that non-competes are often hidden or obscured. Several workers said their non-compete was buried in other paperwork or confusingly worded or vague. Some commenters stated that their employer refused to allow them to have a copy of their non-compete. Many workers said their employers gave them misleading or incorrect information about the terms or enforcement of non-competes. Each of the above categories included not only workers from low-wage industries, but also workers from high-wage industries. While these practices appear to be commonplace, based on the comments, the Commission also notes that even workers who knew about non-competes before accepting the job offer—and who did not report being misled about the non-compete—did not report bargaining or negotiating over it.

Only a small number of workers reported any negotiating over non-competes. For example, a sales worker said they were able to negotiate a non-compete, though that worker still supported the proposed rule. A surgeon group stated hospitals were willing to negotiate over non-competes, but that hospitals use the non-competes as a negotiating tactic to drive down surgeon salaries.

Few workers who submitted comments reported being compensated for signing a non-compete. Among those workers who did report receiving compensation, most still said they considered their non-competes to be exploitative or coercive. For example, some workers said they were laid off and then required to sign a non-compete as a condition for receiving severance. A few workers said their employer had threatened to withhold their commissions and/or pay on departure if they did not sign a non-compete. One worker reported never receiving the compensation associated with a non-compete, because they were terminated two months after signing.

In addition, the Commission finds that employers frequently impose non-competes even when they are unenforceable under State law. An economist suggested that non-competes may be used in States in which they are unenforceable because the employer hopes the State's policy might change, or the employer might be able to forum-shop to apply the law of another jurisdiction more favorable to non-competes. Some commenters stated that firms may remind workers they are subject to a non-compete upon departure even when those non-competes are unenforceable because they hope that workers and competitors will abide by them.

These comments that employers often use unenforceable non-competes are supported by research finding that employers frequently use non-competes even when they are unenforceable under State law.[424] This research suggests that employers may believe workers are unaware of their legal rights, or that employers may be seeking to take advantage of workers' lack of knowledge of their legal rights or the challenges workers face enforcing their rights.

A far smaller number of commenters—a group that included many businesses and trade organizations, and very few workers—argued that non-competes were not exploitative or coercive. An industry organization said non-competes are understandable to a layperson with respect to their geographic scope, time in effect, and industry to which they apply, while an alternative trade secret case would be more complex. But even if workers understand the basic terms of non-competes, that does not alter the Commission's core concern that non-competes are exploitative and coercive because they take advantage of unequal bargaining power between employers and workers and force workers to stay in jobs they want to leave or otherwise bear significant harms or costs. It also does not alter the Commission's concern that non-competes tend to negatively affect competitive conditions. Moreover, the Commission notes that the available evidence indicates that many workers are not aware of the applicable law governing non-competes or their rights under those laws.[425] In addition, many commenters stated that non-competes were not disclosed to them before they started their job. Furthermore, the Commission addresses why trade secret law is a less restrictive alternative for protect employers' legitimate interests in Part IV.D.2.

A few commenters stated that unequal bargaining power does not constitute an unfair method of competition. In response, the Commission notes that it does not find that unequal bargaining power itself is an unfair method of competition; rather, unequal bargaining power informs its analysis of exploitation and coercion.

The comment record indicates that while some highly paid workers may seek the assistance of counsel when negotiating non-competes, many do not. Commenters did not present studies or other quantitative evidence that undermines the finding in Starr, Prescott, & Bishara that less than 8% of workers seek assistance of counsel in connection with non-competes.[426] The Commission thus finds that the vast majority of workers lack assistance of counsel in connection with entering non-competes. The Commission believes that its definition of senior executives, discussed in Part IV.C.4, captures those workers who are most likely to seek assistance of counsel. To the extent any other individual workers seek assistance of counsel and/or are able to actually bargain over non-competes sufficient that a given non-compete is not exploitative and coercive, the Commission still finds that such non-competes are unfair methods of competition for the independent reason that they are restrictive and exclusionary conduct that tends to negatively affect competitive conditions.

Overall, the comments provide strong support for the Commission's finding that, with respect to workers other than senior executives, employers almost always unilaterally impose non-competes—exploiting their superior bargaining power to significantly restrict workers' abilities to leave for better jobs or engage in competitive activity.

[424] Starr, Prescott, & Bishara, *supra* note 68 at 81.

[425] *See supra* note 413 and accompanying text.

[426] Starr, Prescott, & Bishara, *supra* note 68 at 72.

ii. Non-Competes With Workers Other Than Senior Executives Trap Workers in Jobs or Force Them to Otherwise Bear Significant Harms and Costs

The Commission finds that non-competes are exploitative and coercive because they force workers to either stay in jobs they want to leave or bear other significant harms and costs, such as leaving the workforce or their field for a period of time; relocating out of their area; or violating the non-compete and facing the risk of expensive and protracted litigation. In addition, the Commission finds non-competes exert a powerful *in terrorem* effect: they trap workers in jobs and force them to bear these harms and costs even where workers believe the non-competes are overbroad and unenforceable, due to workers' fear that having to defend a lawsuit from their employer for any length of time would devastate their finances or ruin their professional reputations.

The comment record provides strong support for this finding. Many workers submitted comments supportive of the Commission's preliminary finding that non-competes coerce workers into remaining in their current jobs. Many workers reported staying in their jobs because they feared harm to their careers if they were forced out of their field; feared having to relocate or endure a lengthy commute due to a non-compete; or feared their non-competes would cause them to be unemployed if they left. Several workers reported they were unable to take a specific desired job because of a non-compete. Many workers recounted how non-competes trapped them in jobs with poor working conditions or where they were subject to illegal conduct, including sexual harassment.[427] Some workers said they were subject to particularly broad, even global, non-competes, meaning leaving their field was their only option if they left their current job. These comments spanned both lower-wage workers and workers in high-wage industries.

Illustrative examples of the comments the Commission received include the following:

- I am a journalist who has been forced to move across the country three times, and leave my field entirely for one year, in order to comply with stringent non-compete agreements. . . . In [one] situation, I was stuck working for abusive management who fostered a toxic and abusive workplace, and I had to work there for more than a year until I could find a job in another city entirely because they had threatened to sue me under the non-compete if I left and worked for another local station. . . . [E]ven if these clauses are unenforceable, as we've all heard before, who can afford the legal representation to go up against a corporation and their lawyers when the lawsuit threat comes? My life would have been very different if I weren't trapped by non-competes at points in my career.[428]
- As a veterinarian I support the elimination of non-compete agreements. In our profession they still are overwhelmingly the normal expectation with contracts. . . . [C]ompanies use the fear of litigation to enforce them. As veterinary medicine very quickly becomes more corporate owned, basically they pit us as a singular employee against large corporations that have substantial means both financially and legally. No reasonable employee wants to take on that battle or even can financially take on that battle. So regardless if the clauses are 'unenforceable' they are enforced via intimidation. . . . When [my] job was a terrible fit and my boss ultimately ended up 'not renewing my contract' I was still left with a noncompete. This basically eliminated my ability to work within a reasonable distance of our home. I ended up commuting an hour and 15 minutes one way for 10 months until my husband, myself, and my very young child were able to move closer to my new job. While it was likely legally unreasonable in nature, I did not have the resources financially to even consider the legal battle that would have had to happen for reconsideration and I desperately needed an income to continue to pay the student debt that comes with being a young doctor. Furthermore I had a baby that needed my focus as well.[429]
- I was fired unjustly 11/2021 for declining the Covid vaccine. My medical and religious exemptions were both denied. In addition to this, I was required by my former employer contract to abide by the two-year 10 mile restrictive covenant. This greatly hindered my ability to find employment, and I was out of work for approximately three months. I could only find part-time work for a fraction of my former salary. Had I not had the noncompete clause, I could have found a full-time job almost immediately.[430]
- Unfortunately, the average dental school graduate has nearly $300,000 in student loan debt, and most new dentists are unable to make their practice-ownership dreams a reality immediately after residency. Thus, we rely on entry-level associate dentist positions to gain experience, pay off debt, and become fiscally/professionally prepared to become practice owners. Much to my dismay, upon interviewing for my first associate dentist position, I quickly realized how non-competes are being used in the dental profession to prevent vulnerable young dentists like myself from taking the next step in our careers. . . . Although dental associate positions come with relatively high compensation, it doesn't make this issue any less problematic.[431]
- My daughter had an inter-state non-compete enforced as a minimum wage medical scribe. Originally she was working with a medical scribe company in Indiana prior to Covid. Due to COVID and graduating from college she then moved to our home in Oregon. She applied for a medical scribe job in Oregon with a company that did not provide any scribe services in Indiana. But her original scribe company had 1 ''office'' they were providing scribe services to in Salem, Oregon. My daughter had applied with the local scribe company to provide services but when examined further found that her original scribe company from Indiana was going to enforce a $5000 non-compete buy-out fee on her to provide the services in Salem, Oregon that were within the sphere of restriction for her ''new'' local scribe opportunity.[432]

Many commenters explained that non-competes forced them to relocate and described the toll the relocation took on their families. Other commenters stated that their families have been forced to live apart, or they had been separated from elderly relatives, due to a non-compete forcing the relocation of one of the family members. Many commenters described how long commutes undertaken to avoid non-competes increased transportation costs and caused the worker to lose precious time with their families.

The comment record bolsters the Commission's finding that employers wield non-competes to coerce and exploit workers into refraining from competitive activity even where non-competes are unenforceable. Many workers explained that they—and others in their industry—abided by non-competes, even where they believed the non-compete was overbroad and likely unenforceable. According to a law firm specializing in executive compensation, even workers who can afford counsel may be unwilling to mount a long and uncertain legal battle to challenge a non-compete. The firm said employers almost always have deeper pockets and more access to counsel than individual workers, making workers more reluctant to litigate. Commenters further stated that employers may be able to deduct litigation costs as a business expense, giving them the wherewithal to enforce their non-competes.

Many workers with non-competes stated that they feared legal action from their employer or enormous legal fees if they left their current job, and most of those workers said they could not afford litigation. Workers also stated that they are reluctant to engage in litigation against an employer because it would harm their reputation in their industry.

Many workers reported being threatened with litigation over a non-

[427] These comments are addressed in greater detail in Part IV.B.3.a.iii.

[428] Individual commenter, FTC–2023–0007–0747.

[429] Individual commenter, FTC–2023–0007–2855

[430] Individual commenter, FTC–2023–0007–7561.

[431] Individual commenter, FTC–2023–0007–8858.

[432] Individual commenter, FTC–2023–0007–15249.

compete when they attempted to leave an employer. Some commenters said their non-competes contained additional clauses making litigation more difficult, such as attorneys' fee-shifting provisions or forced arbitration. Other workers feared having to pay financial penalties or feared having their compensation clawed back if their employer claimed they violated the non-compete. Each of the above comment categories included numerous comments from workers in high-wage industries.

Commenters asserted that employers have several advantages in litigation, further increasing the risk of challenging a non-compete. A commenter said even an extremely overbroad non-compete may be enforceable because a court can modify it to reduce its scope or duration. An employment attorney said employers who use overbroad non-competes to stifle competition suffer few if any negative consequences for doing so. The employment attorney further said that most employers do well even in a legal regime that nominally disfavors non-competes, due to the chilling effect of the threat of litigation. One researcher cited in the NPRM stated that non-competes have a powerful chilling effect because State laws generally do not prohibit employers from requiring employees to sign overbroad non-competes. Accordingly, the researcher recommended that non-competes be banned rather than restricted in scope, thereby preventing the possibility of lawsuits (and the threat thereof).

No commenters submitted studies or empirical evidence to contradict or otherwise call into question the research cited in the NPRM finding employers frequently use non-competes even when they are unenforceable under State law. Many commenters said they perceived non-competes to be a tool used to intimidate workers, and others specifically said they had been intimidated when their employers took legal action against other workers who left. These comments spanned workers in both lower-wage and high-wage industries.

The comments reflected that fields with high compensation levels were not immune from coercion and exploitation, and that, to the contrary, specialization can increase employers' ability to coerce and exploit workers. For example, some commenters said highly trained and/or specialized workers face heightened challenges in finding a job that does not violate a non-compete without relocating or become entirely unemployable, given the smaller number of such specialized jobs available. One commenter said that many workers are compensated highly because they are in a small field or have a niche skillset, meaning non-competes significantly limit their ability to find another job in their field. Some commenters in professions requiring advanced education also submitted comments stating that significant student loan debt decreased their bargaining power or increased the financial risk of attempting to change jobs. An employment law firm stated that highly paid or highly skilled workers in roles that are not limited to a single industry or business, such as finance or human resources, are more likely to be able to find employment in another industry, while those with training and expertise in a particular industry or type of business are at a greater risk of unemployment. Some medical organizations and others pointed out that non-competes can be particularly exploitative and coercive for professions such as physicians that require State licenses, credentials, and insurance, making relocation even more difficult.

A far smaller number of commenters claimed non-competes are not exploitative or coercive and do not trap workers in jobs or force workers to bear significant harms or costs. Several commenters argued that, because non-competes are often not exploitative and coercive at the time of contracting, they are also not exploitative and coercive at the time workers seek to leave their jobs. According to these commenters, to the extent a non-compete is bargained for and fairly compensated, that same non-compete does not become exploitative and coercive at the time of departure. In response, the Commission notes that commenters overwhelmingly reported workers rarely bargain in connection with, or receive compensation for, non-competes,[433] and the mere existence of compensation does not automatically make that compensation fair.

Some business and business association commenters contended that workers with higher earnings can more easily forgo wages to wait out non-competes, and thus do not feel forced to stay in their jobs. These commenters also argued that non-competes for these workers are often tied to equity or severance, which the worker can choose to forego if they want to compete. These comments are contrary to the extensive comment record indicating that even workers with higher earnings cannot afford to forgo compensation and feel forced to stay in jobs they want to leave due to non-competes. To the extent any such individual workers bargained for or received compensation for a non-compete, the Commission still finds that such non-competes are unfair methods of competition for the independent reason that they are restrictive and exclusionary conduct that tends to negatively affect competitive conditions.

Overall, the comments provide strong support for the Commission's finding that non-competes are exploitative and coercive because they trap workers in jobs or force them to bear significant harms and costs.

For the foregoing reasons, the Commission finds that non-competes with workers other than senior executives are exploitative and coercive and thus facially unfair under section 5.

3. The Commission Finds That Non-Competes Tend To Negatively Affect Competitive Conditions

Based on the Commission's expertise and after careful review of the rulemaking record, including the empirical research and the public comments, the Commission finds that non-competes tend to negatively affect competitive conditions in labor markets for the reasons explained in this Part IV.B.3.a. (As explained in Part IV.B.3.b, the Commission further finds that non-competes tend to negatively affect competitive conditions in markets for products and services.)

As explained in Part II.F, the legal standard for an unfair method of competition under section 5 requires only a tendency to negatively affect competitive conditions. The inquiry does not turn on whether the conduct directly caused actual harm in a specific instance. Here, the tendency of non-competes to impair competition is clear from their nature and function. In any event, the evidence confirms that non-competes do in fact have a negative effect on competitive conditions.

The Commission turns now to the significant evidence of harm to competition in labor markets from non-competes, including evidence of suppressed labor mobility, suppressed earnings, and reduced job quality.

a. Non-Competes Tend to Negatively Affect Competitive Conditions in Labor Markets

The Commission finds that non-competes tend to negatively affect competitive conditions in labor markets by inhibiting efficient matching between workers and employers.

Labor markets function by matching workers and employers. In a competitive labor market, workers compete for jobs by offering their skills and time (*i.e.,* their labor services) to

[433] *See* Part IV.B.2.b.i.

employers, and employers in turn compete for those labor services by offering better pay, benefits, or other elements of job satisfaction.[434] A worker who is seeking a better job—more pay, better hours, better working conditions, more enjoyable work, or whatever the worker may be seeking—can enter the labor market by looking for work. Prospective employers can compete for the worker's services, and the worker's current employer may also compete by seeking to retain the worker—*e.g.,* by offering a raise, promotion, or other enticement.[435] Ultimately, the worker chooses the job that best meets their objectives, and the employer chooses the worker who best meets theirs. In general, the more jobs and the more workers that are available—*i.e.,* the more competing options the worker and employer each have—the stronger the match will be.

Thus, a key component of a competitive labor market is voluntary labor mobility. Choice—the ability of market participants to satisfy their preferences where possible—facilitates competition. In the labor market, voluntary labor mobility reflects both the choices or preferences of workers and that of rival competitors.

However, non-competes introduce a major friction that tends to impair the competitive functioning of labor markets. Non-competes inhibit the efficient matching between workers and employers via the competitive process because, even if a competing employer offers a better job and the worker wants to accept that better job, the non-compete will prevent the worker from accepting it if the new job is within the scope of the non-compete (or if the worker is unsure or afraid it may be). Meanwhile, the employer who would like to hire the worker is prevented from competing to attract that talent. The result is less competition among employers for the worker's services and less competition among workers for available jobs. Since the worker is prevented from taking many jobs that would otherwise be available, the worker may decide not to look for a job at all. Or the worker may enter the labor market but take a job in which they are less productive, such as when a non-compete forces a worker to leave their field of expertise and training.

In this way, non-competes frustrate competitive processes in labor markets. In competitive markets, the ''unrestrained interaction of competitive forces'' yields a variety of benefits such as lower prices for consumers, better wages and working conditions for workers, and higher quality products.[436] In contrast, when ''[i]ndividual competitors lose their freedom to compete'' in the labor market, the importance of worker preference in setting the level of wages and working conditions is reduced, which is ''not consistent with [the] fundamental goal of antitrust law.'' [437] The restraint imposed by non-competes on the interaction of competing employers and competing workers directly undercuts the functioning of the competitive process in determining wages and working conditions. Accordingly, non-competes facially harm the competitive process and tend to negatively affect competitive conditions in labor markets. Evidence that non-competes have in fact had actual detrimental impacts on outcomes of the competitive process—such as workers' earnings, new business formation, and innovation—demonstrate that non-competes do in fact harm competition.

The Commission notes that the actual effect of any one individual non-compete on the overall level of competition in a particular labor market may be marginal or impossible to discern statistically. However, as explained in Part I.B.2, non-competes are prevalent across the U.S. labor force. The empirical literature and other record evidence discussed in this section reflect that non-competes, in the aggregate, negatively affect competitive conditions in labor markets—resulting in harm not only to workers subject to non-competes and the employers seeking to hire them, but also workers and employers who lack non-competes.

The Commission finds that evidence of the effects of non-competes on workers' labor mobility and earnings is sufficient to support its finding that non-competes tend to negatively affect competitive conditions in labor markets.[438] In addition, the Commission believes that this finding is further bolstered by strong qualitative evidence that non-competes reduce job quality.[439]

The Commission's findings relating to labor mobility and earnings are principally based on the empirical evidence described in Parts IV.B.3.a.i and ii. However, the comments provide strong qualitative evidence that bolsters these findings. Furthermore, the Commission notes that the legal standard for an unfair method of competition under section 5 requires only a tendency to negatively affect competitive conditions; empirical evidence of actual harm is not necessary to establish that conduct is an unfair method of competition. In the case of non-competes, however, there is extensive empirical evidence, as well as extensive corroborating public comments, that non-competes negatively affect competitive conditions in labor markets.

i. Non-Competes Suppress Labor Mobility

Evidence of Suppressed Labor Mobility

The Commission finds that non-competes tend to negatively affect competitive conditions in labor markets by suppressing labor mobility, which inhibits efficient matching between workers and employers. The evidence indicates that non-competes reduce labor mobility. Several empirical studies find that non-competes limit the movement of workers between firms and reduce the pool of labor available to existing employers and potential entrants.[440]

In the NPRM, the Commission described the empirical research on non-competes and labor mobility.[441] The Commission stated that, across the board, studies of non-competes and labor mobility find decreased rates of mobility, measured by job separations, hiring rates, job-to-job mobility, implicit mobility defined by job tenure, and within-industry and between-industry mobility.[442] Based on that body of empirical evidence and its review of the record as a whole following the comment period, the Commission finds that non-competes reduce labor mobility.

Several empirical studies find that non-competes reduce labor mobility. Some of these studies analyze the effects of non-competes on labor mobility across the labor force.

A study by Johnson, Lavetti, and Lipsitz examined the impact on labor mobility of all legal changes in the enforceability of non-competes from 1991 to 2014 across the entire labor force.[443] This study finds that

[434] *See* Treasury Labor Market Competition Report at 3–4.

[435] *See id.*

[436] *See N. Pac. Ry. Co.* v. *United States,* 356 U.S. 1, 4 (1958).

[437] *See NCAA* v. *Bd. of Regents of Univ. of Okla.,* 468 U.S. 85, 106–07 (1984).

[438] *See* Part IV.B.3.a.i–ii.

[439] *See* Part IV.B.3.a.iii.

[440] As the Commission stated in the NPRM, it does not view reduced labor mobility as a harm in and of itself. *See* NPRM at 3490. Instead, the Commission finds that the empirical evidence showing non-competes reduce labor mobility is powerful evidence that non-competes do indeed restrict labor market competition by inhibiting the movement of workers between firms—and therefore efficient matching between workers and firms.

[441] NPRM at 3489.

[442] *Id.*

[443] Johnson, Lavetti, & Lipsitz, *supra* note 388. This study was updated in 2023. The updated

substantial decreases in non-compete enforceability cause a significant increase in job-to-job mobility in industries that use non-competes at a high rate.[444]

Evan Starr's study comparing workers in occupations that use non-competes at a high versus low rate finds that a State moving from mean enforceability to no enforceability would cause a decrease in employee tenure for workers in high-use occupations of 8.2%, compared with those in low-use occupations. Tenure in this study serves as a proxy for mobility, since tenure is the absence of prior mobility.[445] This use of a proxy means the outcome of interest is not precisely measured, and the study is less robust than those that examine changes in legal enforceability of non-competes. The study's findings are, however, consistent with the other studies finding that non-competes reduce labor mobility.

Starr, Prescott, and Bishara's study of non-compete use likewise finds that having a non-compete was associated with a 35% decrease in the likelihood that a worker would leave for a competitor.[446] While this finding is based on the use of non-competes (and is accordingly given less weight), the authors also survey workers, who report that the cause of their reduced mobility is their non-compete. The study finds that the mechanism underlying reduced mobility is not whether non-competes are legally enforceable or not, but rather, it is the worker's belief about the likelihood that their employer would seek to enforce a non-compete. Workers who did not believe that employers would enforce non-competes in court were more likely to report they would be willing to leave for a competitor.[447] This study thus not only supports the Commission's finding that the use of non-competes impacts labor mobility, but also supports the Commission's finding that non-competes can exert an *in terrorem* effect on labor mobility even where they are unenforceable.[448] This supports the need to ensure that workers are aware of the prohibition on non-competes.[449]

Other studies analyze how non-competes affect the labor mobility of specific populations of workers. A study by Jessica Jeffers finds that decreases in non-compete enforceability were associated with a substantial increase in departure rates of workers, especially for other employers in the same industry.[450] This study's sample is limited to knowledge workers (*i.e.,* workers whose primary asset is applying their mental skills to tasks), and the study uses a binary—rather than continuous—measure of non-compete enforceability. It does, however, examine several changes in the enforceability of non-competes to generate its results, making it fairly robust.

In addition, two recent studies examined subgroups of the population that were affected by State law changes and find major effects on those populations' labor force mobility. Balasubramanian et al., in 2022, focused on Hawaii's ban of non-competes for high-tech workers and find that the ban increased mobility by 12.5%.[451] Lipsitz and Starr, in 2022, focused on Oregon's ban of non-competes for hourly workers and find that mobility increased by 17.3%.[452]

Comments Pertaining to Labor Mobility Evidence and Commission Responses

The Commission's finding that non-competes suppress labor mobility is principally based on the empirical evidence described in this Part IV.B.3.a.i. However, the comments provide strong qualitative evidence that bolsters this finding.

Many commenters agreed with the Commission's preliminary finding that non-competes suppress labor mobility and stated that this reduction in labor mobility leads to less labor market competition and poorer wages and working conditions.

In response to the NPRM's discussion of this literature, some commenters questioned the adequacy of the studies. For example, one commenter stated that the available research is either limited to specific sectors of the economy, limited geographically, or limited by small sample sizes. Some commenters claimed the empirical research lacked appropriate counterfactuals.

The Commission acknowledges that some of the studies focus on specific industries or specific geographies, and that the studies vary in the methodologies the authors rely on. These arguments do not undermine the utility of the studies, particularly given that they all find that non-competes reduce labor mobility. Moreover, the Commission finds that each of the studies discussed in this Part IV.B.3.a.i conduct their analyses against appropriate counterfactuals. And while there may be some variation in the magnitude of the effect on mobility among industries, several of the empirical studies find economy-wide effects. That evidence shows that non-competes restrict the movement of workers to a significant degree.

Additionally, the record is replete with examples of commenters who recounted personal stories that accord with the empirical literature. The Commission received comments from several thousand individual workers stating that their mobility is or has been restricted by a non-compete. While some commenters who opposed the proposed rule disputed that non-competes prevent workers from finding other jobs in their industry, the Commission finds the weight of the evidence clearly demonstrates a significant effect on labor mobility.

The Commission further notes that many commenters' submissions substantiated its finding that non-competes can have an *in terrorem* effect on labor mobility even where they would not ultimately be enforceable in court.[453] As many commenters explained, the high costs and complexities of non-compete litigation can have a chilling effect on workers and thus reduce worker mobility regardless of whether a court would enforce the non-compete. For this reason, the very existence of a non-compete is likely to deter workers from switching jobs or starting their own business, even if it would ultimately not be enforced. This supports the Commission's view that not only should non-competes' enforcement be prohibited, it is also important to provide a readily understandable,

version of the study reports results slightly differently than the 2022 version cited in the NPRM, but the analysis and results themselves do not meaningfully change. Accordingly, the update to Johnson, Lavetti, and Lipsitz does not materially affect the Commission's analysis of the study.

[444] *Id.* at 21.

[445] Evan Starr, *Consider This: Training, Wages, and the Enforceability of Covenants Not to Compete,* 72 I.L.R. Rev. 783 (2019). The value is calculated as 8.2% = 0.56/6.46, where 0.56 is the reported impact on tenure and 6.46 is mean tenure in the sample.

[446] Evan Starr, J.J. Prescott, & Norman Bishara, *The Behavioral Effects of (Unenforceable) Contracts,* 36 J. L., Econ., & Org. 633, 652 (2020).

[447] *Id.* at 664.

[448] *See* Part IV.B.2.b.ii.

[449] *See* Part IV.E (describing the final rule's notice requirement).

[450] Jessica S. Jeffers, *The Impact of Restricting Labor Mobility on Corporate Investment and Entrepreneurship,* 37 Rev. Fin. Stud. 1 (2024). The 2024 version of Jeffers' paper finds a decline in the departure rate of 7% of the sample mean, and a decline in the within-industry departure rate of 10%.

[451] Natarajan Balasubramanian, Jin Woo Chang, Mariko Sakakibara, Jagadeesh Sivadasan, & Evan Starr, *Locked In? The Enforceability of Covenants Not to Compete and the Careers of High-Tech Workers,* 57 J. Hum. Res. S349, S351 (2022).

[452] Lipsitz & Starr, *supra* note 72 at 157.

[453] *See* Part IV.B.2.b.ii.

uniform Federal approach, and notice to workers of unenforceability.[454]

Some commenters who generally opposed the rule questioned the virtue of labor mobility, arguing that when colleagues leave, remaining workers can experience increased workloads or harm to their employer. However, this comment ignores the benefits that will also accrue from those same firms having more ready access to incoming potential colleagues as well. The Commission also notes that unfair conduct cannot be justified on the basis that it provides the firm undertaking the conduct with pecuniary benefits.[455]

Some commenters argued labor mobility has generally been increasing in the U.S. labor market. Setting aside whether this is true, it is not probative of whether the practice of using non-competes reduces labor mobility or negatively affects labor market competition.

For these reasons, the empirical evidence that non-competes suppress labor mobility supports the Commission's finding that non-competes tend to negatively affect competitive conditions in labor markets.

ii. Non-Competes Suppress Workers' Earnings

Evidence of Suppressed Earnings

The Commission finds that non-competes suppress workers' earnings as a result, in part, of decreased labor mobility, supporting the Commission's finding that non-competes tend to negatively affect competitive conditions in labor markets. As the NPRM explained, many studies find increased enforceability of non-competes reduces earnings for workers across the labor market generally; for specific types of workers; and even for workers not subject to non-competes.[456] Several major empirical studies of how changes in non-compete enforceability affect workers' earnings show that increased enforceability of non-competes suppresses workers' earnings.

A study conducted by Johnson, Lavetti, and Lipsitz finds that non-competes limit workers' ability to leverage favorable labor markets to receive greater pay.[457] The authors find that when non-competes are more enforceable, workers' earnings are less responsive to low unemployment rates, which workers typically leverage to negotiate pay raises. The authors estimate that a nationwide ban on non-competes would increase average earnings by approximately 3–14%.[458] Of the studies of how non-competes affect earnings, this study has the broadest coverage. It spans the years 1991 to 2014, examines workers across the labor force, and uses all known common law and statutory changes in non-compete enforceability to arrive at its estimates. This study is very robust, as it satisfies all of the principles outlined in Part IV.A.2.

The same study also finds that non-competes increase racial and gender wage gaps by disproportionately suppressing the wages of women and non-White workers. While the study estimates that earnings of White men would increase substantially if a nationwide ban on non-competes is enacted, the comparable earnings increase for workers in other demographic groups would be up to twice as large, depending on the characteristics of the group.[459] The authors estimate that making non-competes unenforceable would close racial and gender wage gaps by meaningful amounts, although the mechanism behind this effect is unclear.[460]

Furthermore, a study conducted by Evan Starr estimates that earnings fall by about 4% where a State shifts its policy from non-enforcement of non-competes to a higher level of enforceability.[461] This study covers a sample which is broadly representative of the entire labor force from 1996 to 2008. Unlike many of the other studies described in this Part IV.B.3, this study does not use a change in enforceability of non-competes to analyze the impact of enforceability. Rather, it examines the differential impact of enforceability on workers in occupations that use non-competes at a high rate versus workers in occupations that use non-competes at a low rate. As described in Part IV.A.2, studies comparing differential usage of non-competes are generally less informative than studies examining changes in enforceability, although in this particular study the comparison between workers in high- and low-use occupations may effectively control for State-level differences between labor markets, lending more credibility to the estimates. More importantly, the Commission notes that the study corroborates the estimates from other studies that rely on more credible research designs, and therefore is appropriately viewed as additional evidence supporting the range of estimated effects on wages across the labor market.

Two additional studies analyze effects of non-competes on earnings for specific populations of workers. A study conducted by Lipsitz and Starr focuses on a natural experiment in Oregon, where non-competes were banned for hourly workers with relatively low earnings. The study estimates that when Oregon stopped enforcing non-competes for hourly workers, their wages increased by 2–3% relative to workers in States that did not experience legal changes. The study also finds a greater effect (4.6%) on workers in occupations that used non-competes at a relatively high rate.[462] The authors additionally find that women's earnings increased at a higher rate, with earnings increases after the non-compete ban of 3.5% for women, versus 1.5% for men.

A study by Balasubramanian et al. focuses on a natural experiment in Hawaii, which banned non-competes for high-tech workers in 2015. The study finds earnings of new hires increased by about 4% after the ban, relative to earnings in other States without bans.[463]

In addition to this research, which shows that increased enforceability of

[454] *See* Part IX.C. *See also supra* note 386 (explaining that studies assessing changes in enforceability of non-competes likely underestimate the effects of non-competes, given that workers may refrain from seeking or accepting work or starting a business even if the non-compete is likely unenforceable, and explaining the importance of notice to workers).

[455] *Atl. Refin. Co.* v. *FTC,* 381 U.S. 357, 371 (1965) (considering that defendant's distribution contracts at issue ''may well provide Atlantic with an economical method of assuring efficient product distribution among its dealers'' and holding that the ''Commission was clearly justified in refusing the participants an opportunity to offset these evils by a showing of economic benefit to themselves''); *FTC* v. *Texaco,* 393 U.S. 223, 230 (1968) (following the same reasoning as *Atlantic Refining* and finding that the ''anticompetitive tendencies of such a system [were] clear''); *L.G. Balfour Co.* v. *FTC,* 442 F.2d 1, 15 (7th Cir. 1971) (''While it is relevant to consider the advantages of a trade practice on individual companies in the market, this cannot excuse an otherwise illegal business practice.''). Justifications that are not cognizable under other antitrust laws are also not cognizable under section 5.

[456] NPRM at 3486–88.

[457] Johnson, Lavetti & Lipsitz, *supra* note 388 at 37.

[458] *Id.* at 3. The NPRM reported an increase in average earnings of 3.3–13.9%. Those numbers were taken from an earlier version of the Johnson, Lavetti, and Lipsitz paper. The updated paper finds an increase in average earnings of 3.2–14.2%. The change does not materially affect the paper's findings or the Commission's analysis of the paper.

[459] *Id.* at 42. The 2023 version of the paper by Johnson, Lavetti, and Lipsitz reports earnings increases of 1.3% for White men, and increases between 1.5–3.2% for workers in other demographic groups, corresponding to a change in non-compete enforceability equal to the difference between the 75th and 25th percentiles. These differences are statistically significant for Black men and non-White, non-Black women.

[460] *Id.* The 2023 version of the paper reports that the earnings gaps would close by 1.5–3.8% given a change in non-compete enforceability equal to the difference between the 75th and 25th percentiles.

[461] Starr, *supra* note 445 at 783.

[462] Lipsitz & Starr, *supra* note 72 at 143.

[463] Balsubramanian et al., *supra* note 451 at S349.

non-competes reduces workers' earnings across the labor market generally and for specific types of workers, two empirical studies find that increased enforceability of non-competes suppresses earnings even for workers who are *not* subject to non-competes.

The Johnson, Lavetti, and Lipsitz study, in a separate analysis, isolates the impact of a State's enforceability policy on workers not directly affected by that policy to demonstrate that non-competes affect not just the workers subject to non-competes, but the broader labor market as well. The study finds that increases in non-compete enforceability in one State have negative impacts on workers' earnings in bordering States, and that the effects are nearly as large as the effects in the State in which enforceability changed (but taper off as the distance to the bordering State increases).[464] The study estimates that a legal change in one State has an effect on the earnings of workers just across that State's border that is 76% as great as for workers in the State in which the law was changed.[465] In other words, when one State changes its law to be more permissive of non-competes and itself experiences a decrease in workers' earnings of 4%, workers just across the border (*i.e.,* workers who share a labor market)[466] would experience decreased earnings of 3%.[467] The authors conclude that, since the workers across the border are not directly affected by the law change (*i.e.,* contracts that they have signed do not become more or less enforceable), this effect must be due to changes in the local labor market.[468] The researchers based their analysis on where workers worked, rather than their residence, so the results are not tainted by workers who worked in the State where the law changed but lived across the border.

The second of these studies, a study conducted by Starr, Frake, and Agarwal, analyzed workers without non-competes who worked in States and industries in which non-competes were used at a high rate.[469] The authors find that, when the rate of use of non-competes in an industry in a State is higher, wages are lower for workers who do not have non-competes but who work in the same State and industry. This study also finds that this effect is stronger where non-competes are more enforceable.[470]

The authors show that the reduction in earnings (and in labor mobility) is due to a reduction in the rate of job offers. Individuals in State/industry combinations that use non-competes at a high rate do not receive job offers as frequently as individuals in State/industry combinations in which non-competes are not frequently used.[471] The authors also demonstrate that decreased mobility and earnings are not due to increased job satisfaction (*i.e.,* if workers are more satisfied with their jobs, they may be less likely to change jobs, and more likely to accept lower pay).[472]

Given some methodological limitations of this study, the Commission views it as supporting the other evidence that non-competes have negative spillover effects on earnings for workers without non-competes and reduce labor mobility. Namely, the research design relies on cross-sectional differences in enforceability of non-competes. Although this study also examines the use of non-competes, it does not compare individuals who are bound by non-competes to individuals who are not. Instead, it examines the rate of use across industries and States, and therefore avoids the statistical biases inherent in studies which compare individuals with and without non-competes. The authors also employ tests to increase confidence in the causal interpretation of these results, but they cannot conclusively rule out explanations outside of the scope of their data.

Several additional studies examine the association between non-compete use—rather than enforceability—and earnings. For the reasons described in Part IV.A.2, the Commission finds that these studies are less credible in measuring how non-competes affect earnings, and accordingly the Commission gives these studies minimal weight.

In one such study, Starr, Prescott, and Bishara examine survey results and find that non-compete use is associated with 6.6% to 11% higher earnings.[473] In another study, using Payscale.com data, Balasubramanian, Starr, and Yamaguchi find that individuals with non-competes (regardless of what other post-contractual restrictions they had) had 2.1–8.2% greater earnings than individuals with no post-contractual restrictions. However, this positive association may be due to non-competes often being bundled with NDAs. The authors find that, compared with individuals subject only to NDAs, non-competes are associated with a 3.0–7.3% *decrease* in earnings, though the authors do not disentangle this effect from the effects of non-solicitation and non-recruitment provisions.[474] Another study, by Lavetti, Simon, and White, finds that use of non-competes among physicians is correlated with greater earnings (by 14%) and greater earnings growth.[475] Finally, Rothstein and Starr find that greater use of non-competes is correlated with higher earnings.[476]

Because these studies merely reflect correlation and are unlikely to reflect causation, the Commission gives them little weight. The NPRM noted that the Lavetti, Simon, and White physician study partially mitigates this methodological flaw by comparing earnings effects in a high- versus a low-enforceability State (Illinois versus California). However, at best, this comparison is a cross-sectional comparison with a minimally small number of States being compared. The study does not consider changes in non-compete enforceability over time. Therefore, it is impossible to disentangle underlying differences in those two States from the effects of non-compete enforceability. The Commission accordingly gives this study, like the other studies reliant on comparisons of populations using non-competes and not using non-competes, little weight, though the shortcoming is slightly mitigated in the case of this study. While this study is specific to physicians, the Commission nonetheless finds that studies employing stronger methodologies (especially studies of

[464] The NPRM cited an earlier version of Johnson, Lavetti, and Lipsitz's study that estimated that a legal change in one State would have an effect on the earnings of workers just across that State's border that was 87% as great as for workers in the State in which the law was changed. NPRM at 3488. The data cited in this final rule reflect an updated version of this study.

[465] Johnson, Lavetti, & Lipsitz, *supra* note 388 at 51. Seventy-six percent is calculated as the coefficient on the donor State NCA score (−.137) divided by the coefficient on own State NCA score (−.181).

[466] See U.S. Econ. Rsch. Serv., Commuting Zones and Labor Market Areas, *https://www.ers.usda.gov/data-products/commuting-zones-and-labor-market-areas/.*

[467] The Commission notes that the estimates in the updated version of Johnson, Lavetti, and Lipsitz's study are slightly different, but qualitatively similar to the earlier estimates noted in the NPRM. The results remain statistically significant and do not materially affect the Commission's analysis.

[468] Johnson, Lavetti, & Lipsitz, *supra* note 388 at 30.

[469] Evan Starr, Justin Frake, & Rajshree Agarwal, *Mobility Constraint Externalities,* 30 Org. Sci. 961 (2019), online ahead of print at *https://pubsonline.informs.org/doi/abs/10.1287/orsc.2018.1252* at 6.

[470] *Id.* at 11.

[471] *Id.* at 10.

[472] *Id.* at 13.

[473] Starr, Prescott, & Bishara *supra* note 68 at 75.

[474] Balasubramanian, Starr, & Yamaguchi, *supra* note 74 at 40. The percentage range is calculated as $e^{-0.030}-1$ and $e^{-0.076}-1$, respectively.

[475] Lavetti, Simon, & White, *supra* note 82 at 1051. The increase in earnings is calculated as $e^{0.131}-1$.

[476] Rothstein & Starr, *supra* note 77 at 1.

workers positioned similarly in the income distribution [477] and studies which broadly represent the U.S. workforce [478]) provide compelling evidence that non-competes significantly suppress wages.

Comments Pertaining to Suppressed Earnings and Commission Responses

The Commission's finding that non-competes suppress earnings is principally based on the empirical evidence described in this Part IV.B.3.a.ii. However, the comments provide strong qualitative evidence that bolsters this finding.

The Commission received thousands of comments from workers describing how non-competes suppressed their earnings. These commenters spanned a wide variety of industries, hailed from across the U.S., and recounted a common experience: a non-compete prevented them from earning more. Illustrative examples of these comments include the following:

- I worked at a TV station. A corporation owned us and forced me to sign a yearly non-compete in order to remain in my position. After a few years, I was offered a management job with a much bigger title and much more money. . . . However, the corporation that owned us wouldn't even talk about letting me out of the non-compete. They wouldn't even discuss a settlement. They totally refused to allow me to pursue a much higher salary and a much higher position, no matter what was offered. I was forced to choose between staying in my current job, and not being able to improve my job or money, or being unemployed for 6 months.[479]
- I have been subject to a non-compete for 11 years in aggregate as a physician. Because of my non-compete, I am unable to take a position with another organization without having to drive much farther outside of my non-compete stipulated geographic restrictions (which would add to the time that I am away from my family, and costs more in fuel and vehicle maintenance). Because of my non-compete, I haven't had a raise in 6 years, because I can't negotiate with my employer because I have no bargaining position to negotiate from if I don't have options of alternate employment within the restrictions of my non-compete.[480]
- I recently received two job offers with better compensation, but I had my non-compete reviewed by an attorney and learned that it would open myself up to a significant lawsuit and potential fines. I most likely have to sit out a year and either work completely outside my field where I have advanced degrees or not work at all. Since I am the primary breadwinner, this is not financially possible for my family, so I have to stick with my current employer who has not given me a pay increase in 2 years.[481]
- I am a Certified Nurse Practitioner and signed [a non-compete]. I live in Minnesota and would be required to travel one hour one way in order to fulfill [the] agreement. . . . My employer increased my responsibilities (on-call hours added) without additional pay using vague language in my binding agreement. I would have to hire a lawyer and spend thousands of dollars to file a lawsuit to get the agreement releasing me. . . . My employer took advantage of my binding agreement and did not increase my [Relative Value Unit] rate in 5 years for my or other Nurse Practitioners in our organization.[482]
- I was just starting out in my career when I finally got a part time job in my field of geology. Unfortunately, it didn't last long and I was let go. But because of a non compete agreement I had to sign I couldn't take another job in my field even though I had a good lead on one. Instead I had to take a job as a waitress making less than minimum wage.[483]
- I work for an IT company, low-level employee just above minimum wage, and I had to sign one of these to get the job even though I don't know any knowledge above what someone could learn in 10 or 15 hours on YouTube, yet I still had to sign this which makes it so I can't compete . . . if they offered me better pay.[484]
- I began working for my employer 10 years ago as a very young and inexperienced single mother. I desperately needed a job that could pay more than minimum wage, and I eagerly accepted my position and non-compete status. I have now been working at almost the same rate of pay (as raises are not readily given to us regardless of recessions or cost of living increases)—for a DECADE. My children are approaching college age, and I will absolutely need a higher income to help fund their educations.[485]
- I am in the laboratory medicine field and was laid off from a job as an implementation rep for an instrument vendor. Other companies were the competition, and I was held to a non-compete. This caused me to go from a six figure salary with great benefits back to the hospital making barely 60k as a single mother with twins and no emergency fund saved! I later went into the UV disinfection field and developed a tremendous amount of knowledge regarding minimizing the spread of infections in hospitals (pre-covid). After 5 years, I was laid off and prevented from continuing in this niche field that I had spent so much time developing a skillset and statistics within. I was only given a 2 week severance (along with a reminder of legal action if I worked for the competition). Companies use this as a bully tactic![486]

In addition to receiving thousands of comments recounting personal stories of non-competes stymieing the commenters' ability to get a better-paying job or a raise, many commenters also described how, over the long term, non-competes can lower wages and diminish career prospects for workers forced to sit out of the market or start over in a new field. The Commission also received numerous comments stating that non-competes exacerbate wage gaps based on gender and race, including by decreasing entrepreneurship and wages to a greater extent for women and people of color and by giving firms more power to engage in wage discrimination.[487]

With respect to the empirical literature, numerous commenters agreed that there is a wealth of empirical evidence to support the Commission's preliminary finding that, by inhibiting efficient matching between workers and employers, the use of non-competes is harming workers by suppressing their earnings. In addition to the literature discussed in the NPRM and in this final rule, some commenters pointed to a 2016 report from the Treasury Department that examines the correlation between non-compete enforceability and both earnings and earnings growth at the State level. The Treasury report finds that a one-standard-deviation increase in State-level enforceability of non-competes is correlated with 1.38% to 1.86% lower earnings, which can be found in both lower earnings upon starting a job and lower earnings growth.[488] The Commission agrees with commenters that this provides additional support for the final rule. However, the Commission gives less weight to cross-sectional studies of enforceability, like the 2016 Treasury report, that examine the correlation between non-compete enforceability and earnings growth.[489] The Commission relies more heavily on the studies that find that non-competes suppress earnings based on examining natural experiments.

Some commenters opposing the rule argued that studies of non-compete use, including the studies described in this Part IV.B.3.a.ii, show a positive association between non-compete use and earnings, especially when early notice of non-competes is provided,

[477] Balasubramanian et al., *supra* note 451.

[478] Johnson, Lavetti, & Lipsitz, *supra* note 388.

[479] Individual commenter, FTC–2023–0007–8067.

[480] Individual commenter, FTC–2023–0007–0616.

[481] Individual commenter, FTC–2023–0007–0651.

[482] Individual commenter, FTC–2023–0007–0857. Relative value units are a component of a methodology that calculates earnings for some healthcare workers.

[483] Individual commenter, FTC–2023–0007–11973.

[484] Individual commenter, FTC–2023–0007–11137.

[485] Individual commenter, FTC–2023–0007–7238.

[486] Individual commenter, FTC–2023–0007–2416.

[487] *See also* Part IV.B.3.a.iii (summarizing comments from workers and worker advocates stating that non-competes increase illegal conduct by employers and make it harder for workers to report illegal conduct).

[488] Dept. of the Treasury, *Non-Compete Contracts: Economic Effects and Policy Implications* (March 2016) at 20.

[489] *See* Part IV.A.2.

while others cautioned against interpreting these relationships as causal. The Commission agrees with commenters who caution against a causal interpretation of these studies, which are unable to determine whether non-compete use causes differences in earnings, whether earnings cause differences in non-compete use, or whether a third factor simultaneously determines both, as discussed in Part IV.A.2.

Some commenters opposing the rule stated that the most comprehensive study of the earnings effects of non-competes (the Johnson, Lavetti, and Lipsitz study described in this Part IV.B.3.a.ii) examines only relatively incremental changes in laws governing the enforceability of non-competes (*i.e.,* changes other than full bans), and claimed that this study thus does not shed light on the effects of a full prohibition. In response, the Commission notes that the analysis in Johnson, Lavetti, and Lipsitz finds that the effects of changes in non-compete enforceability are broadly linear. This means the effect of a change in enforceability twice the size of another change results in a change in workers' earnings that is approximately twice as large. As a result, the Commission finds that it would be appropriate to extrapolate from the effects of incremental changes in non-compete laws to the effects of prohibitions, at least in the context of worker earnings.[490] In other words, if incremental changes in enforceability lead to a certain level of earnings effects, it is reasonable to presume—based on the linearity of the relationship between changes in enforceability and workers' earnings—larger changes will lead to larger effects.

That said, in the regulatory impact analysis, the Commission does not extrapolate from the incremental changes observed in these studies with respect to earnings effects.[491] Instead, the Commission follows a conservative approach and assumes that the prohibition in the final rule, even though it is comprehensive, will have the same effects on earnings as the incremental legal changes observed in these studies. Therefore, even if the effects of changes in non-compete enforceability are not linear, the Commission's analysis of the economic impacts of the final rule is not undermined because, if anything, it underestimates the benefits of the rule.

A commenter argued that the Johnson, Lavetti, and Lipsitz dataset is outdated because it examines enforceability between 1991 and 2014. In response, the Commission finds that while the enforceability measures contained in that dataset do not perfectly reflect current enforceability due to changes in State law in the intervening several years, the measures still reflect the impacts of non-compete enforceability on economic outcomes, and likely still have strong predictive power.

Some commenters opposing the rule asserted that the overall competitiveness of U.S. labor markets undermines the argument that workers suffer from non-competes. In response, the Commission notes that a range of factors have weakened competition in labor markets.[492] In any event, the level of competitiveness of a labor market does not justify use of a practice that tends to negatively affect competitive conditions.

Some commenters opposing the rule pointed to academic writings, including a summary of the research by an FTC economist writing in his personal capacity in 2019, stating that there was limited evidence on the effects of such clauses. The Commission finds that these writings are generally outdated and disagrees with them. As the various explanations of the empirical research in Parts IV.B and IV.C illustrate, much of the strongest evidence on the effects of non-competes has been published in recent years. The Commission notes further that Evan Starr, one expert who voiced concerns over the state of the evidence in the past, submitted a comment that was broadly supportive of the interpretation of the evidence in the NPRM and of the proposed rule.[493]

Other comments opposing the rule stated that the heterogeneity of the impact of a non-compete ban on earnings undermined the Commission's preliminary finding regarding the effects of non-competes on earnings. These commenters asked whether the population-wide average effects noted in certain studies apply across the workforce or only to certain individuals (*e.g.,* at certain points in the income distribution), certain professions, or in certain geographies (*e.g.,* where local labor markets tend to be more concentrated). Another commenter argued that if a ban on non-competes drives up earnings for highly skilled workers, wages might decrease for other categories of workers.[494]

In response to these comments, the Commission finds that, while estimates of the magnitude of the effect of non-competes on earnings vary to some extent across groups of workers, the effects are directionally and qualitatively similar across groups. For example, while Balasubramanian et al. do not report a table with average earnings for workers in their study, workers in the high tech jobs studied tend to be relatively highly paid, and the study finds non-competes suppress these workers' earnings.[495] On the lower end of the earnings spectrum, Lipsitz and Starr report average earnings of $16.41 per hour for workers in their study, which corresponds to annual earnings of approximately $34,133 per year (assuming 2,080 hours worked per year), and their study likewise finds that non-competes suppress the earnings of these workers.[496]

Additionally, Johnson, Lavetti, and Lipsitz's study of workers across the economy shows that, while college-educated workers and workers in occupations and industries in which non-competes are used at a high rate experience relatively larger adverse effects on their earnings from non-compete enforceability, the estimated effect of increased enforceability on other workers is still negative (albeit statistically insignificant in this study).[497] In short, while these studies do not estimate the magnitude of negative effects for every subset of the population, the finding of negative effects on earnings is consistent across dissimilar subsets of the population.

A commenter that opposed the NPRM asserted that a categorical ban could decrease wages for highly paid workers, arguing that such workers could negotiate higher wages in exchange for the non-compete that they would lose with a ban. This speculative assertion is belied by the comment record, which indicates that the highly paid, highly skilled workers who are not senior

[490] *See* Figure 3; Johnson, Lavetti, & Lipsitz, *supra* note 388 at 17.

[491] *See* Part X.F.5.

[492] See Treasury Labor Market Competition Report at i.

[493] Comment of Evan Starr, FTC–2023–0007–20878.

[494] These commenters were generally referring to higher-wage workers, but not senior executives. Comments that focused on senior executives are addressed in Part IV.C.

[495] Workers in the occupation Computer and Information Research Scientists (SOC code 15–1221) in the private sector had median earnings of $156,620 in 2022, while Software Developers (SOC code 15–1252) in the private sector had median earnings of $127,870 in 2022. BLS, Occupational Employment and Wage Statistics, *https://www.bls.gov/oes/tables.htm.* These private-sector data are from the May 2022 National industry-specific and by ownership XLS table (*see* table labeled ''national_owner_M2022_dl'').

[496] Lipsitz & Starr, *supra* note 72 at 148.

[497] Johnson, Lavetti, & Lipsitz, *supra* note 388 at 57.

executives are also unlikely to negotiate non-competes.[498] It is also belied by empirical evidence that non-competes suppress earnings for highly paid workers.[499]

Similarly, commenters opposing the rule questioned whether earnings effects merely result from firms hiring different types of workers after changes in non-compete enforceability (for example, workers with different levels of experience or education). In response to these comments, the Commission first notes that the studies find adverse impacts across the labor force. Therefore, even if a different mix of types of workers were hired due to non-compete enforceability, the evidence shows workers' wages are suppressed across the labor force when non-competes are more enforceable. Additionally, the Commission notes that the study by Lipsitz and Starr compares the earnings growth of individual workers before and after the legal change in Oregon, showing that earnings growth increased after the non-compete ban. This provides some evidence that the effects observed in the literature are not simply due to substitution, since individual workers' earnings trajectories would not be changed if all the effects were simply due to firms substituting one type of worker for another.[500]

Some commenters opposing the rule asserted that enforceability indices are likely measured with substantial error. These commenters argue that the indices are based on qualitative analyses of State laws and not data on how frequently non-competes are actually enforced or the results of these enforcement cases. The Commission finds the enforceability indices are sufficiently reliable, because they are generated through careful analysis of State law that takes into account variation in legal enforceability along multiple dimensions.[501] Moreover, a 2024 study using enforcement outcome data finds that a non-compete ban in Washington increased earnings, consistent with the studies using enforceability indices.[502]

Some commenters opposing the rule asserted that Hawaii's prohibition of non-competes in the technology industry may not have covered the workers claimed (in particular, omitting workers in the broadcast industry).[503] These commenters also asserted that Hawaii simultaneously banned non-solicitation clauses.

The Commission finds the study of Hawaii's non-compete ban to be informative, despite these limitations. First, any workers omitted from coverage by the statute, but considered as affected in the study, would lead to a phenomenon known as ''attenuation bias,'' which causes estimated effects to underestimate the true impact.[504] Second, the non-solicitation agreements banned by the Hawaii law were non-solicitation of coworker agreements (otherwise known as non-recruitment agreements)—agreements under which workers are barred from recruiting former coworkers, as opposed to non-solicitation of client agreements, under which workers are barred from soliciting former clients. While non-solicitation of coworker agreements may have a marginal impact on workers' earnings (*e.g.,* in situations in which workers only find out about job opportunities via past coworkers), the Commission does not find it likely that they have a major effect on workers' earnings. They may prevent some workers from hearing about some job opportunities, but unlike non-competes, they do not prevent workers from taking those opportunities. And unlike non-solicitation of client agreements, they do not frustrate workers' ability to build up a client base after moving to a new employer. The Commission therefore finds it likely that much of the impact identified in the study of the Hawaii law is due to non-competes. The Commission also notes that the Hawaii study is directionally consistent with the results from other more robust studies that use different methodologies.

Some commenters opposing the rule argued that the impact of Oregon banning non-competes for low-wage workers may have been limited because the law did not affect existing non-competes; because non-competes were already disfavored in Oregon before the law change; and because the law included multiple carve-outs. Commenters also argued the negative effects on earnings found in Oregon may have been confounded by the Great Recession.

The Commission finds that those concerns are not a compelling reason to discard the study. The study carefully examines multiple comparisons of workers within Oregon and across States. The results therefore cannot be explained by a differential response of Oregon to the Great Recession, a differential response of hourly workers to the Great Recession, or even a differential response of hourly workers in Oregon to the Great Recession. The Commission also does not believe that the study is undermined because the law did not affect existing non-competes and included multiple carve-outs, or because non-competes were disfavored in Oregon before the law changed. These factors likely mitigated the magnitude of the law's negative effect on earnings, rather than exaggerating it.

Some commenters opposing the rule argued that Johnson, Lavetti, and Lipsitz[505] claim that ''[t]he overall effect of [non-compete] enforceability on earnings is ambiguous,'' and that this undermines the Commission's preliminary findings. However, these commenters take this quote out of context. The authors were referring to a theoretical model, not to the empirical work in their paper. When economists do empirical research, they often begin by constructing a theoretical model and describing what the theory would predict; they then describe their empirical findings, which may show a different result. The authors described that it is unclear, theoretically, whether non-compete enforceability would increase or decrease earnings. However, the empirical findings of the study were clear: as the authors stated, ''We find that increases in [non-compete] enforceability decrease workers' earnings.''[506] The fact that the authors described the theoretical results of a hypothesized model as ambiguous does not undermine the fact that their study had clear empirical results.

Some healthcare businesses and trade organizations opposing the rule argued that, without non-competes, physician shortages would increase physicians' wages beyond what the commenters view as fair. The commenters provided no empirical evidence to support these assertions, and the Commission is unaware of any such evidence. Contrary to commenters' claim that the rule would increase physicians' earnings beyond a ''fair'' level, the weight of the evidence indicates that the final rule

[498] *See* Parts IV.B.2.b.i and IV.C.1.

[499] *See, e.g.,* Balasubramanian et al., *supra* note 451.

[500] Lipsitz & Starr, *supra* note 72, Online Appendix at 18.

[501] Norman D. Bishara, *Fifty Ways to Leave Your Employer: Relative Enforcement of Covenants Not to Compete, Trends, and Implications for Employee Mobility Policy,* 13 U. Pa. J. Bus. L. 751 (2011); Barnett & Sichelman, *supra* note 389.

[502] Takuya Hiraiwa, Michael Lipsitz, & Evan Starr, *Do Firms Value Court Enforceability of Noncompete Agreements? A Revealed Preference Approach* (2024), *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4364674.*

[503] Balasubramanian et al., *supra* note 451.

[504] Attenuation bias occurs when the independent variable (here, whether a worker is covered by the ban) is measured with error.

[505] Matthew S. Johnson, Kurt Lavetti, & Michael Lipsitz, *The Labor Market Effects of Legal Restrictions on Worker Mobility* (2021) at 11; *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3455381.*

[506] *Id.* at 2.

will lead to fairer wages by prohibiting a practice that suppresses workers' earnings by preventing competition; that is, the final rule will simply help ensure that wages are determined via fair competition. The Commission also notes that it received a large number of comments from physicians and other healthcare workers stating that non-competes exacerbate physician shortages.[507]

One commenter opposing the rule criticized the analysis in the Johnson, Lavetti, and Lipsitz study, suggesting that data on where individuals live are not necessarily indicative of where individuals work, and that identified spillover effects may simply be due to cross-border commuters. The Commission disagrees, because, as noted, the study considers whether the workers are subject to enforceable non-competes based on their work location.

A commenter also argued that if the absence of non-competes helped workers, one would expect California, North Dakota, and Oklahoma to have the highest median incomes among all the States. The Commission believes this expectation is inapt. Given the evidence that non-competes suppress workers' earnings, earnings in California, North Dakota, and Oklahoma are likely higher than they would be if non-competes were enforceable, but there is no reason to expect they would necessarily be higher than all other States.

One commenter opposing the rule asserted that the Commission's citation of one study in the NPRM was insufficient to show that non-competes are directly tied to discriminatory behavior by employers, or that non-competes worsen racial or gender wage gaps. The Commission does not rest its finding in this final rule that non-competes tend to negatively affect competitive conditions on findings of increased discriminatory behavior or exacerbation of gender and wage gaps. The Commission merely notes that there are two empirical studies—described under ''Evidence of suppressed earnings''—that find that non-competes do, in fact, exacerbate earnings gaps.

One commenter opposing the rule stated that closing racial and gender wage gaps may harm racial minorities and women if their wages were to fall in absolute terms. Another commenter argued that the proposed rule would reduce capital investment and output, which would decrease White male workers' wages. In response, the Commission notes that the study by Johnson, Lavetti, and Lipsitz shows that the impact of a decrease in non-compete enforceability on earnings is positive for workers in each of these groups.

The empirical evidence makes clear that, by restricting a worker's ability to leave their current job to work for a competitor or to start a competing business, non-competes reduce workers' earnings, supporting the Commission's finding that non-competes tend to negatively affect competitive conditions in labor markets.

iii. Non-Competes Reduce Job Quality

In the NPRM, the Commission recognized that non-competes may also negatively affect working conditions, *i.e.,* job quality,[508] although this had not been studied in the empirical literature (likely because it is harder to quantify). Competition in labor markets yields not only higher earnings for workers, but also better working conditions.[509] In a well-functioning labor market, workers who are subject to poor working conditions can offer their labor services to an employer with better working conditions. Such workers can also start businesses, giving them more control over working conditions. Non-competes frustrate this competitive process by restricting a worker's ability to switch jobs or start a business. Furthermore, in a well-functioning labor market, employers compete to retain their workers by improving working conditions. Where workers are locked into a job—because their alternative employment options are restricted—those competitive forces are diminished and working conditions can suffer. The Commission accordingly sought comment on this topic.

In response, thousands of workers with non-competes described how, by frustrating these competitive processes, non-competes prevent them from escaping poor working conditions or demanding better working conditions. Based on the large number of comments the Commission received on this issue and the wide variety of negative and severe impacts commenters described, the Commission finds that, in addition to suppressing earnings, non-competes negatively affect working conditions for a significant number of workers.

The Commission finds that the effects of non-competes on labor mobility and workers' earnings are sufficient, standing alone, to support its finding that non-competes with workers other than senior executives tend to negatively affect competitive conditions in labor markets. However, the Commission believes its finding that non-competes are an unfair method of competition is further bolstered by this strong qualitative evidence related to non-competes degrading working conditions.

Numerous workers and worker advocacy organizations described how non-competes compel workers to endure jobs with poor working conditions. Illustrative examples of these comments include the following:

- In March 2018, I was fired from a job in local news for refusing to go into an unsafe situation. I'd recently received a letter from a man threatening to kidnap me. When my boss decided he would still send me out alone in the field, I fought him on it, lost, and was terminated. Three weeks later, I found out I was pregnant. Unable to work in my field because of a noncompete enforced even AFTER I was terminated, I had no choice but to apply for WIC and government assistance, and work at a retail job making half my previous salary. I wanted to work. I wanted money to support my child. I wanted money to move closer to home, to escape a domestic violence situation. My noncompete kept me in a horrible spot, and nearly cost me my life.[510]
- I started my first job as a Nurse Practitioner in 2019. All positions I interviewed for required a non-compete. . . . In my case, I work for an employer that is hostile, discriminated against me during pregnancy and maternity leave and has raised his voice at me in meetings. He told me I was lucky to even have a job after becoming pregnant. I learned after starting at the practice that he has shown this pattern before with previous employees. I say this because all of these above-mentioned reasons are why I have the right to want to quit my job and move on. I desperately want to leave and start another job but I can't because of the non compete. I feel like a prisoner to my job. I feel depressed in my work conditions and I feel like I have no way out.[511]
- I'm a barber and violated a non-compete about 6 months ago. . . . I worked for my previous employer for two years in a toxic environment. I told my employer how work was affecting my home life on more than one occasion and she did nothing. . . . How was I to know that I would be working in a toxic environment when I applied? So ultimately, I decided in order to be happy and make a living wage, I'd have no choice but to violate my non-compete. She came after me in no time flat. Now I'm paying legal fees and at risk of going to court and losing my job for 6 more months. . . . [I]f I'm working in poor working conditions, I should be able to work where I please. For two years, my job and employer affected my mental health. I chose to take anti-depressants after things got bad at work, upped my dosage twice as work

[507] *See* Part IV.B.3.b.iv for a more detailed summary of these comments.

[508] NPRM at 3504.

[509] Treasury Labor Market Competition Report at i.

[510] Individual commenter, FTC–2023–0007–12813.

[511] Individual commenter, FTC–2023–0007–4989.

became progressively worse and since I've left, I've stopped taking my medication.[512]

- I am a commissioned employee in the mortgage world, and I had a non-compete with my former company in Ohio. Near the end of my time at this company, they merged with another company and put the new company in charge of the sales staff. It was miserable. We started having issues, even with having basic supplies, and it went from just harming me to harming my ability to get business complete, which harms the consumer. I left and I was sued for a three year period. . . . I really do not feel that [non-competes] should be allowed. You are stuck at employers and they can treat you in any manner that they please because they know that they can make your life a living hell if you leave them.[513]
- Like many new graduates in the medical field, I signed on with a company that made numerous empty promises. . . . What I was not prepared for, was the company's strategic increase in facilities in which I was to perform services under this contract. In the short span of 2 years, I did neurophysiological monitoring for 24 facilities . . . . When working conditions fell apart regardless of my requests for adequate sleep following 36 hours straight of working on call at my designated stroke hospital, time for meals or breaks within 18+ hour work days, and a reasonable travel distance within the area the company demanded I relocate to, I was met with threats from HR regarding my non-compete if I were to leave. . . . Working conditions became so intense, I was placed on migraine medications at the recommendations of my doctor and required three separate trips in the ER for medical conditions related to stress, inability to eat or drink while tied within tens of hours long surgeries . . . . Again I was met with threats from HR and now their legal team.[514]

Many commenters stated that non-competes harm working conditions for lower-wage workers. However, there were many commenters in higher-wage jobs who also stated that non-competes harmed their working conditions. For example, numerous physicians explained that they were trapped in jobs with poor working conditions because of non-competes. Many of these physicians described how non-competes accelerate burnout in their profession by making it harder for workers to escape bad working conditions or demand better working conditions. Many commenters recounted how they left poor work environments but non-competes harmed them by forcing them to leave their field, move out of the area where they lived, or spend time and money defending themselves from legal action. Many commenters argued that prohibiting non-competes would increase workers' bargaining power and in turn incentivize employers to provide better work environments.

Workers in both high-wage and low-wage professions, as well as worker advocacy groups, stated that by diminishing workers' competitive alternatives, non-competes keep workers trapped in jobs where they experience dangerous, abusive, or toxic conditions; discrimination; sexual harassment; and other forms of harassment. These commenters also described how non-competes trap some workers in jobs where their employer commits wage and hour violations, such as wage theft, as employers that use non-competes can insulate themselves from the free and fair functioning of competitive markets and are thus more likely to be able to steal worker wages with impunity. Several commenters said they were unable to receive benefits because a non-compete rendered them unable to switch to a job with better benefits or rendered them unable to leave their job when their employer took their benefits away. A professional membership network for survivors of human trafficking explained that traffickers masquerading as legitimate businesses use non-competes to prevent trafficking victims from leaving.

Some workers and advocacy organizations stated that non-competes increase the potential for harm from retaliation. These commenters stated that restricting a worker's employment opportunities makes it even harder for workers to find new jobs after experiencing retaliation. These commenters argued that this discourages workers from reporting fraud, harassment, discrimination, or labor violations. A labor union commented that, by making it harder for workers to find new jobs, non-competes can deter unionization and chill activities protected by the National Labor Relations Act, including activities to address unsafe, unfair, or unsatisfactory working conditions. According to a trade organization of attorneys, whistleblower protections may come too late for a fired whistleblower who cannot obtain another job because of a non-compete. Several commenters provided survey or case evidence showing that workers who report sexual harassment, wage theft, or poor working conditions are frequently retaliated against, including by being fired.[515] These commenters stated that, because non-competes make it harder for these workers to find new jobs, non-competes decrease the likelihood that workers report these kinds of harms.

Many workers described how, by limiting their ability to get out of harmful workplace environments, non-competes contributed to stress-related physical and mental health problems. Many commenters, particularly in the healthcare profession, stated that suicide is a major problem in their profession and described non-competes as one of the stressors, because non-competes make it harder to leave jobs with unsustainable demands, leaving workers feeling trapped.

While thousands of commenters described, often in personal terms, how non-competes have negatively affected their working conditions, the Commission received few comments from workers or worker advocates stating that non-competes improved working conditions. The few comments received stated that workers who remain with an employer can be harmed by departing and competing colleagues, via increased workloads or harm to their employer.

Taken together, these comments provide strong qualitative evidence that non-competes degrade working conditions, which supports the Commission's finding that non-competes tend to negatively affect competition in labor markets.

b. Non-Competes Tend to Negatively Affect Competitive Conditions in Product and Service Markets

Based on the Commission's expertise and after careful review of the rulemaking record, including the empirical research and the public comments, the Commission finds that non-competes tend to negatively affect competitive conditions in markets for products and services by inhibiting new business formation and innovation.

New businesses are formed when new firms are founded by entrepreneurs or spun off from existing firms. New business formation increases competition by reducing concentration, bringing new ideas to market, and forcing incumbent firms to respond to new firms' ideas instead of stagnating. New businesses disproportionately create new jobs and are, as a group, more resilient to economic

[512] Individual commenter, FTC–2023–0007–3323.
[513] Individual commenter, FTC–2023–0007–3955.
[514] Individual commenter, FTC–2023–0007–1252.

[515] For example, the National Women's Law Center, which operates and administers the TIME'S UP Legal Defense Fund, reported that among individuals who contacted the Fund to request legal assistance related to sexual harassment in the workplace, 72% reported facing retaliation, and, among those, 36% had been fired. Comment of Nat'l Women's L. Ctr., FTC–2023–0007–20297 at 5 (citing Jasmine Tucker & Jennifer Mondino, *Coming Forward: Key Trends and Data from the TIME'S UP Legal Defense Fund,* 4 (Oct. 2020), *https://nwlc.org/wp-content/uploads/2020/10/NWLC-Intake-Report_FINAL_2020-10-13.pdf*).

downturns.[516] With respect to spinoffs, research shows that spinoffs within the same industry are highly successful relative to other entrepreneurial ventures.[517]

Non-competes, however, tend to negatively affect competitive conditions in product and service markets by inhibiting new business formation in two ways. First, since many new businesses are formed by workers who leave their jobs to start firms in the same industry, non-competes reduce the number of new businesses that are formed in the first place.[518] Second, non-competes deter potential entrepreneurs from starting or spinning off new businesses—and firms from expanding their businesses—by locking up talented workers.[519] Non-competes thus create substantial barriers to potential new entrants into markets and also stymie competitors' ability to grow by making it difficult for those entrants to find skilled workers.

Innovation refers to the process by which new ideas result in new products or services or improvements to existing products or services. Innovation may directly improve economic outcomes by increasing product quality or decreasing prices, and innovation by one firm may also prompt other firms to compete and improve their own products and services. However, non-competes tend to negatively affect competitive conditions in product and service markets by inhibiting innovation.

Non-competes tend to reduce innovation in three ways. First, non-competes prevent workers from starting businesses in which they can pursue innovative new ideas.[520] Second, non-competes inhibit efficient matching between workers and firms.[521] Where workers are less able to match with jobs that maximize their talents, employers' ability to innovate is constrained. Third, and relatedly, non-competes reduce the movement of workers between firms.[522] This decreases knowledge flow between firms, which limits the cross-pollination of innovative ideas.

As described in Parts IV.B.3.b.i and ii, the Commission finds that the effects of non-competes on new business formation and innovation are sufficient to support its finding that non-competes tend to negatively affect competitive conditions in product and service markets. In addition, as described in Parts IV.B.3.b.iii and iv, the Commission believes this finding is further bolstered by evidence that non-competes increase concentration and consumer prices, as well as evidence that non-competes reduce product quality.

The Commission's findings relating to new business formation and innovation are principally based on the empirical evidence described in Parts IV.B.3.b.i and ii. However, the comments provide strong qualitative evidence that bolsters these findings. Furthermore, the Commission notes that the legal standard for an unfair method of competition under section 5 requires only a tendency to negatively affect competitive conditions; empirical evidence of actual harm is not necessary to establish that conduct is an unfair method of competition. In the case of non-competes, however, there is extensive empirical evidence, as well as extensive corroborating public comments, that non-competes negatively affect competitive conditions in product and service markets.

i. Non-Competes Inhibit New Business Formation

Evidence of Inhibited New Business Formation

The Commission finds that non-competes tend to negatively affect competitive conditions in product and service markets by inhibiting new business formation. The weight of the empirical evidence establishes that when non-competes become more enforceable, the rate of new business formation (*i.e.,* the number of new businesses formed) declines.

Several empirical studies assess the effects of non-competes on the rate of new business formation. A study conducted by Jessica Jeffers examines several State law changes in the technology sector and the professional, scientific, and technical services sector and finds a decline in new firm entry when non-competes become more enforceable. Jeffers finds that as non-competes became more enforceable, the entry rate of new firms decreases substantially.[523] Jeffers' study uses several changes in non-compete enforceability that are measured in a binary fashion. While this study therefore does not satisfy all the principles outlined in Part IV.A.2, it satisfies most of them and is accordingly quite robust and weighted highly.

Another study, conducted by Matt Marx, examines the impact of several changes in non-compete enforceability between 1991 and 2014 on new business formation, and likewise finds a negative effect of non-competes on new business formation.[524] Marx finds that, when non-competes become more enforceable, men are less likely to found a rival startup after leaving their employer, that women are even less likely to do so (15% less likely than men), and that the difference is statistically significant.[525] This study therefore supports both that non-competes inhibit new business formation and that non-competes tend to have more negative impacts for women than for men. Marx uses several changes in non-compete enforceability measured in a continuous fashion. The study therefore satisfies the principles outlined in Part IV.A.2 and is weighted highly.

In addition, Johnson, Lipsitz, and Pei analyze the extent to which non-compete enforceability affects the rate of firm entry in high-tech industries. They find that an average increase in non-compete enforceability decreases the establishment entry rate by 3.2%.[526] Outside of examining only innovative industries, this study's methodology is otherwise strong, and the study is therefore weighted highly. While this study uses multiple changes in a granular measure of non-compete enforceability, a quite robust methodology, the study is limited to high-tech industries.

In addition, a study conducted by Can and Fossen indicates that decreases in enforceability of non-competes in Utah and Massachusetts increased entrepreneurship among low-wage workers.[527] Can and Fossen examine just two changes in non-compete enforceability, measured in a binary fashion, and the study is therefore given slightly less weight than studies which

[516] *See, e.g., The Importance of Young Firms for Economic Growth,* Policy Brief, Ewing Marion Kauffman Foundation (Sept. 24, 2015).

[517] Aaron K. Chatterji, *Spawned With a Silver Spoon? Entrepreneurial Performance and Innovation in the Medical Device Industry,* 30 Strategic Mgmt. J. 185 (2009).

[518] *See, e.g.,* Evan Starr, Natarajan Balasubramanian, & Mariko Sakakibara, *Screening Spinouts? How Noncompete Enforceability Affects the Creation, Growth, and Survival of New Firms,* 64 Mgmt. Sci. 552 (2018).

[519] *See, e.g.,* Shi, *supra* note 84.

[520] *See* Part IV.B.3.b.i.

[521] *See* Part IV.B.3.a. While the Commission focuses on the most direct negative effects on competition in product and service markets in this Part IV.B.3.b, inefficient matching between workers and firms may have additional negative effects, including on output.

[522] *See* Part IV.B.3.a.i.

[523] Jeffers, *supra* note at 450. The 2024 version of Jeffers' study reports a 7% impact.

[524] Matt Marx, *Employee Non-Compete Agreements, Gender, and Entrepreneurship,* 33 Org. Sci. 1756 (2022).

[525] *Id.* at 1763.

[526] Matthew S. Johnson, Michael Lipsitz, & Alison Pei, *Innovation and the Enforceability of Non-Compete Agreements,* Nat'l. Bur. Of Econ. Rsch. (2023) at 36.

[527] Ege Can and Frank M. Fossen, *The Enforceability of Non-Compete Agreements and Different Types of Entrepreneurship: Evidence From Utah and Massachusetts,* 11 J. of Entrepreneurship and Pub. Pol. 223 (2022).

examine more changes or use a more granular measure of enforceability. The study corroborates the results of studies using these stronger methodologies.

Furthermore, a study conducted by Benjamin Glasner focused on high-tech industries finds that technology workers increased entrepreneurial activity in Hawaii after non-competes were restricted, but finds no effect on entrepreneurial activity from Oregon's restriction on non-competes with low-wage workers.[528] Similar to the study by Can and Fossen, this study by Glasner uses two changes in non-compete enforceability measured in a binary fashion. Additionally, a study published by Stuart and Sorenson shows that increased enforceability of non-competes decreases the amount by which firm acquisitions and IPOs induce additional local business formation.[529] This study uses cross-sectional variation in non-compete enforceability measured in a binary fashion, and studying the amount by which firm acquisitions and IPOs induce additional local business formation does not cover all entrepreneurship. These studies are thus given more limited weight, but generally are in line with other evidence that non-competes reduce new business formation and innovation.

Additionally, a study conducted by Starr, Balasubramanian, and Sakakibara analyzes the effect of non-compete enforceability on spinouts (*i.e.,* when a firm creates a new business by splitting off part of its existing business). The authors find that, when non-compete enforceability increases by one standard deviation, the rate of spinouts within the same industry decreases by 32.5%—a major decrease in new business formation.[530] Research shows that spinouts within the same industry are highly successful, on average, when compared with typical entrepreneurial ventures.[531] This study uses cross-sectional differences in non-compete enforceability, measured in a continuous fashion, though it attempts to avoid problems related to the use of cross-sectional differences in non-compete enforceability by using law firms—which likely do not use non-competes due to ethical limits in the legal profession [532]—as a control group. The Commission therefore gives this study somewhat less weight than studies of changes in non-compete enforceability, though the findings corroborate the findings of the studies by Jeffers and Marx.

In addition, a study by Salomé Baslandze shows that non-competes reduce new business formation, finding that greater non-compete enforceability inhibits entry by spinouts founded by former employees of existing firms.[533] Baslandze notes that spinouts tend to innovate more and are relatively higher quality than other new firms. This study examines changes in non-compete enforceability on a continuous measure but assumes that changes over a 19-year period occur smoothly over time instead of identifying exactly when the legal changes were made. While this study uses changes in non-compete enforceability and corroborates the findings of the aforementioned studies on new business formation, the assumption regarding the timing of changes yields an imprecise measure of non-compete enforceability over time. The Commission therefore gives this study somewhat less weight than studies which precisely identify the timing of changes in non-compete enforceability.

Finally, in a 2011 study, Samila and Sorenson find that when non-competes are more enforceable, rates of entrepreneurship, patenting, and employment growth slow. They find that an increase in venture capital funding creates three times as many new firms where non-competes are unenforceable, compared to where non-competes are enforceable.[534] This study uses cross-sectional variation in non-compete enforceability along two dimensions, both of which are measured in a binary fashion. Due to this measurement, the Commission gives this study less weight, though its results corroborate the findings of the other studies on new business formation.

The Commission gives minimal weight to two additional studies. One of these estimates the job creation rate at startups increased by 7.8% when Michigan increased non-compete enforceability.[535] However, the Commission places less weight on this study than the studies discussed previously because it examines only one legal change in one State and because the change to non-compete enforceability was accompanied by several other simultaneous changes to Michigan's antitrust laws. Thus, it is not possible to isolate the effect of the change in non-compete enforceability standing alone.

The other study finds mixed effects of non-compete enforceability on the entry of businesses into Florida. The study examines a legal change in Florida which made non-competes more enforceable. The authors find larger businesses entered the State more frequently (by 8.5%) but smaller businesses entered less frequently (by 5.6%) following the change.[536] Similarly, Kang and Fleming find that employment at large businesses rose by 15.8% following the change, while employment at smaller businesses effectively did not change.[537] This study examines a single change in non-compete enforceability. However, the Commission gives this study minimal weight because the study does not examine new business formation specifically; instead, it assesses the number of ''business entries,'' which does not necessarily reflect new business formation because it also captures existing businesses moving to the State.

Additional research analyzes the effects of non-competes on the number of jobs created by new businesses.[538]

[528] Benjamin Glasner, *The Effects of Noncompete Agreement Reforms on Business Formation: A Comparison of Hawaii and Oregon,* Econ. Innovation Group White Paper (2023), *https://eig.org/noncompetes-research-note/.*

[529] Toby E. Stuart & Olav Sorenson, *Liquidity Events and the Geographic Distribution of Entrepreneurial Activity,* 48 Admin. Sci. Q. 175 (2003).

[530] Starr, Balasubramanian, & Sakakibara, *supra* note 518 at 561. 32.5% is calculated as 0.0013/0.004, where 0.0013 is the coefficient reported in Table 2, Column 6, and 0.004 is the mean WSO entry rate reported in Table 1 for ''nonlaw'' firms.

[531] For reviews of the literature, *see, e.g.,* Steven Klepper, *Spinoffs: A Review and Synthesis,* 6 European Mgmt. Rev. 159 (2009) and April Franco, *Employee Entrepreneurship: Recent Research and Future Directions,* in Handbook of Entrepreneurship Research 81 (2005).

[532] *See* Am. Bar Ass'n, Model Rule 5.6, *https://www.americanbar.org/groups/professional_responsibility/publications/model_rules_of_professional_conduct/rule_5_6_restrictions_on_rights_to_practice/.*

[533] Salomé Baslandze, *Entrepreneurship Through Employee Mobility, Innovation, and Growth,* Fed. Res. Bank of Atlanta Working Paper No. 2022–10 (2022), *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4277191.*

[534] Samila & Sorenson find that a 1% increase in venture capital funding increased the number of new firms by 0.8% when non-competes were enforceable, and by 2.3% when non-competes were not enforceable. Sampsa Samila & Olav Sorenson, *Noncompete Covenants: Incentives to Innovate or Impediments to Growth,* 57 Mgmt. Sci. 425, 432 (2011). The values are calculated as $0.8\% = e^{0.00755} - 1$ and $2.3\% = e^{0.00755 + 0.0155} - 1$, respectively.

[535] Gerald A. Carlino, *Do Non-Compete Covenants Influence State Startup Activity? Evidence from the Michigan Experiment,* Fed. Res. Bank of Phila. Working Paper No. 21–26 at 16 (2021).

[536] Hyo Kang & Lee Fleming, *Non-Competes, Business Dynamism, and Concentration: Evidence From a Florida Case Study,* 29 J. Econ. & Mgmt. Strategy 663, 673 (2020).

[537] *Id.* at 674. The value is calculated as $15.8\% = e^{0.1468} - 1$.

[538] In the NPRM, the Commission stated that the evidence relating to the effects of non-competes on job creation was inconclusive. However, in the final rule, the Commission does not make a separate finding that non-competes reduce job creation.

While the research described previously shows that non-competes inhibit the rate of new business formation, this research indicates that even where new businesses are created, these new businesses have fewer workers where non-competes are more enforceable. This evidence suggests that non-competes not only prevent small businesses from being formed, but they also hinder entrepreneurship by tending to reduce the number of employees new firms are able to hire.

In addition to analyzing the rate of firm entry in high-tech industries, Johnson, Lipsitz, and Pei analyzes the number of jobs created at newly founded firms in innovative industries.[539] Using evidence from several State law changes, the authors find that increases in non-compete enforceability lead to a reduction in the number of jobs created at newly founded firms in innovative industries (though not necessarily across all industries or all types of firms) by 7.2%.[540]

A study by Starr, Balasubramanian, and Sakakibara finds that increases in non-compete enforceability decreased average per-firm employment at new firms.[541] In the NPRM, the Commission stated that this study found that several increases in non-compete enforceability were associated with a 1.4% increase in average per-firm employment at new firms.[542] However, upon further review of the study, the Commission interprets this study as finding that increases in non-compete enforceability decreased average per-firm employment at new firms—both for spinouts within the same industry and spinouts into a different industry.[543] For spinouts into a different industry, average per-firm employment at the time of founding decreases by 1.4% due to greater non-compete enforceability. For spinouts into the same industry, average per-firm employment decreases by 0.3%.[544] At seven years after founding, the results are similar: spinouts into a different industry have average per-firm employment that is 1.5% lower due to greater non-compete enforceability, while spinouts into the same industry have per-firm employment that is 0.7% lower.[545] The Commission notes that this study compares States with different levels of enforceability, using law firms as a control group, instead of considering changes in non-compete enforceability. It is therefore given less weight than studies with stronger methodologies.[546]

Comments Pertaining to Inhibited New Business Formation and the Commission's Responses

The Commission's finding that non-competes inhibit new business formation is principally based on the empirical evidence described in this Part IV.B.3.b.i. However, the comments provide strong qualitative evidence that bolsters this finding.

Hundreds of commenters agreed with the Commission's preliminary finding that non-competes reduce new business formation. Illustrative examples of comments the Commission received include the following:

- I am a hairstylist . . . and have been with the company for 11 years. Our work conditions have changed drastically over the years and Covid has really sent us on a sharp decline. It is not the same salon I signed on to work for. That being said, a few coworkers want to open a salon and take some of us with them to bring back the caliber of service we want to give our clients. Our non-compete contracts state that we can't work within 30 miles of this salon. We didn't expect that standards would drop so low and they would raise prices so high that we lost so many clients. . . . We have all had enough of the toxic environment and need to be free of this unfair contract.[547]
- I am a veterinarian that has had to suffer under non-compete clauses my entire career. I have had to sell my home and relocate several times including moving out of State due to non-compete clauses. I'm currently stuck in a [non-compete covering a] 30 mile radius of all 4 practices of a group of hospitals I work for. This basically keeps me from working in an enormous area. I had to sign it due to circumstances out of my control and they took advantage of my situation. I recently tried to start my own business, not related to the type of practice that I have the non-compete clause with, and had to abandon the idea because I couldn't get funding without my current employer releasing me from the contract or by relocating again out of the huge area of non-compete.[548]
- We own a small family practice in urban Wisconsin. I previously was employed by a large healthcare organization and burned out. When I left to star[t] my own business, I was restricted from working close by, by a non-compete. I spent $24,000 [in] legal fees challenging this successfully. . . . Now as a business owner for 5 years, we have the opportunity to hire some physician assistants who have been terminated without cause from my prior employer. I am unable to do so because they also had to sign non-competes. I have seen many disgruntled patients who have delayed care because of this.[549]
- I am aesthetic nurse practitioner wanting to start my own business but I am tied to a 2 year 10 mile non compete. I was basically obligated to sign the non-compete when I needed to reduce my hours to finish my master's degree (that I paid for and they wanted me to get). I feel forced to stay at a job that is not paying me what I am worth.[550]
- I am a licensed social worker with a non-compete which is hindering my employment options. . . . I would like to start my own business as the mental health facility I work for is not supportive of mental health. This rule would be a great benefit for mental health professionals and those seeking quality mental health services.[551]
- As a recently graduated physician, I wanted to start my own practice and become a small business owner. However, I also needed a source of income to start out and wanted to work part time at a local hospital for income and benefits. However, due to a non-compete clause in their contracts, I could not start my own business and practice in the same city if I was to work with them. This hindered my ability to work as much as I wanted (ended up having to work as an independent contractor for significantly less

Instead, it cites the research described herein—which relates solely to job creation at newly founded firms—to support its finding that non-competes inhibit new business formation.

[539] Johnson, Lipsitz, and Pei, *supra* note 526 at 36.

[540] *Id.* While this study satisfies each of the other metrics outlined in Part IV.A.2, the sample is restricted to firms in innovative industries, and therefore the outcome of interest is not reflective of the entire population.

[541] Starr, Balasubramanian, & Sakakibara, *supra* note 518 at 552.

[542] NPRM at 3488–89.

[543] While this study satisfies some of the principles for robust design outlined in Part IV.A.2, the Commission notes that average per-firm employment does not precisely correspond to the economic outcome of interest, which is overall employment or job creation.

[544] Calculated as 1.4% − 1.1%, based on the effect for non-within-industry spinouts (1.4%) and the relative impact on within-industry spinouts compared with non-within-industry spinouts (− 1.1%). *See* Starr, Balasubramanian, & Sakakibara, *supra* note 518 at 561.

[545] Calculated as 1.5% − 0.7%, based on the effect for non-within-industry spinouts (1.5%) and the relative impact on within-industry spinouts compared with non-within-industry spinouts (− 0.8%). *See id.* at 563.

[546] There are also two studies analyzing how non-competes affect job creation or employment generally. Neither study relates to new business formation specifically. Goudou finds a decreased job creation rate from an increase in non-compete enforceability in Florida. Felicien Goudou, *The Employment Effects of Non-compete Contracts: Job Retention versus Job Creation* (2023), *https://www.jesugogoudou.me/uploads/JMP_Felicien_G.pdf*. This study considers just one change in non-compete enforceability, and is therefore given less weight, though the results corroborate findings in papers which satisfy more of the guideposts in Part IV.A.2. Additionally, the 2023 version of Johnson, Lavetti, & Lipsitz, *supra* note 388, finds that increased non-compete enforceability reduces employment by 1.9%, though they do not estimate the impact on job creation directly. Rather, the authors look only at the closely related metric of changes in overall employment. This study otherwise has a strong methodology, as discussed in Part IV.B.3.a.ii.

[547] Individual commenter, FTC–2023–0007–3299.

[548] Individual commenter, FTC–2023–0007–1448.

[549] Comment of Three Oaks Health, FTC–2023–0007–1397.

[550] Individual commenter, FTC–2023–0007–10157.

[551] Individual commenter, FTC–2023–0007–11922.

shifts per month and no benefits), and made it more difficult to get my business off the ground due to expenses for providing my own benefits. Banning non-compete clauses would significantly help the ability for citizens to pursue starting small businesses or other work to increase their income and prosperity.[552]

- Mr. Z had worked for a company for over 15 years installing windshields in vehicles. He was a lower-level employee making $18.50 an hour and did not learn any trade secrets or confidential information. After years of working for the company the employer refused to raise his wages despite his experience, so he decided to start his own business. Shortly after giving notice and beginning his new endeavor, he received a letter from his previous employer informing him that he was in breach of his non-compete agreement and the employer would enforce it if he continued with his business plan.[553]
- Non-competes have prohibited me from making a living as a fitness and wellness professional to such an extent, that it hurt me economically. I opened up my own business that was different than my previous employer, even though it was different and I told him I was going to focus on a different area in wellness, my previous employer sued me. I ended up having to hire an attorney to defend myself and when it was all said and done, I spent close to 12,000 in fees and penalties.[554]
- Non compete agreements are detrimental to the average worker, preventing them from pursuing better paying job offers or from starting their own business in the same industry. I am directly affected by a non-compete clause I had signed as part of a job acceptance. I am now forming my own business in the same industry as my employer, and cannot do business within a 50-mile radius of my employer. That radius covers the hometown I live in. Even though we are in the same industry, we have very different target markets.[555]

As these comment excerpts reflect, many potential entrepreneurs wrote to the Commission to describe how they wanted to strike out on their own, but a non-compete preventing them from doing so. These comments indicate that non-competes have deprived communities of homegrown businesses—with respect to everything ranging from tech companies, to hair salons, to physician practices, and many more types of firms. This deprives markets of competing firms that can reduce concentration—which in turn has benefits for lowering prices and raising the quality of products and services, and increasing innovation in bringing new ideas to market—as well as depriving communities of opportunities for new job creation.

Even where entrepreneurs were able to start businesses, they explained how non-competes prevented them from hiring talented workers and made it harder for their nascent businesses to grow and thrive. Many other commenters described personal experiences in which their newly formed businesses were threatened by litigation costs related to non-competes. Other commenters stated that the threat of litigation related to non-competes increases the risk and cost of starting a new business, particularly if that business intends to compete against a large incumbent firm. One commenter stated that incumbent firms can use non-compete litigation as a mechanism to chill startup formation where startups lack the resources to contest a non-compete.

Numerous small businesses and organizations representing small businesses submitted comments expressing support for the proposed rule and describing how it would help small business owners. These commenters contend that categorically prohibiting non-competes will empower small businesses by providing them with new access to critical talent and will drive small business creation as entrepreneurial employees will be free to compete against their former employers. Many small businesses also argued that non-competes can hinder small business formation and can keep small businesses from growing once they are formed. The extensive comments the Commission received from small businesses are also addressed in Part XI.C.

Some small businesses said they spent tens or hundreds of thousands of dollars defending themselves from non-compete lawsuits. A one-person surveying firm said it has to regularly turn down work because of the former employer's threat to sue over a non-compete. A small, five-worker firm said it was sued by a billion-dollar company for violating a non-compete despite the fact that the firm waited out the non-compete period and did not use proprietary information or pursue the former employer's customers; it fears the legal fees will force it out of business. A legal aid organization relayed the story of a client, a self-employed beauty worker who was unable to provide their service during a non-compete lawsuit despite working outside the non-compete geographic radius. The CEO of one small transport and logistics company said a ban would remove a tool used mostly by the largest companies in each industry to maintain their market dominance, as small competitors cannot match their legal budgets. Further, many workers said they would open their own business if non-competes were banned.

Many small businesses shared their experiences of how non-competes have made hiring more difficult. For example, a small physician practice said non-competes made it difficult to compete with larger practices to attract and retain physicians. A small business and a medical association said small businesses could not afford a lawsuit when hiring workers. An IT startup tried to hire an executive who had retired from a large firm, but the large firm sued the startup to enforce what the startup said was an unenforceable non-compete. According to the startup, because a lawsuit would have cost up to $200,000, it was forced to settle and could not work with numerous potential clients, and its growth was significantly slowed. It stated that it continues to turn away many potential hires to avoid being sued over non-competes.

Other commenters raised additional issues relevant to hiring. According to one technology startup organization, the inability to assemble the right team is a major reason startups fail, and small businesses lose opportunities because they must avoid hiring workers who are subject to even unenforceable non-competes. That organization also said startups currently face legal and time costs from navigating the patchwork and complexity of State non-compete laws, especially when trying to determine if a potential hire's non-compete is enforceable; the time and expense of navigating this landscape will thus often cause the startups to forego that hire. That organization said some non-competes prevent experienced workers from counseling, advising, or investing in startups, and such mentoring can double a startup's survival rate.

Several self-identified entrepreneurs commented that because of their non-competes, they feared not being able to operate, build, or expand their business. Numerous workers reported that they wanted to or planned to start their own business, but their non-compete made them too afraid to do so. A public policy organization referenced the Census Bureau's Annual Business Survey to argue that a majority of business owners and an even higher majority of Black business owners view starting their own business as the best avenue for their ideas, and that non-competes may prevent these potential entrepreneurs' ideas from coming to market.

Several commenters stated that non-competes make it harder for new businesses to hire workers with relevant

[552] Individual commenter, FTC–2023–0007–11777.

[553] Comment of NW Workers' Justice Project, FTC–2023–0007–15199 (discussing a client).

[554] Individual commenter, FTC–2023–0007–12904.

[555] Individual commenter, FTC–2023–0007–12697.

experience or industry knowledge. Some commenters argued that non-compete bans, such as in California, have contributed to higher rates of successful start-ups, while new firms in States where non-competes are more enforceable tend to be smaller and are more likely to fail.

In contrast, several commenters opposed to the rule argued that non-competes promote new business formation by protecting small and new firms' investments, knowledge, and workers from appropriation by dominant firms poaching their employees. Commenters also theorized that, while non-competes directly inhibit employee spinoffs, they may encourage businesses to enter the market by enhancing their ability to protect their investments. As described in Part IV.D.2, the Commission finds that firms have viable alternatives for protecting these investments that burden competition to a less significant degree than non-competes. The Commission further notes that these commenters did not provide evidence to support their assertions.

In addition, when assessing how non-competes affect new business formation, the Commission believes it is important to consider the net impact. It is possible that the effects described by these commenters and the effects described by the Commission earlier in this Part IV.B.3.b.i can be occurring at the same time. That is, a non-compete might in some instances be protecting a firm's investments in a manner that is productivity-enhancing holding all else equal. But even that same non-compete can—and certainly non-competes in the aggregate do—inhibit new business formation by prohibiting workers from starting new businesses and by locking up talented workers, preventing the worker from efficiently matching with the job that is the highest and best use of their talents. What the empirical evidence shows is that non-competes reduce new business formation, overall and on net, indicating that the tendency of non-competes to inhibit new business formation more than counteracts any tendency of non-competes to promote new business formation.

Other commenters said non-competes protect firms' value and assets for sale in future acquisitions, which they said drives seed capital investment in start-ups. An investment industry organization commented that private-equity financing, particularly for early-stage companies, often includes non-competes and is used to support growth, in turn increasing competition. In response, the Commission notes that these commenters provided no empirical evidence that decreases in non-compete enforceability have affected seed capital investment and private-equity financing. Moreover, the Commission notes that there is no indication that small businesses or early-stage companies in States that have banned or limited non-competes have been unable to obtain financing. To the contrary, California, where non-competes are unenforceable, has a thriving start-up culture.

Other commenters addressed empirical research related to new business formation. Some commenters similarly argued that research on the average quality of employee spinouts due to changes in non-compete enforceability may imply negative effects of the rule (*e.g.,* if prohibiting non-competes decreases average employment or average survival rates of new firms). Some commenters also noted that the Baslandze study finds that weaker non-compete enforceability increases the rate at which spinouts form but result in a lower proportion of high-quality spinouts.[556]

In response to these comments, the Commission notes commenters primarily referenced Starr, Balasubramanian, & Sakakibara[557] to support this view. The findings in this study have been misinterpreted by commenters. This study actually finds that spinouts that form when non-compete enforceability is stricter are *lower* quality (*i.e.,* create fewer jobs), but that the effect is less drastic for spinouts within the same industry versus spinouts into different industries. Coupled with other evidence discussed in Part IV.B.3.b.i, the weight of which points to increased job creation due to the rule, the Commission finds that empirical studies have not established that non-competes lead to higher-quality startups or higher-quality spinouts. The Commission also notes that the result in the Baslandze study regarding the quality of spinouts is theoretical, and the study does not test this theory empirically.

Commenters also argued that non-competes may have different effects on different types of workers—for example, across different industries, occupations, or levels of pay—and that these differences may affect the impacts of non-competes on new business formation. In response, the Commission notes that the studies show negative effects across a range of industries and are directionally consistent, even if they do not provide results for all subgroups.

Commenters asserted that non-competes may affect job creation through several different mechanisms. The Commission agrees and finds that, regardless of the specific mechanism, the weight of the evidence indicates that non-competes inhibit job creation.

Commenters opposing the rule also questioned the usefulness of studies of Michigan's law change, given that existing non-competes remained enforceable under the Michigan law; they state that as a result, it would take longer for effects from the law to be realized. As noted under ''Evidence of inhibited new business formation,'' the Commission gives minimal weight to this study, but for other reasons.

In an ex parte communication entered into the record, the author of the study of the Michigan law change expressed concern over the Commission's interpretation of the study.[558] In particular, he stated that his methodology mitigated concerns that the study's findings of an increase in the job creation rate may be due to decreases in that rate's denominator (total employment). While the Commission does not agree with this assessment,[559] the Commission places less weight on the study for different reasons, as noted.

Some commenters who opposed the rule also addressed the evidence relating to non-competes and job creation, although these commenters generally did not focus on job creation related to new businesses specifically. Some of these commenters asserted that the studies addressed in the NPRM indicated that non-competes are associated with a greater number of jobs available and increased rates of job creation, rather than decreased rates of job creation. Some asserted that the evidence on job creation is mixed and that the issue is understudied. In the NPRM, the Commission stated that the evidence relating to the effects of non-competes on job creation was inconclusive. However, in the final rule,

[556] Baslandze, *supra* note 533 at 40.

[557] Starr, Balasubramanian, & Sakakibara, *supra* note 518.

[558] Ex Parte Communication: Email from G. Carlino to E. Wilkins (Jan. 30, 2023), *https://www.ftc.gov/system/files?file=ftc_gov/pdf/P201200NonCompeteNPRMExParteCarlinoRedacted.pdf.*

[559] In particular, the long time period and the difference-in-difference methodology used in the study do not mitigate concerns that decreases in employment due to non-compete enforceability could drive increases in the job creation rate. The concern is not that the findings somehow represent effects on anything other than the average job creation rate (as noted by the author in his ex parte communication), but that a rate is comprised of a numerator and denominator, and effects on either may drive effects on the rate as a whole. This concern is shared by at least two empirical studies of non-competes. *See* Johnson, Lavetti, & Lipsitz *supra* note 388 at 19 and Johnson, Lipsitz, & Pei *supra* note 526 at 19.

the Commission does not make a separate finding that non-competes reduce job creation. Instead, it cites the research described herein—which relates to job creation at newly founded firms—to support its finding that non-competes inhibit new business formation.

ii. Non-Competes Inhibit Innovation

Evidence of Inhibited Innovation

The Commission finds that non-competes tend to negatively affect competitive conditions in product and service markets by inhibiting innovation. Three highly reliable empirical studies find that non-competes reduce innovation.

One such study, a study by Zhaozhao He, finds that the value of patents, relative to the assets of the firm, increases by about 31% when non-compete enforceability decreases.[560] In contrast to some other studies of innovation discussed here, He's study focuses on the value of patents, rather than the mere number of patents. The study does so to mitigate concerns that patenting volume may not represent innovation.[561] The study analyzes the impact of several legal changes to non-compete enforceability, using a binary measure of non-compete enforceability. While this study therefore does not satisfy all the principles outlined in Part IV.A.2, it nonetheless satisfies many of them and contains a reasonably strong methodology.

A second study, by Johnson, Lipsitz, and Pei, finds that increased enforceability of non-competes decreases the rate of ''breakthrough'' innovations and innovations which make up the most cited patents. This study lends weight to the finding that non-competes harm both the quantity and the quality of innovation.[562] The authors also show that when non-compete enforceability decreases, patenting increases even in industries where most new innovations are patented. These increases imply that the effect is a true increase in innovation, rather than firms substituting between patents and non-competes.

Johnson, Lipsitz, and Pei also show that State-level changes in non-compete policy do not simply reallocate innovative activity across State lines, which would result in no change in innovation at the national level. Instead, they find that decreasing non-compete enforceability, even in one State, increases innovative activity nationally.[563] Johnson, Lipsitz, and Pei's study uses several legal changes to analyze the impact of enforceability. It also uses several metrics of quality and quantity to mitigate concerns over whether patenting is an accurate reflection of innovation, especially in this context. The study thus satisfies all the principles outlined in Part IV.A.2 and is therefore given substantial weight by the Commission.

A third study, by Rockall and Reinmuth, finds that non-competes have a significant negative impact on innovation. They further find that this effect is not driven solely by the entry of new businesses. Their work suggests a potentially central role for knowledge spillovers, which are hampered when worker mobility is diminished. The study uses many changes to non-compete enforceability quantified on a continuous basis and considers several metrics which represent the quantity and quality of patenting, in order to accurately capture the relationship between non-competes and innovation.[564] Similar to the study by Johnson, Lipsitz, and Pei, this study therefore satisfies all the principles described in Part IV.A.2 and is given substantial weight.

The Commission places the greatest weight on the foregoing three studies, in which factors unrelated to the legal changes at issue are less likely to drive the results. There are additional studies that relate to non-competes and innovation, but the Commission gives them less weight.

A study by Samila and Sorenson finds that venture capital induced less patenting by 6.6 percentage points when non-competes are enforceable.[565] However, the authors note that patenting may or may not reflect the true level of innovation, as firms may use patenting as a substitute for non-competes where they seek to protect sensitive information.[566] Furthermore, this study assesses only the quantity of patents and does not take into account the quality of patents, which would be a better proxy for innovation. For this reason, the Commission gives less weight to this study (although its findings are directionally consistent with the first three studies described herein). This study also uses cross-sectional variation in non-compete enforceability, which is measured along two dimensions in a binary fashion. In addition, a study by Gerald Carlino examined how patenting activity in Michigan was affected by an increase in non-compete enforceability. The study finds that mechanical patenting increased following the change in the law, but that drug patenting fell, and that the quality of computer patents fell.[567] However, the increase in mechanical patenting appears to have primarily occurred approximately 14 years after non-compete enforceability changed. This suggests that some other mechanism may have led to the increase in patenting activity.[568] Moreover, the study uses a single change in non-compete enforceability to generate its results, and it uses only one measure of innovation outside of patent quantity—quality as measured by patent citations. Finally, this study examines a change to non-compete enforceability which was accompanied by several other changes to Michigan's antitrust laws, making it impossible to identify the effect of the change in non-compete enforceability standing alone. For these reasons, the Commission gives less weight to this study.

A study by Clemens Mueller does not estimate the overall impact of non-compete policy on innovation, but instead focuses on career detours of inventors.[569] Mueller shows that inventors are more likely to take ''career detours''—that is, to change industries to avoid the reach of their non-compete—when enforceability of non-competes is stricter. Due to the lower match quality between that inventor and their new industry, the innovative productivity of those inventors suffers after they take career detours. However, the Commission assigns this study less weight because, while its methodology satisfies the principles outlined in Part IV.A.2, the study is only informative of the productivity of individuals taking career detours. It does not address whether innovation in the aggregate increases. Mueller uses several changes in non-compete enforceability to generate results, but those changes are measured in binary—rather than continuous—fashion.

Coombs and Taylor examine the impact of non-compete enforceability on innovation. They find that research

[560] Zhaozhao He, *Motivating Inventors: Non-Competes, Innovation Value and Efficiency* 21 (2023), *https://ssrn.com/abstract=3846964*. Thirty one percent is calculated as $e^{0..272} - 1$.

[561] *Id.* at 17.

[562] Johnson, Lipsitz, & Pei, *supra* note 526.

[563] *Id.*

[564] Emma Rockall & Kate Reinmuth, *Protect or Prevent? Non-Compete Agreements and Innovation* (2023), *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4459683*.

[565] Samila & Sorenson, *supra* note 534 at 432. The value is calculated as $6.6\% = e^{0.0208 + 0.0630} - e^{0.0208}$.

[566] *Id.*

[567] Carlino, *supra* note 535 at 40.

[568] *Id.* at 48.

[569] Clemens Mueller, *Non-Compete Agreements and Labor Allocation Across Product Markets,* Proceedings of the EUROFIDAI-ESSEC Paris December Finance Meeting 2023 (2023), *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4283878*.

productivity, as measured by the number of products in biotechnology firms' prospectuses, was lower in California than other States, which they suggest implies that California's ban on non-competes hampers research productivity.[570] However, this study is purely cross-sectional, and results may be due to other differences between California and other States; the Commission accordingly places less weight on this study.

Two additional studies address firm strategies related to innovation. However, the Commission gives them little weight because the outcomes studied do not inform how non-competes would affect the overall level of innovation in the economy. The first, by Raffaele Conti, uses two changes in non-compete enforceability (in Texas and Florida), and indicates that firms engage in riskier strategies with respect to research and development (''R&D'') when non-compete enforceability is greater.[571] However, this study does not address whether these riskier strategies lead to greater innovation. The second, by Fenglong Xiao, finds that increases in non-compete enforceability led to increases in exploitative innovation (*i.e.,* innovation which stays within the bounds of the innovating firm's existing competences) in the medical device industry.[572] The study finds this increase in exploitative innovation leads to an increase in the rate at which new medical devices are introduced. However, the study also finds that explorative innovation (*i.e.,* innovation which moves outside those bounds) decreased, and explorative innovation is the mode of innovation which the empirical literature has found to be associated with high growth firms.[573] The net impact on innovation from this study is thus unclear. The study examines several changes in non-compete enforceability, measured with a binary indicator of non-compete enforceability.

[570] Porcher L. Taylor, III, and Joseph E. Coombs, *Non-Competition Agreements and Research Productivity in the Biotechnology Industry,* 26 Frontiers of Entrepreneurship Rsch. 1 (2006).

[571] Raffaele Conti, *Do Non-Competition Agreements Lead Firms to Pursue Risky R&D Strategies?,* 35 Strategic Mgmt. J. 1230 (2014).

[572] Fenglong Xiao, *Non-Competes and Innovation: Evidence from Medical Devices,* 51 Rsch. Pol'y 1 (2022).

[573] Alessandra Colombelli, Jackie Krafft & Francesco Quatraro, *High-Growth Firms and Technological Knowledge: Do Gazelles Follow Exploration or Exploitation Strategies?,* 23 Indus. And Corp. Change 262 (2014).

Comments Pertaining to Inhibited Innovation and the Commission's Responses

The Commission's finding that non-competes inhibit innovation is principally based on the empirical evidence described in this Part IV.B.3.b.ii. However, the comments provide strong qualitative evidence that bolsters this finding.

Several academics and economic research groups, among other commenters, agreed with the Commission's preliminary finding that non-competes inhibit innovation. Commenters argued that non-competes reduce knowledge flow and collaboration, force workers to leave their field of expertise, and discourage within-industry spinouts that promote innovation. Many commenters stated that banning non-competes would make it easier for workers to pursue innovative ideas and to hire the best talent to help develop those ideas. Illustrative examples of comments the Commission received include the following:

• I am a geneticist at Stanford University, and I am co-founding a biotech startup that aims to discover new cancer immunotherapies. Many of the most talented geneticists, immunologists, cancer biologists, and other scientists with unique and valuable skillsets for drug development are bound by non-competes that prevent them from leaving jobs at big pharma companies to join biotech startups like mine. The result is artificial scarcity in the market for top scientific talent—a phenomenon that precludes healthy competition between industry incumbents and new entrants. Given that much of our country's most cutting-edge translational research happens within biotech startups, and given that many of the most successful drugs on the market originate in biotech startups, non-competes in pharma and biotech prevent the most talented scientists from working on the most innovative science and obstruct the development of new treatments and cures for human disease—leaving our society worse off.[574]

• As a practicing Physician for over thirty years, and one who trained fellows in pain management, who followed many of their students' careers, I was able to see the detriments of unfair Non-Compete clauses in their contracts. Often a physician would take a job, and if it did not work out, the restrictions were so severe, that they would need to move to a new geographic location in order to be employed. . . . Other scenarios exist as well. Where large institutions can block scientific discovery of their research physicians from moving to other institutions which may be better able to support their research, potentially blocking the promotion of scientific discovery.[575]

[574] Individual commenter, FTC–2023–0007–0198.

[575] Individual commenter, FTC–2023–0007–3885.

• I am an engineer in the orthopedic space. I have an idea for a truly innovative foot and ankle plating system that I believe could become the standard of care for fracture fixation and foot deformity correction. It could save 10–15 minutes of operating room time per surgery, which studies show carries a cost of $1000 (times millions of surgeries annually). It does not directly compete with my former employer's product, but I have to wait a year to start engaging surgeons about it because of a very broad non-compete, for a product that does not even compete.[576]

• I currently work as a mid-level technical employee at a company that enforces long (a year or longer) noncompetes. . . . After working for larger companies for a few years after college, many of my friends started their own companies. Some succeeded massively and some didn't but what was common among most of them was that the companies they started were somewhat related to what they were working on before. They either saw a gap in the industry while working for a larger company, or had a bold idea in their domains that they wanted to quit their jobs and try executing it. All this risk taking has in turn resulted in innovation, more competition, and hundreds of jobs. This would not have been possible if these people were under non-compete agreements from their previous employers. In fact, many of my friends who are currently working for companies that have non-competes have personally told me that they want to try a different approach than the current incumbents in their industry, but they simply can't take this risk because of the long non-competes they are under. Note that non-competes are even more consequential for workers of relatively less experience because sitting out for 1 year while only having 3 to 4 years of experience is a lot more detrimental to one's career when compared to an individual with 20 years of experience. Given that younger workers are more willing to take risks and try new ideas, the impact of non-competes on innovation is far worse than many think.[577]

• I am an engineer who has worked on software and hardware in several domains, including the semiconductor industry. I perceive non-competes to not only be detrimental to free trade but also to be detrimental to American innovation and manufacturing. If the United States is serious about supporting the growth of the semiconductor industry in the U.S., it must ensure that semiconductor companies inside the United States truly act to benefit American innovation. . . . The FTC would act prudently to ban such agreements.[578]

• I am a physician. I have worked for public entities for my entire career. I have worked under non-competes for my entire career. The result of these non-compete clauses is that myself and my colleagues keep our imagination and creativity locked away. We see novel applications of pharmaceuticals and medical devices which our leadership

[576] Individual commenter, FTC–2023–0007–0760.

[577] Individual commenter, FTC–2023–0007–19807.

[578] Individual commenter, FTC–2023–0007–12872.

does not want to pursue, and we are also precluded from pursuing these ideas due to the noncompete. We see new ways to reach people and help people with our unique skill sets, and our noncompete keeps us from being able to reach them. The noncompete allows our employer to own us. They monopolize the talent of their workforce and this deprives the community of the innovation that may stem from the unleashing of the creativity of the physician workforce. I see the direct impact of non-compete clauses. The public has so much to gain by releasing healthcare workers from their noncompete clauses. These talented individuals, once released from their noncompetes, will begin to contribute to their communities with new ideas and innovation that will serve their communities. Many entities have so many reasons to avoid innovation and this stifles the individuals who work for them and oppresses new ideas. Once released from the bureaucracy and burden of non-competes I believe you will see an abundance of community outreach, device innovation and community service from many physicians currently subjugated by their noncompete clauses.[579]

A research organization said a ban on non-competes would increase the value workers realize from creativity and inventiveness, though it also asserted that non-competes can incentivize firms to create and share information. Some workers commented that they had innovative ideas or research that their employer was unwilling to pursue, but the worker could not leave to pursue their ideas elsewhere. A commenter also argued that captive workforces can stifle competition for workers and for clients or patients that leads to innovation. According to several commenters, trapping workers in jobs can also lead to decreased productivity and so-called ''quiet quitting.''

Some commenters contended that California's ban on non-competes helped Silicon Valley and other industries in California thrive. For example, a public policy organization pointed to industry clusters where studies have identified job hopping, which may otherwise be prohibited by non-competes, as the primary mechanism of knowledge diffusion and argued that restricting non-competes for knowledge workers would improve the U.S.'s competitiveness. Other commenters questioned whether non-competes played a role in Silicon Valley's growth. In response, the Commission notes that it does not attribute California's success in the technology industry to its non-compete laws. The Commission merely notes (in Part IV.D) that the technology industry is highly dependent on protecting trade secrets and that it has thrived in California despite the inability of employers to enforce non-competes, suggesting that employers have less restrictive alternatives for protecting trade secrets.

Other commenters opposing the rule argued that non-competes may promote innovation by encouraging firms to make productivity-enhancing investments and by decreasing the risk of workers leaving. These commenters stated that non-competes protect firms' investments in workers, R&D, intellectual capital, and innovation. The Commission does not believe that non-competes are needed to protect valuable firm investments. As described in Part IV.D.2, the Commission finds that firms have less restrictive alternatives that protect these investments adequately while burdening competition to a less significant degree.

In addition, when assessing how non-competes affect innovation, the Commission believes it is important to consider the net impact. It is possible that the effects described by these commenters and the effects described by the Commission earlier in this Part IV.B.3.b.ii can be occurring at the same time. That is, a non-compete might in some instances be protecting a firm's investments in a manner that is productivity-enhancing holding all else equal. But even that same non-compete can—and certainly non-competes in the aggregate do—inhibit innovation by preventing workers from starting new businesses in which they can pursue innovative ideas; inhibiting efficient matching between workers and firms; and reducing the movement of workers between firms. What the empirical evidence shows is that non-competes reduce innovation, overall and on net, indicating that the tendency of non-competes to inhibit innovation more than counteracts any tendency of non-competes to promote innovation.

The Commission addresses the available evidence on the relationship between non-competes and firm investment in Part IV.D.1.

A business commenter contended that worker mobility does not necessarily improve innovation since the new firm may be unable or unwilling to use the worker's knowledge or ideas, or the new start-up may fail and leave consumers with less innovative products and services. In response, the Commission notes that it is certainly possible that some workers switch jobs to firms that are unable or unwilling to use their knowledge or ideas, or to startups that may fail. However, the fact that the empirical evidence shows that reduced non-compete enforceability increases innovation suggests that these effects are outweighed by workers who can switch jobs to firms that make better use of their talents, or to startups that thrive and bring innovative new products to market.

Other commenters stated that non-competes promote the sharing of ideas and information within firms and incentivize risk-taking. The Commission is not aware of evidence that non-competes promote the sharing of ideas within firms specifically, but in any event the Commission explains in Part IV.D.2 that trade secrets and NDAs provide less restrictive means than non-competes for protecting confidential information. With respect to risk-taking, the Commission notes that the Conti study finds that firms engage in riskier R&D strategies when non-compete enforceability is greater, but it is not clear whether these riskier R&D strategies translate into increased innovation.

Commenters also argued that non-competes may have different effects on different types of workers—for example, across different industries, occupations, or levels of pay—and that these differences may affect the impacts of non-competes on innovation. In response, the Commission notes that the most methodologically robust studies show negative effects across a range of industries and are directionally consistent, even if they do not provide results for all subgroups.

A research organization argued that non-competes decrease the likelihood that innovative technologies are developed outside the U.S. and that non-competes promote economic growth, competitiveness, and national security. The Commission is not aware of any reliable evidence of the effects of non-competes on whether innovative technologies are developed outside the U.S. However, the weight of the empirical evidence indicates that non-competes reduce the amount of innovation occurring within the U.S.

Some commenters noted that innovation hubs have emerged in States that enforce non-competes. In response, the Commission notes that it does not find that it is impossible for innovation hubs to emerge where non-competes are enforceable. Instead, the Commission finds that, overall, non-competes inhibit innovation.

One commenter performed an empirical exercise in which he correlated Global Innovation Index rankings of innovation clusters with the enforceability of non-competes in each location. The commenter found that only one of the top five clusters bans non-competes, and only three others in the top 100 ban non-competes. The

[579] Individual commenter, FTC–2023–0007–2340.

commenter cited the success of Chinese innovation clusters, noting that non-competes are permitted in each of them.[580] The Commission does not find this evidence persuasive. Other differences across countries may explain these results better than policy towards non-competes, which is one factor among many that affect the level of innovation in an economy.

Some commenters argued that the empirical research cited in the NPRM has mixed results. These commenters point to the study by Xiao (2022) showing that non-competes increase exploitative innovation (innovation that incrementally extends firms' existing capabilities), but not explorative innovation (innovation that extends the scope of firms' capabilities). In response, the Commission notes that, within this particular study, the net impact of non-competes on innovation was unclear. But the Commission does not believe the evidence overall is mixed, given that the three empirical studies of the effects of non-competes on innovation that use the most reliable empirical methods all find that non-competes reduce innovation.

Some commenters claimed that two studies cited in the NPRM—the Xiao and Conti studies—had findings that were omitted or misinterpreted: first, the Xiao finding that non-compete enforceability increases the rate of new discoveries of medical devices due to increases in the rate of exploitative innovation but not explorative innovation); and second, the Conti finding that greater non-compete enforceability leads to riskier innovation, which these commenters assert is a positive outcome.[581] In response, the Commission notes that the NPRM described both of these findings and did not omit or misinterpret them.[582] The Commission explains why it gives these studies little weight under ''Evidence of inhibited innovation.''

A commenter asserted that the He study is insufficient evidence to support a finding, and that the study examines the effects of non-compete enforceability on the value of patents, which the commenter asserts misses other aspects of innovation. In response, the Commission believes that the He study is methodologically robust and that, while no single metric can capture all aspects of innovation, the value of patents is a meaningful proxy. The Commission also notes that the effects observed in the He study are considerable, as the study finds that the value of patents, relative to the assets of the firm, increases by about 31% when non-compete enforceability decreases. In addition, the Commission notes that the comment record provides substantial qualitative support in line with the empirical findings. Furthermore, additional research, published since the release of the NPRM, helps confirm the Commission's finding regarding the effect of non-competes on innovation. As described under ''Evidence of inhibited innovation,'' this evidence moves beyond assessing the impact of non-competes on the value of patents or the number of patents to identify the quality of new innovation, as well as the mechanisms underlying these effects.

Many commenters referred to a law review article, which was also submitted as a comment itself, that critiques the literature on non-competes and innovation.[583] First, the authors argue that a measure of enforceability used in part of the economic literature is incorrect and that a more recently developed measure is imperfect but better.[584] The Commission agrees with the authors that the more recently developed measure of enforceability, the scale based on Bishara (2011), is stronger than other measures of enforceability due to its granularity. This metric is used in many studies cited in this final rule, including the Johnson, Lipsitz, and Pei study, which largely reinforces the conclusions in the He study, lending weight to the conclusions in these studies that non-competes suppress the overall level of innovation in the economy.

Second, the authors argue that a given non-compete may be governed by the laws of a State other than the State where the worker lives, which undermines the reliability of studies analyzing the effects of non-compete enforceability. The authors argue that cross-border enforcement of non-competes may be a difficult issue to properly address in empirical work and has not been accounted for in the work to date. In response, the Commission notes that if the State law that applied to a given non-compete were totally random—for example, if a non-compete in Oregon was no more likely to be governed by Oregon's law than any other State's law—we would expect to observe no effects on economic outcomes (such as earnings, innovation, and new business formation) from changes in State law. Instead, the empirical research shows that changes in State law have clear impacts on economic outcomes in particular States. This indicates that enough non-competes within a particular State are subject to that State's law for changes in that State's law to affect economic outcomes in that State.

Third, the authors argue that there is a lack of data on the use of non-competes and that such data are needed to completely assess the effects of non-competes. Although there is not comprehensive data on individual workers' employment agreements, the Commission believes the studies that examine changes in enforceability do so based on sufficient data to be reliable and are otherwise methodologically sound. These studies are also highly probative with respect to the effects of the final rule because what they are examining—how changes in the enforceability of non-competes affect various outcomes—matches closely with what the final rule does. The Commission also notes that there is considerable data regarding the prevalence of non-competes, which it discussed in Part I.B.2.

Fourth, the article argues that some studies of non-competes have small sample sizes, which may lead to measurement error. In response to concerns about small sample sizes, the Commission notes that the most recent studies use a greater breadth of variation in the legal environment surrounding non-competes, overcoming this obstacle. Fifth, the article expresses concern about certain studies that are based on legal changes in Michigan. The Commission takes this critique into account throughout this final rule and notes it when discussing the applicable studies that examine legal changes in Michigan, including under ''Evidence of inhibited innovation.''

In an ex parte communication included in the public record, the author of one of the studies of innovation stated that studies which examine multiple legal changes may be biased, since affected parties may anticipate the legal change and adjust their behavior prior to the date that the legal change is made. The author stated that examination of the legal change in Michigan was therefore preferable, since it was ''inadvertent'' and therefore not

[580] Comment of Mark Cohen, FTC–2023–0007–12064, at 12–13.

[581] Referring to Xiao, *supra* note 572 and Conti, *supra* note 571.

[582] NPRM at 3492–93.

[583] Barnett & Sichelman, *supra* note 389.

[584] The allegedly flawed measures use binary indicators for enforcement versus non-enforcement, or binary indicators for several facets of enforceability (Stuart and Sorenson, *supra* note 529; Mark J. Garmaise, *Ties that Truly Bind: Noncompetition Agreements, Executive Compensation, and Firm Investment,* 27 J. L., Econ., & Org. (2011)), and the more recent measure is more nuanced (Bishara, *supra* note 501).

subject to anticipation effects.[585] The Commission agrees that, in general, anticipation effects can bias the findings of empirical studies. However, empirical work shows that the legal changes used in much of the literature on non-competes are not subject to anticipation effects.[586] This may be because the vast majority are changes based on judicial decisions, rather than statutory changes, as hypothesized by researchers.[587] Moreover, even if anticipation effects occur in studies of non-compete enforceability, that would likely not change the measurable observed benefits of reducing non-compete enforceability, and may indeed lead to underestimation of observed benefits. Underestimation would occur if parties were adjusting their behavior in advance of the change in enforceability in the same direction as the effects observed after the change. This would occur if, for example, firms began to decrease use of non-competes in advance of a decrease in non-compete enforceability, knowing that those non-competes would soon be less enforceable. This ultimately would mean that the actual effects on labor mobility, earnings, new business formation, innovation, and other outcomes could be even greater. Additionally, the legal change in Michigan is subject to other criticism, as discussed under ''Evidence of inhibited innovation'' and by commenters.

iii. Non-Competes May Increase Concentration and Consumer Prices

Evidence of Increased Concentration and Consumer Prices

As described in Parts IV.B.3.b.i and ii, the Commission finds that non-competes tend to negatively affect competitive conditions in product and service markets by inhibiting new business formation and innovation, and have in fact done so. The Commission finds that these effects, standing alone, are sufficient to support its finding that non-competes tend to negatively affect competitive conditions in product and service markets.

However, the Commission notes that there is also evidence that non-competes increase industrial concentration more broadly, which in turn tends to raise consumer prices. The empirical literature on these effects is less developed than the empirical work documenting declines in new business formation and innovation; specifically, the empirical evidence on consumer prices relates only to healthcare markets (though the evidence on concentration spans all industries in the economy). For this reason, the Commission does not rest its finding that non-competes tend to negatively affect competitive conditions in product and service markets on a finding that non-competes increase concentration and consumer prices. However, there are several reliable studies finding that non-competes increase concentration and/or consumer prices, bolstering the Commission's finding that non-competes tend to negatively affect competitive conditions in product and service markets.

The Commission finds that non-competes reduce new business formation.[588] By doing so, non-competes may increase concentration. Non-competes may also stunt the growth of existing firms that would otherwise better challenge dominant firms, for example, by limiting potential competitors' access to talented workers.[589]

Non-competes may also affect prices in a variety of ways. By suppressing workers' earnings, non-competes decrease firms' costs, which firms may theoretically pass through to consumers in the form of lower prices. However, non-competes may also have several countervailing effects that would tend to increase prices. First, non-competes may increase concentration, which could lead to less competition between firms on price, and therefore higher prices for consumers. Second, by inhibiting efficient matching between workers and firms, non-competes may reduce the productivity of a firm's workforce, which may lead to higher prices. Third, by inhibiting innovation, non-competes may hinder the development of lower-cost products or more efficient manufacturing processes.

One study, by Hausman and Lavetti, focuses on physician markets. The study finds that as the enforceability of non-competes increases, these markets become more concentrated, and prices for consumers for physician services increase. The study finds that while non-competes allow physician practices to allocate clients more efficiently across physicians, this comes at the cost of greater concentration and higher consumer prices. This study examines several changes in non-compete enforceability measured continuously. The authors note that, in theory, if decreased non-compete enforceability decreases earnings, then the fall in prices may simply be due to pass-through of labor costs. However, empirical research shows that decreased non-compete enforceability increases earnings (as discussed in Part IV.B.3.a.ii). Even if that were not the case, Hausman and Lavetti show that labor cost pass-through cannot explain their findings.[590] This study satisfies all of the principles described in Part IV.A.2, and is accordingly weighted highly by the Commission.

Another study, by Lipsitz and Tremblay, examines all industries in the economy and shows empirically that increased enforceability of non-competes at the State level increases concentration.[591] Lipsitz and Tremblay theorize that non-competes inhibit entrepreneurial ventures that could otherwise enhance competition in goods and service markets. The authors show that the potential for harm is greatest in the industries in which non-competes are likely to be used at the highest rate.[592]

If the general causal link governing the relationship between enforceability of non-competes, concentration, and consumer prices acts similarly to that identified in the study by Hausman and Lavetti, then it is plausible that increases in concentration identified by Lipsitz and Tremblay would lead to higher prices in a broader set of industries than healthcare. Lipsitz and Tremblay use several changes in non-compete enforceability measured in a continuous fashion, but do not measure the impact on consumer prices or welfare. The Commission therefore finds the study's conclusion that non-competes increase concentration highly robust, but the study is not itself direct empirical evidence of a relationship between non-competes and prices.

Two additional studies assess the effects of non-competes on concentration and prices. However, the Commission gives these studies little weight.

A study of physician non-competes by Lavetti, Simon, and White finds that prices charged by physicians with non-competes are similar to those charged by physicians without non-competes.[593]

[585] Ex Parte Communication: Email from G. Carlino, *supra* note 558.

[586] Johnson, Lavetti & Lipsitz, *supra* note 388 at 12–14.

[587] *Id.* at 12.

[588] *See* Part IV.B.3.b.i.

[589] *See* Part IV.C.2.c.i (describing a study addressing how non-competes force firms to make inefficiently high buyout payments).

[590] Naomi Hausman & Kurt Lavetti, *Physician Practice Organization and Negotiated Prices: Evidence from State Law Changes,* 13 Am Econ. J. Applied Econ. 278 (2021).

[591] Michael Lipsitz & Mark Tremblay, *Noncompete Agreements and the Welfare of Consumers* 6 (2021), *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3975864.* Concentration is measured by an employment-based Herfindahl-Hirschman Index (HHI).

[592] *Id.* at 3.

[593] *See* Lavetti, Simon, & White, *supra* note 82.

The Commission gives this study less weight because it merely analyzes differences between workers based on the use of non-competes.[594]

A study by Younge, Tong, and Fleming finds that non-competes contribute to economic concentration because non-compete enforceability increases the rate of mergers and acquisitions.[595] This study uses one change in non-compete enforceability—in Michigan—to generate its results. However, in addition to its use of a single legal change in a single State, the change to non-compete enforceability was accompanied by several other changes to Michigan's antitrust laws, so it is not possible to identify the effect of the change in non-compete enforceability standing alone.

Comments Pertaining to Increased Concentration and Consumer Prices and the Commission's Responses

Several commenters addressed the question of whether non-competes affect concentration and consumer prices. Some commenters asserted that the rule would lower consumer prices by improving matches between employers and workers, increasing productivity. Commenters also argued that locking up talent, particularly in specialized markets, prevents entrepreneurship and new business formation and can thus contribute to increased concentration.

Some commenters opposing the NPRM claimed that banning non-competes could increase concentration. These commenters argued that larger firms could discourage companies from expanding into new and underserved markets by poaching, or threatening to poach, their key employees, leading to increased costs that could force some firms out of business. These commenters also argued that non-competes protect small businesses from dominant consolidators, as high recruitment, retention, and other costs may induce small businesses to sell or larger businesses may hire away their workers. A medical trade organization stated that without non-competes, independent practices might not be able to afford to hire and thus may be unable to grow or compete.[596]

While these commenters theorize that prohibiting non-competes would increase concentration, the Commission notes that the available evidence indicates that non-competes increase concentration, rather than reducing it. The Commission further notes that these theories are inconsistent with the robust empirical literature finding that non-competes reduce new business formation, as well as with the hundreds of comments from small businesses, including physician practices, recounting how non-competes stymied their ability to enter markets or grow because they make it harder to hire talent.

Several commenters claimed that prohibiting non-competes would increase worker earnings and increase transaction costs related to hiring, which firms would pass through to consumers in the form of higher prices. However, the only study of how non-competes affect prices—the Hausman and Lavetti study—finds that decreased non-compete enforceability *decreases* prices in the healthcare market, rather than increasing them. Moreover, while it is theoretically possible that higher labor costs could be passed on to consumers in the form of higher prices, there are several countervailing effects from prohibiting non-competes that would tend to lower prices. Additionally, empirical research shows that labor cost pass-through cannot explain decreases in prices in healthcare markets associated with non-competes becoming less enforceable.[597]

An insurance company stated that insurance premiums would increase if the rule allows non-profit hospitals to dominate the hospital market and have more leverage in network negotiations. These commenters do not provide any empirical evidence to support this assertion. Moreover, for the reasons described in Part V.D.5, the Commission disagrees that the ability to use non-competes will provide a material competitive advantage to non-profit hospitals. Another commenter stated that if non-competes are prohibited, physicians will leave States with lower market reimbursement rates for those with higher rates, increasing healthcare costs and shortages. Commenters did not cite any empirical evidence that supports this hypothetical assertion that the final rule would increase healthcare costs or shortages due to physicians leaving States with lower reimbursement rates, and the Commission is aware of none. However, the Commission notes that it received many comments from doctors, nurses, and other healthcare professionals asserting that non-competes worsen healthcare shortages.[598]

Some commenters stated that non-competes may improve access to physicians due to non-compete-led consolidation or more efficient patient-sharing within practices, and that Hausman and Lavetti's study is unable to quantify these benefits. In response, the Commission notes that there is no empirical literature bearing out this theory, and that the commenters overwhelmingly stated that non-competes decrease patients' access to the physicians of their choice, increase healthcare shortages, and negatively affect the quality of health care.[599]

iv. Non-Competes May Reduce Product and Service Quality and Consumer Choice

The negative effects of non-competes on competition may also degrade product and service quality and consumer choice. Competition encourages firms to expand their product offerings and innovate in ways that lead to new and better products and services.[600] However, by inhibiting new business formation, increasing concentration, and reducing innovation, non-competes reduce competitive pressure in product and service markets, which may reduce product quality and consumer choice. In addition, poor working conditions and less optimal matching of workers and firms may lead to reductions in the quality of products and services. For these reasons, non-competes may tend to negatively affect competitive conditions in product and service markets by reducing product quality and consumers' options.

Such effects are less readily quantifiable than the other negative effects of non-competes on product and service markets—*i.e.,* the negative effects on new business formation, innovation, concentration, and consumer prices. It is thus unsurprising that there are not reliable empirical studies of these effects. However, the Commission received an outpouring of public comments on this issue. Hundreds of commenters, primarily from the healthcare field, described how

[594] *See* Part IV.A.2 (describing the shortcomings of such studies).

[595] Kenneth A. Younge, Tony W. Tong, & Lee Fleming, *How Anticipated Employee Mobility Affects Acquisition Likelihood: Evidence From a Natural Experiment,* 36 Strategic Mgmt. J. 686 (2015).

[596] *See also* Part XI.C.2, which addresses these types of comments in greater detail.

[597] Hausman & Lavetti, *supra* note 590.

[598] These comments are summarized in greater detail in Part IV.B.3.b.iv.

[599] *See* Part IV.B.3.b.iv.

[600] In the NPRM, the Commission noted that innovation and entrepreneurship can, in turn, have positive effects on product quality. *See* NPRM at 3492. The Commission did not make specific findings on the effect of non-competes on consumer choice. However, the Commission discussed the closely related questions of how non-competes affect new business formation, innovation, concentration, and consumer prices. *See id.* at 3490–93.

non-competes reduce product and service quality and consumer choice.

The large number of comments the Commission received on this issue, the wide variety of impacts commenters describe, and the fact that the impacts commenters describe are overwhelmingly negative, indicate that non-competes reduce product quality and consumer choice, further bolstering the Commission's finding that non-competes tend to negatively affect competitive conditions in product and service markets.[601]

The commenters who addressed the effects of non-competes on product quality and consumer choice primarily discussed the healthcare industry. The majority of these comments focused on how non-competes harm patient care. Hundreds of physicians and other commenters in the healthcare industry stated that non-competes negatively affect physicians' ability to provide quality care and limit patient access to care, including emergency care. Many of these commenters stated that non-competes restrict physicians from leaving practices and increase the risk of retaliation if physicians object to the practices' operations, poor care or services, workload demands, or corporate interference with their clinical judgment. Other commenters from the healthcare industry said that, like other industries, non-competes bar competitors from the market and prevent providers from moving to or starting competing firms, thus limiting access to care and patient choice. Physicians and physician organizations said non-competes contribute to burnout and job dissatisfaction, and said burnout negatively impacts patient care.

In addition, physicians and physician organizations stated that, to escape non-competes, physicians often leave the area, and that this severs many physician/patient relationships. These commenters stated that non-competes therefore cause patients to lose the knowledge, trust, and compatibility that comes with long-established relationships. These commenters also said that strong physician/patient relationships and continuity of care improve health outcomes, particularly for complex, chronic conditions or patients who need multiple surgeries. These commenters described how patients who lose their physicians to non-competes either travel long distances to see that physician, switch physicians, or lose access entirely if no other physicians are available. One physician argued that taking away a patient's ability to choose their provider violates the Patients' Bill of Rights.[602]

One medical society cited a 2022 survey of Louisiana surgeons in which 64.4% of the surgeons believed non-competes force patients to drive long distances to maintain continuity of care, and 76.7% believed they force surgeons to abandon their patients if they seek new employment.[603] This study had a small sample size and thus the Commission gives it limited weight, but the Commission notes that it accords with the many comments the Commission received describing how patients must drive long distances to maintain continuity of care—or are unable to do so, resulting in harms to their health. Illustrative comments on how non-competes affect the quality of patient care include the following:

- As a primary care physician I truly hope to see [the rule] move forward. I recently left my position at one company and for a year commuted an hour to be outside of my non-compete radius. I recently returned to my community and discovered I have more patients than I can count who simply didn't get care for over a year because they didn't want to find a new [primary care physician] but also couldn't make the hour drive to see me at my new location. The commute was annoying for me, but ultimately the only ones truly hurt were patients. Let's stop hurting our patients by restricting their ability to see their physicians.[604]
- My practice has operated since the 1990s in Danville, Kentucky. We are the only cardiology practice that has been present and has worked tirelessly to serve this rural community. The practice was a private practice originally. Unfortunately, just as most cardiac practices throughout the country have had to, our practice had to come under the control of these hospital systems to maintain its viability. . . . The CEO and the administration . . . have squeezed us out and forced us to leave the area with the employment contract non-compete in place. . . . I have spent the last 6 months hugging patients, medical staff, nursing who are stricken by the fact that we are being pushed out. Patients desperately ask me how they can maintain care if they have to travel up to an hour to see their doctors with this change. They worry how they can pay for the steep gas prices to see their doctors. . . . They are truly concerned for the health of their families. All the while all I can do is tell them that my non-compete does not allow me, their cardiologist for the past decade, to give them any advice on how to maintain their care.[605]
- As a Physician, I had a non compete clause in my contract that extended two counties wide (100 square miles). . . . [W]hen I would not sign a contract amendment regarding pay that was very unfavorable and nebulous I was called in and summarily dismissed 'no cause.' Because of that I had to work out of state and my patients were instantly without a physician. The community did not have enough physicians to be able to care for the patients who now had no medical provider. During COVID this lack of access to healthcare for patients most certainly led to increased unnecessary illness and death. . . . Patients are suffering with access to healthcare, and physician shortages are being exacerbated because every time a physician has to leave because of a non compete clause they start hiring and credentialing all over again and it can take months for them to be able to work again.[606]
- Being a therapist, non-competes are extremely scary when it comes to patient care. Some include date ranges in which we cannot communicate with our patients, some of whom have severe trauma histories or suicidal ideations. If a clinician changes companies but is unable to continue meeting a patient, who is at fault if there is an injury or death? . . . Some non-competes include mileage in which a clinician cannot create their own company or rent out an office within a certain radius—how is this a safe practice? How can clients continue to work on their mental health and desire to stay alive if they have to change clinicians due to a noncompete clause?[607]
- Due to mistreatment and to escape workplace toxicity, one of my colleagues left our practice in compliance to our non-compete conditions, even though they caused great hardship. I, too, wanted to leave, but could not because doing so would have harmed my family's well being. What I witnessed in the aftermath was unconscionable. There was a void in patient care and months later, there still is a void. Not only was this physician required to move quite a distance from the practice, he was forbidden to even inform his patients that he was leaving. The practice in turn, did not inform the patients, and when asked, just informed them that he was no longer with the practice. Consequently, wait times to treat cancers doubled and now have tripled.[608]
- I would like to open a new clinic in my town, but my noncompete would disallow that from happening immediately. Furthermore, I worry that my patients that need medical care wouldn't be able to access it at my current clinic because the providers

[601] As described in Parts IV.B.3.b.i and ii, the Commission finds that the effects of non-competes on new business formation and innovation, standing alone, are sufficient to sustain its finding that non-competes tend to negatively affect competitive conditions in product and service markets.

[602] *See* President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry, *Consumer Bill of Rights and Responsibilities, Executive Summary* (1997), *https://govinfo.library.unt.edu/hcquality/cborr/index.htm.*

[603] *See* William F. Sherman et al., *The Impact of a Non-Compete Clause on Patient Care and Orthopaedic Surgeons in the State of Louisiana: Afraid of a Little Competition?,* 14 Orthopedic Revs. (Oct. 2022), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9569414/.*

[604] Individual commenter, FTC–2023–0007–19853.

[605] Individual commenter, FTC–2023–0007–4072.

[606] Individual commenter, FTC–2023–0007–4440.

[607] Individual commenter, FTC–2023–0007–4270.

[608] Individual commenter, FTC–2023–0007–2384.

are booked out 6+ months, and if one left that would make those immediately increase to nearly a year, which could potentially cause my patient lasting damage. If I could open my own clinic locally without the constraints of the noncompete, those patients would be able to continue care as necessary with me, and I wouldn't feel stuck with poor management worsening patient care for my patients.[609]

- As a veterinarian, I can personally assure the FTC that such restrictions have caused both death and permanent disability of pets. . . . In nearly every scenario I have heard of, the veterinary business that requires and enforces non-compete clauses is underserving the pet-owning public. This is the current situation for veterinary medicine on a national level. Hospitals are so overwhelmed that they are not accepting new patients, turning away emergency cases, and imposing extremely long (several months or more) waiting lists for appointments and/or scheduled procedures. If a hospital cannot accommodate the patients who require veterinary care, that hospital is not able to compete with the existing demand for services. . . . Is it fair for pet owners who cannot get their pets in to see a veterinarian (even on emergency situations) to have the veterinary hospitals who refuse to see their pets remove other options for care via non-compete clauses? These clauses are being blatantly abused by certain large veterinary businesses so that these organizations can maintain a pool of potential patients (on waiting lists) to draw from. Unfortunately, many of these dogs and cats die while waiting to be seen. At least in my profession, the non-compete concept has reached an epitome of unethical conduct. In addition, economic growth has been stunted due to self-serving greedy people in power. Please get rid of this horrible clause and lets make sure pets and their owners get what they need, when they need it.[610]

Some hospital associations argued that a study of physician markets[611] shows that non-competes improve patient care. According to these commenters, this research finds that non-competes make in-practice referrals more likely, increasing revenue and wages and providing patients with more integrated and better care. In response, the Commission notes that while the study finds that non-competes make physicians more likely to refer patients to other physicians within their practice—increasing revenue for the practice—it makes no findings on the impact on the quality of patient care. The Commission further notes that pecuniary benefits to a firm cannot justify an unfair method of competition.[612]

Some medical practices argued that within-group referrals allow physicians to coordinate care plans and simplify logistics, and that non-competes protect the stability of those care teams to patients' benefit. Some industry associations and hospitals argued that non-competes improve patient choice and continuity of care because they stop physicians from leaving a health provider, benefiting patients who cannot follow the provider due to geographic or insurance limitations. One physician association said physicians leaving jobs can be costly to patients, who must transfer records and reevaluate insurance coverage.

The Commission notes that the vast majority of comments from physicians and other stakeholders in the healthcare industry assert that non-competes result in worse patient care. The Commission further notes that the American Medical Association discourages the use of non-competes because they ''can disrupt continuity of care, and may limit access to care.'' [613] In addition, there are alternatives for improving patient choice and quality of care, and for retaining physicians, that burden competition to a much less significant degree than non-competes.

A related issue frequently raised in the comments is the impact non-competes have on healthcare shortages. According to many commenters, non-competes contribute to shortages by preventing physicians from moving to areas where their skills and specialties are needed; forcing physicians out of such areas; or forcing them out of practice entirely due to contractual restrictions or burnout. Such shortages, according to these commenters, decrease access to care, increase wait times, lead to canceled procedures, and decrease the quality of care. Many commenters stated that these effects of non-competes are particularly acute in rural, underserved, and less affluent areas that already have difficulty attracting healthcare professionals. Some commenters argued that provider shortages can, in combination with non-competes, create monopolies.

A smaller number of commenters from the healthcare industry argued that non-competes alleviate healthcare shortages and prevent hospital or facility closures by keeping physicians from leaving underserved areas and reducing fluctuations in labor costs. Some of these commenters asserted that a ban on non-competes would upend healthcare labor markets, thereby exacerbating healthcare workforce shortages, especially in rural and underserved areas. A medical society argued that non-competes can allow groups to meet contractual obligations to hospitals, as physicians leaving can prevent the group from ensuring safe care. As the Commission notes, there are not reliable empirical studies of these effects, and these commenters do not provide any. However, the Commission notes that the rule will increase labor mobility generally, which makes it easier for firms to hire qualified workers.

Commenters in a variety of industries beyond healthcare markets also provided a wide range of examples of how non-competes diminish the quality of goods and services, including preventing businesses from hiring experienced staff and creating worker shortages. Commenters stated that, where firms in a market use non-competes, it can be difficult for other firms to remain in the market, and consumers thus lose the freedom to choose providers. Several comments pointed favorably to the American Bar Association's longstanding ban on non-competes for most lawyers to protect clients' freedom to choose their lawyer, in contrast with other highly paid and highly skilled professions such as physicians and their patients or clients.[614]

Commenters from outside the healthcare industry mainly focused on how non-competes increase concentration within industries, which reduces firms' incentive to innovate and results in consumers having fewer choices. Other commenters described how non-competes lock highly talented workers out of their fields or force them into jobs where they are less productive, depriving the marketplace of the products and services they would have developed. Illustrative examples of these comments include the following:

- As a software developer who often works under contracts containing sections stipulating non-compete agreements, I have observed first hand how they can harm the economy by bolstering monopolies, such as in sectors where clientele only have a single choice for meeting their engineering needs. Often, these clients have no other options and are forced to meet whatever arbitrary price point is set by the leading (sole)

[609] Individual commenter, FTC–2023–0007–1206.

[610] Individual commenter, FTC–2023–0007–0677.

[611] Lavetti, Simon, & White, *supra* note 82.

[612] *See supra* note 305 and accompanying text.

[613] *See, e.g.,* Comment of Am. Med. Ass'n, FTC–2023–0007–21017, at 4–5 (citing AMA *Code of Medical Ethics* Opinion 11.2.3.1). After the comment period closed, the AMA adopted a policy supporting banning non-competes for physicians in clinical practice who are employed by hospitals, hospital systems, or staffing companies, though not those employed by private practices. This policy change does not have legal effect. Andis Robeznieks, *AMA Backs Effort to Ban Many Physician Noncompete Provisions,* Am. Med. Ass'n (Jun. 13, 2023), *https://www.ama-assn.org/medical-residents/transition-resident-attending/ama-backs-effort-ban-many-physician-noncompete.*

[614] *See* Model Rule 5.6, *supra* note 532.

company, and that company may in turn operate howsoever they choose without feeling the need to adopt reasonable business practices that might exist were there competition.[615]

- As an aspiring tree care professional, non-compete agreements prevent me from switching employers/companies to access better work conditions or opportunities. No tree service company has ever invested in me. I learned to climb and saw while working for Federal agencies (USDA and NPS), and also through self-education and practice on my own. I believe that non-compete agreements have adversely limited competition in the tree service industry. This hurts employees who could do better if they were free to change their place of employment, and it hurts consumers who have fewer tree service providers to choose from.[616]
- I worked in a business supplying technology and materiel considered critical for national defense. I was labeled an expert in the field by my DoD customers and commended multiple times for solving logistical and technical problems with protective equipment during the previous two wars. I lead development contracts from the DoD to advance the state-of-the-art in warfighter protection, which set multiple records for figures of merit within my business, and which our program manager volunteered was the most exciting technology she had ever managed. When my business decided to discontinue that technology and transfer me, my noncompete agreement prevented me from continuing to support the DoD. I was removed from consideration at another firm in the third round of interviews because of my noncompete agreement—again, for a technology my business had decided to not pursue and had transferred me out of. So, instead of having the opportunity to advance my career into management in the service of protecting warfighters, I had to exit that industry and move laterally, into a different industry that cannot value 20 years of my expertise, and which will not further the defense of my country. If the FTC had nationalized a prohibition on noncompete clauses two years ago, this would not have happened, and I would have had the opportunity to advance my career, improve my family's economic fortune, and continue to contribute to our nation's defense.[617]

Overall, the Commission believes that the large number of comments it received on the issue of product quality and consumer choice and the wide variety of overwhelmingly negative impacts commenters describe further bolsters the Commission's finding that non-competes tend to negatively affect competitive conditions in product and service markets.

4. Prohibitions in Section 910.2(a)(1)

Based on the totality of the evidence, including its review of the empirical literature, its review of the full comment record, and its expertise in identifying practices that harm competition, the Commission adopts § 910.2(a)(1), which defines unfair methods of competition related to non-competes with respect to workers other than senior executives. Section 910.2(a)(1) provides that, with respect to a worker other than a senior executive, it is an unfair method of competition for a person to enter into or attempt to enter into a non-compete clause; enforce or attempt to enforce a non-compete clause; or represent that the worker is subject to a non-compete clause.

Part IV.A sets forth the Commission's determination that the foregoing practices are unfair methods of competition under section 5, and Parts IV.B.1 through IV.B.3 explain the findings that provide the basis for this determination. In this Part IV.B.4, the Commission explains the three prongs of § 910.2(a)(1) and addresses comments on proposed § 910.2(a).[618]

a. Entering Into or Attempting To Enter Into (§ 910.2(a)(1)(i))

Proposed § 910.2(a) would have provided that it is an unfair method of competition for an employer to, among other things, ''enter into or attempt to enter into a non-compete clause with a worker.'' The Commission adopts this same language in the final rule in § 910.2(a)(1)(i). As a result, the final rule prohibits persons from entering into or attempting to enter into non-competes with workers other than senior executives as of the effective date. (Section 910.2(a)(2)(i) separately prohibits persons from entering into or attempting to enter into non-competes with senior executives as of the effective date.)

A business commenter requested that the Commission remove ''attempt to enter into'' from § 910.2(a) on the basis that it may encourage workers to sue employers for contractual provisions that have no practical effect on the worker or which are not finalized in any employment agreement. The Commission disagrees that conduct that would be covered by the attempt provision—such as presenting the worker with a non-compete, even if the employer and worker do not ultimately execute the non-compete—has no practical effect on the worker. The Commission is concerned that such attempts to enter into non-competes still have *in terrorem* effects that deter competition. For example, workers presented with non-competes may not realize they are not bound by them. Such workers may therefore refrain from seeking or accepting other work or starting a business, yielding the same tendency of non-competes to negatively affect competitive conditions that motivate this final rule.

The Commission accordingly finalizes the language as proposed.

b. Enforcing or Attempting To Enforce (§ 910.2(a)(1)(ii))

Proposed § 910.2(a) would have provided that it is an unfair method of competition for an employer to, among other things, ''maintain with a worker a non-compete clause.'' In addition, proposed § 910.2(b)(1) would have provided that, to comply with this prohibition on maintaining a non-compete, an employer that entered into a non-compete with a worker prior to the compliance date must ''rescind the non-compete no later than the compliance date.''

As elaborated in Part IV.E, the Commission has decided not to finalize a rescission requirement. As a result, the Commission also removes ''maintain'' from the text of § 910.2(a), to avoid any ambiguity about whether the final rule contains a rescission requirement. Instead of a rescission requirement, the final rule focuses more narrowly on the future enforcement of existing non-competes with workers other than senior executives. It provides that, with respect to a worker other than a senior executive, it is an unfair method of competition for a person to enforce or attempt to enforce a non-compete clause. An employer attempts to enforce a non-compete where, for example, it takes steps toward initiating legal action to enforce the non-compete, even if the court does not enter a final order enforcing the non-compete.

For workers other than senior executives, this prohibition on enforcing a non-compete applies to all non-competes, but affects only enforcement or attempted enforcement conduct taken after the effective date of the rule. In so doing, the Commission reduces the burden on employers by eliminating the need to take steps to formally rescind provisions of existing contracts, instead simply requiring that employers refrain from enforcing or attempting to enforce in the future (after the effective date) non-competes that are rendered unenforceable by this provision of the rule.

As explained in Part IV.C, the Commission in the final rule does not prohibit the future enforcement or attempted enforcement of existing non-

[615] Individual commenter, FTC–2023–0007–5818.
[616] Individual commenter, FTC–2023–0007–1980.
[617] Individual commenter, FTC–2023–0007–4446.
[618] Several commenters requested changes to proposed § 910.2(a) to provide various exceptions to coverage under the final rule. The Commission addresses these comments in Part V.C.

competes with senior executives. The Commission considered whether to take this approach for workers other than senior executives, but based on the totality of the evidentiary record concludes that such non-competes should not remain in force after the effective date for three main reasons. First, existing non-competes with workers other than senior executives negatively affect competitive conditions to a significant degree, for the same reasons as new non-competes. The Commission believes that non-competes with such workers that were entered into before the effective date implicate the concerns described in Part IV.B.3—relating to the negative effects of non-competes on competitive conditions in labor, product, or service markets—to the same degree as non-competes entered into as of the effective date. Of course, the Commission notes that the empirical evidence quantifying the harms to competition from non-competes by definition relates to existing non-competes.

Second, for workers other than senior executives, existing non-competes not only impose acute, ongoing harms to competition, they also impose such harms on individual workers by restricting them from engaging in competitive activity by seeking or accepting work or starting their own business after their employment ends. As described in Part IV.B.2.b, the Commission received thousands of comments from workers that described non-competes as pernicious forces in their lives that forced them to make choices that were detrimental to their finances, their careers, and their families. These concerns are less present for senior executives, who are far more likely than other workers to have negotiated their non-compete and received compensation in return, thereby mitigating this kind of acute, ongoing harm.

Third, because the Commission finds that non-competes with workers other than senior executives generally are not bargained for and such workers generally do not receive meaningful, if any, compensation for non-competes, the practical considerations that are present with respect to existing non-competes for senior executives (discussed in Part IV.C.3) are far less likely to be present for other workers. For these reasons, the Commission concludes that, consistent with the proposed rule, existing non-competes with workers other than senior executives should not remain in force after the effective date.

Several commenters argued that the Commission should allow all existing non-competes to remain in effect. Some of these commenters argued that the rule would upset bargained-for agreements. Commenters asserted that workers who received benefits in exchange for agreeing to non-competes would receive a windfall if such clauses cannot be maintained and are no longer enforceable. A few of these commenters also argued that invalidating existing non-compete agreements will upset workers' economic interests because they will lose out on enhanced compensation that they have received or expect to receive in exchange for their non-competes. Some commenters contended that invalidating existing non-competes would be especially harmful to workers' interests in non-competes tied to particularly large amounts of compensation, complex compensation arrangements, or unique forms of compensation such as equity grants. Relatedly, some commenters expressed concern that the NPRM did not explain whether employers could recoup benefits already paid in exchange for non-competes. A few commenters suggested that they have given workers confidential and trade secret information in exchange for the worker agreeing to a non-compete that may no longer be enforceable.

The Commission is not persuaded by comments arguing that the rule would upset existing bargained-for agreements. As noted in Part IV.B and Part IV.C, the Commission finds that workers who are not senior executives are unlikely to negotiate non-competes or to receive compensation for them. Moreover, the Commission has also determined that non-competes with senior executives that predate the effective date may be enforced,[619] which will substantially reduce the number of workers with complex compensation arrangements whose non-competes are rendered unenforceable after the effective date.

Other commenters argued that employers relied on the expectation of a non-compete when deciding how much to invest in training their workers or the extent to which they share trade secrets with their workers. In response, the Commission notes that firms that are concerned about retention have tools other than non-competes for retaining workers, including fixed-duration employment contracts (*i.e.,* forgoing at-will employment and instead making a mutual contractual commitment to a period of employment) and providing improved pay and benefits (*i.e.,* competing on the merits to retain the worker's labor services). In addition, while some workers that have received training may leave a firm for a competitor, firms will also be able to attract highly trained workers *from* competitors, and this increased job-switching will likely lead to more efficient matching between workers and employers overall.[620]

The Commission is not persuaded by commenters who contended that invalidating existing non-competes would disturb employer expectations with respect to sharing trade secrets or other commercially sensitive information. As explained in Part IV.D.2, the Commission finds that employers have adequate alternatives to non-competes to protect these interests, including trade secret law and NDAs, and that these alternatives do not impose the same burden on competition as non-competes. Some commenters contended that employers may not have adequate alternatives in place for existing non-competes and that former workers may not agree to new NDAs. But the Commission finds that it is rare for an employer who entered into a non-compete agreement as a means of protecting trade secrets or commercially sensitive information to have not also entered into an NDA with the worker.[621] This is especially true given that non-competes are generally less enforceable than NDAs.[622] In any event, nothing in the final rule prevents employers from entering new NDAs with workers.

Some commenters contended that invalidating existing non-competes would enable new employers to ''free ride'' off former employers' investments in training. The Commission addresses comments about ''free riding'' and training investments in Part IV.D.2.

Several comments argued that a final rule should not invalidate existing non-competes because the economic impact is too unpredictable. These commenters maintained that the number of individual employment contracts that would be invalidated means that the economic impact would be exceptionally widespread, and likely impossible to accurately predict. In response, the Commission notes that it

[619] *See* Part IV.C.3.

[620] *See* Part IV.B.3.a.

[621] *See, e.g.,* Balasubramanian, Starr, & Yamaguchi, *supra* note 74 at 35 (finding that 97.5% of workers with non-competes are also subject to a non-solicitation agreement, NDA, or a non-recruitment agreement, and 74.7% of workers with non-competes are subject to all three provisions).

[622] Camilla A. Hrdy & Christopher B. Seaman, *Beyond Trade Secrecy: Confidentiality Agreements that Act Like Noncompetes,* 133 Yale L. J. 669, 676 (2024) (''Courts across jurisdictions routinely give confidentiality agreements 'more favorable treatment' than noncompetes. And confidentiality agreements are not typically subject to the same limitations that are applied to noncompetes. . . . Overall, courts tend to apply a default rule of enforceability.'') (internal citations omitted).

has assessed the benefits and costs of the final rule and finds that the final rule has substantial benefits that clearly justify the costs (even in the absence of full monetization).[623]

c. Representing (§ 910.2(a)(1)(iii))

Proposed § 910.2(a) would have provided that it is an unfair method of competition for an employer to, among other things, ''represent to a worker that the worker is subject to a non-compete clause where the employer has no good faith basis to believe that the worker is subject to an enforceable non-compete clause.'' The Commission adopts the same language in the final rule. Pursuant to § 910.2(a)(1)(iii), it is an unfair method of competition for an employer to represent that a worker other than a senior executive is subject to a non-compete clause. The ''good faith'' language remains in the final rule but, for clarity, it has been moved to § 910.3, which contains exceptions to the final rule.[624]

Under this ''representation'' prong, the final rule prohibits an employer from, among other things, threatening to enforce a non-compete against the worker; advising the worker that, due to a non-compete, they should not pursue a particular job opportunity; or telling the worker that the worker is subject to a non-compete. The Commission believes that this prohibition on representation is important because workers often lack knowledge of whether employers may enforce non-competes.[625] In addition, the evidence indicates that employers frequently use non-competes even when they are unenforceable under State law, suggesting that employers may believe workers are unaware of or unable to vindicate their legal rights.[626] Employers can exploit the fact that many workers lack knowledge of whether non-competes are unenforceable under State law by representing to workers that they are subject to a non-compete when they are not or when the non-compete is unenforceable. Such misrepresentations can have *in terrorem* effects on workers, causing them to refrain from looking for work or taking another job, thereby furthering the adverse effects on competition that the Commission is concerned about.

In addition, threats to litigate against a worker—even where the worker is aware of the Commission's rule and believes the non-compete is unenforceable—may deter the worker from seeking or accepting work or starting their own business. As explained in Part IV.B.2.b.ii, many commenters—including highly paid workers—explained in their comments that they believed their non-compete was unenforceable, but they nevertheless refrained from seeking or accepting work or starting their own business because they could not afford to litigate against their employer for any length of time. For this reason, the Commission believes it is important for the final rule to prohibit employers not only from enforcing or attempting to enforce non-competes against workers other than senior executives, but also threatening to do so.

A commenter suggested limiting the ''representation'' prong to instances where the employer has no good-faith basis to believe the non-compete is valid ''under local or State law,'' even if the non-compete is invalid under the final rule. The Commission does not adopt this approach because representing to workers that they are subject to a non-compete, where the rule provides that the non-compete is unenforceable, would mislead the worker and would tend to deter them from competing against the employer by seeking or accepting work or starting a business.

C. Section 910.2(a)(2): Unfair Methods of Competition—Non-Competes With Senior Executives

In the NPRM, the Commission proposed to prohibit non-competes—including non-competes entered into before the effective date—with all workers.[627] The Commission preliminarily found that all non-competes, whether with senior executives or other workers, were restrictive conduct that negatively affected competitive conditions.[628] However, while the Commission preliminarily found that non-competes with workers other than senior executives were exploitative and coercive, the Commission stated that this finding did not apply to senior executives.[629] The Commission requested comment on that preliminary finding, as well as on whether non-competes with senior executives should be excluded from the rule or otherwise subject to a different standard. The NPRM did not define the term ''senior executive,'' but sought comment on potential approaches to defining the term.[630]

In the final rule, the Commission does not find that senior executives—specifically, highly paid workers with the highest levels of authority in an organization—are exploited or coerced in connection with non-competes, and it describes the record on this issue in Part IV.C.1. The Commission does, however, find that non-competes with senior executives are an unfair method of competition, based on the totality of the evidence, including its review of the empirical literature, its review of the full comment record, and its expertise in identifying practices that impair competitive conditions in the economy. Specifically, the Commission finds that such non-competes are restrictive and exclusionary conduct that tends to negatively affect competitive conditions in product and service markets and labor markets. Indeed, non-competes with senior executives may tend to negatively affect competitive conditions in product and service markets to an even greater degree than non-competes with other workers, given the outsized role senior executives play in forming new businesses and setting the strategic direction of firms with respect to innovation. The Commission explains the basis for these findings in Part IV.C.2.

Because non-competes with senior executives are not exploitative or coercive, however, this subset of workers is less likely to be subject to the kind of acute, ongoing harms currently being suffered by other workers subject to existing non-competes. In addition, commenters raised credible concerns about the practical impacts of extinguishing existing non-competes for senior executives. For these reasons, as described in Part IV.C.3, the Commission allows existing non-competes with senior executives to remain in force—unlike existing non-competes with all other workers, which employers may not enforce after the effective date.

In Part IV.C.4, the Commission explains the final rule's definition of ''senior executive'' and the related definitions it is adopting.[631] The Commission finds that the final rule's definition of ''senior executive'' appropriately captures the workers that are more likely to have complex compensation packages that present practical challenges to untangle, and who are less likely to be exploited or coerced in connection with their non-competes. To capture this subset of

[623] *See* Part X.E.

[624] *See* Part V.C.

[625] *See* Prescott & Starr, *supra* note 413 at 10–11.

[626] *See* Starr, Prescott, & Bishara, *supra* note 68 at 81.

[627] NPRM, proposed § 910.2(a).

[628] *Id.* at 3500.

[629] *Id.* at 3502–04.

[630] *Id.* at 3520.

[631] *See* § 910.1.

workers for whom the Commission decides to leave existing non-competes unaffected, the final rule adopts a definition of senior executive that uses both an earnings test and a job duties test. Specifically, the final rule defines the term ''senior executive'' to refer to workers earning more than $151,164 who are in a ''policy-making position'' as defined in the final rule.[632]

Finally, in Part IV.C.5, the Commission explains the regulatory text it is adopting in § 910.2(a)(2), which defines unfair methods of competition related to non-competes with senior executives.

1. The Commission Does Not Find That Non-Competes With Senior Executives Are Exploitative or Coercive

The Commission stated in the NPRM that its preliminary finding that non-competes are exploitative and coercive did not apply to senior executives. The Commission stated that non-competes with senior executives are unlikely to be exploitative or coercive at the time of contracting, because senior executives are likely to negotiate the terms of their employment and may often do so with the assistance of counsel.[633] The Commission also stated that such non-competes are unlikely to be exploitative or coercive at the time of the executive's potential departure, because senior executives are likely to have bargained for a higher wage or more generous severance package in exchange for agreeing to the non-compete.[634] The Commission sought comment on whether there are other categories of highly paid or highly skilled workers (*i.e.,* other than senior executives) who are not exploited or coerced in connection with non-competes.[635]

Based on the totality of the record, including the many comments submitted on these questions, the Commission finds that senior executives—specifically, highly paid workers with the highest levels of authority in an organization—are substantially less likely than other workers to be exploited or coerced in connection with non-competes. For these reasons, the Commission does not find that non-competes with senior executives are exploitative or coercive.

There is little empirical evidence on the question of whether non-competes with senior executives are exploitative or coercive. A 2006 study of non-competes with CEOs finds that many of these workers negotiated a severance period as long or longer than their non-compete period, making it easier to sit out of the market.[636] However, this study was limited to very-high-earning CEOs at large public companies—the average total compensation of the CEOs studied was $1.65 million [637]—so its findings do not necessarily capture the experiences of other senior executives. Many Americans work in positions with ''senior executive'' classifications. According to BLS, there were almost 3.4 million ''top executives'' in the U.S. in 2022 at firms under private ownership, and the median income for these workers was $99,240.[638]

The comment record on whether senior executives experience exploitation and coercion in relation to their non-competes is mixed. Many commenters asserted that, because some senior executives negotiate their non-competes with the assistance of expert counsel, they are likely to have bargained for a higher wage or more generous severance package in exchange for agreeing to the non-compete, and thus their non-competes are not exploitative or coercive. Several commenters stated that senior executives frequently negotiate non-competes for valuable consideration and/or typically agree to non-competes only in exchange for compensation. Some senior executives said they were not exploited or coerced in connection with non-competes.[639] Several commenters agreed with the Commission's preliminary finding that senior executives often obtain the assistance of counsel with respect to non-competes. Some commenters stated that to the extent a non-compete is not exploitative or coercive at the time of contracting, it is also not exploitative or coercive at the time of departure. One CEO stated that non-competes should be permissible for senior executives when they are entered into in exchange for severance and when the senior executive leaves voluntarily.

The Commission notes that a relatively small number of self-identified senior executives submitted comments in their personal capacity. While the Commission did receive some comments from self-identified senior executives suggesting that their non-competes were exploitative and coercive, such comments were far less common than for other workers. However, some senior executives did report experiencing similar issues of exploitation and coercion. Several senior executives said that their non-competes were required and non-negotiable. Multiple senior executives described their own non-competes as ''one-sided'' in favor of the employer. Some senior executives said they were not given consideration for the non-compete, and even some who said they received consideration still said their non-competes were exploitative and coercive. For example, some senior executives said they: (1) were required to sign a non-compete under threat of losing their job or their earned compensation; (2) were forced into a stock share buyout that included a non-compete; or (3) could obtain long-term compensation only if they signed a non-compete. Two advocacy groups stated that many senior executives may lack power to avoid non-competes and that employers still hold most of the leverage in employment negotiations, even with respect to senior executives. An employment law firm stated that in its experience, it had not seen higher compensation for senior executives and other highly paid workers in jurisdictions where non-competes were allowed, and that employers rarely provide compensation for non-competes. The firm said that senior executives and other highly paid workers are more likely to receive severance payments, but such payments are paid only in some cases. It said that even when paid, the severance payments often do not fully compensate for what a senior executive could have otherwise earned during the non-compete period.

Furthermore, several self-identified senior executives said they felt unable to leave their company because of their non-competes. Many of these commenters said they feared being unemployed. Some senior executives said they feared or could not afford litigation, while two senior executives said that they could not afford to fight non-competes they believed were unenforceable. Several self-identified senior executives, having spent their careers in one industry, said they were forced to sit out of the market for long periods, forgoing earnings and the ability to work. Others reported struggling to find a job and suffering

[632] *Id.*

[633] NPRM at 3503.

[634] *Id.* at 3504.

[635] *Id.* at 3503–04.

[636] Stewart J. Schwab & Randall S. Thomas, *An Empirical Analysis of CEO Employment Contracts: What Do Top Executives Bargain For?,* 63 Wash. & Lee L. Rev. 231, 256–57 (2006).

[637] *Id.* at 244.

[638] BLS, Occupational Employment and Wage Statistics, *Tables Created by BLS, https://www.bls.gov/oes.tables.htm.* These data are from the May 2022 National XLS table for Top Executives under private ownership.

[639] For the sake of readability, the Commission refers to the commenters based on how they described themselves. For example, if a commenter said they were a senior executive, the Commission refers to them as a senior executive (rather than as a ''self-described senior executive'').

financially, including living on Social Security or nearing bankruptcy.

One law firm specializing in executive compensation said many senior executives may have achieved top roles at companies because they have spent decades in the same industry and would struggle to find work with firms other than competitors. Another law firm said senior executives blocked from an industry could lose their long-cultivated reputation in the industry and, as a result, time out of an industry could harm their careers. Worker advocacy organizations and a law firm said senior executives tend to be relatively older and, as older workers are forced out of the job market, they are likely to be losing out on increasingly scarce employment opportunities relative to their younger counterparts. Another advocacy group argued that the Commission did not provide sufficient evidence to support its preliminary finding that non-competes are not exploitative and coercive for senior executives. A few commenters suggested that senior executives from historically marginalized groups may be paid less and have less bargaining power than other senior executives.[640]

Critically, the Commission received an outpouring of comments indicating that highly paid workers who are *not* senior executives (*i.e.,* who are not workers with the highest levels of authority in an organization) are often coerced or exploited via non-competes. The Commission received many comments from workers in relatively higher-wage fields—such as medicine, engineering, finance and insurance, and technology—who stated that employers exploited and coerced them through the use of non-competes.[641] The vast majority of higher-wage workers who are not senior executives reported that they lacked bargaining power in relation to their employer; did not negotiate their non-compete or receive compensation for it; and/or were not informed of the non-compete until after they received the job offer. Many of these workers stated that their non-compete was hidden or obscured; that their employers misled them about the terms of a non-compete; and/or that the non-compete was confusingly worded or vague. In addition, many high-wage workers recounted how non-competes coerced them into refraining from competing against their employer by forcing them to stay in jobs they wanted to leave or forcing them to leave their profession, move their families far away, and/or commute long distances. And a large share of high-wage workers argued that even where their non-competes were overbroad and likely unenforceable, they were deterred from seeking or accepting other work or starting a business by the threat of a lawsuit from their employer, which they said would be ruinous to their finances and professional reputations.[642] The Commission accordingly finds that higher-wage workers who are not senior executives are often exploited and coerced through employers' use of non-competes.

In addition, the Commission believes it is appropriate to conclude that lower-earning workers, regardless of their job title or function in an organization, are more likely to be exploited or coerced in connection with non-competes. As noted, many workers classified as ''top executives'' make under $100,000. Commenters did not self-report their income, so the Commission cannot definitively determine that the self-identified senior executives who reported exploitation and coercion are lower-wage senior executives. Because of their incomes, however, lower-wage senior executives are likely subject to many of the same exploitative and coercive factors that affect other workers, such as the inability to afford a non-compete lawsuit, forgo work for a lengthy period, leave the field, or relocate.[643] Comments from some senior executives confirmed that they did not have sufficient bargaining power to negotiate the non-compete or consideration for it, suffered serious financial harm from non-competes, and could not afford to litigate their non-competes. Accordingly, the Commission finds that a mere job title alone is insufficient to confer bargaining power on a worker, and lower-wage senior executives can be subject to the same exploitation and coercion that other workers face.

However, having considered the comments and the available empirical evidence on this question, the Commission does not find that non-competes with highly paid workers who are also senior executives are likely to be exploitative or coercive. The Commission stresses that it is not affirmatively finding that such non-competes can never be exploitative or coercive. The Commission has simply determined the record before it is insufficient to support such a finding at this time.

2. The Use of Non-Competes With Senior Executives is an Unfair Method of Competition Under Section 5

While the Commission does not find that non-competes with senior executives are exploitative and coercive, the Commission determines that these non-competes are nonetheless unfair methods of competition, for the reasons described herein.

To determine whether conduct is an unfair method of competition under section 5, the Commission assesses two elements: (1) whether the conduct is a method of competition, as opposed to a condition of the marketplace and (2) whether it is unfair, meaning that it goes beyond competition on the merits. The latter inquiry has two components: (a) whether the conduct has indicia of unfairness and (b) whether the conduct tends to negatively affect competitive conditions. These two components are weighed according to a sliding scale.[644]

Non-competes with senior executives satisfy all the elements of the section 5 inquiry. As described in Part IV.C.2.a, these non-competes are methods of competition. As described in Part IV.C.2.b, these non-competes are facially unfair conduct because they are restrictive and exclusionary. And as described in Part IV.C.2.c, these non-competes tend to negatively affect competitive conditions in product and service markets and in labor markets. Because the Commission finds that non-competes with senior executives are unfair methods of competition, the Commission declines to exclude them from the final rule. However, as described in Part IV.C.3, the final rule allows existing non-competes with senior executives to remain in effect, due to the considerations described therein.

[640] One of those commenters cited two *USA Today* articles that examined Federal workforce records for 88 companies in the S&P 100 to assess the number of Asian and Latina women in executive positions. The articles did not include the underlying data used for the evaluation. *See* Jessica Guynn & Jayme Fraser, *Asian Women Are Shut Out of Leadership at America's Top Companies. Our Data Shows Why,* USA Today (Apr. 25, 2022), *https://www.usatoday.//money/2022/04/25/asian-women-executives-discrimination-us-companies/7308310001/?gnt-cfr=1;* Jessica Guynn & Jayme Fraser, *Only Two Latinas Have Been CEOs at a Fortune 500 Company: Why So Few Hispanics Make It to the Top,* USA Today (Aug. 2, 2022), *https://www.usatoday.com/story/money/2022/08/02/hispanic-latina-business-demographics-executive//?gnt-cfr=1.* These news reports find a disparity in the number of Asian and Latina women in senior executive roles at these companies but make no specific findings on bargaining power. While lack of representation and other factors may impact bargaining power, the Commission believes that these two articles (with no underlying data provided) are insufficient evidence at this time to find exploitation and coercion with respect to this subset of senior executives.

[641] *See* Part IV.B.2.b.i–ii.

[642] *See* Part IV.B.2.b.ii.

[643] *See id.*

[644] *See* Part II.F.

a. The Commission Finds That Non-Competes With Senior Executives are a Method of Competition, Not a Condition of the Marketplace

With respect to the first element—whether conduct is a method of competition—the Commission finds that non-competes with senior executives are a method of competition for the same reasons as non-competes with other workers.[645]

b. Non-Competes With Senior Executives are Facially Unfair Conduct Because They are Restrictive and Exclusionary

In Part IV.B.2.a, the Commission finds that non-competes with workers other than senior executives are facially unfair conduct because they are restrictive and exclusionary. The Commission finds that non-competes with senior executives are facially unfair conduct for the same reasons.

Like non-competes for all other workers, the restrictive nature of non-competes with senior executives is evident from their name and function: non-competes restrict competitive activity. They prevent senior executives from seeking or accepting other work or starting a business after leaving their job. And like non-competes for all other workers, non-competes with senior executives are exclusionary because they impair the opportunities of rivals. Where a worker is subject to a non-compete, the ability of a rival firm to hire that worker is impaired. In addition, where many workers in a market are subject to non-competes, the ability of firms to expand into that market, or entrepreneurs to start new businesses in that market, is impaired. While non-competes may impair the opportunities of rivals in all labor markets, non-competes for senior executives are especially pernicious in this regard. Senior executives are relatively few in number, are bound by non-competes at high rates,[646] and have highly specialized knowledge and skills. Therefore, it can be extremely difficult for existing firms and potential new entrants to hire executive talent and to form the most productive matches.

Because senior executives are often compensated in return for their promise not to compete, some commenters argue that non-competes with senior executives are not unfair methods of competition. However, agreements can present concerns under the antitrust laws even when both parties benefit. Here, non-competes with senior executives are not unfair methods of competition under section 5 because they are unfair to the individual executive, but because they tend to negatively impact competitive conditions—*i.e.,* harm competition in product and service markets, as well as in labor markets—by imposing serious negative externalities on other workers, rivals, and consumers.[647]

c. Non-Competes With Senior Executives Tend To Negatively Affect Competitive Conditions

The Commission finds non-competes with senior executives tend to negatively affect competitive conditions in product and service markets and in labor markets. As explained in Part II.F, the legal standard for an unfair method of competition under section 5 requires only a tendency to negatively affect competitive conditions. The inquiry does not turn on whether the conduct directly caused actual harm in a specific instance. Here, the tendency of non-competes to impair competition is obvious from their nature and function, as it is for non-competes with workers who are not senior executives. And even if this tendency were not facially obvious, the evidence confirms that non-competes with senior executives do in fact negatively affect competitive conditions.

i. Non-Competes With Senior Executives Tend To Negatively Affect Competitive Conditions in Product and Service Markets

In the NPRM, the Commission stated that non-competes with senior executives may harm competition in product and service markets in unique ways.[648] The Commission stated that non-competes with senior executives may contribute more to negative effects on new business formation and innovation than non-competes with other workers, to the extent that senior executives may be likely to start competing businesses, be hired by potential entrants or competitors, or develop innovative products and services.[649] The Commission also stated that non-competes with senior executives may also block potential entrants, or raise their costs, to a high degree, because such workers are likely to be in high demand by potential entrants.[650] The Commission preliminarily concluded that, as a result, prohibiting non-competes for senior executives may have relatively greater benefits for consumers than prohibiting non-competes for other workers.[651]

Based on the Commission's expertise and after careful review of the rulemaking record, including the empirical research and the public comments, the Commission finds that non-competes with senior executives tend to negatively affect competitive conditions in markets for products and services, inhibiting new business formation and innovation.

Non-Competes With Senior Executives Inhibit New Business Formation and Innovation

In Part IV.B.3.b, the Commission described the extensive empirical evidence indicating that non-competes inhibit new business formation and innovation. The Commission's finding in Part IV.B.3.b that non-competes inhibit new business formation and innovation does not examine non-competes with senior executives specifically. However, the Commission finds that non-competes with senior executives inhibit new business formation and innovation at least as much as non-competes with other workers and likely to a greater extent, given the outsized role of senior executives in forming new businesses, serving on new businesses' executive teams, and setting the strategic direction of businesses with respect to innovation.

Specifically, non-competes with senior executives tend to negatively affect competitive conditions in product and service markets in three ways. First, non-competes with senior executives inhibit new business formation. In Part IV.B.3.b.i, the Commission finds that non-competes with workers other than senior executives inhibit new business formation. The Commission finds that non-competes with senior executives inhibit new business formation as much as non-competes with other workers and likely to a greater extent, due to the important role senior executives play in new business formation.

Senior executives are particularly well-positioned to form new businesses because of their strategic expertise and business acumen; knowledge of multiple facets of their industries; experience making policy decisions for businesses; and ability to secure financing. Senior executives are also often crucial to the formation of startups, because startups often begin by

[645] *See* Part IV.B.1.

[646] *See* Part I.B.2 (noting studies estimating that about two-thirds of senior executives work under non-competes).

[647] *See* Part IV.C.2.i–ii (describing the negative effects of non-competes with senior executives on markets for products and services and labor markets).

[648] NPRM at 3502.

[649] *Id.* at 3513.

[650] *Id.*

[651] *Id.*

forming a leadership team, which is often comprised of experienced and knowledgeable executives from elsewhere in the industry.[652] Empirical research shows that when startups hire top management teams from other firms, they are more likely to grow beyond their initial stages [653] and that top managers' experience in an industry allows startups to grow more quickly.[654] Additionally, empirical research finds that startups that hire top management teams with experience are more likely to become successful businesses.[655] Empirical research also finds that, in addition to experience, top management teams that have worked together in the past are more successful than those that have not.[656] For these reasons, non-competes with senior executives not only inhibit new business formation by blocking the executives from forming new businesses; they also prevent other potential founders from forming new businesses, because potential founders are less likely to start new businesses when they are unable to assemble the executive team they need because so many executives in the industry are tied up by non-competes. By inhibiting new business formation, these non-competes deprive product and service markets of beneficial competition from new entrants—competition that in turn tends to benefit consumers through lower prices or better product quality.

Second, non-competes with senior executives inhibit innovation. In Part IV.B.3.b.ii, the Commission finds that non-competes with workers other than senior executives inhibit innovation. The Commission finds that non-competes with senior executives inhibit innovation at least as much as non-competes with other workers and likely to a greater extent, because senior executives play a crucial role in setting the strategic direction of firms with respect to innovation.

Non-competes with senior executives inhibit innovation by impeding efficient matching between workers and firms. As described in Part IV.B.3.a, labor markets function by matching workers and employers. The same is true for senior executives. Executives compete for roles at firms, and firms compete to attract (often highly sought-after) executives; executives choose the role that best meets their objectives, and firms choose the executive who best meets theirs. Non-competes impede this competitive process by blocking executives from pursuing new opportunities (*i.e.,* positions that are within the scope of their non-compete) and by preventing firms from competing to attract their talent. Thus, because non-competes are prevalent, the quality of the matches between executives and firms suffers.

By inhibiting efficient matching between firms and executives, non-competes frustrate the ability of firms to hire executives who can best maximize the firm's capacity for innovation. Senior executives play an important role in advancing innovation at firms.[657] Senior executives are often a fundamental part of the innovative process, guiding the strategic direction of the firm in terms of topics of new research and the depth of new research; determining the allocation of R&D funding; and making the decision to develop (and supervising the development of) new products and services.[658]

Research shows that labor mobility among senior executives may tend to foster innovation. Empirical research finds that executives with shorter job tenures tend to engage in more innovation than those who are longer tenured at firms.[659] In addition, empirical research shows that the strength of executives' external networks—which are likely stronger among executives hired externally—increase the rate of innovation.[660] Finally, when senior executives are hired by new companies, they bring their experience and understanding of the industry, which may cross-pollinate with the capabilities of the new company, cultivating new research which would not otherwise be achieved.[661] By inhibiting efficient matching between executives and firms, non-competes impede the ability of firms to develop innovative products and services that benefit consumers.

Furthermore, empirical research shows that better matching among executives and firms drives productivity as well as innovation. When firms and executives have a higher quality match, the firm as a whole is more productive.[662] By inhibiting efficient matching between firms and executives, non-competes tend to reduce the productivity of firms.

In theory, firms that seek to hire an executive could just pay the executive's employer (or former employer) to escape the non-compete. However, research by Liyan Shi describes how non-competes with senior executives force firms to make inefficiently high buyout payments. Shi ultimately concludes that ''imposing a complete ban on noncompete clauses would be close to implementing the social optimum.'' [663]

Shi explains that firms and executives jointly create market power by entering into non-competes and excluding rivals from hiring experienced labor in a competitive labor market. The existence of a non-compete forces rivals to make an inefficiently high buyout payment, where the inefficiency arises due to the market power of the incumbent firm created by the non-compete. Rival firms must either make these payments, which therefore lead to deadweight economic loss, or forgo the payment—and, consequently, the ability to hire a talented executive (and perhaps the ability to enter the market at all, for potential new firms).[664] New and small businesses in particular might be unable to afford these buyouts. By calibrating

[652] *See, e.g.,* Leslie Crowe, *How to Hire Your First Leadership Team* (Oct. 24, 2023), *https://baincapitalventures.com/insight/how-to-hire-your-first-leadership-team-as-a-startup-founder/.*

[653] Bradley Hendricks, Travis Howell, & Christopher Bingham, *How Much Do Top Management Teams Matter in Founder-Led Firms?,* 40 Strategic Mgmt. J. 959 (2019).

[654] Yasemin Y. Kor, *Experience-Based Top Management Team Competence and Sustained Growth,* 14 Org. Sci. 707 (2003).

[655] Agnieszka Kurczewska & Michał Mackiewicz, *Are Jacks-of-All-Trades Successful Entrepreneurs? Revisiting Lazear's Theory of Entrepreneurship,* 15 Baltic J. of Mgmt. 411 (2020).

[656] Kathleen M. Eisenhardt, *Top Management Teams and the Performance of Entrepreneurial Firms,* 40 Small Bus. Econ. 805 (2013).

[657] *See, e.g.,* Jean-Philippe Deschamps, *Innovation Leaders: How Senior Executives Stimulate, Steer and Sustain Innovation* (John Wiley & Sons, 2009); Jean-Philippe Deschamps & Beebe Nelson, *Innovation Governance: How Top Management Organizes and Mobilizes For Innovation* (John Wiley & Sons, 2014).

[658] Christopher Kurzhals, Lorenz Graf-Vlachy, & Andreas König, *Strategic Leadership and Technological Innovation: A Comprehensive Review and Research Agenda,* 28 Corp. Governance: An Int'l Review 437 (2020); Pascal Back & Andreas Bausch, *Not If, But How CEOs Affect Product Innovation: A Systematic Review and Research Agenda,* 16 Int'l J. of Innovation and Tech. Mgmt. 1930001 (2019); Vassilis Papadakis & Dimitris Bourantas, *The Chief Executive Officer as Corporate Champion of Technological Innovation: An Empirical Investigation,* 10 Tech. Analysis & Strategic Mgmt. 89 (1998) (finding that CEO characteristics significantly influence technological innovation, and that the influence is particularly powerful for new product introductions).

[659] Vincent L. Barker III & George C. Mueller, *CEO Characteristics and Firm R&D Spending,* 48 Mgmt. Sci. 782 (2002).

[660] Qing Cao, Zeki Simsek, & Hongping Zhang, *Modelling the Joint Impact of the CEO and the TMT on Organizational Ambidexterity,* 47 J. of Mgmt. Stud. 1272 (2010); Olubunmi Faleye, Tunde Kovacs, & Anand Venkateswaran, *Do Better-Connected CEOs Innovate More?,* 49 J. of Fin. And Quant. Analysis 1201 (2014).

[661] *See, e.g.,* Orly Lobel, *Talent Wants to Be Free* (Yale Univ. Press, 2013).

[662] Yihui Pan, *The Determinants and Impact of Executive-Firm Matches,* 63 Mgmt. Sci. 185 (2017); Matthew Ma, Jing Pan, & Xue Wang, *An Examination of Firm-Manager Match Quality in the Executive Labor Market* (2021), *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3067808.*

[663] Shi, *supra* note 84 at 427.

[664] *Id.*

this theoretical model to data on executive non-competes and executive compensation, the study shows that banning non-competes would result in nearly optimal social welfare gains.

Shi notes that such a mechanism could be tempered by the ability of a labor market to provide viable alternative workers for new or competing businesses. However, when a particular type of labor is somewhat scarce, when on-the-job experience matters significantly, or when frictions prevent workers from moving to new jobs—all of which tend to be the case for senior executives—there is no way for the market to fill the gap created by non-competes.

Some of the evidence in this study arises from analysis of non-compete use coupled with non-compete enforceability. Other evidence in the study, including the finding that a ban on non-competes is close to optimal, relies not on use at the individual level, but on prevalence of non-competes across a labor market. The latter approach does not rely, therefore, on comparing individuals with and without non-competes, and is therefore not subject to the estimation bias that leads the Commission to give less weight to evidence based on the use of non-competes.

Relevant Comments and Commission Responses

Many commenters stated that non-competes with senior executives reduce new business formation and innovation, confirming the Commission's findings. Several senior executives recounted personal experiences in which a non-compete prevented them from starting a business. A tech executive stated that they knew many tech executives who would have left their roles to start within-industry spinoffs if not for their non-competes. A senior executive stated that they had planned to start a small business that would not have harmed the former employer but had signed a non-compete that prevented them from doing so. A former executive stated that they were sued after starting a new business despite confirming with the CEO of their former employer that doing so would not violate the non-compete. Another senior executive said their non-compete prevented them from taking a job at a smaller, more innovative company in their industry. Some commenters warned that permitting non-competes for senior executives would reinforce dominant positions for industry incumbents who can foreclose new entrants from access to critical talent and expertise. An advocate for startups stated that small businesses significantly benefit from mentorship from experienced founders, which can be inhibited by non-competes.

Other commenters argued that the Commission should exclude senior executives from coverage under the final rule because doing so would benefit competition in product and service markets. These commenters generally stated that non-competes may promote innovation by encouraging firms to make productivity-enhancing investments, such as investments in developing trade secrets. The Commission does not believe that non-competes are needed to protect valuable firm investments. As discussed in Part IV.D, the Commission finds that employers have less restrictive alternatives for protecting valuable investments and that these alternatives are available for senior executives as well as for other workers.

In addition, when assessing how non-competes with senior executives affect competition in product and service markets, the Commission believes it is important to consider the net impact. It is possible that the effects described by these commenters and the effects described by the Commission earlier in this Part IV.C.2.c.i can be occurring at the same time. That is, a non-compete with a senior executive might in some instances be protecting a firm's investments in a manner that is productivity-enhancing, holding all else equal. At the same time, however, that same non-compete may restrict the executive's ability to start a new business after leaving the firm. And even that same non-compete can—and certainly non-competes in the aggregate do—prevent the most efficient match between senior executives and the firms that can make the highest and best use of their talents, and decrease knowledge flow between firms, which limits the cross-pollination of innovative ideas. What the empirical evidence shows is that overall, *i.e.,* in net effect, non-competes reduce new business formation and innovation,[665] indicating that the tendency of non-competes to inhibit new business formation and innovation more than counteracts any effect of non-competes on promoting new business formation and innovation by protecting a firm's investments.

A commenter—referencing the Shi study—argued that banning buyout clauses in non-competes would enhance economic efficiency relative to banning non-competes altogether. Other commenters, including Shi, the author of the study, disagreed with this claim.[666] In response to these comments, the Commission finds that prohibiting buyout clauses would not enhance efficiency relative to prohibiting non-competes altogether. The Commission does not believe prohibiting buyout clauses would address the tendency of non-competes for senior executives to negatively affect competitive conditions, because it would mean that fewer executives could escape their non-competes, reducing labor mobility and efficient matching between executives and firms even further.

Some commenters disputed the Commission's legal rationale for prohibiting non-competes with senior executives. One comment stated that the NPRM did not cite any case law where a non-compete for a senior executive violated antitrust law and argued that there is no widespread case law to support a *per se* ban. In response, the Commission notes that it is determining that non-competes are an unfair method of competition under section 5, not a *per se* violation of the Sherman Act. For the reasons described in this Part IV.C.2, the Commission finds that non-competes are restrictive and exclusionary and that, based on the totality of the evidence, they tend to negatively affect competitive conditions at least as much as non-competes with other workers, and likely even more so, given the outsize role of senior executives in new business formation and innovation. For these reasons, the Commission finds that these non-competes are an unfair method of competition under section 5.

Another commenter stated that the NPRM did not satisfy the standard for finding a tendency to negatively affect competitive conditions for senior executives as set forth in the Commission's section 5 Policy Statement.[667] The commenter stated that a *per se* ban on non-competes considers neither the size, power, or purpose of the firm nor how non-competes interact with individual markets. The commenter argued that the evidence cannot justify an economy-wide ban.

The Commission finds that non-competes for senior executives are an unfair method of competition under section 5 for all the reasons described in this Part IV.C.2. The Commission states the applicable legal standard under section 5 in Part II.F, which is consistent with the standard set forth in the Policy Statement. As noted in Part

[665] *See* Part IV.B.3.b.i–ii.

[666] Comment of Liyan Shi, FTC–2023–0007–19810.

[667] *See* FTC Policy Statement, *supra* note 286.

II.F, the Commission need not make a separate showing of market power or market definition. Nor must the Commission show that the conduct directly caused actual harm in the specific instance at issue. Instead, the inquiry under section 5 focuses on the nature and tendency of the conduct. Moreover, as noted in Part II.F, the Commission may consider the aggregate effect of conduct as well. The language in the Policy Statement stating that the size, power, and purpose of the respondent may be relevant is not limiting, but instead provides guidance regarding factors the Commission may consider in evaluating potentially unfair methods of competition. This guidance may be especially relevant in individual cases and less so in section 5 rulemakings. Finally, as described in Part II.F, a finding that conduct is an unfair method of competition does not require definition of a market or consideration of individual markets. Moreover, as described in Part V.D, the Commission considered and finds no basis for excluding particular industries or workers.

ii. Non-Competes With Senior Executives Tend to Negatively Affect Competitive Conditions in Labor Markets

The effects of non-competes with senior executives on product and service markets are the primary reason why the Commission finds that non-competes with senior executives are an unfair method of competition. However, non-competes also tend to negatively affect competitive conditions in labor markets.

Non-Competes With Senior Executives Suppress Labor Mobility and Earnings

In Part IV.B.3.a, the Commission describes extensive empirical evidence that non-competes reduce labor mobility and worker earnings. The Commission's finding in Part IV.B.3.a that non-competes suppress labor mobility and earnings does not examine non-competes with senior executives specifically. However, the evidence cited by the Commission is also probative with respect to non-competes with senior executives.

Non-competes reduce labor mobility for senior executives for the same reasons they reduce labor mobility for other workers—they directly restrict workers from seeking or accepting other work or starting a business after they leave their job. In Part IV.B.3.a.i, the Commission cites empirical evidence that non-competes reduce labor mobility. This evidence shows that non-competes reduce labor mobility for all subgroups of workers that have been studied, including inventors, high-tech workers, low-wage workers, and workers across the labor force. The impact of non-competes on labor mobility is direct, since non-competes directly prohibit certain types of mobility. Therefore, the Commission finds the non-competes restrict the labor mobility of senior executives as well.

This finding is supported by Mark Garmaise's study of the relationship between non-compete enforceability and the labor mobility and earnings of executives.[668] Garmaise finds that stricter non-compete enforceability reduces within-industry executive mobility by 47% and across-industry executive mobility by 25%. The study, which is limited to senior executives, uses multiple legal changes in non-compete enforceability, measured along multiple dimensions in a binary fashion. The Shi study qualitatively confirms these results—that executives experience greater labor mobility in the absence of non-competes.[669] However, that study examines use, and not just enforceability, of non-competes, so the Commission gives it less weight.

Furthermore, by inhibiting efficient matching between executives and firms—through a similar mechanism as for all other workers [670]—non-competes reduce executives' earnings. Like non-competes for other workers, non-competes block senior executives from switching to a job in which they would be better paid. And by doing so, non-competes decrease opportunities (and earnings) for senior executives who are not subject to non-competes—as well as for workers who are not senior executives, but who would otherwise move into one of those roles.

As described in Part IV.B.3.a.ii, the empirical research indicates that non-competes suppress wages for a wide range of subgroups of workers across the spectrum of income and job function, including workers who are not subject to non-competes. Importantly, an empirical study that does focus on senior executives finds that non-competes suppress earnings of senior executives. The Garmaise study finds that decreased enforceability of non-competes increases executives' earnings by 12.7%.[671] Garmaise also finds that decreased enforceability of non-competes increases earnings growth for CEOs by 8.2%. Since much of the increase in earnings is attributable to an increase in earnings growth (as opposed to earnings at the start of the employment relationship), Garmaise hypothesizes that earnings increase because CEOs are more likely to invest in their own human capital when they have no non-compete.[672] However, Garmaise also notes that while non-competes may offer benefits to firms which use them, there may be negative impacts across the labor markets in which they are used.[673] This is the only study of executive earnings that does not examine the use of non-competes: it examines multiple legal changes in non-compete enforceability, measured along multiple dimensions (though in a binary fashion).

As noted in Part IV.C.1, many senior executives negotiate valuable consideration for non-competes. However, the evidence suggests that non-competes still have a net negative effect on senior executives' earnings, because the suppression of earnings through reduced labor market competition more than cancels out the compensation that some of these executives individually receive for their non-competes.

A second study, by Kini, Williams, and Yin,[674] simultaneously estimates the impact of non-compete enforceability and non-compete use on earnings and finds a positive correlation. The Commission gives this study less weight because it analyzes the use of non-competes. As described in Part IV.A.2, such studies cannot easily differentiate between correlation and causation. Kini, Williams, and Yin use an enforceability measure to generate their estimates, but do not estimate models that omit use of non-competes, meaning that the Commission does not interpret the findings as representing a causal relationship.

Relevant Comments and Commission Responses

Many commenters addressed negative effects of non-competes with senior executives on competition in labor markets. Non-competes, these commenters stated, can negatively affect a senior executive's career when they leave their field or sit out of the workforce for a period, causing their skills and knowledge (particularly in fast-paced fields) to stagnate and affecting their reputations. Like other workers, some senior executives said their non-compete limited their options and earnings in their specialized field.

[668] Garmaise, *supra* note 584.

[669] Shi, *supra* note 84.

[670] *See* Part IV.B.3.a.

[671] Garmaise, *supra* note 584 at 403. The reduction in earnings is calculated as $e^{-1.3575*0.1} - 1$, where -1.3575 is taken from Table 4.

[672] *Id.* at 402.

[673] *Id.* at 379.

[674] Kini, Williams, & Yin, *supra* note 83.

Other commenters argued the Commission should exclude senior executives from the rule because they earn more compensation, including higher wages, for non-competes than they would gain under the final rule. Many of these commenters argued that because senior executives have bargaining power, any findings on decreased wages would not apply to them. Some employers stated they compensated their senior executives for non-competes. Some industry organizations stated that some additional compensation and bonuses might not be offered if non-competes are banned. One business stated the compensation it pays executives takes their non-competes into account. Another business stated it provides severance benefits in exchange for non-competes that fully compensate the executive for the duration of the non-compete.

In response to these comments, the Commission notes the Garmaise study indicates that non-competes have a net negative effect on earnings for senior executives in the aggregate because they suppress competition, even if individual senior executives receive some amount of compensation for their personal non-compete. Garmaise's analysis accounts for any compensation the executive receives for the non-compete.

An industry trade organization stated that non-competes create job opportunities for executives and other highly skilled workers, rather than restricting them, because, without non-competes to protect confidential information, employers will often be reluctant to expand their executive teams. The Commission notes this assertion is unsupported by empirical evidence, and the Commission finds that firms have less restrictive alternatives for protecting confidential information.[675]

An investment industry organization stated that the Commission cannot assume senior executives will be equally or more effective at new firms compared to their old firms. In response, the Commission notes that voluntary labor mobility—for senior executives and all workers—typically reflects a mutually beneficial outcome. To the extent a firm is willing to pay more to attract a particular worker to come work for them, it is typically because the firm places a higher value on the worker's productivity than the worker's current employer. In addition, the Commission notes that many commenters stated that non-competes often force senior executives to sit out of the workforce, causing them to lose valuable knowledge and skills. In general, senior executives are more likely to be effective when they can remain in the industry in which they have experience and expertise, rather than starting over in a new industry because of a non-compete.

An industry trade organization stated that the Commission's assertion that wages are reduced across the labor market is inconsistent with the NPRM's preliminary finding that non-competes are not coercive or exploitative for senior executives, because when more issues are left for negotiation, the job market is increasingly competitive, as workers can differentiate themselves through their terms and tailor their terms to each employer. The Commission does not believe these findings are in tension. Agreements do not need to be exploitative or coercive to inhibit efficient matching between workers and firms or to negatively affect competitive conditions. Furthermore, the Commission believes that executives have many other ways to differentiate themselves other than based on non-compete terms.

One commenter argued that the findings in the Kini, Williams, and Yin study should not be interpreted as representing a causal relationship. Upon further consideration, the Commission agrees with this comment and does not interpret this study causally, as described in this Part IV.C.2.c.ii.

For these reasons, the Commission finds that non-competes with senior executives are an unfair method of competition. As a result, the Commission declines to exclude senior executives from the final rule altogether.

3. The Final Rule Allows Existing Non-Competes With Senior Executives To Remain in Effect

The final rule prohibits employers from, among other things, entering into or enforcing new non-competes with senior executives—*i.e.,* non-competes entered into on or after the effective date.[676] However, the Commission decides to allow existing non-competes with senior executives—*i.e.,* non-competes entered into before the effective date—to remain in effect. The Commission describes the basis for this determination in this Part IV.C.3.

The Commission believes the evidence could provide a basis for prohibiting employers from enforcing existing non-competes with senior executives, as the final rule does for all other workers, given the tendency of such agreements to negatively affect competitive conditions.[677] However, the Commission has decided to allow existing non-competes for senior executives to remain in effect, based on two practical considerations that are far more likely to be present for senior executives than other workers. First, as described in Part IV.C.1, senior executives are substantially less likely than other workers to be exploited or coerced in connection with non-competes. As a result, this subset of workers is substantially less likely to be subject to the kind of acute, ongoing harms currently being suffered by other workers with existing non-competes (even if senior executive's existing non-competes are still harming competitive conditions in the economy overall). Second, commenters raised credible concerns about the practical impacts of extinguishing existing non-competes for senior executives, as described in this Part IV.C.3.[678]

Numerous businesses and trade associations argued that, if the final rule were to invalidate existing non-competes for senior executives, that would present practical challenges for employers, because many such non-competes were exchanged for substantial consideration. According to commenters, consideration exchanged for non-competes includes long-term incentive plans, bonuses, stock awards, options, or severance payments, among other arrangements.

Some commenters were concerned about a potential windfall for workers. They argued that if the non-compete portion of the contract were rescinded or otherwise invalidated, the worker may be left with any benefits already received in exchange for the non-compete, such as equity or bonuses, and could also compete. An industry association stated that some of its members' workers have already received thousands or hundreds of thousands of dollars in additional compensation alongside non-competes, though it was unclear what each worker received. Some business associations said businesses do not have a clear way to recover those payments or benefits. A commenter asked whether a worker who forfeited equity for competing could get the equity back or if executives who were compensated by their new

[675] *See* Part IV.D.2.

[676] § 910.2(a)(2).

[677] *See* Part IV.C.2

[678] Because the Commission proposed to require employers to rescind existing non-competes—*see* NPRM, proposed § 910.2(b)(1)—many of these comments addressed the proposed rescission requirement specifically. Comments that pertain only to the issue of rescission, and that do not apply to whether existing non-competes for senior executives may remain in effect generally, are addressed in Part IV.E.

employers for the non-compete would be paid twice.

The Commission views the problem as more complex than these commenters suggest. First, the empirical evidence and comments illustrate that in many cases, non-competes are currently trapping workers, including senior executives, in their jobs, meaning the employer is getting not only the benefit of trapping that individual worker, but also the benefit of non-competition.[679] In such circumstances, employers may have already received part or all of the benefit they sought from entering a non-compete, though the value would be difficult if not impossible to quantitatively assess. Moreover, it is impracticable for the Commission to untangle whether, to the extent some workers received compensation that was denominated consideration for a non-compete, that non-compete simultaneously suppressed other compensation to the worker such as wages. For example, some commenters who described negotiating their non-competes stated the employer used it as a tactic to drive down wages.

In addition, most workers subject to a non-compete are subject to other restrictive covenants,[680] both mitigating any purported harm and complicating any quantitative valuation of a non-compete.

The Commission also notes that, to the extent equity was provided as consideration, owning a share in the prior employer may induce workers not to risk lowering the value of that equity by competing. However, the concern about workers seeking already-forfeited compensation is misplaced, as the final rule will not impact workers who forfeited compensation for competing under a then-valid non-compete.

Overall, however, where an employer has provided meaningful consideration in exchange for a non-compete, the comments indicate that being unable to enforce that non-compete may complicate that exchange in a way that would be difficult to value and untangle. These difficult practical assessments indicate that the final rule should contain a limited, easily administrable exception for existing non-competes with senior executives, who are considerably more likely than other workers to have negotiated non-competes and received substantial consideration in return.

In addition, an employment attorney suggested that employers may suspend any mid-stream benefits and terminate unvested options and stock and cancel bonuses. One commenter suggested employers may seek refunds from workers, which could create uncertainty. Similarly, an industry association said senior workers who signed a non-compete as part of a severance agreement might see their severance payments taken away, as employers would need to decide whether to continue paying despite the elimination of non-competes or, to the extent they legally can, attempt to renegotiate any outstanding severance agreements. Finally, a business said executives in the middle of their contracts might need to renegotiate those contracts. The Commission shares these concerns about the practicalities of untangling non-competes that are more likely to have been bargained for. Senior executives who engaged in a fair bargaining process may have obtained significant consideration and planned accordingly, as have their employers. While employers' ability to stop payments or claw back consideration is uncertain, any efforts to do so could be disruptive.

Other commenters stated that they believed rescission could result in litigation against workers. An employment lawyer said litigation was difficult to predict but that there could be litigation seeking declarations from courts on how the rule impacts existing contracts. A group of commenters stated that rescinding or invalidating agreements would lead to increased litigation against workers who received the benefit of the bargain but were no longer bound by a non-compete in exchange, and that such litigation would seek to nullify severance agreements, employment agreements, clawback agreements, and others.

One business said the NPRM was silent on how to address specially taxed arrangements, but the business did not provide additional details on any such arrangements. A law firm said workers who received consideration in a prior year would have paid taxes on it and would now need to amend their prior tax return to get a refund if they have to pay back that consideration, while employers might have to amend their return to reflect the loss of a deduction. That law firm also said some executives and other workers use and plan for non-competes to reduce their ''golden parachute'' tax burden.

Finally, an accountant explained that valuations of senior executive non-competes are conducted during many merger and acquisition transactions. Similarly, an industry association said acquisition prices may include the value of non-competes that ensure the buyer retains certain talent, so if non-competes were rescinded or invalidated the buyer would lose the value of what they paid for with no way to recoup the costs. The commenter stated that the bargained-for value of such sales may decrease if existing senior executive non-competes cannot be enforced. The exemption for existing non-competes addresses this concern. Moreover, this concern does not exist for future transactions in any event, since they would not account for non-competes that have been banned.

In response to the foregoing comments, the Commission finds it plausible that rendering existing non-competes with senior executives enforceable could create some of these practical implementation challenges. The Commission accordingly elects to exclude existing non-competes with senior executives from the rule, reducing the burden of implementation of the final rule.

The Commission also understands that some of these practical concerns could arise for workers other than senior executives if they received substantial consideration in exchange for a non-compete. However, the evidence indicates that any such agreements with workers other than senior executives are very rare, and that such workers are more likely to experience exploitation and coercion in connection with non-competes. Therefore, allowing only existing non-competes with senior executives to remain in force will significantly reduce these practical concerns for employers. In contrast, a wider exemption for all existing agreements would leave in place a large number of non-competes that tend to harm competitive conditions, including a large number of exploitative and coercive non-competes for which no meaningful consideration was received.

Some commenters suggested the Commission exempt from the final rule non-competes in exchange for which the worker received consideration. One business asked for an exception to the final rule for paid non-competes, asserting that such an exception would allow workers to receive guaranteed payments while accessing information and training and would allow workers to start their own businesses after the non-compete period. Another business recommended allowing non-competes that provide severance equal to a worker's salary for the non-compete period. An employment attorney suggested an exception from the rule for non-competes that are part of a severance agreement or where the

[679] *See* Part IV.B.2.b.

[680] *See* Balasubramanian, Starr, & Yamaguchi, *supra* note 74 (finding that 97.5% of workers with non-competes are also subject to a non-solicitation agreement, NDA, or non-recruitment agreement, and 74.7% of workers with non-competes are also subject to all three other types of provisions).

worker receives a paid non-compete period or garden leave, which the attorney says do not align with the Commission's concerns about non-competes and represent a balanced trade-off.

The Commission declines to adopt an exception for non-competes in exchange for which the worker received consideration (whether under an existing or future non-compete). The fact that a worker received compensation for a non-compete does not mean the worker received fair compensation, *i.e.,* compensation commensurate with earnings that would be received in a competitive labor market. In addition, such an exception would raise significant administrability concerns. For example, a rule that exempts non-competes exchanged for ''substantial consideration'' or ''meaningful consideration'' would not provide sufficient clarity to employers and workers to avoid significant compliance costs and litigation risks. Requiring a brighter-line specific amount (or standard) of compensation would be unlikely to appropriately capture highly fact-specific, varying financial circumstances of workers and firms. Moreover, it would be difficult to prevent employers from suppressing compensation or benefits along other dimensions (*e.g.,* a requirement for severance equal to the worker's salary during the non-compete period as one commenter suggested could lead to the salary being suppressed). The Commission also notes, however, that while it is not adopting a blanket exemption from the final rule for non-competes in exchange for which the worker received consideration, it is satisfying this request to some extent by adopting an exemption for existing non-competes for senior executives, which are the non-competes most likely to have been exchanged for consideration.

Finally, the Commission concludes that allowing existing non-competes for senior executives to remain in effect is appropriate despite the significant negative effects of such non-competes on competition described in Part IV.C.2. The Commission took into consideration that non-competes with senior executives are less likely to be causing ongoing harm to individuals by preventing them from seeking or accepting other work or starting their own business, because such non-competes were likely to have been negotiated or exchanged for consideration. In addition, the negative effects of these non-competes on competitive conditions will subside over time as these non-competes expire.

4. Defining Senior Executives

As noted earlier, the Commission did not define the term ''senior executive'' in the NPRM. Instead, the Commission requested comment on how the term should be defined.[681] In this final rule, the Commission adopts a definition of ''senior executive'' to isolate the workers who are least likely to have experienced exploitation and coercion and most likely to have bargained for meaningful compensation for their non-compete. Workers for whom exploitation and coercion concerns are likely most relevant and who are unlikely to have bargained for or received meaningful consideration for a non-compete—namely, lower-earning workers, and relatively higher paid or highly skilled workers who lack policy-making authority in an organization—do not fall within this final definition.

This definition is relevant because, as explained in Part IV.C.2, the basis for the Commission's findings that non-competes with senior executives are unfair methods of competition differs in some ways from the evidence and rationales underpinning its findings that non-competes with other workers are unfair methods of competition. Furthermore, as explained in Part IV.C.3, the final rule allows existing non-competes with senior executives to remain in force, while prohibiting employers from enforcing existing non-competes with other workers after the effective date.

The Commission defines ''senior executives'' based on an earnings test and a job duties test. In general, the term ''senior executives'' refers to workers earning more than $151,164 [682] who are in a ''policy-making position'' as defined in the final rule. The Commission adopted this definition after considering the many comments on who senior executives are and how to define them. Notably, the Commission concluded that, unlike highly paid senior executives, highly paid workers other than senior executives and lower-wage workers with senior executive titles as a formal matter likely experience exploitation and coercion and are unlikely to have engaged in bargaining in connection with non-competes, much like lower-wage workers.[683] In other words, the Commission finds that the only group of workers that is likely to have bargained for meaningful compensation in exchange for their non-compete is senior executives who are both highly paid and, as a functional matter, exercise the highest levels of authority in an organization.[684] The Commission estimates that approximately 0.75% of workers are such senior executives.[685]

a. Definition of ''Senior Executive''

The NPRM requested comment on how to define senior executives while providing sufficient clarity to employers and workers.[686] The NPRM stated that there is no generally accepted legal definition of ''senior executive'' and that the term is challenging to define given the variety of organizational structures used by employers.[687] The NPRM raised the possibility of looking to existing Securities and Exchange Commission (''SEC'') definitions; adopting a definition closely based on a definition in an existing Federal regulation; adopting a new definition; defining the category according to a worker's earnings; using some combination of these approaches; or using a different approach.[688] Commenters proposed a wide variety of definitions, largely focused on two types: an exception based on a worker's job duties or title, and an exception based on a compensation threshold. Upon review of the full record, the Commission determines that a test that combines both of these criteria best captures the subset of workers who are likely to have bargained for meaningful compensation in exchange for their non-compete in a readily administrable manner.

i. The Need for a Two-Part Test

Many commenters suggested combining a compensation threshold with a job duties test. For example, one business supported excepting workers who met a combination of tests based on a compensation threshold, FLSA exemption status, and access to trade secrets. A law firm suggested the final rule should account for both pay, exempting only low-wage hourly workers, and job duties in determining an exception. One commenter suggested defining ''senior executive'' based on total compensation, job title, and job duties. Though the Commission does not adopt these specific duties and wage combinations, the Commission agrees that a combined approach is necessary.

The Commission has determined that the definition of ''senior executive'' should include both a compensation threshold and job duties test, similar to

[681] NPRM at 3520.

[682] This threshold is based on the 85th percentile of earnings of full-time salaried workers nationally. *See* Part IV.C.4.b.

[683] *See* Part IV.C.1.

[684] *See id.*

[685] *See* Part X.F.11.

[686] NPRM at 3520.

[687] *Id.*

[688] *Id.*

the DOL regulations that define and delimit the FLSA's exemption for executive employees.[689] The key advantage of a compensation threshold, as one industry organization commenter stated, is that compensation thresholds are objective and easily understood by all stakeholders—yielding significant administrability benefits. However, since not all workers above any given compensation threshold are senior executives, a job duties test is also needed to identify senior executives.

The two-part test isolates the workers most likely to have bargaining power to negotiate meaningful consideration for a non-compete and least likely to experience exploitation and coercion in connection with non-competes. A compensation threshold ensures that stakeholders do not need to spend time assessing the job duties of workers below the threshold—minimizing the amount of detailed analysis stakeholders must undertake. A compensation threshold also helps ensure that workers who work in positions with ''senior executive'' classifications but likely lack meaningful bargaining power due to their relatively low incomes and who likely did not receive meaningful consideration for a non-compete are excluded from the definition. The job duties test ensures that the definition identifies the individuals most likely to have bespoke, negotiated agreements—those with the highest level of authority over the organization—while also ensuring that high-earning workers who are not senior executives, who likely experience exploitation and coercion from non-competes and do not generally bargain over them, are not captured by the definition.[690]

Clarity from a compensation threshold is essential, as without clarity workers and employers would often be uncertain about a non-compete's enforceability (absent adjudication), and such uncertainty often fosters *in terrorem* effects.[691] For example, an attorney commenter stated that an exception for executive, management, and professional employees and those with access to trade secrets would inherently lack clarity. A lack of clarity could also facilitate evasion by employers, as one law firm commented.

While there may be some workers other than senior executives as defined here who may have bargained for consideration for a non-compete, the benefits to workers and employers of a clear and administrable definition outweigh the risk that some bargained-for non-competes are invalidated. In Part IV, the Commission finds even bargained-for non-competes tend to negatively affect competitive conditions. The Commission finds that the need to avoid an overinclusive exception that increases those harms to competitive conditions outweighs the risk that in rare instances private parties with non-competes other than with senior executives may need to restructure their employment agreements to utilize less restrictive alternatives that burden competition to a lesser degree.

Many commenters sought an exception for senior executives and/or highly paid and highly skilled workers based on justifications such as access to trade secrets or confidential information, rather than compensation thresholds. Some argued that compensation thresholds do not align with or allow individualized assessments of which workers meet a given justification such as access to confidential information. One law firm commented that a bright-line compensation threshold would eliminate non-competes for lower wage workers while allowing non-competes for what the commenter viewed as legitimate business purposes. Some commenters opposed an exception for senior executives because they believed ''senior executive'' would be too difficult to define. In Part V.D.2, the Commission explains why it is not adopting an exception for workers based on their access to trade secrets and other intellectual property. Further, in the Commission's view, eliminating the need for individualized assessments for most workers is the primary advantage of a compensation threshold, not a drawback (although the Commission declines to adopt a compensation threshold alone for reasons stated previously and in Part V.D.1). However, the evidence indicates that an exception for existing senior executive non-competes is appropriate, which the Commission defines here.

Commenters, both those supporting and opposing the rule, pointed out several issues with compensation thresholds standing alone. Some commenters were concerned a compensation threshold would exclude some workers, such as many physicians, from the final rule's benefits based on their income level. Two commenters said an exception would penalize the advancement of workers near a threshold and those workers may have to choose between higher wages or being free from a non-compete. Including the job duties tests alongside the compensation threshold mitigates the risk of such cliff effects, assuming they exist (which is far from clear).

Some commenters asserted a threshold would need to be updated for inflation, while one law firm commented that frequent updates would make the final rule more difficult to understand and implement. Commenters also pointed out the need to explain when the threshold would be measured. While adjusting for inflation could be important to ensure the final rule continues serving its intended function if the compensation threshold governed a total exemption from the rule (as these commenters assume), it is unnecessary to the final rule because the exception adopted applies only to existing non-competes (*i.e.,* it has only one-time application). The Commission explains in Part IV.C.4.b its reasons for declining to adopt a locality adjustment.

ii. The Final Rule's Definition of ''Senior Executive''

Based on the considerations described in Part IV.C.4.a.i, the Commission adopts a two-pronged definition of ''senior executive'' in § 910.1. Under § 910.1, a senior executive is a worker who was in a policy-making position and who received from a person for the employment:

- Total annual compensation of at least $151,164 in the preceding year (under paragraph (2)(i)); or
- Total compensation of at least $151,164 when annualized if the worker was employed during only part of the preceding year (under paragraph (2)(ii)); or
- Total compensation of at least $151,164 when annualized in the preceding year prior to the worker's departure if the worker departed from employment prior to the preceding year and the worker is subject to a non-compete (under paragraph (2)(iii)).

Paragraph (2)(ii) applies to workers who were in a policy-making position during only part of the preceding year, which includes workers who were hired or who left a business entity within the preceding year as well as workers who were promoted to or demoted from a policy-making position in the preceding year. Paragraph (2)(iii) ensures that the exception applies to senior executives who departed from the employer more than one year before the effective date but are still subject to a non-compete (*e.g.,* a worker who left more than a year ago and has a non-compete term of 18 months). To account for those senior executives, paragraph (2)(iii) considers total annual compensation in the year preceding their departure.

[689] The FLSA is the Federal statute establishing minimum wage, overtime, recordkeeping, and youth employment standards. *See* 29 U.S.C. 201 *et seq.*

[690] *See* Part IV.C.1.

[691] *See* Part IX.C.

To clarify the definition's compensation threshold, the final rule includes definitions of ''total annual compensation'' and ''preceding year.'' To clarify the job duties test, the final rule includes definitions of ''policy-making position'' as well as two additional terms that are in the definition of ''policy-making position'': ''officer'' and ''policy-making authority.'' These definitions are described in Parts IV.C.4.b and IV.C.4.c.

b. Defining the Compensation Threshold

Pursuant to § 910.1, the senior executive exception applies only to workers who received total annual compensation of at least $151,164 from a person for employment in a policy-making position in the most relevant preceding year. Section 910.1 further defines ''total annual compensation'' and ''preceding year,'' respectively. This threshold is based on the 85th percentile of earnings of full-time salaried workers nationally.[692]

The Commission draws this line between more highly paid and less highly paid workers based on its assessment of which workers are more likely to experience exploitation and coercion and less likely to have engaged in bargaining in connection with non-competes and the need to implement a two-part test. As commenters noted, there is no single compensation threshold above which zero workers will have been coerced and exploited and below which zero workers will have been uncompensated for the non-compete that binds them. Based on the Commission's expertise and after careful review of the rulemaking record, including relevant data, the empirical research, and the public comments, the Commission concludes $151,164 in total annual compensation reflects a compensation threshold under which workers are likely to experience such exploitation and coercion and are less likely to have bargained for their non-competes, while providing employers a readily administrable line. With this line, market participants can easily know that workers below the line cannot be subject to non-competes, minimizing both *in terrorem* effects and eliminating the administrative burden of conducting a job duties test for those workers.

The Commission looked to several sources and suggestions from the comments in selecting a threshold. Numerous commenters suggested the Commission should look to the FLSA, and some specifically recommended the FLSA regulations' threshold for highly compensated employees.[693] DOL sets the compensation threshold for highly compensated employees in its overtime regulations under the FLSA based on earnings of full-time salaried workers. Since January 2020, based on a regulation adopted in 2019, that threshold is $107,432 and reflects the 80th percentile of full-time salaried workers nationally using combined 2018 and 2019 data.[694] In September 2023, DOL proposed raising that threshold to the 85th percentile of full-time salaried workers nationally and, *inter alia,* updating the amount to reflect more current earnings data. For 2023, the 85th percentile of full-time salaried workers nationally is $151,164.[695] The Commission recognizes DOL's expertise in determining who qualifies as a highly compensated worker and employers' likely familiarity with DOL regulations. Given this familiarity, the Commission borrows from DOL's definition of compensation to minimize compliance burdens on employers.

Another Federal regulatory threshold for high wage workers noted by commenters also aligns with the 85th percentile of full-time salaried workers nationally in 2023 or approximately $150,000. In the retirement context, the IRS sets a threshold for highly compensated employees at $150,000 for 2023 and $155,000 for 2024.[696] Additionally, the District of Columbia bans non-competes for workers making less than $150,000.[697]

The Commission analyzed occupational wage data to identify a threshold that would capture more highly paid senior executives, who are likely to have bespoke, negotiated non-competes. BLS's most recent wage data indicates that workers in the ''chief executive'' category have a median wage of $209,810.[698] Thus, most ''chief executives,'' most if not all of whom would meet the duties component of the two-part test in this final rule, earn well above the $151,164 compensation threshold, ensuring that the threshold is likely not underinclusive. The Commission notes that some very high-wage occupations have a median wage above $151,164, including: physicians; surgeons; computer and information systems managers; and dentists.[699] To qualify for the exemptions, these workers would have to also meet the job duties portion of the senior executive test, which is appropriate because the Commission finds that workers in these professions are often subject to coercion and exploitation and rarely have bespoke, negotiated non-competes.

The Commission also considered a lower wage threshold of approximately $100,000, which would be closer in range to the DOL highly compensated employee threshold of $107,432 that DOL adopted in 2019. According to 2022 BLS data, the median wage for ''top executives'' in the U.S. is $99,240.[700] Workers in the ''top executive'' category include ''chief executives,'' but also include officials with less authority like ''general and operations managers.'' The latter have an annual median wage of $97,030 with their earnings at the 75th percentile being $154,440.[701] The Commission believes that a significant number of general and operations managers (some of whom may be in a policy-making position) likely do not have bespoke, negotiated non-competes. For example, a vice president of operations of a local retail chain with only a few locations would likely be in this category. The same vice president—unlike the vice president of a multinational

[692] BLS, Labor Force Statistics from the Current Population Survey, *https://www.bls.gov/cps/// nonhourly-workers.htm* (based on the data from the table ''Annual average 2023'').

[693] However, at the time of commenting the highly compensated employee threshold was $107,432 and the Department had not proposed a new threshold.

[694] 29 CFR 541.601; *see also* Defining and Delimiting the Exemptions for Executive, Administrative, Professional, Outside Sales, and Computer Employees, NPRM, 88 FR 62152, 62157 (Sept. 8, 2023) (hereinafter ''2023 FLSA NPRM'').

[695] *See* Bur. Of Labor Stats., Research Series on Percentiles of Usual Weekly Earnings of Nonhourly Full-Time Workers, at *https://www.bls.gov/cps/research/nonhourly/earnings-nonhourly-workers.htm* (based on the table ''Annual average 2023''); 2023 FLSA NPRM at 62153. The DOL proposed a threshold at $143,998, the 85th percentile of full-time salaried workers at the time the 2023 FLSA NPRM was proposed. When the highly compensated employee test was originally created in 2004, its $100,000 threshold exceeded the annual earnings of 93.7% of salaried workers. *Id.* at 62159.

[696] IRS, *Definitions,* (Aug. 29, 2023) (Highly Compensated Employees), *https://www.irs.gov/retirement-plans/plan-participant-employee/definitions;* IRS, *COLA Increases for Dollar Limitations on Benefits and Contributions,* (updated Nov. 7, 2023), *https://www.irs.gov/retirement-plans/cola-increases-for-dollar-limitations-on-benefits-and-contributions.*

[697] DC Code sec. 32–581.02(a)(1) (effective Oct. 1, 2022) (where the employee's compensation is less than $150,000, or less than $250,000 if the employee is a medical specialist, employers may not require or request that the employee sign an agreement or comply with a workplace policy that includes a non-compete).

[698] BLS Occupational Employment and Wage Statistics, *supra* note 49. These data are from the May 2022 National XLS table for Chief Executives under private ownership.

[699] *See id.* These data are from the May 2022 National XLS table for private ownership.

[700] *Id.* These data are from the May 2022 National XLS table for Top Executives under private ownership.

[701] *Id.* These data are from the May 2022 National XLS table for General and Operations Managers under private ownership.

corporation—is unlikely to possess the same bargaining power or to have a bespoke, negotiated employment agreement. Moreover, to the extent an individual's total compensation is under $151,164, in the unlikely event the individual received consideration for their non-compete, such consideration is unlikely to represent a significant part of their compensation.

Similarly, the Commission believes a $107,432 (or thereabouts) threshold would be overinclusive and individuals who likely do not have bespoke, negotiated non-competes—and who were likely to be exploited and coerced—could meet the threshold test. The $107,432 threshold was adopted based on earnings in 2018 and 2019. Adjusting for inflation, $107,432 in June 2019 is the equivalent of $130,158 in February 2024. Moreover, as noted previously, BLS data reflect that chief executives generally earn significantly more than $130,158. In contrast, occupations with a median wage below $151,164 but above $107,432 include: advertising, marketing, promotions, public relations, purchasing, and sales managers; financial managers; software developers; physician assistants; optometrists; nurse practitioners; and pharmacists.[702] These are occupations that the comment record reflects often experience coercion and exploitation with respect to non-competes and rarely have negotiated or compensated non-competes. A civic organization commenter also argued that the DOL regulations' ''highly compensated employee'' definition's $107,432 threshold was close to the median wage in some industries and areas and cited several cases that it said demonstrate that adopting this threshold would exclude workers who are vulnerable to exploitation and coercion.

Accordingly, the Commission adopts a threshold of $151,164. This threshold, combined with the duties test, reflects highly compensated individuals who are most likely to have the bespoke, complex non-competes that the Commission elects to leave undisturbed, and who the Commission finds are less likely to experience coercion and exploitation. This threshold also has significant administrability benefits, as it is calculated in accord with definitions used in FLSA compliance, with which employers are generally familiar. This alignment will yield efficiency benefits that reduce compliance burdens on employers.

After careful review, the Commission decided not to choose a threshold higher or lower in part because as the compensation threshold in the rule increased, fewer small businesses and firms in areas with lower wages and costs of living would have senior executives with non-competes who would qualify for the exception as compared to larger businesses. Similarly, the lower a threshold is, the more workers who live in areas with higher wages and costs of living would fall above the threshold.[703]

The Commission also declines to adopt a locality adjustment. Some commenters said that a uniform national threshold could lead to geographic disparities because of the different cost of living and average incomes in different areas. Geographic disparities are difficult to resolve, as disparities often exist not just between States, but, for example, between urban and rural areas within a State. The Commission considered this factor in selecting the $151,164 threshold compared to other options. Tailoring a compensation threshold to every locality or even State or region would be burdensome and generate significant confusion for workers and employers. The Commission finds that the importance of a uniform threshold to avoid confusion and for administrability outweighs the drawbacks of any geographic disparities, particularly in light of comments from employers stating that the existing patchwork of State laws is burdensome to navigate. The Commission notes that neither DOL nor IRS have adopted thresholds for highly compensated individuals that vary geographically. Given the rise in remote work, applying geographic variation to employers and workers would also prove burdensome. Moreover, total annual compensation under § 910.1 includes traditional bonuses or compensation a senior executive might receive, such as a bonus tied to performance that is paid pursuant to any prior contract, agreement, or promise. The rule also allows for the entire amount of such bonuses to be credited to total annual compensation, thus, increasing the likelihood of capturing highly compensated policy-making individuals across the nation.

The Commission estimates that approximately 92% of workers will fall below this compensation threshold, ensuring that existing non-competes will be unenforceable for the vast majority of workers most likely to experience exploitation and coercion in connection with non-competes.[704] The Commission also estimates that approximately 0.75% of workers are likely to be considered senior executives.[705] The compensation threshold reflects the Commission's finding that non-competes are very rarely bargained for, and to the extent they are, below $151,164 such bargaining is almost non-existent and consideration for a non-compete, if any, is likely to be relatively small. Pairing the compensation threshold with the duties test will also minimize compliance costs, as employers and the Commission will not need to conduct job duties tests for those workers whose compensation fall below the threshold.

i. Definition of ''Total Annual Compensation''

Section 910.1 provides that ''total annual compensation'' is based on the worker's earnings over the preceding year. It is based on DOL's regulation defining ''total annual compensation'' for highly compensated employees in 29 CFR 541.601(b)(1) and matches DOL's determination of what types of compensation can count towards total annual compensation for highly compensated employees.

Section 910.1, like DOL's definition, states that total annual compensation may include salary, commissions, nondiscretionary bonuses and other nondiscretionary compensation earned during that 52-week period. Nondiscretionary bonuses and compensation includes compensation paid pursuant to any prior contract, agreement, or promise, including performance bonuses the terms of which the worker knows and can expect.[706] The definition further states that total annual compensation does not include board, lodging and other facilities as defined in 29 CFR 541.606, and does not include payments for medical insurance, payments for life insurance, contributions to retirement plans and the cost of other similar fringe benefits. Section 541.606 is part of DOL's regulations concerning salary requirements for employees employed in a bona fide executive, administrative, or professional capacity, and applies to

[702] *Id.*

[703] *See also* 2023 FLSA NPRM at 62176.

[704] *See* Steven Ruggles, Sarah Flood, Matthew Sobek, Daniel Backman, Annie Chen, Grace Cooper, Stephanie Richards, Renae Rodgers, & Megan Schouweiler. IPUMS USA: Version 15.0 [dataset]. Minneapolis, MN: IPUMS, 2024. *https://doi.org/10.18128/D010.V15.0* (American Community Survey 2022 data, adjusted to 2023 dollars and excluding government and non-profit workers).

[705] *See* Part X.F.11.

[706] 29 CFR 778.211(c); *see also* U.S. DOL, Fact Sheet #56C: Bonuses under the Fair Labor Standards Act (FLSA) (Dec. 2019), *https://www.dol.gov/agencies/whd/fact-sheets/56c-bonuses.*

highly compensated employees.[707] That regulation cross-references DOL's regulations on wage payments under the FLSA in 29 CFR part 531, including the term ''other facilities'' defined in 29 CFR 531.32.

This regulatory text makes one modification to the DOL approach to correspond to the final rule's purposes and the non-compete context. Based on comments received, the Commission decided not to adopt DOL's base salary requirement for highly compensated employees in its definition of compensation, which serves a different purpose than the definition adopted here. The 2019 DOL regulation requires that a portion of the worker's total annual compensation must be paid on a salary or fee basis in order to qualify as a highly compensated employee, to ensure that the worker receives at least a base salary and to guard against potential abuses.[708] In contrast, the exception in § 910.2(a)(2) applies only to senior executives. The Commission understands that compensation for senior executives can be structured in many different ways. A law firm commented that senior executive compensation can be particularly complex, as base salary may be 20% or less of a senior executive's annual pay, and much of their pay is variable and does not vest until the end of the year. One comment said some CEOs receive only a $1 salary and receive the rest of their compensation in other forms. The definition of total annual compensation in the final rule is designed to allow for different forms of nondiscretionary compensation without requiring employers to pay a particular amount as salary.

ii. Definition of ''Preceding Year''

The definitions of ''senior executive'' and ''total annual compensation'' in § 910.1 use the term ''preceding year.'' To provide clarity and facilitate compliance, the Commission defines the term ''preceding year'' in § 910.1 as a person's choice among the following time periods: the most recent 52-week year, the most recent calendar year, the most recent fiscal year, or the most recent anniversary of hire year. The term ''preceding year'' is drawn from DOL's FLSA regulations in 29 CFR 541.601(b)(4), which states that ''[t]he employer may utilize any 52-week period as the year, such as a calendar year, a fiscal year, or an anniversary of hire year. If the employer does not identify some other year period in advance, the calendar year will apply.'' Here, the Commission similarly gives employers flexibility to minimize compliance costs, as many employers may have compensation more readily available based on the last calendar year, their fiscal year, or the anniversary of a worker's hire as part of tax and other reporting requirements.

iii. Other Proposed Compensation Thresholds

In seeking to exempt senior executives and highly paid workers from the rule altogether, commenters suggested several possible wage-related thresholds, including specific dollar thresholds (*e.g.,* $100,000) not tied to any existing metric or standard; whether the worker is an hourly worker; annual compensation at or above some multiple of the Federal poverty level or minimum wage, as in New Hampshire, Maine, and Rhode Island statutes; State average wages or ten times the local median wage; and $330,000, the IRS annual compensation limit for 401(k) retirement contributions.[709]

As explained in Part V.D, the Commission declines to exempt workers from the rule altogether based on their earnings. With respect to defining the workers whose *existing* non-competes the Commission exempts, the Commission also declines to use these thresholds or standards. For the reasons described in this Part IV.C.4.b, the Commission believes the compensation threshold it is adopting—in combination with the job duties test it is adopting—most effectively isolates the workers (namely, senior executives) who are likely to bargain with employers and receive compensation for their non-competes and who are unlikely to be exploited or coerced in connection with non-competes. While thresholds based on State lines or metrics would reflect differences in wages and costs of living among States, they would not reflect differences between, for example, urban and rural areas within a State and could generate confusion where the threshold varies between States, in addition to increasing compliance burdens by requiring employers to assess which State adjustment applies—a particularly challenging task in increasingly cross-border and remote work environments. Using the local median wage would generate too much unpredictability for employers and workers and would face the same administrability and confusion challenges to an even higher degree. In contrast, a uniform national compensation threshold as part of the test provides clarity that reduces the risks of *in terrorem* effects and increases ease of compliance. Finally, the $330,000 threshold is an annual compensation limit, while the IRS has a different test to identify highly compensated employees. A $330,000 threshold would be too high for employers in areas with lower average incomes and costs of living and would likely exclude from the definition many senior executives who bargained for their non-compete in exchange for consideration.

One business recommended an exception for individuals in the top 10% income tier at their respective employers to exempt workers at start-ups that might not be able to compensate their workers at a high level but whose workers may still be exposed to trade secrets. Another proposed using Internal Revenue Code section 414(q), defining highly compensated employee as the highest paid 1% or 250 employees in the corporation. A percentage threshold, however, has significant practical issues including workers entering and exiting, earnings changes, and factoring in independent contractors, workers at subsidiaries, or workers at parent companies. It would also lead to disparities between large and small firms, as large firms could use non-competes for far more workers than could small firms.

Other commenters pointed to State laws setting a compensation threshold to support excluding highly paid workers from the final rule or suggested the Commission look to those States as an example. A public policy organization that supported a categorical ban said any threshold should be at least higher than $100,000, citing research on Washington's non-compete reforms that indicated employers did not value non-competes up to that threshold.[710] The compensation threshold the

[707] 29 CFR 541.601(a)(1) (''[A]n employee with total annual compensation of at least $107,432 is deemed exempt under section 13(a)(1) of the Act if the employee customarily and regularly performs any one or more of the exempt duties or responsibilities of an executive, administrative or professional employee as identified in subparts B, C or D of this part.'').

[708] 29 CFR 541.601(b)(1); Defining and Delimiting the Exemptions for Executive, Administrative, Professional, Outside Sales and Computer Employees, 69 FR 22122, 22175 (Apr. 23, 2004) (''This change will ensure that highly compensated employees will receive at least the same base salary throughout the year as required for exempt employees under the standard tests, while still allowing highly compensated employees to receive additional income in the form of commissions and nondiscretionary bonuses.'').

[709] IRS, *COLA Increases for Dollar Limitations on Benefits and Contributions,* (updated Nov. 7, 2023), *https://www.irs.gov/retirement-plans/cola-increases-for-dollar-limitations-on-benefits-and-contributions;* Treas. Reg. sec. 1.401(a)(17)–1.

[710] Hiraiwa, Lipsitz & Starr, *supra* note 502.

Commission is adopting is higher than this amount.

c. Defining the Job Duties Component

i. Definitions of ''Officer,'' ''Policy-Making Authority,'' and ''Policy-Making Position''

In NPRM, the Commission suggested that the final rule's definition of senior executive could be based on SEC Rule 3b–7.[711] The Commission did not receive comments specifically addressing this option, but the Commission carefully considered arguments for and against job duties or job title distinctions as well as numerous comments on potential job duties tests, alone or in combination with compensation thresholds, before determining that a modified version of SEC Rule 3b–7's job duties requirements would best meet the exception's goals. The duties test adopted by the Commission is precise and more tailored than the other definitions proposed by commenters[712] and minimizes the risk that workers who likely experienced exploitation and coercion are included in the definition of senior executive. The test focuses primarily on job duties, rather than solely on job titles, because businesses do not all use the same job titles, and a job title might not reflect the worker's actual level of authority in an organization, which is a key indicator of whether a worker is likely to face exploitation and coercion or to have bargained in connection with non-competes.

Section 910.1 defines ''policy-making position'' as a business entity's president, chief executive officer or the equivalent, any other officer of a business entity who has policy-making authority, or any other natural person who has policy-making authority for the business entity similar to an officer with policy-making authority. The definition of ''policy-making position'' further states that an officer of a subsidiary or affiliate of a business entity that is part of a common enterprise who has policy-making authority for the common enterprise may be deemed to have a policy-making position for the business entity for purposes of this paragraph. Finally, the definition of ''policy-making position'' states that a natural person who does not have policy-making authority over a common enterprise may not be deemed to have a policy-making position even if the person has policy-making authority over a subsidiary or affiliate of a business entity that is part of the common enterprise.

Section 910.1 also defines terms used in the definition of ''policy-making position.'' Section 910.1 defines ''officer'' as a president, vice president, secretary, treasurer or principal financial officer, comptroller or principal accounting officer, and any natural person routinely performing corresponding functions with respect to any business entity whether incorporated or unincorporated. To account for differences in the way business entities may use and define job titles, the definition includes workers in equivalent roles. By incorporating this definition of ''officer,'' ''senior executive'' applies to workers at the highest levels of a business entity.

This definition is nearly verbatim of the SEC definition of ''officer'' in 17 CFR 240.3b–2. That term ''officer'' is used in SEC Rule 3b–7.[713] To maintain consistency with the SEC regulations by ensuring that ''officer'' has the same meaning, and to utilize the SEC's expertise in this area, the Commission adopts the SEC's definition of ''officer.''

Section 910.1 defines ''policy-making authority'' as final authority to make policy decisions that control significant aspects of a business entity or a common enterprise. The definition further states that policy-making authority does not include authority limited to advising or exerting influence over such policy decisions or having final authority to make policy decisions for only a subsidiary of or affiliate of a common enterprise.

Accordingly, for a worker to be a senior executive, in addition to meeting the compensation threshold, the worker must be at the level of a president, chief executive officer or the equivalent, officer (defined in § 910.1), or in a position that has similar authority to a president or officer. Further, an officer or other qualifying person must have policy-making authority. Presidents, chief executive officers, and their equivalents are presumed to be senior executives (*i.e.,* employers do not need to consider the further element of ''policy-making authority''). The term ''chief executive officer or the equivalent'' was added to the definition of ''policy-making position'' to increase clarity on who was included and to reflect the wider range of businesses with various structures that are subject to the final rule (as compared to SEC Rule 3b–7). The definition of ''policy-making position'' includes workers with equivalent authority because job titles and specific duties may vary between companies. This ensures that the term ''senior executive'' is broad enough to cover more than just a president or chief executive officer, especially for larger companies, as others may have final policy-making authority over significant aspects of a business entity.

For example, many executives in what is often called the ''C-suite'' will likely be senior executives if they are making decisions that have a significant impact on the business, such as important policies that affect most or all of the business. Partners in a business, such as physician partners of an independent physician practice, would also generally qualify as senior executives under the duties prong, assuming the partners have authority to make policy decisions about the business. The Commission notes that such partners would also likely fall under the sale of business exception in § 910.3 if the partner leaves the practice and sells their shares of the practice. In contrast, a physician who works within a hospital system but does not have policymaking authority over the organization as a whole would not qualify.

The Commission changed some aspects of SEC Rule 3b–7 to fit the context of this rulemaking. First, because § 910.2(a)(2) will extend to non-public companies, unlike SEC regulations, the final rule's definition of ''policy-making position'' does not include the phrase ''any vice president of the registrant in charge of a principal business unit, division or function (such as sales, administration or finance)'' in the definition of ''executive officer.''[714] The Commission believes that in the context of this final rule, in which the definition is relevant to a broader array of entities than public companies, that phrase would encompass workers who, despite their titles, are among those who are likely to be coerced or exploited by non-competes. For example, this aspect of the definition can be too easily applied to managers of small departments, who the Commission finds

[711] 17 CFR 240.3b–7; NPRM at 3520.

[712] *See* Part IV.C.4.c.ii.

[713] 17 CFR 240.3b–7 (''The term executive officer, when used with reference to a registrant, means its president, any vice president of the registrant in charge of a principal business unit, division or function (such as sales, administration or finance), any other officer who performs a policy making function or any other person who performs similar policy making functions for the registrant. Executive officers of subsidiaries may be deemed executive officers of the registrant if they perform such policy making functions for the registrant.''); 17 CFR 240.3b–2 (''The term officer means a president, vice president, secretary, treasury or principal financial officer, comptroller or principal accounting officer, and any person routinely performing corresponding functions with respect to any organization whether incorporated or unincorporated.'').

[714] 17 CFR 240.3b–7.

are unlikely to have bargained for their non-competes. At the same time, a manager who does in fact have policy-making authority would meet the definition of ''officer'' in § 910.1 and thus be included in the definition of senior executives (if the manager also meets the compensation threshold). Similarly, depending on the organization, a vice president may have final policy-making authority over significant aspects of a business entity. The adapted definition is based on functional job duties rather than formal job titles.

Second, SEC Rule 3b–7 uses the term ''policy making function'' as part of its definition of the types of job duties that could classify a person as an ''executive officer.'' [715] While the term ''policy making function'' is undefined in SEC Rule 3b–7 and other SEC regulations, the Commission believes that defining the term ''policy-making authority'' in § 910.1 would provide greater clarity and facilitate compliance with the final rule. The final rule applies to a wider range of business entities than SEC rules, and the Commission seeks to minimize the need to consult with counsel about the meaning of this term. The Commission is also concerned that if the term is left undefined, employers could, inadvertently or otherwise, label too many workers who have any involvement in the employer's policy making as senior executives, especially workers without bargaining power.

In defining this term, the Commission seeks to broadly align with the SEC's definition of ''executive officer'' while focusing on senior executives in a wider variety of entities, who are less likely to experience exploitation and coercion. As explained in Part IV.C.4.b with respect to the compensation threshold, there is no job duties test that will exclude every worker who experiences exploitation and coercion with respect to non-competes while including every worker who does not. Building on the SEC definition provides firms and workers with a more administrable definition that isolates workers at the most senior level of an organization.

To ensure that the final rule's job duties test for senior executives broadly aligns with the SEC definition, the Commission looked to case law interpreting that SEC definition. Few courts have interpreted SEC Rule 3b–7's ''policy making function'' language, though some courts view it as an officer test.[716] In the most in-depth discussion, the U.S. District Court for DC considered a defendant who was a member of a corporate body that discussed important policy decisions and made recommendations to the CEO, and supervised and had ''substantial influence'' over a major aspect of the company's business. However, the court held that only the CEO, and not the defendant, had authority to make company policy and ultimate decisions on significant issues.[717] The court conducted a fact-intensive analysis of the defendant's duties and held that the defendant did not have the authority to make policy. The court also held that the term did not include individuals solely ''involved in discussing company strategy and policy.'' [718]

The Commission finds this case law instructive and thus defines ''policy-making authority'' in the final rule as ''final authority to make policy decisions that control significant aspects of a business entity and does not include authority limited to advising or exerting influence over such policy decisions.'' Adding this definition provides stakeholders with additional clarity as to what type of authority meets the definition of ''senior executive'' and prevents overbroad application of the definition. It expressly does not include workers who merely advise on or influence policy, as a wide range of workers in an organization can advise on or influence policy without being a senior executive.

In order to ensure that lower-level workers, whom the Commission finds likely experience exploitation and coercion, are not included in the definition of senior executive, policy-making authority is assessed based on the business as a whole, not a particular office, department, or other sublevel. It considers the authority a worker has to make policy decisions that control a significant aspect of a business entity without needing a higher-level worker's approval. For example, if the head of a marketing division in a manufacturing firm only makes policy decisions for the marketing division, and those decisions do not control significant aspects of the business (which would likely be decisions that impact the business outside the marketing division), that worker would not be considered a senior executive. Similarly, in the medical context, neither the head of a hospital's surgery practice nor a physician who runs an internal medical practice that is part of a hospital system would be senior executives, assuming they are decision-makers only for their particular division. The definition is limited to the workers with sufficient pay and authority such that they are more likely to have meaningful bargaining power and actually negotiated their non-competes.

For the same reason, the Commission added language to the definitions of ''policy-making authority'' and ''policy-making position'' to exclude from the definition of ''senior executives'' workers with policy-making authority over only a subsidiary or affiliate of a common enterprise who do not have policy-making authority over the common enterprise. One commenter argued that the proposed definition of ''business entity'' would allow firms to divide themselves into separate entities to evade the final rule. In addition to sharing this concern, the Commission is concerned that executives of subsidiaries or affiliates of a common enterprise [719] could rely on their final authority to make policy decisions for only that subsidiary or affiliate to classify the head of each office as a senior executive even though that individual only has authority over one component of a coordinated common enterprise. Rather, the worker must have policy-making authority with respect to the common enterprise as a whole, not just a segment of it, to be a senior executive. Workers who head a subsidiary or affiliate of a common enterprise are similar to department heads; the senior executives controlling the entire common enterprise control those individual subsidiaries and affiliates. As the Commission has explained, the Commission finds that department heads and other highly paid non-senior executives do not have sufficient bargaining power to avoid exploitation and coercion and are unlikely to have bargained in connection with non-competes. The job duties test identifies the workers with the highest levels of authority in an organization, *i.e.,* the workers most likely to have bargaining power and a bespoke, negotiated agreement, and a

[715] *Id.*

[716] *See, e.g., SEC* v. *Enters. Solutions,* 142 F. Supp. 2d 561, 570, 574 (S.D.N.Y. 2001) (finding that a so-called consultant's role was ''sufficiently similar to the duties of an officer or director of the company that his involvement, along with his history of criminal and regulatory violations, ought to have been disclosed'' where the consultant controlled the company, including hiring the CEO, arranging loans from companies controlled by the consultant, negotiating acquisitions, and putting his daughter on the board in his place); *In re Weeks,* SEC Release No. 8313 at *9 (Oct. 23, 2003) (finding a consultant was *de facto* in charge of the company while the officers and directors were figureheads who lacked authority and influence over the company).

[717] *SEC* v. *Prince,* 942 F. Supp. 2d 108, 133–36 (D.D.C. 2013).

[718] *Id.* at 136.

[719] *FTC* v. *WV Universal Mgmt., LLC,* 877 F.3d 1234, 1240 (11th Cir. 2017) (''[C]ourts have justly imposed joint and several liability where a common enterprise exists'').

common enterprise is effectively a single organization. Such workers may have a senior executive job title, but they are unlikely to meet the job duties test.

To be considered a ''common enterprise'' for the purposes of defining policy-making authority and policy-making position, the Commission looks beyond legal corporate entities to whether there is a common enterprise of ''integrated business entities.'' [720] This means that the various components of the common enterprise have, for example, one or more of the following characteristics: maintain officers, directors, and workers in common; operate under common control; share offices; commingle funds; and share advertising and marketing.[721] Therefore, the definitions of policy-making authority and policy-making position include provisions whose purpose is to exclude those executives of a subsidiary or affiliate of a common enterprise from being considered senior executives. For example, if a business operates in several States and its operations in each State are organized as their own corporation, assuming these businesses and the parent company meet the criteria for a common enterprise, the head of each State corporation would not be a senior executive. Rather, only the senior executives of the parent company (or whichever company is making policy decisions for the common enterprise) could qualify as senior executives for purposes of this final rule, because they are the workers with the highest level of authority in the organization and most likely to have bargaining power and a bespoke, negotiated agreement. However, a worker could qualify as a senior executive even if they were an executive of one or more subsidiaries or affiliates of the common enterprise, so long as that senior executive exercised policy-making authority over the common enterprise in its entirety. These provisions are consistent with the approach taken elsewhere in this final rule to focus on real-world implications and authority rather than formal titles, labels, or designations. This exclusion from the definitions of ''policy-making authority'' and ''policy-making position'' applies only to common enterprises; for subsidiaries or affiliates that are not part of a common enterprise, a worker could qualify as a senior executive if they have policy-making authority over that subsidiary or affiliate and meet all of the requirements.

The Commission has also substituted ''business entity'' in the definitions of ''officer'' and ''policy-making position'' where SEC Rule 3b–7 uses the word ''registrant'' and 17 CFR 240.3b–2 uses ''organization,'' because ''registrant'' has a specific meaning in the SEC context that is inapplicable to the wider array of business entities covered by this final rule and because ''business entity'' is defined in § 910.1 and is used throughout this final rule. The Commission substituted ''natural person'' where SEC Rule 3b–7 and 17 CFR 240.3b–2 use ''person'' because ''person'' is separately defined for purposes of this final rule in § 910.1.

ii. Other Proposed Job Duties Tests

The FLSA

Numerous commenters suggested basing a job duties test on the categories of occupations that are exempt from requirements under the FLSA. Some commenters suggested using only some of the exemptions such as executive employees,[722] administrative employees, learned or creative professionals, or workers in the practice of medicine.[723] DOL's regulations also set a salary threshold at not less than $684 per week ($35,568 annually),[724] though other commenters suggested using a higher compensation threshold.

One civic organization opposed applying any FLSA exemptions, stating that the FLSA provides numerous exemptions that do not relate to any non-compete policy considerations, and an exception or more lenient standards for FLSA-exempt workers would not solve the problems caused by non-competes. It opposed using the FLSA's executive, administrative, or professional exemptions, arguing that updates to the FLSA's salary threshold are often delayed and outdated, often falling below the poverty threshold, and the duties test serves as a loophole for wage and hour protections.

Commenters offered several reasons for adopting the FLSA exemptions: these categories are already well-established in Federal law; nonexempt workers under the FLSA tend not to have access to trade secrets or be able to take an employer's goodwill and are thus less likely to harm the employer; the exemptions would capture both wage and job duties tests; some States use a similar standard to the FLSA in their non-compete statutes; and the exemptions would ban non-competes for low-skilled workers for whom there are insufficient justifications for non-competes. An employment attorney also pushed back on the NPRM's concerns that the FLSA exemptions could enable misclassification,[725] asserting that misclassification under the FLSA is unlawful and penalized, and thus usually inadvertent.

The Commission does not adopt the FLSA exemptions for purposes of this final rule because it would exempt millions of non-competes that harm competition and workers. For example, the FLSA exempts most highly paid and highly skilled workers,[726] who the Commission finds experience exploitation and coercion (except where those workers are also senior executives).[727] The Commission also adopts brighter-line rules than the FLSA to ease compliance burdens and address *in terrorem* effects that result from uncertainty about whether a non-compete is unenforceable.[728] Although the Commission does not believe that the FLSA job duties tests are appropriate for this final rule, it does view the FLSA wage threshold methodology for ''highly compensated employees'' as a useful benchmark.[729]

Trade Secret and Confidential Information Exceptions

Numerous commenters urged the Commission not to ban non-competes for workers who have access to trade secrets and confidential information, often noting this justification is commonly used for highly paid and highly skilled workers, including senior executives. One comment expressly stated that this exception should apply regardless of earnings, though many

[720] *See FTC* v. *E.M.A. Nationwide, Inc.,* 767 F.3d 611, 636–37 (6th Cir. 2014).

[721] *See id.* (''If the structure, organization, and pattern of a business venture reveal a 'common enterprise' or a 'maze' of integrated business entities, the FTC Act disregards corporateness. Courts generally find that a common enterprise exists 'if, for example, businesses (1) maintain officers and employees in common, (2) operate under common control, (3) share offices, (4) commingle funds, and (5) share advertising and marketing.'") (quoting *FTC* v. *Wash. Data. Res.,* 856 F. Supp. 2d 1247, 1271 (M.D. Fla. 2012)). In assessing a common enterprise, ''no one factor is controlling,'' and ''federal courts routinely consider a variety of factors.'' *FTC* v. *Wyndham Worldwide Corp.,* No. CIV.A. 13–1887 ES, 2014 WL 2812049, at *7 (D.N.J. Jun. 23, 2014); *see also Del. Watch Co.* v. *FTC,* 332 F.2d 745, 746 (2d Cir. 1964) (''[T]he pattern and frame-work of the whole enterprise must be taken into consideration.'')

[722] *See* 29 CFR 541.100(a).

[723] *See* DOL, Fact Sheet #17A: Exemption for Executive, Administrative, Professional, Computer & Outside Sales Employees Under the Fair Labor Standards Act (FLSA) (revised Sept. 2019), *https://www.dol.gov/agencies/whd/fact-sheets/17a-overtime.*

[724] *Id.*

[725] *See* NPRM at 3511.

[726] *See* 2023 FLSA NPRM at 62190 (estimating that 36.4 million salaried, white-collar employees currently qualify as FLSA-exempt executive, administrative, or professional employees).

[727] *See* Part IV.C.1.

[728] *See* Part IX.C.

[729] *See* Part IV.C.4.b.

others did not mention compensation thresholds. One business suggested a bright-line rule for the types of confidential business information that can be protected by a non-compete based on existing State statutes, to increase certainty about what is allowed. Commenters suggested exceptions based on a variety of job types they viewed as more likely to be exposed to trade secrets and confidential information, including all highly skilled workers; key scientific, technical, R&D, or sales workers; or workers with highly detailed knowledge of business and marketing plans. The Commission explains why it is not adopting exceptions based on access to trade secrets or other intellectual property in Parts V.D.1 and V.D.2.

Additional Proposed Job Duties and Job Title Tests

The Commission carefully considered several other proposed tests. The NPRM stated that the Commission could base the definition of senior executive on SEC Regulation S–K's definition of senior executives.[730] Commenters did not discuss this potential option. The Commission is not adopting this approach because it bears little relation to the likelihood that a senior executive bargained for a non-compete, and because it would designate roughly seven individuals per company as ''senior executives'' regardless of their compensation level or the size of the company, meaning it would not apply equally among employers or workers.[731] For example, a ten-person company could potentially use non-competes for most of its workforce irrespective of whether they are senior executives, whereas a company with ten thousand employees would be limited to the same number.[732]

One commenter proposed adopting a definition similar to the tax code provision on ''golden parachute payments.'' [733] Several commenters drafted their own definition of senior executive based on job duties, titles, or ownership status, such as C-suite executives and their immediate subordinates, partners and equity holders, managers, workers involved in strategic decision-making, and more.

The Commission carefully considered each proposed definition and how it would operate in practice before selecting the two-part test. Elements of some of these proposals, such as strategy development or decision-making, are also similar to the job duties test the Commission is finalizing. The Commission believes that definitions based on job titles alone would be inadequate because, as one industry association commented, employers define job titles differently, and a title might not accurately reflect a worker's job duties. The other definitions proposed by commenters, such as the provision on golden parachute payments, would generally require a more fact-intensive analysis than the job duties test the Commission is adopting. Market participants would need to conduct the analysis for more workers, including workers who are exploited and coerced by non-competes. A more fact-intensive analysis would require more resources for litigation and is thus likely to have *in terrorem* effects for lower-wage workers.[734] Moreover, many of these proposals would exempt more workers than the Commission's definition, such as managers, even though workers in such roles and occupations are often coerced and exploited by non-competes.

As explained in this Part, the Commission pairs a relatively easy-to-apply job duties test with a compensation threshold to maximize administrability and clarity while identifying those senior executives most likely to have bargained for non-competes. In addition, proposals to except partners, shareholders, and similar groups are likely covered by the sale of business exception if they sell their share of the business upon leaving.

5. Prohibitions in Section 910.2(a)(2)

Based on the totality of the evidence, including its review of the empirical literature, its review of the full comment record, and its expertise in identifying practices that harm competition, the Commission adopts § 910.2(a)(2), which defines unfair methods of competition related to non-competes with respect to senior executives. Section 910.2(a)(2) provides that, with respect to a senior executive, it is an unfair method of competition for a person: (i) to enter into or attempt to enter into a non-compete clause; (ii) to enforce or attempt to enforce a non-compete clause entered into after the effective date; or (iii) to represent that the senior executive is subject to a non-compete clause, where the non-compete clause was entered into after the effective date. Part IV.A.1 sets forth the Commission's determination that the foregoing practices are unfair methods of competition under section 5, and Part IV.C.2 explains the findings that provide the basis for this determination.

Section 910.2(a)(2) uses similar language as § 910.2(a)(1); however, there are two key differences. First, the prohibition in § 910.2(a)(2)(ii) on enforcing or attempting to enforce a non-compete applies only to non-competes entered into after the effective date. Second, the prohibition in § 910.2(a)(2)(iii) on representing that a senior executive is subject to a non-compete applies only where the non-compete was entered into after the effective date. Sections 910.2(a)(2)(ii) and (iii) include this language because, for the reasons described in Part IV.C.3, the Commission has determined not to prohibit existing non-competes with senior executives—*i.e.,* non-competes entered into before the effective date—from remaining in effect.

Otherwise, the explanation of the three prongs of § 910.2(a)(1) in Part IV.B.4—relating to issues such as, for example, what ''attempt to enter into'' and ''attempt to enforce'' mean, and what conduct the ''representation'' prong applies to—is applicable to the corresponding language in § 910.2(a)(2). The good-faith exception in § 910.3 is also applicable to the relevant prohibitions with respect to senior executives and is explained in Part V.C.

D. Claimed Justifications for Non-Competes Do Not Alter the Commission's Finding That Non-Competes Are an Unfair Method of Competition

For the reasons described in Parts IV.B and IV.C, the Commission determines that certain practices related to non-competes are unfair methods of competition under section 5. In this Part IV.D, the Commission finds the claimed justifications for non-competes do not alter the Commission's determination that non-competes are an unfair method of competition.

As noted in Part II.F, some courts have declined to consider justifications altogether and the Commission and courts have consistently held that pecuniary benefit to the party responsible for the conduct in question

[730] *See* NPRM at 3520 (citing 17 CFR 229.402(a)(3)).

[731] *See* 17 CFR 229.402(a)(3).

[732] Additionally, while the reporting obligations of public companies may provide them with an incentive to avoid generating a profusion of ''senior executives,'' privately held companies would not face a similar constraint and could potentially avoid any ''per-company'' limitations through corporate restructuring.

[733] This provision determines who is an ''officer'' ''on the basis of all the facts and circumstances in the particular case (such as the source of the individual's authority, the term for which the individual is elected or appointed, and the nature and extent of the individual's duties) . . . .'' Treas. Reg. sec. 1.280G–1, Q/A–18.

[734] *See* Part IX.C.

is not cognizable as a justification.[735] However, where defendants raise justifications as an affirmative defense, they must be legally cognizable,[736] and non-pretextual,[737] and any restriction used to bring about the benefit must be narrowly tailored to limit any adverse impact on competitive conditions.[738]

In the NPRM, the Commission considered the commonly cited business justifications for non-competes and preliminarily found they did not alter the Commission's determination that non-competes are an unfair method of competition.[739] The Commission has reviewed and considered the comments on its analysis of the justifications for non-competes. For two reasons, the claimed justifications for non-competes do not alter the Commission's determination that non-competes are an unfair method of competition. First, employers have more narrowly tailored alternatives to non-competes for protecting valuable investments that tend to negatively affect competitive conditions to a lesser degree. Second, the asserted benefits from the claimed business justifications from non-competes do not justify the considerable harm from non-competes.

1. Claimed Business Justifications for Non-Competes and Empirical Evidence

Claimed business justifications for non-competes relate to increasing employers' incentives to make productive investments, such as investments in worker human capital (worker training), client and customer attraction and retention, or in creating or sharing trade secrets or other confidential information with workers. According to these asserted justifications, without non-competes, employment relationships are subject to an investment hold-up problem. Investment hold-up would occur where an employer—faced with the possibility that a worker may depart after receiving some sort of valuable investment or obtaining valuable information—opts not to make that investment in the first place, thereby decreasing the firm's productivity and overall social welfare. For example, according to this claimed justification, an employer may be more reticent to make capital investments or invest in workers' human capital by training its workers if it knows the worker may depart for or may establish a competing firm. Similarly, commenters argued that employers may decrease investments or experience harm if a worker takes a trade secret or other confidential information to a competitor.

Courts have cited these justifications when upholding non-competes under State common law and in cases challenging non-competes under the Sherman Act.[740] However, courts have not considered non-competes' aggregate harms, and neither legislatures nor courts have had occasion to consider these justifications in the context of section 5. The Commission has considered them and found them unavailing in cases in which it has successfully obtained consent decrees against non-competes alleged to be an unfair method of competition in violation of section 5.[741]

There is some empirical evidence that non-competes increase investment in human capital of workers, capital investment, and R&D investment. However, the Commission also finds that there are alternatives that burden competition to a lesser degree,[742] and, in any event, these claimed benefits do not justify the harms from non-competes.[743]

As explained in the NPRM, a study by Evan Starr finds that moving from mean non-compete enforceability to no non-compete enforceability would decrease the number of workers receiving training by 14.7% in occupations that use non-competes at a high rate (relative to a control group of occupations that use non-competes at a low rate).[744] The study further finds that changes in training are primarily due to changes in firm-sponsored, rather than employee-sponsored, training.[745]

Firm-sponsored training is the type of investment in human capital that non-competes are often theorized to protect, as the firm may be unwilling to make an unprotected investment. However, the study does not distinguish between core training, *i.e.,* training required to perform job duties, and advanced training, *i.e.,* training with potential to increase productivity beyond the baseline requirements for job performance. When non-competes are more enforceable, workers may receive additional core training rather than advanced training, but this may actually reflect a reduction in efficiency. When non-competes are more enforceable, labor mobility decreases and workers may also move to new industries to avoid potentially triggering non-compete clause violations (as discussed in Part IV.B.2.b.ii), both of which make experienced workers less often available for hire. Firms therefore may need to train workers at a greater rate because they will hire inexperienced workers who require more core training. On the other hand, advanced training can be associated with productivity gains, and firms using non-competes may increase rates of advanced training for experienced workers because non-competes increase the likelihood that firms receive a return on the training investment. The study does not distinguish between these types of training, and thus leaves unclear whether the observed increases in training reflect productivity gains or losses (or neither in net).

Additionally, the Starr study uses data on the use of non-competes, comparing high- and low-use occupations, rather than changes in enforceability; however, the study does not examine differences between individuals who are bound by non-

[735] *Atl. Refin. Co.,* 381 U.S. at 371 (considering that defendant's distribution contracts at issue ''may well provide Atlantic with an economical method of assuring efficient product distribution among its dealers'' and holding that the ''Commission was clearly justified in refusing the participants an opportunity to offset these evils by a showing of economic benefit to themselves''); *FTC* v. *Texaco,* 393 U.S. 223, 230 (1968) (following the same reasoning as *Atlantic Refining* and finding that the ''anticompetitive tendencies of such system [were] clear''); *L.G. Balfour Co.* v. *FTC,* 442 F.2d 1, 15 (7th Cir. 1971) (''While it is relevant to consider the advantages of a trade practice on individual companies in the market, this cannot excuse an otherwise illegal business practice.''). For provisions of the antitrust laws where courts have not accepted justifications as part of the legal analysis, the Commission will similarly not accept justifications when these claims are pursued through section 5.

[736] *See, e.g., FTC* v. *Ind. Fed'n of Dentists,* 476 U.S. 447, 463 (1986); *Fashion Originators' Guild of Am.* v. *FTC,* 312 U.S. 457, 467–68 (1941); *FTC* v. *Superior Ct. Trial Lawyers Ass'n,* 493 U.S. 411, 423–24 (1990).

[737] *See, e.g., Ind. Fed'n of Dentists,* 476 U.S. at 464. *See also United States* v. *Microsoft Corp.,* 253 F.3d 35, 62–64, 74 (D.C. Cir. 2001); *Eastman Kodak Co.* v. *Image Tech. Svcs.,* 504 U.S. 451, 484–85 (1992); *Aspen Skiing Co.* v. *Aspen Highlands Skiing Corp.,* 472 U.S. 585, 608–10 (1985).

[738] *NCAA* v. *Alston,* 594 U.S. 69, 99–104 (2021); *Polygram Holding, Inc.* v. *FTC,* 416 F.3d 29, 38 (D.C. Cir. 2005); 2000 Collaboration Guidelines, sec. 3.36b. *See also Union Circulation Co.* v. *FTC,* 241 F.2d 652, 658 (2d Cir. 1957) (''The agreements here went beyond what was necessary to curtail and eliminate fraudulent practices.'').

[739] NPRM at 3504–08.

[740] *See, e.g., United States* v. *Addyston Pipe & Steel Co.,* 85 F. 271, 281 (6th Cir. 1898); *Polk Bros., Inc.* v. *Forest City Enters.,* 776 F.2d 185, 189 (7th Cir. 1985).

[741] *See* FTC, *In the Matter of O–I Glass, Inc and In the Matter of Ardagh Group S.A., Ardagh Glass Inc., and Ardagh Glass Packaging Inc.,* Analysis of Agreements Containing Consent Order to Aid Public Comment, FTC File No. 2110182 (Jan. 4, 2023) at 6–7; FTC, *In the Matter of Prudential Security, Inc., et al.,* Analysis of Agreement Containing Consent Order to Aid Public Comment, FTC File No. 2210026 (Jan. 4, 2023) at 7; FTC, *In the Matter of Anchor Glass Container Corp. et al.,* FTC File No. 2210182 Analysis of Agreement Containing Consent Order to Aid Public Comment (Mar. 15, 2023) at 6.

[742] *See* Part IV.D.2.

[743] *See* Part IV.D.3.

[744] Starr, *supra* note 445 at 796–97.

[745] *Id.* at 797.

competes and individuals who are not. This study is the only study that attempts to identify the causal link between non-competes and worker human capital investment, and the Commission gives it some weight, though not as much weight as it would receive if it examined changes in non-compete enforceability. The Commission also weights it less highly because it does not distinguish between core and advanced training.

The second study, by Jessica Jeffers, finds knowledge-intensive firms invest substantially less in capital equipment following decreases in the enforceability of non-competes, though the effect is much more muted (and statistically insignificant) when considering all industries.[746] While firms may invest in capital equipment for many different reasons, Jeffers examines this outcome (as opposed to labor-focused outcomes) to avoid looking at R&D expenditure as a whole, which is in large part composed of labor expenses. This allows the study to isolate the effects of non-compete enforceability on investment from other effects of non-competes, such as reduced worker earnings.

Jeffers finds that there are likely two mechanisms driving these effects: first, that firms may be more likely to invest in capital when they train their workers because worker training and capital expenditure are complementary (*i.e.,* the return on investment in capital equipment is greater when workers are more highly trained); and second, that non-competes reduce competition, and firms' returns to capital expenditure are greater when competition is lower, incentivizing firms to invest more in capital.[747] Jeffers does not find any impact of non-compete enforceability on R&D expenditure (intangible investment). The sample in this study's examination of capital investment is limited to incumbent firms, and the study also finds decreases in new firm entry due to increases in non-compete enforceability. The study therefore does not offer clear insights into the overall net effect on capital investment (which includes investment by incumbent firms as well as investment by entering firms). Additionally, the Commission notes that if Jeffers' hypothesis—that firms increase investment in capital because of decreased competition—is correct, then this increased capital investment may not necessarily reflect increased economic efficiency. Jeffers uses multiple changes in non-compete enforceability, measured in a binary fashion, and the Commission therefore gives this study substantial weight, but less weight than studies which additionally measure enforceability in a non-binary fashion.

Two studies published after the release of the NPRM also assess the effects of non-competes on firm investments. A study by Johnson, Lipsitz, and Pei revisits the form of the regressions used by Jeffers. The authors find that greater non-compete enforceability increases R&D expenditure.[748] This is consistent with the NPRM's preliminary finding, and the finding of the Jeffers study, that there is evidence that non-competes increase employee human capital investment and other forms of investment. The Commission gives this study substantial weight because it examines multiple changes in non-compete enforceability measured in a non-binary fashion.

Similarly, a study by Liyan Shi examines the relationship between non-compete enforceability, the use of non-competes among executives, and firm investment.[749] Shi finds that intangible capital (expenditure on R&D) is positively associated with use of non-competes, especially in States that enforce non-competes more strictly. However, Shi finds that—unlike in the Jeffers study—physical capital expenditure has no relationship with the use of non-competes, even in high enforceability States. The Commission notes that this evidence pertains specifically to non-competes with highly paid senior executives: the executives in Shi's study earned $770,000 in cash compensation, on average. The Commission also notes that this evidence arises from analysis of non-compete use coupled with non-compete enforceability. The Commission therefore gives less weight to these empirical findings.

As the NPRM described, there are also two studies examining the impact of non-compete use (as opposed to non-compete enforceability) on investment. However, these studies simply compare differences between samples of workers that do and do not use non-competes, a methodology the Commission gives less weight to.[750] The first is a study by Starr, Prescott, and Bishara using their 2014 survey of non-compete use. They find no statistically significant association with either training or the sharing of trade secrets (after inclusion of control variables) but do not examine other investment outcomes.[751] The second study, by Johnson and Lipsitz, examines investment in the hair salon industry. That study finds that firms that use non-competes train their employees at a higher rate and invest in customer attraction through the use of digital coupons (on so-called ''deal sites'') to attract customers at a higher rate, both by 11 percentage points.[752]

As the Commission stated in the NPRM, it gives these two studies (the 2021 Starr, Prescott, and Bishara studies and the 2021 Johnson and Lipsitz studies) minimal weight, because they do not necessarily represent causal relationships, a point recognized by the authors of both of these studies.[753] Similar to other studies of non-compete use—as opposed to changes in non-compete enforceability—these studies are less reliable because the use of non-competes and the decision to invest may be jointly determined by other characteristics of the firms, labor markets, or product markets.[754]

One additional study, by Younge and Marx, finds that the value of publicly traded firms increased by 9% due to an increase in non-compete enforceability.[755] As the Commission noted in the NPRM, the authors attribute this increase to the value of retaining employees, which comes with the negative effects to parties other than the firm (employees, competitors, and consumers) described in Parts IV.B and IV.C. As the NPRM stated, if the benefits to the firm arise primarily from reductions in labor costs, then the increase in the value of firms is in part a transfer from workers to firms and is therefore not necessarily a benefit of non-competes. However, the authors do not explore the extent to which increases in firm value arise from decreases in labor costs. The authors additionally note that since the time frame used in the study is short, ''there may be deleterious effects of non-competes in the long run'' which are absent in their findings.[756] This study

[746] Jeffers, *supra* note 450 at 28. Jeffers reports 34%–39% increases in capital investment due to increases in non-compete enforceability at knowledge-intensive firms in the 2024 version of the study, and the Commission calculates increases of 7.9% across all sectors (see Part X.F.9.a.i).

[747] *Id.* at 29.

[748] Johnson, Lipsitz, and Pei, *supra* note 526.

[749] Shi, *supra* note 84.

[750] *See* Part IV.A.2.

[751] Starr, Prescott, & Bishara, *supra* note 68 at 76.

[752] Johnson & Lipsitz, *supra* note 80 at 711.

[753] Starr, Prescott, & Bishara, *supra* note 68 at 73; Johnson & Lipsitz, *supra* note 80 at 711.

[754] *See* Part IV.A.2 (describing the analytical framework the Commission is applying to weigh the empirical studies, including why it assigns greater weight to studies assessing changes in non-compete enforceability than to studies of non-compete use).

[755] Kenneth A. Younge & Matt Marx, *The Value of Employee Retention: Evidence from a Natural Experiment,* 25 J. Econ. & Mgmt. Strategy 652 (2016).

[756] *Id.* at 674.

does not address the effects of non-competes on firm investments specifically.

As the Commission stated in the NPRM, it is unaware of any evidence of a relationship between the enforceability of non-competes and the rate at which companies invest in creating or sharing trade secrets.[757] Similarly, the Commission is unaware of any evidence non-competes reduce trade secret misappropriation or the loss of other types of confidential information, difficult areas for researchers to study given the lack of reliable data on firms' trade secrets and confidential information.[758] As explained in Part IV.D.2, even assuming non-competes do reduce misappropriation or information loss, the Commission finds that there are alternatives to protect these investments that burden competition to a lesser degree.

2. Employers Have Alternatives to Non-Competes for Protecting Valuable Investments

a. The Proposed Rule

In the NPRM, the Commission preliminarily found that employers have alternatives to non-competes for protecting valuable investments.[759] The Commission stated that these alternatives may not be as protective as employers would like, but they reasonably accomplish the same purposes as non-competes while burdening competition to a less significant degree.[760]

The Commission stated that trade secret law—a form of intellectual property law that protects confidential business information—already provides significant legal protections for an employer's trade secrets.[761] The Commission also stated that employers that seek to protect valuable investments are able to enter into NDAs with their workers. NDAs, which are also commonly known as confidentiality agreements, are contracts in which a party agrees not to disclose or use information designated as confidential.[762] The Commission further stated that, if an employer wants to prevent a worker from leaving right after receiving valuable investment in their human capital, the employer can sign the worker to an employment contract with a fixed duration.[763] In addition, the Commission stated that employers that wish to retain their workers can also pay their workers more, offer them better hours or better working conditions, or otherwise improve the conditions of their employment—*i.e.,* compete to retain their labor services.[764]

The Commission also noted that in three States—California, North Dakota, and Oklahoma—employers generally cannot enforce non-competes, so they must protect their investments using one or more of these less restrictive alternatives.[765] The Commission stated that the economic success in these three States of industries that are highly dependent on trade secrets and other confidential information illustrates that companies have viable alternatives to non-competes for protecting valuable investments.[766]

b. The Commission's Final Findings

Based on the totality of the evidence, including its review of the empirical literature, its review of the full comment record, and its expertise in identifying practices that harm competition, the Commission in this final rule finds that the asserted business justifications for non-competes do not alter the Commission's determination that non-competes are an unfair method of competition. Employers have alternatives to non-competes for protecting valuable investments that burden competition to a less significant degree. Rather than restraining a broad scope of beneficial competitive activity—by barring workers altogether from leaving work with the employer or starting a business and by barring competing employers and businesses from hiring those workers—these alternatives are much more narrowly tailored to limit impacts on competitive conditions.

For the protection of trade secrets and other confidential information, these alternatives include enforcement of intellectual property rights under trade secret and patent law, NDAs, and invention assignment agreements. Employers also have alternative mechanisms to protect their investments in worker human capital, including fixed duration contracts, and competing on the merits to retain workers by providing better pay and working conditions.

The experiences of certain States in banning non-competes bolster this conclusion. Non-competes have been void in California, North Dakota, and Oklahoma since the 1800s.[767] In these three States, employers generally cannot enforce non-competes, so they must protect their investments using one or more less restrictive alternatives. There is no evidence that employers in these States have been unable to protect their investments (whether in human capital, physical capital, intangible assets, or otherwise) or have been disincentivized from making them to any discernible degree. Rather, in each of these States, industries that depend on highly trained workers and trade secrets and other confidential information have flourished. California, for example, is home to four of the world's ten largest companies by market capitalization, and it also maintains a vibrant startup culture.[768] Technology firms are highly dependent on highly-trained and skilled workers as well as protecting trade secrets and other confidential information—and, since the 1980s, California has become the epicenter of the global technology sector, even though employers cannot enforce non-competes.[769] Indeed, researchers have posited that high-tech clusters in California may have been aided by increased labor mobility due to the unenforceability of non-competes.[770] In

[757] Recent evidence suggests that trade secret litigation does not increase following bans on non-competes. Brad N. Greenwood, Bruce Kobayashi, Evan Starr, *Can You Keep a Secret? Banning Noncompetes Does Not Increase Trade Secret Litigation* (2024), *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4771171*. The Commission does not rely on this study to support the findings described in this Part IV.D.

[758] *See, e.g.,* David S. Levine & Christopher B. Seaman, *The DTSA at One: An Empirical Study of the First Year of Litigation Under the Defend Trade Secrets Act,* 53 Wake Forest L. Rev. 106, 120–22 (2018).

[759] NPRM at 3505–07.

[760] *Id.*

[761] *Id.* at 3505–06.

[762] *Id.* at 3506–07.

[763] *Id.* at 3507.

[764] *Id.*

[765] Since the NPRM was issued, Minnesota has become the fourth State to make non-competes unenforceable. *See* Minn. Stat. Ann. sec. 181.988 (effective July 1, 2023).

[766] NPRM at 3507.

[767] Non-competes have been void in California since 1872, in North Dakota since 1865, and in Oklahoma since 1890. *See* Ronald J. Gilson, *The Legal Infrastructure of High Technology Industrial Districts: Silicon Valley, Route 128, and Non-Compete Clauses,* 74 N.Y.U. L. Rev. 575, 616 (1999) (California); *Werlinger* v. *Mut. Serv. Casualty Ins. Co.,* 496 NW2d 26, 30 (N.D. 1993) (North Dakota); Brandon Kemp, *Noncompetes in Oklahoma Mergers and Acquisitions,* 88 Okla. Bar J. 128 (2017) (Oklahoma). Minnesota also recently prohibited non-competes, through a law that took effect in July 2023. *See* Minn. Stat. sec. 181.988. However, Minnesota's experience is too new to draw conclusions about the ability of industries that depend on trade secrets to thrive where non-competes are unenforceable.

[768] Josh Dylan, *What Is Market Cap In Stocks?,* Nasdaq.com (Aug, 12, 2022), *https://www.nasdaq.com/articles/what*marketcap-in-stocks; Ewing Marion Kauffman Found., *State Entrepreneurship Rankings, https://www..com/public_affairs//02/25/_foundation_state_entrepreneurship_rankings.html.*

[769] *See, e.g.,* Gilson, *supra* note 767 at 594–95.

[770] *See, e.g., id.* at 585–86, 590–97; Bruce Fallick, Charles A. Fleischman, & James B. Rebitzer, *Job-Hopping in Silicon Valley: Some Evidence Concerning the Microfoundations of a High-Technology Cluster,* 88 Rev. Econ. & Statistics 472, 477 (2006).

North Dakota and Oklahoma, the energy industry has thrived, and firms in the energy industry depend on highly-trained workers as well as the ability to protect trade secrets and other confidential information.

The Commission finds that the economic success in these three States of industries that are highly dependent on highly trained workers, trade secrets, and other confidential information illustrates that non-competes are not necessary to protect employers' legitimate interests in trained workers or securing their intellectual property and confidential information. These alternatives are available to employers and viable both with respect to senior executives and to workers other than senior executives. The Commission addresses these alternatives in this Part IV.D.2.b and summarizes and responds to the comments on these alternatives in Part IV.D.2.c.

i. Trade Secret Law

The Commission finds that trade secret law provides employers with a viable, well-established means of protecting investments in trade secrets, without the need to resort to the use of non-competes with their attendant harms to competition. Trade secret law is a form of intellectual property law that is specifically focused on providing employers with the ability to protect their investments in trade secrets.[771]

Forty-seven States and DC have adopted the Uniform Trade Secrets Act (''UTSA'').[772] The UTSA provides a civil cause of action for trade secret misappropriation, which refers to disclosure or use of a trade secret by a former employee without express or implied consent.[773] The UTSA also provides for injunctive and monetary relief, including compensatory damages, punitive damages, and attorney's fees.[774]

In addition, in 2016, Congress enacted the Defend Trade Secrets Act of 2016 (''DTSA''), which established a civil cause of action under Federal law for trade secret misappropriation.[775] The DTSA brought the rights of trade secret owners ''into alignment with those long enjoyed by owners of other forms of intellectual property, including copyrights, patents, and trademarks.'' [776] Similar to State laws modeled on the UTSA, the DTSA authorizes civil remedies for trade secret misappropriation, including injunctive relief, damages (including punitive damages), and attorney's fees.[777] The DTSA also authorizes a court, in ''extraordinary circumstances,'' to issue civil ex parte orders for the ''seizure of property necessary to prevent the propagation or dissemination of the trade secret that is the subject of the action.'' [778] There is thus a clear Federal statutory protection that specifically governs protection of trade secrets.

Trade secret theft is also a Federal crime. The Economic Espionage Act of 1996 (''EEA'') makes it a Federal crime to steal a trade secret for either (1) the benefit of a foreign entity (''economic espionage'') or (2) the economic benefit of anyone other than the owner (''theft of trade secrets'').[779] The EEA authorizes substantial criminal fines and penalties for these crimes.[780] The EEA further authorizes criminal or civil forfeiture, including of ''any property constituting or derived from any proceeds obtained directly or indirectly as a result of'' an EEA offense.[781] The EEA also requires offenders to pay restitution to victims of trade secret theft.[782]

Under the UTSA, DTSA, and EEA, the term ''trade secret'' is defined expansively and includes a wide range of confidential information.[783] The viability of trade secret law as a means for redressing trade secret theft is illustrated by the fact that firms regularly bring claims under trade secret law. A recent analysis by the legal analytics firm Lex Machina finds that 1,156 trade secret lawsuits were filed in Federal court in 2022.[784] In addition, an analysis by the law firm Morrison Foerster finds that 1,103 trade secret cases were filed in State courts in 2019.[785] The number of cases filed in State court has held steady since 2015, when 1,161 cases were filed.[786] The fact that a considerable number of trade secret lawsuits are filed in Federal and State courts—over 2,200 cases per year—and the fact that this number has held relatively steady for several years suggests that many employers themselves view trade secret law as a viable means of obtaining redress for trade secret theft.

The use of trade secret law burdens competition to a lesser degree than the use of non-competes. Trade secret law provides firms with a viable means of redressing trade secret misappropriation—and deterring trade secret misappropriation by workers—without blocking beneficial competitive activity, such as workers switching to jobs in which they can be more productive or starting their own businesses.

ii. NDAs

NDAs provide employers with another well-established, viable means for protecting valuable investments.[787]

[771] Brian T. Yeh, *Protection of Trade Secrets: Overview of Current Law and Legislation,* Cong. Rsch. Serv. 4 (Apr. 22, 2016) (Report R43714), *https://sgp.fas.org/crs/secrecy/R43714.pdf.*

[772] *See* Levine & Seaman, *supra* note 758 at 113. The three States that have not adopted the UTSA offer protection to trade secrets under a different statute or under common law. Yeh, *supra* note 771 at 6 n.37.

[773] Uniform Trade Secrets Act with 1985 Amendments (Feb. 11, 1986) at sec. 1(2).

[774] *Id.* at secs. 2–4.

[775] Defend Trade Secrets Act of 2016, Public Law 114–153, 130 Stat. 376, 379 (2016).

[776] U.S. Senate, Report to Accompany S. 1890, the Defend Trade Secrets Act of 2016, S. Rep. No. 114–220 at 3 (2016).

[777] 18 U.S.C. 1836(b)(3).

[778] 18 U.S.C. 1836(b)(2).

[779] 18 U.S.C. 1831 (economic espionage); 18 U.S.C. 1832 (theft of trade secrets).

[780] 18 U.S.C. 1831 through 1832.

[781] 18 U.S.C. 1834, 2323.

[782] 18 U.S.C. 1834, 2323.

[783] The UTSA generally defines a ''trade secret'' as information that (1) derives independent economic value from not being generally known to other persons who can obtain economic value from its disclosure or use and (2) is the subject of reasonable efforts to maintain its secrecy. UTSA, *supra* note 773 at sec. 1(4). The DTSA and EEA use a similar definition. 18 U.S.C. 1839(3). The Supreme Court has held that ''some novelty'' is required for information to be a trade secret, because ''that which does not possess novelty is usually known.'' *Kewanee Oil Co.* v. *Bicron Corp.,* 416 U.S. 470, 476 (1974). As the high court of one State noted in applying a State statute based on the UTSA, ''business information may . . . fall within the definition of a trade secret, including such matters as maintenance of data on customer lists and needs, source of supplies, confidential costs, price data and figures.'' *U.S. West Commc'ns, Inc.* v. *Off. of Consumer Advoc.,* 498 NW2d 711, 714 (Iowa 1993). *See also Confold Pac., Inc.* v. *Polaris Indus., Inc.,* 433 F.3d 952, 959 (7th Cir. 2006) (''A trade secret is really just a piece of information (such as a customer list, or a method of production, or a secret formula for a soft drink) that the holder tries to keep secret by executing confidentiality agreements with employees and others and by hiding the information from outsiders by means of fences, safes, encryption, and other means of concealment, so that the only way the secret can be unmasked is by a breach of contract or a tort.'').

[784] Gloria Huang, *Lex Machina Releases its 2023 Trade Secret Litigation Report,* Lex Machina (Jul. 13, 2023), https://.com/blog/lex-machina-releases-its-2023-trade-secret-litigation-report/.

[785] Kenneth A. Kuwayti & John R. Lanham, Morrison Foerster, Client Alert, *Happy Anniversary, DTSA: The Defend Trade Secrets Act at Five* (May 25, 2021), *https://www.mofo.com///210525-defend-trade-secrets-act-dtsa.*

[786] *Id.* at n.5.

[787] The Commission uses the term ''NDA'' to refer to contractual provisions that are designed to protect trade secrets or other business information that has economic value. Employers may also seek to use NDAs to protect other kinds of information, such as information about discrimination, harassment, sexual assault, corporate wrongdoing, or information that may disparage the company or its executives or employees. These types of NDAs have been widely criticized for, among other things, their pernicious effects on workers. *See, e.g.,* Rachel S. Arnow-Richman et al., *Supporting Market Accountability, Workplace Equity, and Fair Competition by Reining In Non-Disclosure Agreements,* UC-Hastings Research Paper 2–6 (Jan. 2022), *https://papers.ssrn.com/sol3/.?abstract_=.*

NDAs are contracts in which a party agrees not to disclose and/or use information designated as confidential. If a worker violates an NDA, the worker may be liable for breach of contract.[788] Employers regularly use NDAs to protect trade secrets and other confidential business information. Researchers estimate that between 33% and 57% of U.S. workers are subject to at least one NDA.[789] One study finds that 95.6% of workers with non-competes are also subject to an NDA; 97.5% of workers with non-competes are also subject to a non-solicitation agreement, NDA, or a non-recruitment agreement; and 74.7% of workers with non-competes are subject to all three provisions.[790] In most States, NDAs are more enforceable than non-competes.[791] While some commenters argued that NDAs would not be an adequate alternative to non-competes because of the NPRM's proposed functional definition of ''non-compete clause,'' the final rule will not prevent employers from adopting garden-variety NDAs; rather, it prohibits only NDAs that are so overbroad as to function to prevent a worker from seeking or accepting employment or operating a business.[792]

Appropriately tailored NDAs burden competition to a lesser degree than non-competes. Such NDAs may prevent workers from disclosing or using certain information, but they generally do not prevent workers from seeking or accepting other work, or starting their own business, after their employment ends. As the Tenth Circuit has stated, workers subject to NDAs, unlike workers subject to non-competes, ''remain free to work for whomever they wish, wherever they wish, and at whatever they wish,'' subject only to the terms that prohibit them from disclosing or using certain information.[793]

iii. Other Means of Protecting Valuable Investments

The Commission finds that employers have additional well-established means of protecting valuable investments in addition to trade secret law and NDAs. For the protection of trade secrets and other confidential information, the Commission finds that these additional means include patent law and invention assignment agreements. Patent law provides inventors with the right, for a certain period of time, to exclude others from making, using, offering for sale, or selling an invention or importing it into the U.S.[794] During the period when patent protection is effective, patents grant the patent holder these exclusive rights, while other firms may use trade secrets if they are independently developed, reverse-engineered, or inadvertently disclosed.[795] In some cases, however, firms may choose to keep their invention a trade secret rather than seeking a patent because patent protection only lasts a certain number of years, after which the invention becomes part of the public domain.[796] Where a technology, process, design, or formula is able to meet the rigorous standards for patentability, patent law provides companies with a less restrictive alternative than non-competes for protecting it.[797]

Employers can further protect their property interests in these forms of intellectual property through appropriately tailored invention assignment agreements. These are agreements that give the employer certain rights to inventions created by the employee during their employment with a firm.[798] Like patent law, this tool, when appropriately tailored, provides employers with additional protection for some of their most valuable intellectual property interests.

With respect to investments in worker human capital, the Commission finds that these less restrictive alternatives include fixed duration contracts and competing on the merits to retain workers. If an employer wants to prevent a worker from leaving right after receiving valuable training, the employer can sign the worker to an employment contract with a fixed duration. An employer can establish a term that is long enough for the employer to recoup its human capital investment, without restricting who the worker can work for, or their ability to start a business, after their employment ends. In doing so, the employer makes a commitment to the worker and vice versa.

Finally, instead of using non-competes to lock in workers, the Commission finds that employers that wish to retain their workers can also compete on the merits for the worker's labor services—*i.e.,* they can provide a better job than competing employers by paying their workers more, offering them better hours or better working conditions, or otherwise improving the conditions or desirability of their employment. These are all viable tools for protecting human capital investments and other investments an employer may make that do not rely on suppressing competition.

c. Comments and Responses to Comments

Many commenters agreed with the Commission's preliminary finding that employers have less restrictive alternatives to non-competes. These commenters asserted that trade secret law, combined with NDAs, creates a powerful deterrent to post-employment disclosures of trade secrets and confidential information, and that these tools adequately protect valuable investments in the absence of non-competes. The Commission agrees with these commenters. Other commenters asserted that the alternatives to non-competes identified in the NPRM are inadequate for protecting employer investments. The Commission summarizes and responds to the comments it received on less restrictive alternatives in this Part IV.D.2.c.

i. Comments and Responses to Comments on Trade Secrets and Other Confidential Information

Several commenters who generally supported the proposed rule stated that trade secret law and NDAs offer meaningful enforcement advantages to employers compared with non-competes. A few commenters stated that, unlike non-competes, trade secret law and NDAs are broadly enforceable in all fifty States. A few commenters stated that, while monetary penalties for breaching non-competes are ordinarily difficult to obtain, employers can obtain substantial monetary recovery for trade secret law and NDA violations. The Commission agrees with these comments.

Several commenters stated that the scope of trade secret law is limited in various respects. Several commenters stated, for example, that customer lists, pricing, and bid development information are typically excluded from the definition of ''trade secret'' under the DTSA and the law of many States.

[788] *See* Chris Montville, *Reforming the Law of Proprietary Information,* 56 Duke L.J. 1159, 1168 (2007).

[789] Arnow-Richman, *supra* note 787 at 2–3.

[790] Balasubramanian, Starr, & Yamaguchi, *supra* note 74 at 44. The value 97.5% is calculated as (1 − 0.6%/24.2%), where 0.6% represents the proportion of workers with only a non-compete (see Table 1 on page 36), and no other post-employment restriction, and 24.2% represents the proportion of workers with a non-compete, regardless of what other post-employment restrictions they have.

[791] Montville, *supra* note 788 at 1179–83.

[792] *See* Part III.D.2.b.

[793] *MAI Basic Four, Inc.* v. *Basis, Inc.,* 880 F.2d 286, 288 (10th Cir. 1989).

[794] 35 U.S.C. 271.

[795] Yeh, *supra* note 771 at 3–4.

[796] *Id.* at 4–5. *See also United States* v. *Dubilier Condenser Corp.,* 289 U.S. 178, 186 (1933) (rather than seeking a patent, an inventor ''may keep his invention secret and reap its fruits indefinitely.'').

[797] Yeh, *supra* note 771 at 4–5.

[798] *See, e.g., Milliken & Co.* v. *Morin,* 731 SE2d 288, 294–95 (S.C. 2012); *Revere Transducers, Inc.* v. *Deere & Co.,* 595 NW2d 751, 759–60 (Iowa 1999); *Ingersoll-Rand Co.* v. *Ciavatta,* 542 A.2d 879, 886–87 (N.J. 1988).

In response to these comments, the Commission notes that customer information may be classified as trade secrets under certain circumstances, such as when the information is not generally known or not otherwise easy to obtain and when a firm has taken measures to protect the confidentiality of the information.[799] Employers may also use NDAs to protect such information. NDAs broadly protect all information defined as confidential, regardless of whether such information constitutes a ''trade secret'' under State or Federal law.[800]

Some commenters argued that other tools under intellectual property law, such as patent and trademark law, are inadequate to protect employers' investments. These commenters misinterpret the Commission's findings. The Commission did not find in the NPRM, nor does it find in this final rule, that patent law standing alone or trademark law standing alone provide employers benefits equal to the benefits they may reap from an unfair method of competition, namely the use of non-competes. Rather, the Commission finds that patent law can be used, together with the other tools the Commission cites, including NDAs and fixed-term employment contracts, to protect legitimate investments in intellectual property and worker human capital investment and therefore that these tools, taken together, are viable alternatives to non-competes.

A number of commenters stated that there are enforceability disadvantages to trade secret law and NDAs compared to non-competes. Several commenters stated that trade secret law and NDAs are inadequate to protect employer investments prophylactically because employers can enforce them only after the trade secrets or other confidential information have already been disclosed. These commenters stated that trade secrets and confidential information can be highly valuable, and its value could be destroyed as soon as a worker discloses such information to a competing employer. Additionally, some commenters argued that trade secret law and NDAs are inadequate to protect employers' investments because enforcement outcomes for trade secrets and NDAs are less predictable and certain than with non-competes. Some comments suggested that this purported clarity of non-competes benefits workers, arguing that non-competes offer bright lines workers can follow to ensure against unintended violations. Other commenters assert that non-competes themselves are not necessarily effective as a prophylactic remedy, because it is often unclear whether a particular non-compete is enforceable, and non-competes are difficult to enforce in many jurisdictions. A few commenters stated that prophylactic remedies are already available under trade secret law in almost half of U.S. States where the doctrine of inevitable disclosure is recognized, while other commenters were concerned that not all States recognize the doctrine. Other commenters argued the inevitable disclosure doctrine may be worse for workers, and one commenter argued that the final rule would increase the use of the inevitable disclosure doctrine and thus reduce worker mobility.

Some commenters stated that prophylactic remedies are necessary to adequately protect trade secrets and confidential information because workers can exploit their former employers' trade secrets and confidential information without ever disclosing the information themselves, thus leaving aggrieved employers with no recourse under trade secret law or an NDA. Specifically, these commenters argued that when workers take new roles, they will inevitably use their knowledge of former employers' confidential information. For example, where a worker has experience with attempts and failures to develop new ideas or products with a former employer, they will likely use this knowledge to prevent a new employer from making similar mistakes, thus free riding off the former employer's development efforts, costs, and time. A commenter argued that preventing non-competes from restricting this type of misappropriation would discourage investment and harm innovation in the long run.

The Commission believes that what some commenters describe as the ''prophylactic'' benefits of non-competes—that an employer can block a worker from taking another job, without respect to any alleged misconduct—is also the source of their overbreadth because it enables employers to restrict competition in both labor markets and product and service markets, as detailed in Parts IV.B and IV.C. That employers prefer to wield non-competes as a blunt instrument on top of or in lieu of the specific legal tools designed to protect legitimate investments in intellectual property and other investments cannot justify an unfair method of competition. The Commission also disagrees that banning non-competes would discourage investment and would harm innovation in the long run. As discussed in Part IV.B.3.b.ii, the Commission finds that the weight of the evidence indicates that non-competes reduce innovation by preventing workers from starting businesses in which they can pursue innovative new ideas; inhibiting efficient matching between workers and firms (making it less likely that workers match with firms that can maximize their talent and productivity); and decreasing the cross-pollination of ideas.

Additionally, the Commission notes that non-compete agreements themselves cannot be said to provide ironclad ''prophylactic'' protections against disclosure of trade secrets and other confidential information. As other commenters point out, in the absence of this rule, it is often unclear whether and to what extent a specific non-compete is enforceable, and they are difficult to enforce in many jurisdictions. Moreover, non-competes do not prevent the worker from disclosing trade secrets or confidential information after the end of the non-compete period or outside of the clause's geographic restriction. The Commission also notes that, as a few commenters stated, prophylactic remedies are already available under trade secret law in almost half of U.S. States where the doctrine of inevitable disclosure is recognized.[801]

Several commenters argued that detecting and proving violations of NDAs and trade secret law is more

[799] *See U.S. West Commc'ns, Inc.* v. *Off. of Consumer Advoc.,* 498 NW2d 711, 714 (Iowa 1993) (''business information may . . . fall within the definition of a trade secret, including such matters as maintenance of data on customer lists and needs . . .''); *Guy Carpenter & Co.* v. *Provenzale,* 334 F.3d 459, 467 (5th Cir. 2003) (''A customer list may be a trade secret, but not all customer lists are trade secrets under Texas law. The broader rule of trade secrets, that they must be *secret,* applies to customer lists''); *Home Paramount Pest Control Cos.* v. *FMC Corporation/Agricultural Prods. Group,* 107 F. Supp. 2d 684, 692 (D. Md. 2000) (''There is no question that a customer list can constitute a trade secret.''); *Liebert Corp.* v. *Mazur,* 827 NE2d 909, 922 (2005) (''[W]hether customer lists are trade secrets depends on the facts of each case.'').

[800] *See, e.g., Tendeka, Inc.* v. *Glover,* No. CIV.A. H–13–1764, 2015 WL 2212601 at *14 (S.D. Tex. May 11, 2015).

[801] In some States, under the ''inevitable disclosure doctrine,'' courts may enjoin a worker from working for a competitor of the worker's employer where it is ''inevitable'' the worker will disclose trade secrets in the performance of the worker's job duties. *See, e.g., PepsiCo, Inc.* v. *Redmond,* 54 F.3d 1262, 1269, 1272 (7th Cir. 1995). The inevitable disclosure doctrine is controversial. Several States have declined to adopt it altogether, citing the doctrine's harsh effects on worker mobility. *See Bayer Corp.* v. *Roche Molecular Sys., Inc.,* 72 F. Supp. 2d 1111, 1120 (N.D. Cal. 1999); *LeJeune* v. *Coin Acceptors, Inc.,* 849 A.2d 451, 470–71 (Md. 2004). Other States have required employers to meet high evidentiary burdens related to inevitability, irreparable harm, and bad faith before issuing an injunction pursuant to the doctrine. *See generally* Eleanore R. Godfrey, *Inevitable Disclosure of Trade Secrets: Employee Mobility* v. *Employer Rights,* 3. J. High Tech. L. 161 (2004).

difficult than for non-competes, and that enforcement is accordingly more expensive, because it is more difficult to detect and obtain evidence of the disclosure or use of confidential information than it is to determine that a former worker has moved to a competitor. Some commenters asserted that trade secret litigation is expensive because the cases are fact-intensive and involve litigating multiple challenging issues. Some commenters argued that as a result, the proposed rule conflicted with Congressional intent underlying the DTSA. A few commenters similarly argued that breaches of non-solicitation agreements are difficult to detect and can be enforced only after the solicitation has occurred. While the Commission recognizes that trade secrets litigation and NDA and non-solicitation enforcement may be more costly than non-compete enforcement in some instances, the Commission is not persuaded that higher costs associated with alternative tools make those tools inadequate. The comments do not establish that pursuing remedies through trade secrets litigation or NDA enforcement are prohibitively expensive. In any event, the Commission and courts have consistently held that pecuniary benefit to the party responsible for the conduct in question is not cognizable as a justification.[802] While employers may find that protecting trade secrets and confidential information or customer relationships by using non-competes to restrict worker mobility, regardless of whether that worker would misappropriate confidential information or solicit customers, is easier for them, the Commission finds that same overbreadth of non-competes imposes significant negative externalities on workers, consumers, businesses, and competition as a whole.[803] This overbreadth that employers benefit from wielding is what causes the harms from non-competes relative to more narrowly-tailored alternatives.

Some commenters contended that higher burdens for establishing violations of trade secret and IP laws will harm employer incentives to share trade secrets with workers and to invest in valuable skills training. The Commission is not persuaded that higher evidentiary burdens render trade secret law and NDAs inadequate for protecting employers' valuable investments. Heightened standards are a valuable mechanism to filter out overbroad restrictions on beneficial competitive activity. The comment record is replete with examples of workers bound by non-competes who lacked knowledge of trade secrets or whose employment with a competitor never threatened their previous employer's investments. To the extent trade secret law and NDAs require higher evidentiary showings, that makes these alternatives more tailored tools for protecting employers' valuable investments without unduly restricting a worker from engaging in competitive activity.

Some commenters argued that, without non-competes, employers would limit access to valuable trade secrets within the workplace because trade secret law requires employers to show reasonable efforts to maintain the secrecy of an alleged trade secret to prove a violation, and that reduced rates of intrafirm trade secrets sharing will ultimately harm innovation as well as workers. In response, the Commission notes that the empirical evidence indicates otherwise: when non-competes are more enforceable, the overall level of innovation decreases.[804] Furthermore, these comments seem to overstate the burden of reasonable efforts to keep information secret. Under the DTSA, courts have found that employers meet this requirement by sharing information at issue only among workers bound by NDAs or maintaining such information in password-protected digital spaces.[805] Accordingly, assertions that employers will need to take extraordinary precautions to maintain secrecy over trade secrets and confidential information are inconsistent with standards courts typically recognize for determining whether reasonable efforts were taken to keep such information confidential. The Commission is not persuaded that requirements in trade secret law to show reasonable efforts to maintain secrecy will deter intrafirm information sharing, or otherwise make alternative tools inadequate.

Several commenters argued that the Commission should not find that employers have adequate alternatives to protecting their valuable investments because there is a lack of empirical evidence specifically showing that trade secret law and NDAs are effective for the purpose of protecting trade secrets and confidential information. In response, the Commission notes that trade secret law is a body of law that is specifically designed to protect the interests being asserted; employers consistently bring cases under this body of law; and a preference among firms for a blunter instrument for protecting trade secrets and confidential information cannot justify an unfair method of competition that imposes significant negative externalities on workers, other firms, consumers, and the economy.[806] An industry trade organization commenter stated that neither fixed-duration employment contracts nor improved pay, benefits, or working conditions specifically protect against the disclosure of confidential information. In response, the Commission notes that firms can protect against the disclosure of confidential information using trade secret law and NDAs, and, where applicable, patent law and invention assignment agreements. And in response to these commenters, the Commission notes that companies in California, North Dakota, and Oklahoma have been able to protect their trade secrets and other confidential information adequately using tools other than non-competes since the late nineteenth century. Industries that are highly dependent on trade secrets and other confidential information have flourished in those States even though non-competes have been unenforceable.

A few commenters disputed the NPRM's contention that the rate at which employers pursue trade secrets litigation is evidence of the viability of trade secret law as a means for redressing trade secret theft or protecting confidential information, in part because those employers were not necessarily relying exclusively on trade secret law. The Commission does not assert that these data, alone, conclusively establish trade secret law is a perfect vehicle for redressing trade secret theft. Rather, the data show trade secret litigation is more than a mere theoretical possibility—it is an avenue many companies choose to redress trade secret theft and indeed it is the body of law designed and developed for this very purpose. Accordingly, the Commission believes that the fact that many companies bring claims under the well-established body of State and Federal law on trade secrets is relevant evidence that trade secret law provides a viable means for redressing trade secret theft.

Some commenters suggested a higher volume of trade secrets litigation in California may reflect a higher rate of trade secret disclosure due to the State's policy against enforcing non-competes. However, these commenters did not

[802] *See supra* note 305 and accompanying text.

[803] *See* Parts IV.B and IV.C.

[804] *See* Part IV.B.3.b.ii.

[805] *See e.g., In re Adegoke,* 632 B.R. 154, 167 (Bankr. N.D. Ill. 2021); *Houser* v. *Feldman,* 569 F. Supp. 3d 216, 230 n.7 (E.D. Pa. 2021); *AvidAir Helicopter Supply, Inc.* v. *Rolls-Royce Corp.,* 663 F.3d 966, 974 (8th Cir. 2011).

[806] *See* Parts IV.B. and IV.C (describing the negative externalities from non-competes).

provide evidence to support this hypothesis. The Commission also notes industries in California that depend on protecting trade secrets have thrived despite the inability to enforce non-competes; indeed, the State is the capital of the global technology industry. Therefore, regardless of whether there is a higher rate of trade secret litigation in California, the less restrictive alternatives identified in this Part IV.D have provided sufficient protection to enable these companies to grow, thrive, and innovate. Furthermore, the rate of trade secret litigation in California may result from factors unique to California's economy, such as California's high concentration of technology companies relative to other States. As such, the Commission does not believe there is credible evidence to suggest trade secrets are disclosed at a higher rate in California than in other jurisdictions.[807]

Many commenters agreed with the Commission's preliminary conclusion that the economic success in California, North Dakota, and Oklahoma of industries highly dependent on trade secrets and other confidential information illustrates that companies have viable alternatives to non-competes for protecting valuable investments. In contrast, a few commenters argued that the Commission mischaracterized California's non-compete ban because they claim that California permits non-competes to protect trade secrets, citing dicta from the 1965 California Supreme Court case *Muggill* v. *Reuben H. Donnelley Corp.*[808] However, the Commission is unaware of any cases in which a California court has actually upheld a non-compete agreement under California law based on the dicta in this opinion, and commenters do not point to any.[809] To the contrary, California courts have consistently refused to enforce non-competes even where employers alleged they were needed to protect trade secrets.[810]

Another commenter argued that California's experience does not necessarily demonstrate anything about the effect of banning non-competes because California employers impose non-competes at rates comparable to other States. In response, the Commission notes that while Starr, Prescott, and Bishara state that workers are covered by non-competes at ''roughly the same rate'' in States where non-competes are unenforceable and enforceable,[811] when the authors control for employee characteristics to compare ''observationally equivalent employees,'' they find that non-competes are less common (by 4–5 percentage points) in nonenforcing States compared to States that permit vigorous enforcement of non-competes.[812] Additionally, California, North Dakota, and Oklahoma are still distinct from other States because employers may not actually enforce non-competes, even if employers in those States continue to enter into them.

A commenter argued that the Commission misattributes California's success in the technology industry and North Dakota's and Oklahoma's success in the energy industry to their non-compete laws, rather than the presence of top universities and venture capital firms in the State (in the case of California) or of abundant natural resources in the State (in the case of North Dakota and Oklahoma). The Commission believes that this commenter mischaracterizes its analysis. The Commission does not attribute California's success in the technology industry and North Dakota's and Oklahoma's success in the energy industry to their non-compete laws. The Commission merely notes that these industries are highly dependent on protecting trade secrets and having highly trained workers, and that these industries have thrived in these States despite the inability of employers to enforce non-competes.

One commenter argued that there are no alternatives that adequately protect employers' legitimate interests because other restrictive employment agreements do not sweep as broadly as non-competes. In this Part IV.D, the Commission concludes that less restrictive alternatives such as trade secret law, IP law, and NDAs are adequate to protect trade secrets and other confidential information even where they do not sweep as broadly as non-competes. Indeed, the Commission believes that non-competes are overbroad with respect to protecting trade secrets and other confidential information, because they enable employers to restrict a wide swath of beneficial competitive activity without respect to any alleged misconduct. That employers prefer to wield non-competes as a blunt instrument on top of or in lieu of the specific legal tools designed to protect legitimate investments in intellectual property and other investments cannot justify an unfair method of competition.

ii. Comments and Responses to Comments on Human and Physical Capital Investment

Several commenters addressed the evidence concerning the effects of non-competes on human capital investment and other investment. Several commenters asserted that, even if non-competes increased human capital investment, they still left workers worse off because they suppressed workers' mobility and wages overall. Workers and worker advocates also argued that workers lose the value of their skills and human capital investment when non-competes force them to sit out of the workforce, and non-competes can decrease their incentive to engage in human capital investment since they cannot capitalize on their skills and knowledge. These commenters stated that many workers, particularly highly skilled workers, have had some form of education prior to working for their employer, diminishing any potential need for non-competes to protect the employers' human capital investment. For example, many physicians pointed out that they had to go through medical school, residency, internships, and/or fellowships—significant investments that they made, not their employers.

Some commenters questioned the link between increased human capital investment and non-compete enforcement, arguing that employer human capital investment will still be provided without non-competes. Other commenters also stated that prohibiting non-competes would make it easier for firms to hire trained workers, because it would be easier for them to switch jobs. More generally, one advocacy organization said that employers frequently make investments that do not work out and should not place the risk of that investment onto their workers. A commenter who discussed physician non-competes argued that investment-based justifications for non-competes overestimate the value added by employers while failing to recognize the value physicians bring to employers.

Some businesses and trade organizations argued that employers invest significant time and money into training workers who lack the specific skills needed for the job. These commenters stated that, without non-competes, employers risk the worker taking that investment to a competitor. Some commenters state that this risk is

[807] *See* NPRM at 3507.

[808] 62 Cal. 2d 239, 242 (Cal. 1965).

[809] *See generally* David R. Trossen, Edwards *and Covenants Not to Compete in California: Leave Well Enough Alone,* 24 Berkeley Tech. L.J. 539, 546 (2009).

[810] *See, e.g., D'sa* v. *Playhut, Inc.,* 102 Cal. Rptr. 2nd 495, 497–501 (Cal. Ct. App. 2nd 2000); *Dowell* v. *Biosense Webster, Inc.,* 102 Cal. Rptr. 3d 1, 11 (Cal. Ct. App. 2nd 2009); *Arthur J. Gallagher & Co.* v. *Lang,* 2014 WL 2195062 (N.D. Cal. May 23, 2014) at *4 n.3.

[811] Starr, Prescott & Bishara, *supra* note 68 at 81.

[812] *Id.* at 68.

greatest in underserved areas and when there are worker shortages. Several commenters said that employment restrictions such as non-competes incentivize businesses to pay for credentials, training, and advanced education that low-wage and other workers would be unable to afford on their own, facilitating upward mobility. For highly educated workers, such as physicians, some employers said they need non-competes to protect payments for continuing education as well as mentorships and on the job training. Businesses and their advocates asserted that in some industries, many new employees are unprofitable for a significant period, requiring up-front investment and training from employers who want to recoup that investment.

In response, the Commission notes that, as described in Part IV.D.2.b.iii, firms have less restrictive alternatives for protecting human capital investments, including fixed-duration contracts and competing on the merits for the worker's labor services through better pay, benefits, or working conditions. Through these means, employers can retain workers without restricting who they can work for, or their ability to start a business, after their employment ends. The Commission also notes that these commenters often inaccurately describe the increased labor mobility afforded by the final rule as a one-way street. While it will be easier under the final rule for workers to switch jobs and work for a competitor, it will also be easier for firms to hire talented workers, since those workers are not subject to non-competes. In general, firms will benefit from access to a wider pool of labor, because the rule eliminates the friction non-competes impose on the free functioning of competition in labor markets. Whether this will be a net benefit to a particular firm, or not, will depend on the firm's ability to compete for workers on the merits to attract and retain talent.

A group of healthcare policy researchers stated that the investment justifications offered by corporate owners of physician practices are misleading since the true value of the investment in the practice is the book of business and referrals. These researchers suggested that non-competes are used to circumvent laws that prohibit payment for physician referrals. The Commission notes that this comment aligns with a statement by researcher Kurt Lavetti at the Commission's 2020 forum on non-competes. Lavetti stated that patient referrals are a valuable asset, but buying or selling those referrals is illegal, so non-competes are a secondary method of protecting that asset.[813]

Commenters also stated that non-competes protect investments other than in human capital, capital expenditures, and R&D, including recruiting and hiring, providing client and customer service, facilities, marketing, and technology, among others. The Commission is unaware of any empirical evidence showing that non-competes increase these types of investments, and commenters did not provide any. In general, however, firms can protect investments in trade secrets and confidential information, and investments in workers, through the less restrictive alternatives described in Part IV.D.2.b.

Two trade organizations stated that prohibiting non-competes could cause businesses to lose staff, and that losing staff could cause them to reduce investments that may be based on staffing assumptions. These commenters did not provide empirical evidence to support these arguments. The Commission also notes that firms would not necessarily lose workers because of the final rule. As described previously, some firms may lose workers because it will be easier for workers to leave for better opportunities, while some firms may gain workers by attracting workers from other firms. Additionally, firms can retain workers by competing on the merits for their labor services—*i.e.,* by offering better jobs than their competitors.

Commenters asserted that Starr, Prescott, and Bishara[814] found that notice of non-competes alongside a job offer is positively correlated with training compared to later notice. In response, the Commission notes that the evidence is a correlation between early notice and training, not a causal finding, so the Commission gives it minimal weight. In addition, regardless of whether there is an increase in training where notice of non-competes is provided along with the job offer instead of later on, this data is not salient on the question of whether employers have less restrictive alternatives to protecting training investments.

A few commenters stated non-competes protect against the ''disclosure'' of general trade knowledge and skills, while the less restrictive alternatives cited in the NPRM do not. Relatedly, some commenters argued prohibiting non-competes and broadly enabling workers to take general trade knowledge and skills to competitors will mean that their new employers will free ride off investments the former employers made in their human capital, which will discourage future investment in human capital. The Commission does not believe preventing workers from using their general trade knowledge and skills, including their gains in trade knowledge and skills through experience with a particular employer, is a legally cognizable or legitimate justification for non-competes. Under State common law, preventing a worker from using their general knowledge and skills with another employer is not a legitimate interest that can justify a non-compete.[815] Indeed, there is a general principle in the law of restrictive employment agreements—and trade secret law as well—that these tools cannot be used to prevent workers from using their general trade knowledge and skills.[816] The Commission does not view the inability to prevent disclosure or use of general skills and knowledge as a shortcoming of trade secret law and NDAs; instead, it considers the use of general skills and knowledge as beneficial competitive activity. Moreover, the Commission notes that sectoral job training strategies can be a tool for employers and workers to access worker training that is transferrable across employers.[817]

One commenter asserted trade secret law and NDAs are inadequate to protect employers' goodwill, while another commenter asserted these tools are inadequate to protect investments in relationships with clients. Regarding whether trade secret law and NDAs are adequate to protect employers' client relationships, the Commission interprets this to refer to employers' concern that a client will follow a worker to a competitor. The Commission believes that employers have alternatives for protecting these investments, including fixed-duration contracts (in the case of goodwill), NDAs (in the case of client lists), and competing on the merits to retain workers and/or clients. Firms can seek to protect client relationships by offering superior service and value—through the free and fair functioning of competition. These more narrowly

[813] Kurt Lavetti, *Economic Welfare Aspects of Non-Compete Agreements,* Remarks at the FTC Workshop on Non-Competes in the Workplace, at 145–46 (Jan. 9, 2020), at *https://www.ftc.gov//files//_events/1556256/non-compete-workshop-transcript-full.pdf.*

[814] Starr, Prescott & Bishara, *supra* note 68 at 53.

[815] *See* NPRM at 3495 n.162.

[816] *See* Montville, *supra* note 788 at 1161.

[817] *See, e.g.,* Mayu Takeuchi & Joseph Parilla, *Federal Investments in Sector-Based Training Can Boost Workers' Upward Mobility,* Brookings Inst. (Dec. 7, 2023), *https://www.brookings.edu/articles/federal-investments-in-sector-based-training-can-boost-workers-upward-mobility/.*

tailored alternatives reasonably protect the applicable interest while burdening competition to a lesser degree because they do not restrict the worker's ability to seek or accept work or start a business after their employment ends. Therefore, while trade secret law and NDAs may not protect goodwill or client relationships, the Commission finds that employers have adequate alternative tools to protect these interests. Furthermore, the Commission notes the final rule does not restrict employers from using trade secret law and NDAs in tandem—along with other alternatives—to protect their investments, and comments maintaining that employers lack adequate alternatives to non-competes because the commenter views just one of these mechanisms as inadequate are unpersuasive.

A commenter argued the final rule may implicate the ability of Federal contractors to provide letters of commitment, which are often required by government agencies and require contractors to identify key personnel who will work on an awarded contract, sometimes for years in the future. In response, the Commission notes that contractors have alternatives to non-competes to retain key personnel, including by using fixed-term employment contracts or providing the key personnel a better job than competitors.

A commenter stated that fixed-duration employment contracts are not necessarily effective at protecting human capital investments because employers may not know at the time of hiring when they will be providing training to a worker. This commenter also stated that improving the pay, benefits, and working conditions of workers is not necessarily an effective means for protecting human capital investments. In response, the Commission notes employers may enter into fixed-duration employment contracts with their workers at any time, not just at the outset of the employment relationship. It further notes competing to retain a trained worker will not work in every instance, but it is an important option available to employers and the provision of training can itself be a competitive differentiator for an employer.

A commenter also asserted California has the highest cost of living and, if this is attributable to the absence of non-competes, the proposed rule could risk increasing the cost of living nationwide. The commenter did not provide evidence to support the existence of an inverse relationship between non-compete enforceability and cost of living, and the Commission is aware of no such evidence. The Commission thus does not believe that there is a basis to conclude the final rule would increase the cost of living nationwide.

iii. Comments Regarding Alternatives to Non-Competes for Senior Executives

Commenters offered the same justifications for non-competes with senior executives: that they increase employers' incentive to make productive investments. However, many commenters argued senior executives are more likely than other workers to have knowledge of trade secrets and other competitively sensitive information or to have customer relationships and thus non-competes for senior executives are necessary, and other tools such as trade secret law and NDAs are not viable alternatives.

In response, the Commission finds that these tools—trade secret law, NDAs, patents, and invention assignment agreements—provide viable means of protecting valuable investments against disclosure by senior executives, just as they do for all other workers. Commenters do not identify any reasons why senior executives are uniquely situated with respect to these less restrictive alternatives—*i.e.,* why trade secret law or NDAs may not adequately protect firm investments from disclosure by senior executives specifically—and the Commission is not aware of any such reasons.

Some commenters argued non-competes with executives and high-wage workers promote competition because they encourage innovation in businesses by providing investors with more confidence that executives will not share trade secrets with competitors, decreasing competition. An industry organization asserted that non-competes allow executives to share ideas and business decisions with other workers within the business and collaborate to make strategic decisions. A commenter stated that an executive leaving to start a competing product could also delay the timeline for both the former employer's product and the competing product. As noted previously, the Commission does not believe there is reliable empirical data on the relationship between non-competes and disclosure of confidential information, but employers have alternatives to protect such information. Further, the empirical evidence shows non-competes overall inhibit innovation on the output side; therefore, to the extent any of these effects are occurring, they are more than outweighed by the negative effects of non-competes on innovation.[818]

According to some commenters, an executive moving to a competitor could unfairly advantage the competitor and irreparably harm the former employer. In response, the Commission notes that there is nothing inherently unfair about an executive moving to a competitor, particularly if this results from competition on the merits (such as the competitor paying more or otherwise making a more attractive offer). If companies seek to retain their executives, they have other means for doing so—such as increasing the executives' compensation or entering fixed-duration contracts—that do not impose significant negative externalities on other workers and on consumers, as non-competes do.[819]

Some commenters also said senior executives may have more client, business partner, and customer relationships than other employees and may contribute substantially to a firm's goodwill. The Commission believes that employers have alternatives for protecting goodwill and client/customer relationships. For example, if a firm wants to keep a worker from departing and taking goodwill or clients or customers with them, it can enter a fixed-duration contract with the worker, otherwise seek to retain the worker through competition on the merits, or seek to retain the client/customer through competition on the merits.

An accountant with experience analyzing executive non-competes for business valuations said such valuations are calculated based on the potential harm if the executive violated the non-compete. In addition, some commenters argued non-competes for senior executives and other important workers increase the value of firms in mergers and acquisitions because they ensure such valuable workers stay after the sale. An investment industry organization said investors seek to ensure the right workers who know the business stay and run the newly acquired business. In addition, that organization said some institutional investors may require contracts retaining key workers.

In response, the Commission notes that valuation of senior executive non-competes in such contexts is part of the reason the Commission is allowing such existing senior executive non-competes to remain in force.[820] In future

[818] *See* Part IV.B.3.b.ii.

[819] *See* Part IV.C.2 (describing the negative externalities of non-competes for senior executives).

[820] *See* Part IV.C.3.

transactions, businesses and investors have other methods of incentivizing senior executives and other workers to remain, including fixed duration contracts and competing to retain workers on the merits, and thereby enhancing the value of firms and transactions—methods that do not impose such significant externalities on other workers and consumers.

Some industry organizations said non-competes increase employer investment in management and leadership training for executives. An investment industry organization said non-competes allow senior executives to access training and experience for their own benefit and the benefit of investors in the firm. In response, the Commission notes that employers have alternative mechanisms to protect their investments in worker training, including fixed-duration contracts and improved compensation.

Some commenters argued that non-competes may improve executive performance, as some executives have non-competes tied to deferred compensation and other future benefits, which encourages long-term value creation by incentivizing executives to focus on long-term rather than short-term gains. A law firm said that forfeiture-for-competition clauses are an important component of deferred compensation agreements, and deferred compensation incentivizes long-term value-building and penalizes, via reduction or forfeiture, harm to the business, which the commenter said includes working for a competitor. The commenter claimed that if forfeiture-for-competition clauses are banned, firms would shift some of the deferred compensation to more short-term awards, which would in turn increase risk-taking and decrease overall wealth accumulation. The commenter cited a review by the Federal Reserve after the 2008 financial crisis which found that deferred compensation can mitigate executive risk-taking activities.[821] It also cited other Federal agencies and court decisions recognizing the value of deferred compensation to mitigate risk. Separately, the firm argued that without forfeiture-for-competition clauses, an executive who moves to a competitor will compete less against their former employer so as not to devalue their equity award, thus degrading competition. Commenters also contended that State courts have recognized forfeiture-for-competition clauses to be reasonable and that some State statutes governing non-competes carve them out.

In response, the Commission recognizes that many existing deferred compensation contracts may have been negotiated to include non-competes or forfeiture-for-competition clauses that may not be easily separated, and the final rule allows existing senior executive non-competes to remain in force.[822] However, the Commission is not persuaded that non-competes are necessary for future deferred compensation agreements. The Federal Reserve study on the value of deferred compensation does not mention non-competes or forfeiture-for-competition clauses. While the study states that clawback provisions may discourage specific types of behavior, it notes that they do not affect most risk-related decisions.[823] The commenter did not explain why non-competes are necessary for deferred compensation to reduce risk-taking or how post-employment competition could impact performance while at the firm. The commenter also did not explain why firms would forgo the benefits of deferred compensation even without a forfeiture-for-competition clause. The commenter separately argued that an executive who moves to a competitor will be conflicted and compete less against their former employer so as not to devalue their equity award. The comment framed this as an anticompetitive problem akin to interlocking directorates under the Clayton Act, as it could increase collusion (though the commenter provided no support for this argument). The commenter did not, however, explain why an executive would move to a competitor if doing so would devalue their own equity. The Commission also does not believe that the solution to this type of anticompetitive behavior, even if it were to occur, is to further restrict competition by blocking the executive from moving to the competitor in the first place.

Some commenters argued that forfeiture-for-competition clauses, which are sometimes attached to deferred compensation arrangements, were also justified. Some commenters contended that workers subject to forfeiture-for-competition clauses who choose to work for a competitor are likely to be compensated by the competitor for whom they will be working. Separately, a law firm and an investment industry organization stated that it would be unfair for companies to continue making deferred compensation or other payments to former workers who now work for a competitor if forfeiture-for-competition clauses were banned. A law firm also stated that forfeiture-for-competition clauses allow senior executives to retire without losing their deferred compensation, which in turn clears a path for younger workers to move up, while protecting senior executives' retirement benefits. In response, the Commission notes that pre-existing agreements for senior executives are not banned under the final rule.[824] The Commission also sees no reason why deferred compensation, including for retiring workers, cannot be used without forfeiture-for-competition clauses.

Some commenters stated that the study by Kini, Williams, and Yin, discussed in the NPRM with respect to senior executive earnings,[825] finds that CEOs with non-competes are more frequently forced to resign their position. Commenters note that Kini, Williams, and Yin also find that CEO contracts more closely align the incentives of executives (with respect to stock prices and risk taking) with shareholders when the executives have non-competes or when those non-competes are more enforceable. In response, the Commission notes that, as indicated by commenters, this study examines the use of non-competes in conjunction with their enforceability. The Commission therefore finds that the results may not reflect a causal relationship. For example, the use of non-competes and the propensity of the board to force an executive to resign may be jointly determined by the strength of the relationship or the trust between management and the board, rather than the use of non-competes causing forced turnover. The Commission also notes that—as shown in the study—there are other methods by which boards may encourage executives to perform, such as by structuring financial incentives to encourage or discourage risk taking, according to the preferences of the board. Boards can also fire poorly performing executives even without non-competes.

One commenter said that a ban on non-competes may encourage U.S. companies to relocate their executive teams outside the U.S. in order to continue using non-competes. The

[821] *See* Bd. of Govs. of the Fed. Reserve Sys., *Incentive Compensation Practices: A Report on the Horizontal Review of Practices at Large Banking Organizations* (Oct. 2011), *https://www.federalreserve.gov/publications/other-reports//incentive-compensation-practices-report-201110.pdf*.

[822] *See* Part IV.C.3.

[823] Federal Reserve Report on Incentive Compensation Practices, *supra* note 821 at 16–17.

[824] *See* § 910.2(a)(2).

[825] *See* Kini, Williams, & Yin, *supra* note 83.

commenter did not provide specific evidence to support this assertion. The Commission believes that firms' decisions on where to locate their executive teams are likely influenced by a multitude of factors other than whether the firm may or may not use non-competes.

3. The Asserted Benefits From These Justifications Do Not Justify the Harms From Non-Competes

a. The Commission's Final Findings

Based on the totality of the evidence, including its review of the empirical literature, its review of the full comment record, and its expertise in identifying practices that harm competition, the Commission in this final rule finds that the claimed business justifications for non-competes do not justify the harms from non-competes—for either senior executives or for workers other than senior executives, whether considered together or separately—because the evidence indicates that increasing enforceability of non-competes has a net negative impact along a variety of measures. Whether the benefits from a practice outweigh the harms is not necessarily an element of section 5,[826] but, in any event, the benefits from the justifications cited in Part IV.D.1 clearly do not justify the harms from non-competes.

Not all the harms from non-competes are readily susceptible to monetization.[827] However, even the quantifiable harms from non-competes are substantial and clearly not justified by the purported benefits. Non-competes cause considerable harm to competition in labor markets and product and service markets. Non-competes obstruct competition in labor markets because they inhibit optimal matches from being made between employers and workers across the labor force through the process of competition on the merits for labor services. The available evidence indicates that increased enforceability of non-competes substantially suppresses workers' earnings, on average, across the labor force generally and for specific types of workers.[828]

In addition to the evidence showing that non-competes reduce earnings for workers across the labor force, there is also evidence that non-competes reduce earnings specifically for workers who are not subject to non-competes.[829] These workers are harmed by non-competes, because their wages are depressed, but they do not necessarily benefit from any purported incentives for increased human capital investment that non-competes may provide. Overall, these harms to labor markets are significant. The Commission estimates the final rule will increase workers' total earnings by an estimated $400 billion to $488 billion over ten years, at the ten-year present discounted value.[830]

The available evidence also indicates non-competes negatively affect competition in product and service markets. The weight of the evidence indicates non-competes have a negative impact on new business formation and innovation.[831] There is evidence that non-competes increase consumer prices and concentration in the health care sector.[832] There is also evidence non-competes foreclose the ability of competitors to access talent.[833] While available data do not allow for precise quantification of some of these effects, they are nonetheless substantial: the Commission estimates that the rule will reduce spending on physician services over ten years by $74–194 billion in present discounted value, will result in thousands to tens of thousands of additional patents per year, and will increase in the rate of new firm formation by 2.7%.[834]

In the Commission's view, the asserted benefits from non-competes do not justify their harms. Even if the businesses using non-competes benefit, pecuniary benefits to the party undertaking the unfair method of competition are not a sufficient justification under section 5.[835] As described in Part IV.D.1, the most commonly cited justifications for non-competes are that they increase employers' incentive to make productive investments in, for example, trade secrets, customer lists, and human and physical capital investment. There is some evidence that non-competes increase human and physical capital investment, as noted previously.[836] However, the empirical literature does not show the extent to which human capital investment and other investment benefits from non-competes accrue to any party besides the employer, and to the extent it addresses this issue it suggests otherwise. For example, in theory, if increased human capital investment from non-competes benefited workers, they would likely have higher earnings when non-competes are more readily available to firms (*i.e.,* when legal enforceability of non-competes increases). However, as explained in Parts IV.B.3.a.ii and IV.C.2.c.ii, the empirical evidence indicates that, on net, greater enforceability of non-competes reduces workers' earnings. Likewise, in theory, if increased human capital investment increased innovation that redounds to the benefit of the economy and society as a whole, one would expect to see legal enforceability of non-competes yield such benefits, but as elaborated in Part IV, the empirical evidence on innovation effects indicates the opposite.

Moreover, the Commission is also not aware of any evidence that these potential benefits of non-competes lead to reduced prices. Indeed, the only empirical study of the effects of non-competes on consumer prices—in the health care sector—finds increased prices as the enforceability of non-competes increases.[837] That study, which finds that non-compete enforceability increased physician pay, also finds that labor cost pass-through is not driving price decreases.[838]

Furthermore, there is no evidence that, in the three States in which non-competes are generally void, the inability to enforce non-competes has materially harmed employers, consumers, innovation (or economic conditions more generally), or workers. As a result, the Commission finds that the asserted benefits from non-competes do not justify the harms they cause.

The Commission finds that the harms from non-competes are clearly not justified by the purported benefits, regardless of whether one considers senior executives or workers other than senior executives together or separately. In this Part IV.D.3, the Commission explains why, for workers overall, the asserted benefits from non-competes do not justify the harms they cause. This is at least as true for senior executives as for other workers. As described in Part IV.C.2.c.i, non-competes with senior executives tend to negatively affect competitive conditions in product and service markets at least as much as non-competes with other workers—and likely to a greater extent—given the outsized role of senior executives in forming new businesses, serving on new

[826] *See* Part II.F (stating that the inquiry as to whether conduct tends to negatively affect competitive conditions focuses on the nature and tendency of the conduct and does not require a detailed economic analysis).

[827] *See, e.g.,* Parts IV.B.3.a.iii and IV.B.3.b.iv.

[828] *See* Part IV.B.3.a.ii; Part IV.C.2.c.ii.

[829] *See* Part IV.B.3.a.ii.

[830] *See* Part X.F.6.

[831] *See* Part IV.B.3.b.i-ii; Part IV.C.2.c.i.

[832] *See* Part IV.B.3.b.iii.

[833] *See* Part IV.C.2.c.i.

[834] *See* Part X.F.6.

[835] *See* Part II.F.

[836] *See* Part IV.D.1.

[837] *See* Part IV.B.3.b.iii.

[838] *See* Hausman & Lavetti, *supra* note 590 at 278.

businesses' executive teams, and setting the strategic direction of businesses with respect to innovation. At the same time, firms have the same less restrictive alternatives available for senior executives as they do for other workers, as described in Part IV.D.2.c.iii. For these reasons, whether one considers non-competes with senior executives or non-competes with other workers, the claimed business justifications for non-competes do not justify the harms from non-competes.

b. Responses to Comments

Commenters focused on the question of whether employers have adequate alternatives to non-competes and the analysis of costs and benefits of the proposed rule in the preliminary regulatory impact analysis, rather than the balancing analysis discussed in this Part IV.D.3 specifically. These comments are addressed in Part IV.D.2 and in Part X, respectively.

E. Section 910.2(b): Notice Requirement for Existing Non-Competes

The Commission proposed to require employers to rescind (*i.e.,* legally modify) existing non-competes and provide notice to inform workers that they are no longer bound by existing non-competes.[839] Based on comments, the Commission is not adopting a rescission requirement in the final rule. Rather than require employers to legally modify existing non-competes, the final rule prohibits employers from enforcing existing non-competes with workers other than senior executives after the compliance date.

The final rule adopts the notice requirement—for workers who are not senior executives—with minor revisions to facilitate compliance and to improve the likelihood of workers being meaningfully informed. The revisions include an option for employers to make the notice more accessible to workers who speak a language other than English. The final rule also simplifies compliance and ensures that workers have prompt notice that their non-competes are no longer in force by requiring employers to provide notice by the effective date, rather than 45 days thereafter.

1. The Proposed Rule

Proposed § 910.2(b)(1) would have required employers to rescind existing non-competes with all workers. Proposed § 910.2(b)(2) would have required employers that rescinded non-competes to provide notice to the affected workers that their non-compete is no longer in effect and may not be enforced.

As proposed, § 910.2(b)(2) had three subparagraphs that imposed various requirements related to the notice. Proposed § 910.2(b)(2)(i) stated that an employer that rescinds a non-compete pursuant to § 910.2(b)(1) must provide notice in an individualized communication to the worker that the worker's non-compete is no longer in effect and may not be enforced. The Commission stated in the NPRM that an employer could not satisfy the notice requirement by, for example, posting a notice at the employer's workplace.[840] Proposed § 910.2(b)(2)(i) also stated that the employer must provide the notice in writing on paper or in a digital format such as an email or text message within 45 days of rescinding the non-compete.

Proposed § 910.2(b)(2)(ii) stated that the employer must provide the notice to both current workers and former workers when the employer has the former worker's contact information readily available. To ease the burden of compliance, proposed § 910.2(b)(2)(iii) provided model language that would satisfy the notice requirement. Proposed § 910.2(b)(2)(iii) and § 910.2(b)(3) provided a safe harbor for employers using the model language, while also permitting an employer to use different language, provided that the language communicates to the worker that the worker's non-compete is no longer in effect and may not be enforced.[841]

In the NPRM, the Commission stated that the purpose of the proposed notice requirement was to ensure that workers are informed that their existing non-competes are no longer in effect. The Commission cited evidence indicating that many workers are not aware of the applicable law governing non-competes or their rights under those laws, and stated that it was therefore concerned that, absent a notice requirement, workers may not know that their non-competes are no longer enforceable as of the effective date.[842]

2. The Final Rule

a. The Final Rule Does Not Require Rescission (Legal Modification) of Existing Non-Competes

The Commission has eliminated the proposed rule's requirement that employers rescind (*i.e.,* legally modify) existing non-competes. The Commission believes the proposed rescission requirement would have imposed unnecessary burdens on employers, as other aspects of the final rule provide less burdensome means of ensuring that workers other than senior executives will not be bound or chilled from competitive activity by non-competes after the effective date. Under § 910.2(a)(1)(ii), it is an unfair method of competition for a person to enforce or attempt to enforce a non-compete (except where, under § 910.3 the person has a good-faith basis to believe that the final rule is inapplicable). Further, under § 910.2(b)(1), the person who entered into the non-compete must provide clear and conspicuous notice to the worker by the effective date that the worker's non-compete clause is no longer in effect and will not be, and cannot legally be, enforced against the worker. These provisions are sufficient to achieve the purposes of the proposed rescission requirement without requiring any affirmative conduct beyond the notice requirement.

The Commission has also eliminated the proposed rescission requirement in response to comments expressing confusion about the requirement and concern about its practical implications. Some comments interpreted the proposed rescission requirement to mean that the worker and employer must be returned to their original positions (*i.e.,* on the day they entered into the non-compete) and presumed to not have entered into it or that it mandated wholly new contracts to replace any existing agreements that contained non-competes. Some commenters objected to what they considered the high compliance costs of rescinding and revising every employment contract with a non-compete. Some businesses said their contracts with senior executives and potentially other workers would be unwound by a rescission requirement. Other commenters said that if the Commission promulgated the proposed rescission requirement, it would be disregarding the role non-competes played in the overall value of the exchange for an employment contract. An industry association said rescission would require assessment of each contract's severability under relevant State law, and the answers would vary widely.

The Commission does not intend for the final rule to have such effect and has omitted the rescission requirement proposed in the NPRM. The Commission also adopts § 910.3(b), which provides an exception for causes of action that accrued before the effective date, to be clear that the final rule does not render any existing non-competes unenforceable or invalid from the date of their origin. Instead, it is an unfair method of competition to enforce

[839] *See* NPRM, proposed § 910.2(b).

[840] *Id.* at 3513.

[841] *Id.* at 3514.

[842] *Id.* at 3513.

certain non-competes beginning on the effective date. Actions taken before the effective date—for example, enforcing an existing non-compete or making representations related to an existing non-compete—are not unfair methods of competition under the final rule. As noted elsewhere, the Commission also exempts from the rule future enforcement of existing non-competes with senior executives.

Commenters also argued that a rescission requirement would be impermissibly retroactive, present due process concerns, and/or constitute an impermissible taking under the Fifth Amendment. The Commission responds to these comments in Part V.B.

Numerous commenters opposed the proposed rescission requirement based on perceived challenges presented by proposed § 910.1(b)(2), which addressed *de facto* non-competes, and its purported ambiguity with respect to which contractual terms employers would be required to rescind. The Commission has removed the rescission requirement for the reasons described in this Part IV.E.2.a and has also revised the proposed rule's language concerning *de facto* non-competes to clarify the scope of the definition.

b. The Final Rule's Notice Requirement

While the final rule does not require rescission (*i.e.,* legal modification) of existing non-competes, the final rule does prohibit enforcement of existing non-competes after the effective date and requires the person who entered into the non-compete with the worker to provide clear and conspicuous notice to the worker, by the effective date, that the worker's non-compete will not be, and cannot legally be, enforced against the worker.[843] The notice must identify the person who entered into the non-compete with the worker and must be on paper delivered by hand to the worker, or by mail at the worker's last known personal street address, or by email at an email address belonging to the worker, including the worker's current work email address or last known personal email address, or by text message at a mobile telephone number belonging to the worker.[844]

Several commenters emphasized the importance of notice, especially for former workers who may be actively refraining from competitive activity (in compliance with a non-compete), and who may continue to do so if they are not informed that their non-compete is no longer in effect. One commenter highlighted the importance of notice, because a non-compete may be coercive regardless of its enforceability. Many commenters emphasized the need for clear and concise language in the notices, including in languages other than English. One commenter asked the Commission to use concrete, lay-friendly terms to help reduce workers' fears of being sued. A commenter that recommended notice in languages other than English suggested that such a requirement apply to medium and large businesses with a threshold percentage of workers (such as 10%) who primarily speak a language other than English.

Commenters also suggested changes in notice procedures to improve the chances of workers receiving and understanding the notice. One commenter stated that text messages should not qualify as a primary means of individual notice because they are too casual, may be automatically deleted, and the sender may not be identifiable. However, in this commenter's view, text messages could be a secondary form of notice. Some commenters suggested that in addition to individual notice, the final rule should require an employer to post a copy of the notice in the workplace and/or online.

A number of commenters asserted that the requirement for employers to provide notice to former workers when ''the employer has the worker's contact information readily available'' was confusing or burdensome. A commenter stated that employers do not update former employees' contact information, so such information is likely incomplete and might be inaccurate. One commenter asserted that a requirement to provide notice within 45 days of the effective date is too difficult for small businesses. Another commenter suggested that the final rule should require contacting only former workers who left the firm two years or less before the effective date, unless the non-compete has elapsed.[845] Some commenters expressed concern that former workers might not be notified under the ''readily available'' standard. A commenter stated that, to avoid confusion and evasion, employers should be required to send notice to former workers at the worker's last known home address, email address, or cell phone number. Commenters also contended that the meaning of ''individualized communication'' was not clear or that compliance with it would be too difficult or burdensome.

The Commission finalizes the proposed rule's notice requirement largely as proposed, with minor revisions to facilitate compliance, reduce burdens on employers, and improve accessibility for non-English speakers.[846] The final rule also requires covered businesses to provide notice by the effective date, rather than 45 days thereafter, to simplify the final rule and to secure its benefits for competition in labor markets and product and service markets as soon as practicable.

The Commission finalizes a notice requirement because the available evidence indicates that many workers are not aware of the applicable law governing non-competes or their rights under those laws, or are unable to enforce their rights—and are chilled from engaging in competitive activity as a result. The evidence shows that even when employers impose non-competes that are unenforceable under State law, many workers believe they are bound by them (or are otherwise unable to enforce their rights to be free of non-competes).[847] As a result, the Commission finds that even after the final rule is in effect, absent a clear notice requirement, many workers may be unaware that, because of the final rule, their employer cannot enforce a non-compete and that the Commission has the authority to take action against employers who violate the final rule. Accordingly, absent notice, these workers may continue to be chilled from switching jobs or starting their own business. This would tend to negatively affect competitive conditions in the

[843] § 910.2(b)(1).

[844] This language mirrors language in other Federal regulations. *See, e.g.,* 17 CFR 9.11 (notice of disciplinary action must be made personally by mail at the person's last known address or last known email address); 29 CFR 38.79 (written notice must be sent to a ''complainant's last known address, email address (or another known method of contacting the complainant in writing)''); 16 CFR 318.5 (providing for written notification at an individual's last known address, or email if the individual chooses that option).

[845] Under the final rule, notice is only required for existing non-competes, *i.e.,* those that have not elapsed.

[846] The Commission notes that this required notice is a routine disclosure of valuable, factual information to workers that does not implicate the First Amendment. *See Milavetz, Gallop & Milavetz, P.A.* v. *United States,* 559 U.S. 229, 249–53 (2010) (citing *Zauderer* v. *Off. of Disciplinary Counsel,* 471 U.S. 626, 651 (1985)). As described in this Part IV.E, the Commission adopts this notice requirement to ensure workers do not wrongly believe they remain bound by unenforceable non-competes after the rule goes into effect. The Commission's conclusion that such notice is necessary to achieve the full benefits of the final rule is based on its expertise and on empirical evidence supporting the Commission's finding of an *in terrorem* effect related to non-competes.

[847] *See* Prescott & Starr, *supra* note 413; *see also* Part IV.B.2.b.ii (describing the Commission's finding that non-competes are exploitative and coercive where they trap workers in jobs or force them to bear significant harms or costs, even where workers believe the non-compete is unenforceable).

same manner as if non-competes were in full force and effect.

A notice requirement helps address this concern by informing individual workers, to the extent possible, that after the effective date the employer will not enforce any non-compete against the worker. The Commission believes that prompt and clear notice to workers other than senior executives that non-competes are no longer enforceable is essential to furthering the purposes of the final rule—to allow workers to seek or accept another job or to leave to start and run a business, and to allow other employers to compete freely for workers. Indeed, the Commission has refined the model language to make it shorter and clearer than the proposed model language.

While the proposed rule would have required employers to provide the notice no later than 45 days after the compliance date, the final rule requires notice no later than the effective date (*i.e.,* no later than 120 days after the final rule is published in the **Federal Register**). The Commission believes that it is practicable and reasonable for employers to provide the notice by the effective date. The Commission has designed the notice requirement to make compliance as easy as possible for employers. The final rule provides safe harbor model language that satisfies the notice requirement;[848] gives employers several options for providing the notice—on paper, by mail, by email, or by text;[849] and exempts employers from the notice requirement where the employer has no record of a street address, email address, or mobile telephone number for the worker.[850]

In addition, while the model language in the proposed rule used the phrase ''the non-compete clause in your contract is no longer in effect,''[851] the model language in the final rule uses the phrase ''[EMPLOYER NAME] will not enforce any non-compete clause against you.''[852] Because this language does not identify the recipient as having a non-compete, the employer does not need to determine which of its workers have non-competes; instead, it can simply send a mass communication such as a mass email to current and former workers.

Furthermore, requiring notice by the effective date simplifies the final rule and allows its benefits to begin sooner. In response to commenters that contended that they need more time to provide workers notice, the Commission believes that providing notice should not be time-consuming, even for small businesses, particularly given that the final rule provides model language, allows use of the worker's last known contact information for notice, allows digital notice, and (unlike in the proposed rule) categorically exempts an employer who has no such information from the notice requirement. Moreover, as described in Part IV.B.2.b.ii, non-competes trap workers in jobs or force them to bear other significant harms or costs—even where workers believe the non-compete is unenforceable. Given the limited burdens associated with providing notice only to workers whose last known contact information is on file and employers' option to simply copy and paste the safe harbor model notice, as well as the known and currently ongoing acute harms of non-competes (including their *in terrorem* effects) and the importance of workers knowing as soon as possible that their non-compete is unenforceable, the Commission declines to extend the time to provide notice.[853] The Commission finds that 120 days is more than adequate for employers to complete this task.

In response to comments expressing concern that the NPRM's ''individualized communication'' requirement was unclear or burdensome, the Commission has removed that language. Instead, the final rule ensures each worker will receive notice while specifying several permissible methods for providing the notice, which furthers compliance certainty while giving employers a range of options and an efficient means of complying. By allowing a number of formats for such communications, including digital formats, employers are more likely to be able to contact workers rapidly, individually, and have flexibility to do so at low cost. Accordingly, § 910.2(b)(2) of the final rule allows for notice by text message, by email, as well as paper notice by hand or by mail to the worker's last known street address. The final rule gives employers flexibility to choose among these methods. In responses to the concerns expressed by the commenter about text messages, the Commission believes that text messages should be a permissible method for providing the notice because they are widely used, delivered quickly, low-cost for employers, and an effective means of communication for workers who do not have email accounts.

In response to comments contending that notice to former workers is too burdensome or difficult, the Commission believes that providing notice to former workers is critical because former workers may be refraining from competitive activity because they believe they are subject to a non-compete. The Commission disagrees that providing notice to former workers will be burdensome. The Commission believes that most employers have contact information for former workers who may be subject to non-competes.[854] And under the final rule, in those rare cases in which an employer has no record of a street address, email address, mobile telephone number, or other method of contacting the worker or former worker, § 910.2(b)(3) exempts the employer from the final rule's notice requirement with respect to the worker. Furthermore, by specifying the circumstances under which notice may not be provided, this exemption also addresses concerns expressed by some commenters that ambiguity in the proposed rule's ''readily available'' standard for notifying former workers would lead to fewer former workers being notified.

In response to comments contending that notice to former workers is too burdensome or difficult, the Commission believes that providing notice to former workers is critical because former workers may be refraining from competitive activity because they believe they are subject to a non-compete. In light of the comments about the proposed ''readily available'' contact information standard, the Commission in this final rule does not adopt that language and instead requires that the notice must be on paper delivered by hand to the worker, or by mail at the worker's last known personal street address, or by email at an email address belonging to the worker, including the worker's current work email address or last known personal email address, or by text message at a mobile telephone number belonging to the worker. The Commission agrees with commenters that stated that most employers have such contact information for both present and former workers. For those rare cases in which

[848] § 910.2(b)(4)–(5).

[849] § 910.2(b)(2)(ii).

[850] § 910.2(b)(3).

[851] NPRM, proposed § 910.2(b)(2)(iii).

[852] § 910.2(b)(4).

[853] The Commission addresses the effective date in Part VIII.

[854] Employers have many record-keeping requirements under State and Federal laws under which they may retain the contact information described in § 910.2(b)(2)(ii). *See, e.g.,* IRS, Circular E, Employer's Tax Guide, Pub. 15, 8 (2024) (''Keep all records of employment taxes for at least 4 years,'' including addresses of employees and recipients and forms with addresses.); USCIS, Handbook for Employers M–274, Sec. 10.0, Retaining Form I–9 (requiring retention of I–9 form, which includes employees' addresses, email addresses, and telephone numbers).

an employer has no record of a street address, email address, mobile telephone number, or other method of contacting the worker or former worker, § 910.2(b)(3) exempts the employer from the final rule's notice requirement.

The Commission agrees with comments that notices in other languages spoken by workers would help achieve the goal of informing workers that their non-competes are no longer enforceable and help employers to comply with the final rule. However, to avoid imposing a burden of translation on employers, § 910.2(b)(6) makes it optional to provide notices in languages other than English. The Commission encourages employers to provide this notice to workers who speak languages other than English. To facilitate the provision of notices in other languages, the final rule provides a model notice in English and links to translations of other languages that are commonly spoken in U.S. homes, including Spanish, Chinese, Arabic, Vietnamese, Tagalog, and Korean.[855]

V. Section 910.3: Exceptions

A. Section 910.3(a): Exception for Persons Selling a Business Entity

In the NPRM, the Commission proposed an exception for certain non-competes between the seller and the buyer of a business that applied only to a substantial owner, member, or partner, defined as an owner, member, or partner with at least 25% ownership interest in the business entity being sold. Based on comments, the Commission adopts an exception for the bona fide sale of a business without requiring that the seller have at least a 25% ownership interest.

1. The Proposed Rule

Proposed § 910.3 allowed non-competes where the restricted party is ''a person who is selling a business entity or otherwise disposing of all of the person's ownership interest in the business entity, or . . . selling all or substantially all of a business entity's operating assets,'' and is also ''a substantial owner of, or substantial member or substantial partner in, the business entity at the time the person enters into the non-compete.'' [856] The Commission proposed to define ''substantial owner, substantial member, and substantial partner'' as ''an owner, member, or partner holding at least a 25 percent ownership interest in a business entity.'' [857] The text of proposed § 910.3 stated that non-competes allowed under the proposed exception would remain subject to Federal antitrust law and all other applicable law.

The Commission stated in the NPRM that its proposal to exempt from the rule non-competes between the seller and the buyer of a business did not reflect a finding that such non-competes are beneficial to competition.[858] Rather, the Commission explained that such non-competes may implicate unique interests and have unique effects, and the evidentiary record did not permit the Commission to thoroughly assess the full implications of restricting their enforceability.[859] The Commission noted that because all States permit non-competes between the seller and the buyer of a business to some degree, and because the laws that apply to these types of non-competes have seen fewer changes recently than the laws applicable to non-competes that arise solely out of employment, there have not been natural experiments allowing researchers to assess this type of non-compete's effect on competition.[860]

2. Comments Received

A few commenters suggested eliminating the proposed exception. These commenters contended that non-competes between the seller and the buyer of a business may still be exploitative and coercive, particularly in the case of small business owners in transactions with larger, better-resourced corporations. However, most commenters who addressed the issue supported an exception that would allow certain non-competes between the seller and the buyer of a business. These commenters agreed with the NPRM that State common law generally applies less-intensive scrutiny to non-competes ancillary to the sale of a business and that every State statute banning non-competes has an exception which allows some or all non-competes between the seller and the buyer of a business. Most of the commenters who supported some form of exception for non-competes between the seller and the buyer of a business contended that they are necessary to protect the value of the sale by ensuring the effective transfer of the business's goodwill. According to these commenters, a buyer will be less willing to pay for a business if they cannot obtain assurance that they will be protected from future competition by the seller, and so a failure to exempt related non-competes may chill acquisitions. Commenters stated that sellers of a business have more bargaining power than workers do and generally receive a portion of the sales price, making exploitation and coercion less likely. They also noted that non-competes between the seller and the buyer of a business remain subject to State limitations on scope, duration, and reasonableness.

Some commenters supported the proposed 25% ownership threshold. However, most commenters who otherwise supported the exception stated that the proposed 25% ownership threshold is too high. They argued that the 25% threshold does not account for the reality of most transactions, in which owners with less than 25% interest in a business may have significant goodwill and receive significant proceeds from a sale. Some commenters focused on the tax costs of the threshold, pointing to IRS provisions that currently allow taxpayers to deduct from their taxable income the portion of the sales price made in exchange for non-competes. Others argued that the 25% threshold would disincentivize equity-based consideration. To avoid these harms, these commenters suggested a variety of other thresholds, including the 5% ownership threshold used in SEC regulations.[861] Some commenters contended that the Commission failed to provide evidence justifying the proposed 25% ownership threshold. Others questioned the effectiveness of ownership as a proxy for goodwill or the likelihood of exploitation and coercion. As examples, these commenters pointed to passive investors who may have significant ownership stakes in a business but none of its goodwill, and owners whose interests may be purchased for less than fair market value or who are excluded from sales negotiations.

A few commenters argued that the proposed 25% threshold would preempt the laws of California and other States which ban non-competes except in the sale of a business, none of which require that the seller have a substantial ownership stake. They pointed to cases in which California courts applied the exception and allowed enforcement of non-competes against shareholders holding as little as a 3% ownership interest. In light of these statutes, some of these commenters urged the Commission to adopt an exception for

[855] *See* Sandy Dietrich & Erik Hernandez, Census Bureau, *Nearly 68 Million People Spoke a Language Other Than English at Home in 2019* (Dec. 6, 2022) at Table 1, *https://www.census.gov/library/stories/2022/12/languages-we-speak-in-united-states.html.*

[856] NPRM, proposed § 910.3.

[857] *Id.,* proposed § 910.1(e).

[858] *Id.* at 3515.

[859] *Id.* at 3514–15.

[860] *Id.*

[861] *See, e.g.,* 17 CFR 240.13d–1 (requiring reporting by beneficial owners holding more than 5% interest in an equity security).

agreements that involve the sale of a business or equity in a company without a threshold ownership requirement.

Some commenters urged the Commission to adopt a case-by-case assessment of business sales based on State law, such as a ''totality of the circumstances'' or ''reasonableness'' test. Others proposed replacing the ownership-based exception with an exception for founders, key workers with IP access, and/or those with goodwill. At least one commenter asked the Commission to use a bright-line rule rather than a functional or definitional test that would require adjudication and interpretation by courts.

Some commenters presented empirical evidence to justify a lower ownership threshold. A few commenters pointed to data suggesting that more than 96% of CEOs of the 3,000 largest publicly traded companies own less than 25% of their company. One commenter pointed to data suggesting that the average duration of a startup's life from fundraising to acquisition is 6.1 years, arguing that it is unlikely for venture-capital backed businesses to operate and grow for that period of time without accepting funding that dilutes founders' and key employees' equity stake in the business. Other commenters supporting a lower threshold provided anecdotal evidence that businesses cede large shares to financial backers, resulting in many owner-operators holding significantly less than a 25% share in their business.

Finally, some commenters focused on eliminating potential loopholes to the proposed exception. Some commenters expressed concern that employers may set up sham transactions with wholly owned subsidiaries in order to impose non-competes that would otherwise be prohibited under the rule, urging the Commission to clarify that the exception applies only to bona fide transfers to an independent third party. Some commenters contended that firms may use ''springing'' non-competes (in which a worker must agree at the time of hiring to a non-compete in the event of some future sale) and repurchase rights, mandatory stock redemption programs, or similar stock-transfer schemes (pursuant to which a worker may be required to sell their shares if a certain event occurs) to impose non-competes on their workers which would otherwise be prohibited. They urged the Commission to address those instances specifically, including by defining the exception by the percentage of total equity value received in liquid proceeds at the time of the relevant transaction.

3. The Final Rule

The Commission adopts a sale of business exception for substantially the same reasons articulated in the NPRM. However, in response to comments concerning the ownership percentage threshold, the Commission modifies § 910.3(a) so that it no longer includes the proposed requirement that the restricted party be ''a substantial owner of, or substantial member or substantial partner in, the business entity'' to fall under the exception. The Commission otherwise adopts this provision largely as proposed. To address commenters' concerns that employers will use sham transactions, stock-transfer schemes or other mechanisms designed to evade the rule, § 910.3(a) requires that, to fall under the exemption, a non-compete must be entered into pursuant to a bona fide sale.

The Commission reiterates that § 910.3(a) does not reflect a finding that non-competes between the seller and the buyer of a business are beneficial to competition or that they are not restrictive and exclusionary or exploitative and coercive. Indeed, the Commission acknowledges that some non-competes between the seller and buyer of a business may be exploitative and coercive due to an imbalance in bargaining power and/or may tend to harm competitive conditions. However, commenters did not present empirical research on the prevalence of non-competes between the seller and the buyer of a business or on the aggregate economic effects of applying additional legal restrictions to non-competes between the seller and buyer of a business. The Commission's decision to adopt § 910.3(a) reflects the view of the Commission and most commenters that, compared to non-competes arising solely out of an employment relationship, non-competes between the sellers and buyers of businesses may implicate unique interests and have unique effects that this rulemaking record does not address.[862]

The proposed requirement that an excepted non-compete bind only a ''substantial'' owner, member or partner of the business entity being sold was designed to allow those non-competes between the seller and the buyer of a business which are critical to effectively transfer goodwill while prohibiting those which are more likely to be exploitative and coercive due to an imbalance of bargaining power between the seller and the buyer. However, commenters persuasively argued that the proposed 25% ownership threshold was too high because it failed to reflect the relatively low ownership interest held by many owners, members, and partners with significant goodwill in their business. The Commission declines to maintain the ''substantial'' interest requirement with a lower percentage threshold for the same reason.

The Commission also declines to adopt a threshold of $1 million, $250,000, or some other dollar limit on the proceeds received by the seller. On the current record, these thresholds were not sufficiently correlated to sellers' goodwill or bargaining power for a broadly generalizable approach. The Commission declines to adopt a ''totality of the circumstances'' or ''reasonableness'' test in the text of § 910.3(a) because they would provide little meaningful guidance to buyers and sellers and would be difficult to administer. For the same reasons, the Commission declines to replace the ownership-based exception with an exception for founders, key workers, workers with access to intellectual property, and/or workers with goodwill. Furthermore, non-competes allowed under the exception will continue to be governed by State law, which generally requires a showing that a non-compete is necessary to protect the value of the business being sold, as well as Federal antitrust law.[863]

Finally, the Commission agrees with commenters' concerns about the risks that firms may abuse the exception through sham transactions with wholly owned subsidiaries, ''springing'' non-competes, repurchase rights, mandatory stock redemption programs, or similar evasion schemes. The Commission adds the term ''bona fide'' and makes changes clarifying that any excepted non-compete must be made ''pursuant to a bona fide sale'' to ensure that such schemes are prohibited under the rule. A bona fide sale is one made in good faith as opposed to, for example, a transaction whose sole purpose is to evade the final rule.[864] In general, the Commission considers a bona fide sale to be one that is made between two

[862] *See* NPRM at 3514–15.

[863] *See, e.g., U.S.* v. *Addyston Pipe & Steel Co.,* 85 F. 271, 281 (6th Cir. 1898) (''For the reasons given, then, covenants in partial restraint of trade are generally upheld as valid when they are agreements [*inter alia*] by the seller of property or business not to compete with the buyer in such a way as to derogate from the value of the property or business sold . . . . Before such agreements are upheld, however, the court must find that the restraints attempted thereby are reasonably necessary . . . to the enjoyment by the buyer of the property, good will, or interest in the partnership bought. . . .'').

[864] Black's Law Dictionary defines bona fide as ''[m]ade in good faith; without fraud or deceit,'' and ''[s]incere; genuine.'' (11th ed. 2019).

independent parties at arm's length, and in which the seller has a reasonable opportunity to negotiate the terms of the sale. So-called ''springing'' non-competes and non-competes arising out of repurchase rights or mandatory stock redemption programs are not entered into pursuant to a bona fide sale because, in each case, the worker has no good will that they are exchanging for the non-compete or knowledge of or ability to negotiate the terms or conditions of the sale at the time of contracting. Similarly, sham transactions between wholly owned subsidiaries are not bona fide sales because they are not made between two independent parties.

The Commission declines to specifically delineate each kind of sales transaction which is not a bona fide sale under the exception to avoid the appearance that any arrangement not listed is allowed under the exception. Courts have effectively identified and prohibited such schemes pursuant to State statutes prohibiting non-competes.[865] In addition, non-competes allowed under the sale-of-business exception remain subject to Federal and State antitrust laws, including section 5 of the FTC Act.

B. Section 910.3(b): Exception for Existing Causes of Action

Proposed § 910.2(a) would have prohibited employers from maintaining an existing non-compete with a worker. The proposed rule also would have required employers to rescind existing non-competes.[866] Commenters argued that any invalidation or rescission required of existing non-competes would be impermissibly retroactive, present due process concerns, and/or constitute an impermissible taking under the Fifth Amendment.

As described in Part IV.C.5, the Commission adopts a modified § 910.2(a) under which existing non-competes for workers who are not senior executives are no longer enforceable. The Commission adds an exception in § 910.3(b) in response to comments raising concerns related to retroactivity. Section 910.3(b) specifies that the final rule does not apply if a cause of action related to a non-compete provision accrued prior to the effective date. This includes, for example, where an employer alleges that a worker accepted employment in breach of a non-compete if the alleged breach occurred prior to the effective date. This provision responds to concerns that the final rule would apply retroactively by extinguishing or impairing vested rights acquired under existing law prior to the effective date.[867] In this Part V.B, the Commission addresses commenters' arguments regarding retroactivity, due process, and impermissible taking under the Fifth Amendment.

1. Retroactivity

A number of commenters asserted that applying the final rule to prohibit the enforcement of existing non-competes would render the final rule impermissibly retroactive. The Commission disagrees. A rule ''does not operate 'retrospectively' merely because it is applied in a case arising from conduct antedating the [rule's] enactment, or upsets expectations based in prior law.'' [868] Rather, courts have explained that an ''administrative . . . rule is retroactive [only] if it takes away or impairs vested rights acquired under existing law, or creates a new obligation, imposes a new duty, or attaches a new disability in respect to transactions or considerations already passed.'' [869] ''A rule that 'alter[s]' the past legal consequences of 'past action' is retroactive,'' while a rule that '''alter[s] only the 'future effect' of past actions, in contrast, is not.'' [870] Agency action ''that only upsets expectations based on prior law is not retroactive.'' [871]

The final rule is not impermissibly retroactive because it does not impose any legal consequences on conduct predating the effective date. The Commission is not creating any new obligations, imposing any new duties, or attaching any new disabilities for past conduct.[872] And to minimize concerns about retroactivity, the Commission adopts § 910.3(b), which states that the final rule does not apply where a cause of action related to a non-compete accrues before the effective date. The notice requirement in § 910.2(b) likewise does not render the final rule impermissibly retroactive because that requirement merely requires notice that non-competes that exist after the effective date will not be enforced in the future with respect to workers other than senior executives. No penalties attach to persons who entered non-competes before the effective date.

This final rule is analogous to the FCC rulemaking upheld in *National Cable & Telecommunications Ass'n* v. *FCC.* There, the agency promulgated a rule that ''forbade cable operators not only from entering into new exclusivity contracts, but also from enforcing old ones.'' [873] The court upheld the rule against a retroactivity challenge because the FCC had ''impaired the future value of past bargains but ha[d] not rendered past actions illegal or otherwise sanctionable.'' [874] This final rule does the same with existing non-competes. The final rule does not render it illegal or otherwise sanctionable for parties to have entered into non-competes before the effective date; it merely provides that persons cannot enforce or attempt to enforce such agreements with workers other than senior executives or represent to such workers that they are bound by an enforceable non-compete after the effective date. It is thus not impermissibly retroactive.

In *National Cable,* the court also considered whether the agency had ''balance[d] the harmful 'secondary retroactivity' of upsetting prior expectations or existing investments against the benefits of applying [its] rules to those preexisting interests.'' [875] While commenters did not frame their objection as one of ''secondary retroactivity,'' some did object that the final rule would upset the benefits of pre-existing bargains. As in *National Cable,* however, the Commission has ''expressly consider[ed] the relative benefits and burdens of applying its rule

---

[865] *See, e.g., Bosley Med. Grp.* v. *Abramson,* 161 Cal. App. 3d 284, 291 (Cal. Ct. App. 1984) (refusing to enforce non-compete imposed on physician under agreement requiring physician to purchase 9% of stock at hiring and resell to corporation upon termination because agreement ''was devised to permit plaintiffs to accomplish that which the law otherwise prohibited: an agreement to prevent defendant from leaving plaintiff medical group and opening a competitive practice'').

[866] *See* proposed § 910.2(b)(1).

[867] As discussed in Part V.B.1, courts have explained that an ''administrative . . . rule is retroactive [only] if it takes away or impairs vested rights acquired under existing law, or creates a new obligation, imposes a new duty, or attaches a new disability in respect to transactions or considerations already passed.'' *Regents of the Univ. of Cal.* v. *Burwell,* 155 F. Supp. 3d 31, 44 (D.D.C. 2016) (alteration in original) (quoting *Nat'l Min. Ass'n* v. *DOL,* 292 F.3d 849, 859 (D.C. Cir. 2002)). But a regulation is *not* retroactive simply because it ''impair[s] the future value of past bargains'' if it does not also ''render[ ] past actions illegal or otherwise sanctionable.'' *Nat'l Cable & Telecomms. Ass'n* v. *FCC,* 567 F.3d 659, 670 (D.C. Cir. 2009).

[868] *Landgraf* v. *USI Film Prods.,* 511 U.S. 244, 269 (1994).

[869] *Burwell,* 155 F. Supp. 3d at 44 (alteration in original) (quoting *Nat'l Min. Ass'n,* 292 F.3d at 859).

[870] *Id.* (alterations in original) (quoting *Ne. Hosp. Corp.* v. *Sebelius,* 657 F.3d 1, 14 (D.C. Cir. 2011)).

[871] *Nat'l Cable,* 567 F.3d at 670 (internal quotation omitted) (quoting *Mobile Relay Assocs.* v. *FCC,* 457 F.3d 1, 11 (D.C. Cir. 2006)).

[872] For instance, the D.C. Circuit found that agency action impermissibly attached a ''new disability'' when a Department of Interior rule made mine operators ineligible for a surface mining permit based on ''pre-rule violations.'' *Nat'l Min. Ass'n* v. *U.S. DOI,* 177 F.3d 1, 8 (D.C. Cir. 1999). Here, the final rule imposes no penalties or other disabilities on persons who entered into non-competes before the effective date.

[873] *Nat'l Cable,* 567 F.3d at 661.

[874] *Id.* at 670.

[875] *Id.* at 670.

to existing contracts.'' [876] This consideration led the Commission to adopt the various exceptions described in the final rule, including the decision not to apply the final rule to non-competes entered into with senior executives before the effective date. As explained in Part IV.B, however, the Commission has determined that, for workers other than senior executives, there are substantial benefits to applying the rule to prohibit the future enforcement of non-competes entered into before the effective date. These benefits include the anticipated increase in worker earnings, new business formation, and innovation.[877] Additionally, the Commission finds such agreements are generally coercive and exploitative, so prohibiting their future enforcement is also a benefit.[878]

In the Commission's view, these significant benefits justify any burdens of applying the final rule to the future enforcement of pre-existing agreements with workers other than senior executives. Having balanced the burdens and benefits of so applying the final rule, the Commission has satisfied its obligation to consider the secondary retroactivity effects of the final rule. Moreover, the Commission notes that non-competes were already subject to case-by-case adjudication under section 5.[879] Employers were thus already responsible, even before the final rule, for ensuring their non-competes are not unfair methods of competition.

2. Takings

The Commission also disagrees with commenters who contended that applying the final rule to non-competes entered into before the effective date would violate the Fifth Amendment by effecting a taking without due compensation. Some comments interpreted the proposed rescission requirement to mean that the worker and employer must be returned to their original positions (*i.e.,* on the day they entered into the non-compete) and presumed to not have entered the agreement, or that the rule would mandate wholly new contracts to replace any existing agreements that contained non-competes. The Commission does not intend the final rule to have such effect and has omitted the rescission requirement proposed in the NPRM. The Commission also adopts § 910.3(b), which provides an exception for causes of action that accrued before the effective date, to clarify that the final rule is purely prospective. The final rule does not render any existing non-competes unenforceable or invalid from the date of their origin. Instead, under the final rule, it is an unfair method of competition to enforce certain non-competes beginning on the effective date. Action taken before the effective date to enforce an existing non-compete or representations made before the effective date related to an existing non-compete are not an unfair method of competition under the final rule. The final rule does not effectuate a taking.

The Takings Clause provides that ''private property'' shall not ''be taken for public use, without just compensation.'' [880] When, as here, ''the government, rather than appropriating private property for itself or a third party, imposes regulations that restrict an owner's ability to use his own property,'' courts consider whether the regulation ''goes too far'' and constitutes a ''regulatory taking.'' [881] Consistent with the Supreme Court's decision in *Penn Central Transportation Co.* v. *City of New York* (''*Penn Central*''), this is necessarily an ''ad hoc, factual inquir[y]'' and focuses on three factors: ''the economic impact of the regulation on the claimant''; ''the extent to which the regulation has interfered with distinct investment-backed expectations''; and ''the character of the governmental action.'' [882] ''[T]he *Penn Central* inquiry turns in large part, albeit not exclusively, upon the magnitude of a regulation's economic impact and the degree to which it interferes with legitimate property interests.'' [883] As a general matter, ''the fact that legislation disregards or destroys existing contractual rights does not always transform the regulation into an illegal taking.'' [884]

Under the *Penn Central* test, the final rule does not effect a taking as a matter of law. First, the economic impact of the regulation on employers with existing non-competes with workers who are not senior executives is insufficient to constitute a taking.[885] The Commission has found that such agreements are rarely the product of bargaining, and that little to nothing is offered in exchange for them. And research has confirmed that for many such agreements, employers do not value the ability to enforce the agreements.[886] The final rule also includes provisions that allow employers and workers to ''moderate and mitigate the economic impact'' of the final rule.[887] The Commission has made clear that employers may continue to use reasonable NDAs and trade secrets law to protect their interests, including customer goodwill.[888] In fact, one study finds that 97.5% of workers with non-competes are also subject to a non-solicitation agreement, NDA, or a non-recruitment agreement, and 74.7% of workers with non-competes are subject to all three provisions.[889] And in cases where non-competes with workers other than senior executives were tied to benefits like cash or equity, the Commission has provided time for those agreements to be renegotiated if necessary.[890] For senior executives, the Commission allows existing agreements to continue to be enforced.

The character of the governmental action here also counsels against viewing the final rule as a taking. ''A 'taking' may more readily be found when the interference with property can be characterized as a physical invasion by government . . . than when interference arises from some public program adjusting the benefits and burdens of economic life to promote the common good.'' [891] There is no physical invasion here, and the final rule is promulgated under the Commission's authority to identify and prohibit unfair methods of competition.[892] Among other economic benefits described in Part IV.B, the Commission finds economy-wide benefits, including increases in new business formation and innovation. The Commission also finds that the final rule will increase earnings for workers by preventing enforcement of agreements that suppress their earnings. Moreover, non-competes have long been subject to government regulation, including not only section 5 of the FTC Act, but also State common

[876] *Id.* at 671.

[877] *See* Part IV.B.

[878] *See* Part IV.B.2.b.

[879] Part I.B.1.

[880] U.S. Const. amend. V.

[881] *Cedar Point Nursery* v. *Hassid,* 594 U.S. 139, 148 (2021).

[882] *Penn Cent. Transp. Co.* v. *City of N.Y.,* 438 U.S. 104 (1978).

[883] *Lingle* v. *Chevron U.S.A. Inc.,* 544 U.S. 528, 540 (2005).

[884] *Connolly* v. *Pension Ben. Guar. Corp.,* 475 U.S. 211, 224 (1986); *see also Nat'l Min. Ass'n* v. *Babbitt,* 172 F.3d 906, 917 (D.C. Cir. 1999) (applying *Connolly* to a Takings challenge to an administrative rule).

[885] *Murr* v. *Wis.,* 582 U.S. 383, 405 (2017); *see also Connolly,* 475 U.S. at 225.

[886] *See* Hiraiwa, Lipsitz, & Starr (2023) (showing that firms do not value the ability to enforce non-competes for workers earning up to $100,000 per year and potentially more).

[887] *Connolly,* 475 U.S. at 225–26.

[888] *See* Part IV.D.2.

[889] Balasubramanian, Starr, & Yamaguchi, supra note 74 at 35.

[890] *See* § 910.6.

[891] *Penn Cent. Transp. Co.* v. *City of N.Y.,* 438 U.S. 104, 124 (1978) (internal citation omitted).

[892] *See* 15 U.S.C. 45(a); *see also* Parts IV.B and C (the Commission's findings outlining the public benefits of the final rule and the public harm from the use of non-competes).

law, State enactments, and other Federal antitrust laws.

Finally, the final rule does not upset investment-backed expectations to the extent necessary to constitute a taking. Even in States that prohibit some or all non-competes, employers make many investments in workers that they would continue to make regardless of their ability to use non-competes, such as training, or that would be protected by other mechanisms, such as reasonable NDAs, trade secret law, and/or fixed term contracts. In other words, non-competes are not a prerequisite to employers' productivity and output, in large part because (as described in Part IV.D) employers have reasonable alternatives to protecting the investments they make. The Commission has also lessened the economic burden of the final rule by creating an exception for situations where a cause of action accrued before the effective date.[893] Furthermore, States and the Federal government have regulated and considered further regulating non-competes for years, and the Commission issued the NPRM more than 18 months before the effective date—and began exploring whether to regulate non-compete agreements more than five years ago.[894] There has thus been ample notice that non-competes may become unenforceable by rule,[895] and prior to this rule non-competes were already subject to case-by-case adjudication under section 5. For all these reasons, the Commission does not believe the final rule constitutes a taking.

3. Due Process

Similarly, the Commission disagrees with commenters who argued that applying the final rule to existing non-competes would present due process concerns. Assuming that these due process concerns are independent of other constitutional concerns like the alleged retroactive application of the final rule,[896] which are addressed in Parts V.B.1 and V.B.2, the Commission disagrees that there is any due process infirmity. Due process requires the government, at a minimum, to provide notice and an opportunity to be heard before depriving any person of property.[897] By issuing the NPRM and engaging in notice-and-comment rulemaking, the Commission has provided sufficient due process. And on top of the notice-and-comment process, there will be further process in an administrative adjudication or in court before any person is found to have violated the rule.

C. Section 910.3(c): Good Faith Exception

The Commission adds an exception in § 910.3(c) in an abundance of caution to ensure the final rule does not infringe on activity that is protected by the First Amendment[898] and to improve clarity in § 910.2(a). The exception states: ''It is not an unfair method of competition to enforce or attempt to enforce a non-compete clause or to make representations about a non-compete clause where a person has a good-faith basis to believe that this part 910 is inapplicable.'' A similar ''good-faith basis'' clause was in proposed § 910.2(a).

As described in Parts IV.B.4 and IV.C.5, the final rule includes a prohibition on enforcing or attempting to enforce non-competes in both § 910.2(a)(1) and (2). Under the *Noerr-Pennington* doctrine, filing a lawsuit—even if the suit may tend to restrict competition and is ultimately unsuccessful—is typically protected under the First Amendment right to petition and immune from antitrust scrutiny.[899] However, courts have recognized that where a lawsuit is a ''sham,'' *i.e.,* objectively baseless and subjectively designed solely to prevent competition, it is not protected.[900] For a non-compete covered by the final rule, enforcing or attempting to enforce the non-compete would likely be considered a ''sham'' lawsuit. Accordingly, such a lawsuit would not enjoy protection under the First Amendment. Section 910.3(b) ensures, however, that if a circumstance arises under which an employer's enforcement of or attempt to enforce a non-compete is protected by the First Amendment, the final rule does not run afoul of it.

As explained in Parts IV.B.4 and IV.C.5, the Commission adopts a prohibition on ''representing'' that a worker is subject to a non-compete in §§ 910.2(a)(1)(iii) and 910.2(a)(2)(iii). In § 910.3(c), the Commission incorporates a ''good-faith'' exception that applies to the prohibition on ''representing'' the worker is subject to a non-compete. Taken together, these provisions of the final rule prohibit an employer from representing to a worker that the worker is subject to a non-compete unless the employer has a good-faith basis to believe the worker is subject to an enforceable non-compete.

The Supreme Court has held ''there can be no constitutional objection to the suppression of commercial messages that do not accurately inform the public about lawful activity.'' [901] Accordingly, ''[t]he government may ban forms of communication more likely to deceive the public than to inform it, . . . or commercial speech related to illegal activity.'' [902] The final rule does not cover protected speech because it prohibits only misrepresentations about whether a non-compete covered by the rule is enforceable. The good-faith exception in § 910.3(b) ensures, however, that the final rule does not run afoul of the First Amendment if a circumstance arises under which an employer's representation that a worker is subject to a non-compete is protected by that Amendment.

In the NPRM, the Commission stated that an employer would have no good faith basis to believe that a worker is subject to an enforceable non-compete ''where the validity of the rule . . . has been adjudicated and upheld.'' Some commenters stated that legal challenges to the final rule will create uncertainty and unpredictability related to compliance. The Commission believes the foregoing statement in the NPRM would contribute to this confusion and does not adopt it in this final rule. The Commission clarifies that the absence of a judicial ruling on the validity of the final rule does not create a good-faith basis for non-compliance. If the rule is in effect, employers must comply.

D. Requests To Expand Final Rule Coverage or To Provide an Exception From Coverage Under the Final Rule

In the NPRM, the Commission preliminarily concluded that applying the rule uniformly to all employers and workers would advance the proposed

[893] *See* § 910.3(b).

[894] *See* Part I.B.

[895] *Connolly* v. *Pension Ben. Guar. Corp.,* 475 U.S. 211, 226 (1986).

[896] Commenters invoking a due process concern outside the retroactivity context provided little contextual detail on the precise substance of the concern, nor did they explain what further process would be due before the Commission could promulgate the rule.

[897] *See, e.g., N. Am. Butterfly Ass'n* v. *Wolf,* 977 F.3d 1244, 1265 (D.C. Cir. 2020) (citing *Mathews* v. *Eldridge,* 424 U.S. 319, 333–34 (1976)).

[898] The Commission adopts § 910.3(b)(3) out of an abundance of caution and does not believe that any of the requirements in the final rule run afoul of the First Amendment because the Commission finds that the use of certain existing non-competes is an unlawful unfair method of competition.

[899] *See E.R.R. Presidents' Conference* v. *Noerr Motor Freight, Inc.,* 365 U.S. 127 (1961); *United Mine Workers of Am.* v. *Pennington,* 381 U.S. 657 (1965).

[900] *Pro. Real Est. Invs., Inc.* v. *Columbia Pictures Indus., Inc.,* 508 U.S. 49, 60 (1993).

[901] *Cent. Hudson Gas & Elec.* v. *Pub. Serv. Comm'n of N.Y.,* 447 U.S. 557, 563 (1980).

[902] *Id.* at 563–64.

rule's objectives to a greater degree than differentiating among workers on the basis of industry or occupation, earnings, another factor, or some combination of factors, and that it would better ensure workers are aware of their rights under the rule.[903] The Commission sought comment on this topic, including what specific parameters or thresholds, if any, should apply in a rule differentiating among workers.[904]

The vast majority of commenters supported the Commission's proposal to ban non-competes categorically for all workers.[905] Commenters from a broad spectrum of job types and industries stated that non-competes harm competition in a way that hurts workers and employers.

Commenters also supported the rule with perspectives specific to particular industries. In response to the Commission's request for comment on the issue, some commenters argued that the Commission should further expand the rule to cover non-competes between franchisors and franchisees.

Other commenters argued the Commission should differentiate among workers and employers along different parameters. They stated that workers with higher earnings, higher skills, specific job titles, or access to specific types of information should be excluded. Some stated that particular industries should be excluded wholesale, including all workers in an industry regardless of their job duties, while some stated that only certain workers in particular industries should be excluded.

In adopting the final rule, the Commission considered each request for exclusion from or expansion of coverage under the final rule and concludes that the use of covered non-competes is an unfair method of competition. The Commission also concludes that applying the final rule as adopted in part 910 to the full extent of the Commission's jurisdiction with respect to covered workers advances the final rule's objectives to a greater degree than differentiating among workers. In response to, *inter alia,* comments regarding the potential costs and difficulties that may result from invalidating existing non-competes for certain senior executives, however, the final rule differentiates between senior executives and other workers by allowing existing non-competes for senior executives to remain in force. The final rule adopts a uniform rule categorically banning new non-competes for all workers. The Commission substantiates its finding that the use of non-competes with workers is an unfair method of competition in Parts IV.B and IV.C.

In this Part V.D, the Commission addresses comments related to differentiation or exclusion of certain workers, employers, or industries. Comments related to expanding or limiting the definition of worker or employer are addressed in Parts III.C and III.G. Comments related to the Commission's jurisdiction and exclusions from the Commission's jurisdiction in the FTC Act are addressed in Part II.E. Comments related to the prevalence of non-competes within and across industries are addressed in Part I.B.2.

Overall, the Commission is committed to stopping unlawful conduct related to the use of certain non-competes to the full extent of its authority and jurisdiction. The Commission finds every use of a non-compete covered by the final rule to be an unfair method of competition under section 5 of the FTC Act for the reasons in Parts IV.B and IV.C. The use of an unfair method of competition cannot be justified on the basis that it provides a firm with pecuniary benefits.[906] To the extent commenters argue for an exception based on this justification, the Commission declines to create any exception on that basis. Moreover, a uniform rule carries significant benefits, which many commenters who otherwise opposed the NPRM acknowledged.[907] Among those benefits is the certainty for both workers and employers from a uniform rule, which also lessens the likelihood of litigation over uncertain applications. Exceptions for certain industries or types of workers would likely increase uncertainty and litigation costs, as parties would dispute whether a specific business falls within an industry-wide exception. Most importantly, exceptions would fail to remedy the tendency of non-competes to negatively affect competitive conditions in the excepted industries or for excepted types of workers and would likely have *in terrorem* effects.

1. Differentiation by Worker Compensation or Skills

Many commenters sought an exception for highly paid or highly skilled workers, often alongside requests for an exception for senior executives, while many others asked the Commission to keep these workers within the scope of the final rule. Commenters seeking an exception argued that highly paid and highly skilled workers in particular did not experience exploitation and coercion and were more likely to have access to confidential information or client or customer relationships, along with the other justifications for non-competes discussed in Part IV.D. Commenters' specific arguments on the evidence concerning highly paid or highly skilled workers are considered in the relevant subsections of Part IV.B. Many commenters proposed using a compensation threshold to differentiate highly paid workers and senior executives, discussed in IV.C.4.b. Other commenters suggested an exception based on the FLSA exemptions or the worker's level of access to confidential information, discussed in Parts IV.C.4. and V.D.2.

The Commission finds that non-competes have a tendency to negatively affect competitive conditions in labor markets and product and service markets, including non-competes binding highly paid and highly skilled workers. The evidence shows that, among the other effects described in Part IV.B, non-competes for highly paid and highly skilled workers suppress wages for these workers,[908] restrict competitors' access to highly skilled workers,[909] and restrict entrepreneurship.[910] Notably, as described in Parts IV.B.2 and IV.C.1, the Commission concludes that non-competes for highly paid or highly skilled workers who are not senior executives are generally exploitative and coercive. The Commission finds that highly paid and highly skilled workers who are not senior executives only rarely negotiate meaningful consideration in exchange for a non-compete. As the Commission finds, the overwhelming response from commenters, particularly workers, was that non-competes are exploitative and

[903] NPRM at 3518. The NPRM's proposed definition of ''worker'' excluded franchisees in the context of franchisee-franchisor relationships. *Id.* at 3520. The NPRM also proposed an exception for certain non-competes between the seller and the buyer of a business.

[904] NPRM at 3519.

[905] The Commission received over 26,000 public comments from a wide range of stakeholders. Among these comments, over 25,000 expressed support for the Commission's proposal to categorically ban non-competes.

[906] *See, e.g., Atl. Refin. Co.* v. *FTC,* 381 U.S. 357, 371 (1965) (''Upon considering the destructive effect on commerce that would result from the widespread use of these contracts by major oil companies and suppliers, we conclude that the Commission was clearly justified in refusing the participants an opportunity to offset these evils by a showing of economic benefit to themselves.''); *see also* Part II.F.

[907] *See* Part IX.C.

[908] *See* Part IV.B.3.a.ii.

[909] *See* Part IV.C.2.c.i.

[910] *See* Part IV.B.3.b.i.

coercive for many workers in highly paid professions other than senior executives.[911] While there may be highly paid or highly skilled workers who do not meet the definition of ''senior executive'' and who are not exploited or coerced, including workers above the definition's total compensation threshold, the Commission explains in Part IV.C.4 why a compensation threshold is necessary—but not sufficient—for purposes of defining senior executives whose existing non-competes may remain in force under the final rule. Further, the Commission finds that employers have sufficient alternatives to non-competes for highly paid and highly skilled workers.[912] The Commission also explains why it is not exempting all non-competes that were exchanged for consideration in Part IV.C.3. Accordingly, the final rule does not include any workers other than highly paid senior executives in the exception from the ban on enforcing existing non-competes. To ensure that only workers for whom there is insufficient evidence of exploitation and coercion are included in the exception, the final rule narrowly defines senior executive in § 910.1.[913]

2. Differentiation by Worker Access to Information

Some commenters suggested excluding workers with access to trade secrets, confidential business information, or other intellectual capital. Commenters contended these workers are uniquely situated because of their access to valuable employer information. Many commenters responded to these arguments and disagreed with them. Some commenters stated that employers overstate the proportion of workers who have access to such information. Commenters also stated that employers exaggerate the amount or quality of information that should be appropriately considered a trade secret, confidential business information, or other intellectual capital, and therefore exaggerate the purported cost to the firm of not being able to use non-competes. Commenters also stated that employers have alternatives to non-competes that generate less harm to competition, to workers, to the economy, and to rival firms, including NDAs and fixed-term employment contracts.

The Commission declines to adopt an exclusion based on workers' access to trade secrets, confidential business information, or other intellectual capital because it finds such an exclusion would be unnecessary, unjustified, unworkable, and prone to evasion. The Commission finds the use of non-competes to be an unfair method of competition and addresses claimed justifications related to trade secrets, confidential business information, or other intellectual capital in Part IV.D. The Commission finds that protecting trade secrets, confidential information, and other intellectual capital is an insufficient justification for non-competes because employers have less restrictive alternatives for protecting such information. Moreover, if the Commission were to exempt workers with access to confidential information, employers could argue that most or all workers fall under the exception, requiring workers to engage in complex and fact-specific litigation over the protected status of the underlying information. As explained in Part IX.C, such case-by-case adjudication of the enforceability of non-competes has an *in terrorem* effect that would significantly undermine the Commission's objective to address non-competes' tendency to negatively affect competitive conditions in a final rule.

3. Differentiation by Industry Other Than Healthcare

Some businesses and organizations argued that specific industries should be exempt from the final rule. The Commission carefully considered these comments and declines to adopt any industry-based exceptions. The Commission notes that while some commenters characterized purported justifications for an exclusion from the final rule as unique to a particular industry, the purported justifications were in fact the same as the those addressed in Part IV.D, namely, the need to protect investments in labor, trade secrets, confidential business information, or other intellectual capital. The Commission addresses those arguments in full in Part IV.D, but in this Part V.C.3 further discusses examples of comments seeking industry-based exceptions.

a. Client- and Sales-Based Industries

Some commenters in client- or sales-based industries, including real estate and insurance, argued they are unique and should be excluded from any rule. A real estate commenter argued that job switching by real estate employees is similar to the sale of a business where the goodwill and book of business generated by the departing employee must remain with the business. A timeshare industry commenter claimed the industry had unique features justifying the use of non-competes with highly paid workers, such as the cost of marketing and cultivation of relationships to bring in and maintain customers as well as the need to protect proprietary targets and strategies for resort development, due in part to the limited number of available resort contracts. A commenter representing insurance marketing organizations (IMOs), which serve as facilitators between insurance carriers, agents, and consumers similarly argued for an exclusion, citing client goodwill, purported trade secrets in sales methods, sales leads, unique compensation structures, and company analyses, and consumer harm from potential agent misconduct if the agent moves to a new IMO and changes the consumer's policy. Some businesses stated that non-competes rarely impact a worker's ability to find other work in their industry, sometimes because the new employer ''buys out'' the non-compete.

The majority of commenters from the real estate and insurance industry workers and small, independent insurance agencies, supported a comprehensive ban. These comments painted a picture consistent with the Commission's findings in Part IV.B regarding indicia of unfairness, including facial unfairness, and the tendency of non-competes to negatively affect competitive conditions in the labor and product and service markets. A worker from the real estate industry stated that non-competes are standard in the industry for all workers, regardless of their position in a company. Commenters stated that they were asked to sign after starting their job, with one worker stating that they faced the option of either signing the non-compete or leaving and losing future commissions for work they had done. Workers noted that they were terminated without cause and still required to comply with a non-compete, and that they had no bargaining power for promotion or wage increases. The following examples are illustrative of the comments the Commission received:

- As an aspiring entrepreneur in the real estate space, I am in a relatively small market where one company dominates. I recently ended my employment with them. They use non-competes to restrict competition and trap employees. The abolition of non-competes is paramount as small towns/cities grow. . . .[914]
- I signed a non-compete after working at a Real Estate Brokerage for several months. I

[911] *See* Part IV.B.2.b.

[912] *See* Part IV.D.2.

[913] For a more detailed discussion of proposed § 910.1(i), *see* Part IV.C.4.a.

[914] Individual commenter, FTC–2023–0007–10710.

was told I had to sign it or I would not be paid on the transactions I had pending. The non-compete was so overreaching—there was no geographical scope, the penalty was more than prohibitive. I was told that no one really enforces them or attempts to. I signed it, collected my outstanding pay and left the company within 90 days. Fast forward 4 years, I have been defending myself in litigation over this non-compete for over 3 years. Unable to afford qualified representation.[915]

- I am a business owner and have had 40 independent contractors under my business at my peak. They were all under non-compete, and if I could go back, I would eliminate the non-compete. It doesn't help the employee or contractor, and it doesn't help the business either. It spurs an unhealthy work environment. Clogs up the judicial system with frivolous cases where they try and scare people from earning a living. . . . I 100% support this ban, and it should go into effect immediately.[916]

Commenters stated that non-competes are standard in the insurance industry and that the industry is facing significant consolidation, fueled in part by private equity firms. These commenters argued that workers in the insurance industry are prohibited from seeking jobs with higher pay and better benefits in their specialty. Commenters stated that they were not able to negotiate better conditions at their current job and that employers can change the employment terms at will, so workers face reduced commissions and pay while still being held to a non-compete. Commenters stated that insurance agents are highly trained and specialized, and non-competes force them to leave their specialty and start over in a new specialty for less pay. Commenters also argued that non-competes thwart consumer choice because insurance agents create relationships with their customers, and customers lose the ability to choose the same agent if the agent is bound by a non-compete. Commenters also noted that standard employment agreements in the insurance industry require workers to pay their own costs to defend against noncompete litigation even if the worker is successful in the challenge such that even if a worker does not violate the terms of a noncompete, or the noncompete is not enforceable, workers who change jobs or start a new agency are often faced with significant legal bills. Commenters noted that although independent licensing agents are meant to be able to contract with multiple insurance companies, they are heavily restricted by non-competes, creating regional monopolies. The following examples are illustrative of the comments the Commission received:

- As a captive ''Independent Contractor'' for a large insurance company, this rule would be a lifeline should I decide to pursue an independent agent opportunity. The insurance company I represent, has gradually cut commissions over the past few years . . . that makes it extremely uncompetitive compared to peers. There is absolutely no reason why I should be held prisoner and not be able to pursue far more favorable, and beneficial opportunities, for both myself and my family.[917]
- Ideally I would like to start my own insurance agency but am currently prevented from doing so due to a non-compete clause. We are already somewhat limited in employment opportunities here in rural West Texas . . . . I'm finding it difficult to find a path to provide for my family during the two year period [of the non-compete], and therefore am considering scrapping the new business idea and remaining at my current job. . . . In a sense, I feel trapped at my current job, and ultimately I feel hobbled from achieving my full potential as a future small business owner.[918]

The Commission declines to adopt an exclusion for client- or sales-based industries such as real estate and insurance. The use of non-competes is an unfair method of competition and the purported justifications raised by commenters do not change the Commission's finding. The Commission also notes that, to the extent commenters seeking an exception are referencing different restrictive covenants, including some garden variety non-solicitation agreements, which do not prohibit or function to prevent a worker from switching jobs or starting a new business as described in Part III.D, the final rule does not apply to them. Thus, the Commission focuses on commenters' purported need for an exclusion based on non-competes alone.

In response to commenters arguing that information and techniques related to sales, including strategy on developing business, is confidential or proprietary and that workers' ability to move to another job or start a business would thus harm them, the Commission notes that any specific information or truly proprietary techniques can be protected by much less restrictive alternatives, such as trade secret law and NDAs. For example, proprietary targets and strategies for timeshares or unique compensation structures or company analyses cited by IMOs can be otherwise protected. Moreover, companies can compete on the merits to retain their customers by offering better products and services. Requiring workers to leave the industry or the workforce is an overbroad restriction that tends to negatively affect—and actually harms—competition with attendant harm to workers and rivals, as outlined in Part IV.B.

With respect to commenter arguments that non-competes are needed to protect specialization related to particular products and skills related to sales, as the Commission finds in Part IV.D, preventing workers from using their general trade knowledge and skills, including their gains in the same through experience with a particular employer, is not a legally cognizable justification for non-competes. That a real estate, insurance, or any other sales agent inherently learns skills and gains knowledge in the performance of their job, becoming a more effective salesperson over time, is not itself a cognizable justification for preventing the worker from re-entering the labor market as a worker or business owner. Employers' efforts to use non-competes to prevent workers from using general trade knowledge and skills is an unfair method of competition under section 5 because it is an attempt to avoid competition on the merits.[919] To the extent employers seek to protect legitimate investments in training, the Commission finds employers have less restrictive alternatives, including fixed duration contracts and better pay or other terms and conditions of employment to retain the worker. Finally, the Commission notes that because all covered employers can no longer maintain or enforce non-competes with workers who are not senior executives, employers may also have a larger pool of trained and experienced workers to hire from.

The Commission disagrees with commenters arguing that a worker leaving a sales position is akin to the sale of a business. Unlike the seller of a business, a worker is in an unequal bargaining position and does not receive compensation when leaving the firm. The fact that a worker generates goodwill for an employer is not a cognizable justification for non-competes. First, it not clear that the employer would lose goodwill associated with their business if a particular worker leaves. Moreover, commenters do not specify the extent to which their legitimate investment in the worker—separate from employing the

[915] Individual commenter, FTC–2023–0007–5502.

[916] Individual commenter, FTC–2023–0007–6782.

[917] Individual commenter, FTC–2023–0007–10919.

[918] Individual commenter, FTC–2023–0007–19441.

[919] *See Nat'l Soc'y of Prof. Engrs.* v. *United States,* 435 U.S. 679 (1978) (confirming that limiting competition, even if based on the specific advantages of doing so because of the particular nature of an industry, is not a cognizable justification).

worker to use their general skills and knowledge to successfully perform the job—generates such goodwill. To the extent employers do seek to protect investments in goodwill, the employer has less restrictive alternatives to attract and retain workers and customers or clients.

b. Industries With Apprenticeships or Other Required Training

Some commenters representing industries with apprenticeships or that require training as a part of employment, such as real estate appraisers, plumbers, and veterinarians, argued their industry should be excluded from the final rule. These commenters contended that a significant investment is needed to make workers productive in their industries and that they need to use non-competes to protect that investment. Each commenter cited an apprenticeship or training period during which they are not able to bill or must bill a lower amount for a worker's labor.

Worker commenters from these industries stated that non-competes leave them unable to launch or progress in their career because non-competes tie them to their first employer. Some appraiser commenters noted that, while their share of the appraisal fee rises to some extent after completing their apprenticeship, they cannot negotiate higher shares of the fee or other better working conditions because of non-competes. A union commenter representing plumbers noted that plumbers with non-competes are not able to accept better offers of employment, with better pay and benefits, including union positions. Other worker commenters mentioned geographic overbreadth and excessively long non-competes of two years. Many veterinarian commenters supported the proposed rule, stating that non-competes artificially held down their compensation and did not allow them to start new practices in areas where the need for more veterinary services is great, with some commenters stating that this contributed to consolidation.

The Commission declines to exclude industries, such as real estate appraisal, plumbing, and veterinary medicine, in which an industry must purportedly invest in significant training or apprenticeship of workers before the employer considers them to be productive. The Commission finds that these employers have less restrictive alternatives—namely fixed duration contracts—to protect their investment in worker training. A return on investment in the training does not require that the worker be unable to work for a period after leaving employment. Moreover, employers stand to benefit from the final rule through having access to a broader labor supply—including incoming experienced workers—with fewer frictions in matching with the best worker for the job.

c. Financial Services

Some commenters representing financial services companies opposed the rule, arguing non-competes are necessary for the industry and their industry is unique because non-competes have been used for decades, while numerous firms have entered the market, workers are mobile, and there is no evidence of blocked or curbed entry, lack of access to talent, lower innovation, or other negative impacts in that market. These commenters mention that mobility and access to talent is possible because new employers often ''buy out'' a worker's non-compete to hire a worker who may be otherwise bound by a non-compete. Several commenters also contend that non-competes are especially vital to firms that focus on securities or commodities trading because disclosure of commercially sensitive information to competitors can be extremely damaging to their former employers' profitability.

Commenters identified three studies which they contend suggest that non-competes improve worker productivity. First, commenters identified two studies on the Broker Protocol, an agreement among financial advisory firms which ostensibly limited the use of NDAs, non-solicitation agreements, and non-competes simultaneously. One study by Gurun, Stoffman, and Yonker finds that firms that joined the Protocol experienced higher rates of employee misconduct and earned increased fees.[920] The other study, by Clifford and Gerken, finds that firms which joined the Protocol invested more heavily in licensure and experienced fewer customer complaints.[921] Commenters noted that these two studies have conflicting findings on advisor misconduct. The authors themselves discuss these findings, with each criticizing the approach of the other. One commenter stated that, from a technical standpoint, the Clifford and Gerken study has a superior approach due to its substantially larger sample size and its analysis of the assumptions underlying the methodologies used in both studies. A third study—a study of the mutual fund industry by Cici, Hendriock, and Kempf—finds that mutual fund managers increase their firms' revenue when non-competes are more enforceable by investing in higher performing funds, attracting new clients, and increasing revenue from fees.[922] This study uses three changes in non-compete enforceability, measured in a binary fashion.

A commenter representing a large group of public equity investors supported the rule, stating that a comprehensive ban would create an inclusive labor market, which is integral to long-term corporate value and a dynamic, innovative, and equitable economy. Financial services worker commenters also supported the rule, citing to their failure to be paid for their skills over time, the threat of litigation in seeking new employment, and the overbroad nature of non-competes in the industry. The following example is illustrative of the comments the Commission received:

- I am a female finance professional with strong qualifications and experience. I am subject to an extremely long and comprehensive non compete contract which I was induced to sign at a young age. I have been offered many positions at other firms who would be more willing to provide me with leadership opportunities and a path to further advancement, but I am unable to consider them and I am essentially trapped at my firm. . . .[923]

The Commission declines to exclude financial services companies over which it has jurisdiction from the final rule. The Commission finds in Part IV.C that non-competes are restrictive, exclusionary, and also exploitative and coercive for higher wage and highly skilled workers, including workers in finance. The Commission also finds in Part IV.B and IV.C that non-competes tend to negatively affect competitive conditions in labor market through reduced labor mobility and in the product and services market through reduced innovation and new business formation. Evidence that new employers sometimes buy out non-competes also suggests that such clauses harm competition by raising the cost to compete and creating deadweight economic loss for the new employer.[924]

The empirical evidence provided by commenters arguing for differentiation

[920] Umit G. Gurun, Noah Stoffman, & Scott E. Yonker, *Unlocking Clients: The Importance of Relationships in the Financial Advisory Industry,* 141 J. of Fin. Econ. 1218–43 (2021).

[921] Christopher P. Clifford & William C. Gerken, *Property Rights to Client Relationships and Financial Advisor Incentives,* 76 J. of Fin. 2409–45 (2021).

[922] Gjergji Cici, Mario Hendriock, & Alexander Kempf, *The Impact of Labor Mobility Restrictions on Managerial Actions: Evidence from the Mutual Fund Industry,* 122 J. of Banking & Fin. 105994 (2021).

[923] Individual commenter, FTC–2023–0007–0953.

[924] *See* Part IV.C.2.c.i.

for the finance industry does not support their claims. The Commission finds that it is difficult to weigh the evidence in the two studies of the Broker Protocol because they reach conflicting results, though the Commission agrees that the technical approach in the Clifford and Gerken study is superior due to its larger sample size. More importantly, both studies primarily concerned non-solicitation agreements, and do not isolate any effects of non-competes. So even if the studies did not reach conflicting results, the Commission believes they still would yield little reliable information about the effects of non-competes specifically. With respect to the study of the mutual fund industry, the Commission notes that under section 5, firms may not justify unfair methods of competition based on pecuniary benefit to themselves.[925] The study does not establish that there were societal benefits from the attraction of new clients or the increased fee revenue—just that the firms benefited. Therefore, this study does not establish a business justification that the Commission considers cognizable under section 5.

d. On-Air Talent

Some commenters opposing the rule stated that investment in on-air talent would be considerably reduced without non-competes. Commenters argued that on-air talent becomes well-known because of employers' investment and reputation and that employers must be able to use non-competes to protect this investment. The Commission also received a number of comments from and on behalf of on-air talent. Those commenters stated that non-competes are ubiquitous for on-air talent, that they are often localized geographically, that they suppress compensation, and that they force workers seeking a better match to move out of their localities. The following example is illustrative of the comments the Commission received:

- I am a professional broadcast journalist subject to a non-compete agreement with every employment contract I have ever signed, which is the industry standard. I understand the need for contractual agreements with on-air talent and some off-air talent, but non-compete agreements have historically offered nothing to employees besides restricting where they work, and how much money they are able to earn . . . [while] knowing that employees would have to completely relocate if they wanted to seek or accept another opportunity.[926]

[925] *Id.*

[926] Individual commenter, FTC–2023–0007–12779.

The Commission declines to exclude on-air talent from the final rule. The Commission finds the use of non-compete agreements is an unfair method of competition as outlined in Part IV.B, and commenters do not provide evidence that a purported reduction in investment in on-air talent would be so great as to overcome that finding. Specifically, the success of on-air talent is a combination of the employer's investment and the talent of the worker, both of which benefit the employer. As noted in Part IV.D, other less restrictive alternatives, including fixed duration contracts and competing on the merits to retain the talent, allow employers to make a return on their own investments. Moreover, as stated in Part II.F, firms may not justify unfair methods of competition based on pecuniary benefit to themselves. Employers in this context do not establish that there are societal benefits from their investment in on-air talent, but only that the firms benefited.

e. Construction

A commenter representing companies who provide skilled workers in construction stated that the Commission should exclude the industry from the rule because non-competes are necessary to the industry's success. The commenter states that non-competes are necessary for investment in innovation and productivity in the industry. The comment cites to three studies. Two of the studies find a general reduction in productivity in construction and conclude, *inter alia,* further study is warranted to better understand the trend—Goolsbee and Syverson [927] and Huang, Chapman, and Burty (''NIST study'' [928]). The third study is a McKinsey & Company report published in 2020 predicting innovation in the construction industry in the coming years.[929]

The evidence cited by this commenter is exclusively about broad trends in productivity in the industry, and what may impact those trends. None of the studies explicitly examines non-competes, and they do not support inferences on the effects of non-competes in this particular industry. Indeed, the Commission finds that the final rule addresses issues raised by the commenter. For example, the commenter notes that productivity in the industry has been broadly declining for years. Notably, this downward trend exists with non-competes in use in the industry. The Commission notes that, under its analysis of the effect of the final rule, productivity will benefit because the final rule frees up labor and allows for greater innovation. The NIST study raises ''skilled labor availability'' as the very first factor that affects productivity. The Commission finds in Part IV that non-competes suppress labor mobility and the Commission believes the final rule will result in firms having access to workers who are a better, more productive fit. The McKinsey & Company report notes that changes in the industry will require adaptation by firms. The Commission believes the final rule will facilitate this adaptation by sharing non-confidential know-how across firms through increased mobility of workers. The rule may also help mitigate, and certainly will not exacerbate, concerns over increased concentration in the industry raised in the McKinsey & Company report, as the Commission finds that non-competes inhibit new business formation in Part IV.B.3.b.i. Moreover, the Commission believes non-competes may increase concentration, as discussed in Part IV.B.3.b.iii.

Additionally, the Commission finds that less restrictive alternatives, including appropriately tailored NDAs and non-solicitation agreements, are sufficient to address disclosure of confidential information and concerns related to client business. With respect to concerns that the construction industry as a whole is suffering from under-investment in capital and that the final rule may further disincentivize capital investment, as the Commission finds in Part IV.B.3.b.i, non-competes inhibit new business formation. The increase in new business formation from the final rule will bring new capital to bear in the industry. The Commission addresses the empirical literature and comments related to capital investment in detail Part IV.D.1. The Commission notes here that it is not clear any purported capital investment associated with non-competes is entirely beneficial because it may be the result of firms over-investing in capital because they do not face competition on the merits. Even if there is some net decrease in capital investment due to the final rule, commenters provide no reason to believe it would be a material amount.

[927] Austan Goolsbee & Chad Syverson, *The Strange and Awful Path of Productivity in the U.S. Construction Sector* (NBER Working Paper 30845, Jan. 2023).

[928] Allison L. Huang, Robert E. Chapman, & David Burty, *Metrics and Tools for Measuring Construction Productivity: Technical and Empirical Considerations,* Nat'l Inst. of Standards and Tech., Bldg. and Fire Rsch. Lab., NIST Special Publication 110 (September 2009).

[929] McKinsey & Co., *The Next Normal in Construction: How Disruption is Reshaping the World's Largest Ecosystem* (June 2020).

4. Exclusion for Covered Market Participants That Have Competitors Outside the FTC's Jurisdiction

The Commission explained in the NPRM that some entities that would otherwise be employers may not be subject to the final rule to the extent they are exempted from coverage under the FTC Act.[930] As described in Part II.E.1, the Act exempts, *inter alia,* ''banks,'' ''persons, partnerships, or corporations insofar as they are subject to the Packers and Stockyards Act of 1921'' [931] as well as an entity that is not ''organized to carry on business for its own profit or that of its members.'' [932] A few business and trade organization commenters argued the Commission should rescind the proposal or should not promulgate the rule because limits on the Commission's jurisdiction mean that the rule will distort competitive conditions where coverage by the final rule may not be universal. These commenters identified industries where employers excluded from the Commission's jurisdiction compete with covered persons, including livestock and meatpacking industries, and areas where government or private employers subject to the State action doctrine compete with covered employers. They contended that excluded employers will be able to use non-competes while their covered competitors are legally prohibited from doing so, advantaging excluded employers.

The Commission declines to rescind the proposal or otherwise refrain from promulgating a rule simply because the rule would not cover firms outside the Commission's jurisdiction. As an initial matter, jurisdictional limits are not unique to the Commission. All agencies have limits on their jurisdiction—many of which do not neatly map to all competitors in a particular market. Moreover, as explained in Parts IV and X, the final rule will have substantial benefits notwithstanding the FTC Act's jurisdictional limits, including increases in worker earnings, new firm formation, competition, innovation, and a decrease in health care prices (and potentially other prices). Furthermore, the Commission finds the risk of material disparate impact in markets where some but not all employers are covered by the final rule is minimal and, in any event, the final rule's overall benefits justify any such potential impact. As commenters acknowledged, excluded employers already compete with covered employers in the same markets. That is, coverage under the FTC Act—whether an employer is subject to the FTC Act and enforcement by the FTC—differs across a range of topics and long predates this final rule, which does not materially alter the status quo in that respect. Moreover, even in the absence of the rule, firms within the jurisdiction of the FTC Act are already subject to potential FTC enforcement against unfair methods of competition, including against non-competes, while firms outside the FTC's jurisdiction are not. The final rule does not alter that basic landscape.

At least one financial services industry commenter stated that national banks are outside of the Commission's jurisdiction and argued the final rule should exclude bank holding companies, subsidiaries, and other affiliates of Federally regulated banks to avoid disparate treatment of workers employed by different affiliates within the same organization, and because those entities are already heavily regulated. The Commission declines to exclude bank holding companies, subsidiaries, and other affiliates of Federally regulated banks that fall within the Commission's jurisdiction. While these institutions may be highly regulated, and depending on the corporate structure non-competes may be allowed for some workers but not others, the Commission finds that neither factor justifies excluding them from the final rule. If Federally regulated banks are concerned about disparate treatment of workers employed by their own different affiliates, they have the option to stop using non-competes across all their affiliates.

A corporation wholly owned by an Indian tribe asserted that the Commission should exclude Indian tribes and their wholly owned business entities from the definition of ''employer.'' The commenter asserted that the FTC Act does not explicitly grant jurisdiction over Indian tribes and their corporate arms. The commenter further argued that critical tribal revenue will be lost if tribal businesses' ability to retain skilled workers is impacted. The Commission declines to categorically exclude tribes or tribal businesses from coverage under the final rule. The FTC Act is a law of general applicability that applies to Indians, Indian Tribes, and tribal businesses.[933] The Commission recognizes, however, that in some instances these entities may be organized in such a way that they are outside the Commission's jurisdiction.[934] Whether a given Tribe or tribal business is a corporation within the FTC Act will be a fact-dependent inquiry. The Commission is aware of no evidence suggesting the final rule would disproportionately impact tribes or tribal businesses.[935]

5. Coverage of Healthcare Industry

Many commenters representing healthcare organizations and industry trade associations stated the Commission should exclude some or all of the healthcare industry from the rule because they believe it is uniquely situated in various ways. The Commission declines to adopt an exception specifically for the healthcare industry. The Commission is not persuaded that the healthcare industry is uniquely situated in a way that justifies an exemption from the final rule. The Commission finds use of non-competes to be an unfair method of competition that tends to negatively affect labor and product and services markets, including in this vital industry; the Commission also specifically finds that non-competes increase healthcare costs. Moreover, the Commission is unconvinced that prohibiting the use of non-competes in the healthcare industry will have the claimed negative effects.

a. Comments Received

Many business and trade industry commenters from the healthcare industry seeking an exception,

[930] NPRM at 3510.

[931] *Id.* (citing 15 U.S.C. 45(a)(2)).

[932] *Id.* (citing 15 U.S.C. 44).

[933] *See Fed. Power Comm'n* v. *Tuscarora Indian Nation,* 362 U.S. 99, 116–17 (1960) (examining case law supporting the conclusion that ''a general statute in terms applying to all persons includes Indians and their property interests''); *FTC* v. *AMG Servs., Inc.,* No. 2:12–CV–00536–GMN, 2013 WL 7870795, at *16–*21 (D. Nev. July 16, 2013), *report and recommendation adopted,* No. 2:12–CV–00536–GMN, 2014 WL 910302 (D. Nev. Mar. 7, 2014) (discussing the FTC Act's applicability to Indian Tribes and tribal businesses).

[934] *See, e.g., AMG Servs.,* 2013 WL 7870795, at *22 (finding genuine dispute of material fact barring summary judgment on question of whether tribal chartered corporations were corporations under the FTC Act).

[935] The commenter also asked the Commission to engage Indian tribes about the proposed rule, citing Executive Order 13175. However, the Commission notes that Executive Order 13175, which requires consultation with Indian Tribes before promulgating certain rules, does not apply to independent regulatory agencies such as the Commission. E.O. No. 13175, 65 FR 67249 (Nov. 6, 2000) (stating that the term ''agency,'' which governs the applicability of the executive order, excludes agencies ''considered to be independent regulatory agencies, as defined in 44 U.S.C. 3502(5)''); 44 U.S.C. 3502(5) (listing the Commission as an ''independent regulatory agency''). The Commission did, however, provide extensive opportunities for public input from any and all stakeholders, including a 120-day comment period (extended from 90 days) and a public forum held on February 16, 2023, that provided an opportunity to directly share experiences with non-competes.

including, for example, hospitals, physician practices, and surgery centers, focused on whether the Commission has jurisdiction to regulate nonprofit entities registered under section 501(c) of the Internal Revenue Code. The Commission addresses its jurisdiction in Part II.E and considers comments related to requests for an industry-based exclusion for all or part of the healthcare industry in this section. As stated in Part II.E, entities claiming tax exempt status are not categorically beyond the Commission's jurisdiction, but the Commission recognizes that not all entities in the healthcare industry fall under its jurisdiction.

Based on the assumption that entities claiming tax-exempt status as nonprofits and publicly owned healthcare organizations would be exempt, many industry commenters contended that for-profit healthcare organizations must be also exempted from the rule as a matter of equal treatment. Commenters cited data from the American Hospital Association (AHA) indicating that as many as 58% of all U.S. hospital systems claim tax-exempt status as nonprofits, 24% are for-profit hospitals, and 19% are State and local government hospitals. One commenter cited AHA data indicating that 78.8% of for-profit hospitals are located in the same Hospital Referral Region (HRR) as at least one entity that claims tax-exempt status as a nonprofit. Many commenters argued that for-profit entities and entities that claim nonprofit status compete for patients, physician and non-physician staff, and market share. These commenters contended that a rule covering only for-profit healthcare entities will distort the market in favor of entities claiming tax-exempt status as nonprofits, which would continue using non-competes. One commenter identifying as an entity claiming nonprofit tax-exempt status argued that such entities need to rely on non-competes to compete with for-profit competitors because, unlike for-profit health systems, they invest significantly in specialized training and mentorship, and offer a guaranteed minimum salary to recent graduates.

Some commenters contended that favoring entities claiming tax-exempt status as nonprofits would have negative effects. Some commenters argued that disparate coverage under the rule may exacerbate consolidation in the healthcare industry by advantaging entities that claim tax-exempt status as nonprofits. They stated that increased consolidation would reduce the available supply of skilled labor for for-profit hospitals, increasing labor costs and contributing to higher prices paid by patients. Commenters noted a trend in physicians increasingly leaving private practice to work at large hospital groups claiming tax-exempt status as nonprofits, which, they contended, may continue to lock those physicians up using non-competes. Industry commenters also argued that insurance premiums will rise more than they would absent the rule because of the greater market power and resulting leverage of entities that claim tax-exempt status as nonprofits in provider network negotiations. One manufacturing industry association commenter argued that the burden of rising premiums will be passed on to manufacturers who provide health insurance to their employees.

Commenters also argued that a rule covering for-profit healthcare providers would cause independent, physician-owned practices, and small community practices to suffer a competitive disadvantage compared to larger entities that claim tax-exempt status as nonprofits and public hospital groups, reducing the number of these practices and interrupting continuity of care for their patients. Commenters stated that such practices will suffer these consequences acutely in States or localities that are particularly saturated with entities that claim tax-exempt status as nonprofits or exempt State or local hospitals, and cited New York and Mississippi as examples. A commenter claimed that public hospitals regulated by the Commission will incur losses because of their reduced ability to hire and retain physicians that perform profitable procedures. One commenter cited a 1996 Commission study to contend that, all else equal, hospitals that claim tax-exempt status as nonprofits set higher prices when they have more market power. A business commenter contended that, given what they considered a large-scale exemption of certain physician employers from the Commission's jurisdiction, the States are more appropriate regulators of non-competes between physicians and employers. Other commenters claimed that the Commission must further study the consequences of differential treatment.

Conversely, many commenters vociferously opposed exempting entities that claim tax-exempt status as nonprofits from coverage under the final rule. Several commenters contended that, in practice, many entities that claim tax-exempt status as nonprofits are in fact ''organized to carry on business for [their] own profit or that of [their] members'' such that they are ''corporations'' under the FTC Act. These commenters cited reports by investigative journalists to contend that some hospitals claiming tax-exempt status as nonprofits have excess revenue and operate like for-profit entities. A few commenters stated that consolidation in the healthcare industry is largely driven by entities that claim tax-exempt status as nonprofits as opposed to their for-profit competitors, which are sometimes forced to consolidate to compete with the larger hospital groups that claim tax-exempt status as nonprofits. Commenters also contended that many hospitals claiming tax-exempt status as nonprofits use self-serving interpretations of the IRS's ''community benefit'' standard to fulfill requirements for tax exemption, suggesting that the best way to address unfairness and consolidation in the healthcare industry is to strictly enforce the IRS's standards and to remove the tax-exempt status of organizations that do not comply. An academic commenter argued that the distinction between for-profit hospitals and nonprofit hospitals has become less clear over time, and that the Commission should presumptively treat hospitals claiming nonprofit tax-exempt status as operating for profit unless they can establish that they fall outside of the Commission's jurisdiction.

The Commission also received many comments about coverage of the health care sector generally under the rule. Some commenters urged the Commission to ensure that health care workers, including doctors and physicians, were covered by the final rule. Several commenters stated that eliminating non-competes would allow doctors wishing to change jobs to stay in the same geographic area, fostering patient choice and improving continuity of care. Other commenters urged the Commission to create an exception for health care workers. Some argued that the evidence does not support the Commission's conclusion that non-competes depress earnings in health care. Other reasons commenters cited in support of an exception included concerns about continuity and quality of care for patients, the increased costs for employers of health care workers, physicians' negotiating power with their employers, and the effect on incentives for employers to train their health care workers.[936]

Thousands of healthcare workers submitted comments supporting a ban on non-competes. Worker commenters

[936] Some commenters also contended that the health care industry should be exempt from the rule because many health care providers fall outside of the Commission's jurisdiction. The Commission summarizes and responds to those commenters in Part II.E.2.

did not always identify whether they were working at for-profit organizations, entities that claim tax-exempt status as nonprofits, or State or local healthcare organizations, but each category was represented in the comments. These commenters detailed the negative effects of non-competes on their families, their mental health, their financial health, and their career advancement, as elaborated in Part IV.B.2.b.ii. Specifically, healthcare workers commented that because non-competes prohibited them from switching jobs or starting their own businesses, they had to stay at jobs with unsafe and hostile working conditions, to take jobs with long commutes, to relocate their families, to give up training opportunities, and to abandon patients who wanted to continue seeing them. Illustrative comments are highlighted in Parts I and IV.

Additionally, commenters stated the hardship patients have suffered because of non-competes when, for example, their physician was required to move out of their area to work for a different employer. The Commission highlights some of these comments in Part IV.B.2.b.ii and includes two further illustrative comments here:

- As a patient, non compete clauses are affecting mine and my [family's] ability to receive medical care. Our pediatrician left a practice and we aren't able to be informed where they are going. When we find out, it is an hour away [because] of the non compete. And when we look for other [doctors] closer they aren't accepting new patients. So for an entire year we are driving 2 [hours] round trip to see our pediatrician until they can move back to a local medical group. The non compete clause is not just affecting the life of the [doctor], but is also impacting many of us who rely on their services.[937]
- As a family physician this has caused much grief and obstructs my desire to work and provide care for underserved populations. I am a NHSC scholarship recipient and due to non compete clauses was unable to continue working in the town I served due to its rurality. This created a maternity desert in the region I served. Now in a more metropolitan area, there has been an exodus of physicians in the area due to non compete clauses that has caused worsening access to primary care, specialty services, including behavioral health and substance use disorder treatment.[938]

A number of physician group commenters stated that nonprofit healthcare organizations regularly impose non-competes on physicians, and that the impact of the rule would be limited if nonprofits are not required to comply. Some physician group commenters urged the Commission to work with other agencies to fill in gaps in applying the rule based on the Commission's jurisdiction, citing the importance of banning non-competes as widely as possible because of the harms they impose on physicians and patients irrespective of employer status. Specifically, commenters suggested that the Commission use its antitrust and referral authority to aggressively monitor nonprofit organizations for antitrust violations, to collaborate with other Federal agencies, including the IRS, and to provide incentives and guidance to States, which can enact measures to ensure that a prohibition on non-competes is implemented comprehensively. One commenter also noted that a ban would bring scrutiny to non-competes and would likely intensify pressure to eliminate them. A few commenters also contended that entities claiming tax-exempt status as nonprofits are subject to the Commission's jurisdiction as ''persons'' under the FTC Act.

b. The Final Rule

After carefully considering commenters' arguments, the Commission declines to exempt for-profit healthcare employers or to exempt the healthcare industry altogether.

First, as described in Part IV, the Commission finds that certain uses of non-competes are an unfair method of competition. The use of unfair methods of competition cannot be justified on the basis that it provides a firm with pecuniary benefits to help them compete with other firms that use similar tactics.[939] In this case, for-profit and other covered entities have urged the Commission to allow them to continue to employ an unfair method of competition (*i.e.,* use non-competes) because some competitors are not prohibited from doing so as they are beyond the Commission's jurisdiction. The Commission is committed to stopping unlawful conduct to the full extent of its jurisdiction. For example, the Commission would not refrain from seeking to enjoin unlawful price fixing by a for-profit within its jurisdiction because entities outside its jurisdiction under the FTC Act would not be subject to the same FTC action.

Second, the Commission disagrees with commenters' contention that all hospitals and healthcare entities claiming tax-exempt status as nonprofits necessarily fall outside the Commission's jurisdiction and, thus, the final rule's purview. As explained in Part II.E.2, a corporation's ''tax-exempt status is certainly one factor to be considered,'' but that status is not coterminous with the FTC's jurisdiction and therefore ''does not obviate the relevance of further inquiry into a [corporation's] operations and goals.'' [940] Accordingly, as noted by commenters, entities that claim tax-exempt nonprofit status may in fact fall under the Commission's jurisdiction. Similarly, whether the final rule would apply to quasi-public entities or certain private entities that partner with States or localities, such as hospitals affiliated with or run in collaboration with States or localities, depends on whether the particular entity or action is an act of the State itself under the State action doctrine, which is a well-established, fact-specific inquiry.[941] Thus, some portion of the 58% of hospitals that claim tax-exempt status as nonprofits and the 19% of hospitals that are identified as State or local government hospitals in the data cited by AHA likely fall under the Commission's jurisdiction and the final rule's purview. Further, many States have banned non-competes for a variety of healthcare professionals in both for-profit and nonprofits entities by statute.[942] Even if

[937] Individual commenter, FTC–2023–0007–10085.

[938] Individual commenter, FTC–2023–0007–0924.

[939] *See Atl. Refin. Co.* v. *FTC,* 381 U.S. 357, 371 (1965) (''Upon considering the destructive effect on commerce that would result from the widespread use of these contracts by major oil companies and suppliers, we conclude that the Commission was clearly justified in refusing the participants an opportunity to offset these evils by a showing of economic benefit to themselves.'').

[940] *In the Matter of the Am. Med. Assoc.,* 94 F.T.C. 701, 1979 WL 199033 (FTC Oct. 12, 1979).

[941] *In the Matter of Ky. Household Goods Carriers Ass'n, Inc.,* 139 F.T.C. 404, 405 (2005) (''The Supreme Court has made clear that the state action doctrine only applies when (1) the challenged restraint is clearly articulated and affirmatively expressed as state policy, and (2) the policy is actively supervised by the State itself.'') (citation and alterations omitted); *see also id.* at 410–13 (applying test); *Elec. Inspectors, Inc.* v. *Vill. of East Hills,* 320 F.3d 110, 117–19 (2d Cir. 2003).

[942] Colo. Rev. Stat. sec. 8–2–113(5)(a) (Colorado statute banning non-competes for physicians); D.C. Code sec. 32–581.01 (D.C. statute banning non-competes for medical specialists earning less than $250,000, compared to $150,000 for other workers); Fla. Stat. sec. 542.336 (Florida statute banning non-competes for physician specialists in certain circumstances); Ind. Code Ann. secs. 25–22.5–5.5–2 and 2.5(b) (Indiana statute banning non-competes for primary care physicians and restricting non-competes for other physicians); Iowa Code sec. 135Q.2(3)(a) (banning non-competes for health care employment agency workers who provide nursing services); Ky. Rev. Stat. sec. 216.724(1)(a) (Kentucky statute banning non-competes for temporary direct care staff of health care services agencies); N.M. Stat. Ann. secs. 24–1I–1 and 2 (New Mexico statute banning non-competes for several types of health care practitioners); S.D. Codified Laws secs. 53–9–11.1–11.2 (South Dakota statute banning non-

Continued

the final rule's coverage extends only to hospitals that do not identify as tax-exempt non-profits based on AHA data, as explained in Part IV.A.1, the Commission finds every use of covered non-competes to be an unfair method of competition and concludes that the evidence supports the Commission's decision to promulgate this final rule, which covers the healthcare industry to the full extent of the Commission's authority.

Relatedly, in response to commenters' concern that large numbers of healthcare workers will not benefit from the final rule because they work for entities that the final rule does not cover, the Commission notes many workers at hospitals, including those that claims tax-exempt status as a nonprofit or government-owned hospital, contract with or otherwise work for a for-profit entity, such as a staffing agency or physician group. Although some of these individuals may work at an excluded hospital, the final rule applies to their employer—the staffing agency or for-profit physician group—because it is covered by the final rule.

The Commission disagrees with commenters stating the ability to use non-competes will provide a material competitive advantage to entities claiming tax-exempt status as nonprofit or publicly owned entities that are beyond the Commission's jurisdiction. To the contrary, those entities outside FTC jurisdiction that continue to deploy non-competes may be at a self-inflicted disadvantage in their ability to recruit workers, even if they derive some short-term benefit from trapping current workers in their employment. Furthermore, commenters' concern that for-profit healthcare entities will be at a competitive disadvantage is based on the false premise that entities outside the jurisdiction of the FTC will not be otherwise regulated or scrutinized with respect to the use of non-competes. States currently regulate non-competes by statute, regulation, and common law. According to the AHA data cited by commenters, over 12% (398/3,113) of nonprofit hospitals and 13% of government hospitals (187/1,409) are in States that ban non-competes for all employers. In any event, even if true, arguments that for-profit and other covered entities could suffer competitive harm by not being able to employ an unfair method of competition would not change the Commission's finding that use of certain non-competes is an unfair method of competition, as further discussed in Part IV.

While the Commission shares commenters' concerns about consolidation in healthcare, it disagrees with commenters' contention that the purported competitive disadvantage to for-profit entities stemming from the final rule would exacerbate this problem. As some commenters stated, the Commission notes that hospitals claiming tax-exempt status as nonprofits are under increasing public scrutiny. Public and private studies and reports reveal that some such hospitals are operating to maximize profits, paying multi-million-dollar salaries to executives, deploying aggressive collection tactics with low-income patients, and spending less on community benefits than they receive in tax exemptions.[943] Economic studies by FTC staff demonstrate that these hospitals can and do exercise market power and raise prices similar to for-profit hospitals.[944] Thus, as courts have recognized, the tax-exempt status as nonprofits of merging hospitals does not mitigate the potential for harm to competitive conditions.[945]

Commenters provide no empirical evidence, and the Commission is unaware of any such evidence, to support the theory that prohibiting non-competes would increase consolidation or raise prices. To the contrary, as elaborated in Parts IV.B.3.a and IV.B.3.b, the empirical literature suggests, and the Commission finds, that the final rule will increase competition and efficiency in healthcare markets, as workers at for-profit healthcare entities will be able to spin off new practices or work for different employers where their productivity is greater. This is true even if the Commission does not reach some portion of healthcare entities. While the Commission's prior research may indicate, as one commenter suggested, that nonprofit hospitals set higher prices when they have more market power, the Commission finds that the final rule is not likely to increase healthcare prices

competes for several types of healthcare practitioners); Tex. Bus. & Com. Code secs. 15.50–.52 (Texas statute restricting the use of non-competes for physicians).

[943] *See, e.g.,* Press Release, Office of U.S. Sen. Chuck Grassley, *Bipartisan Senators Probe Potential Abuse Of Tax-Exempt Status By Nonprofit Hospitals* (Aug. 9, 2023), *https://www.grassley.senate.gov/news/news-releases/bipartisan-senators-probe-potential-abuse-of-tax-exempt-status-by-nonprofit-hospitals;* Request for Information Regarding Medical Payment Products, 88 FR 44281 (July 12, 2023); U.S. Gov't Accountability Off., Testimony Before the Subcommittee on Oversight, Committee on Ways and Means, House of Representatives, *Tax Administration: IRS Oversight of Hospital's Tax-Exempt Status,* GAO–23–106777 (Apr. 26, 2023), *https://www.gao.gov/assets/gao-23-106777.pdf; Pottstown Sch. Dist.* v. *Montgomery Cnty. Bd. of Assessment Appeals,* 289 A.3d 1142 (Pa. Commw. Ct. 2023) (holding that for-profit hospitals purchased by nonprofit claiming tax exempt status under Federal law do not qualify under State law for nonprofit tax exemption); *Phoenixville Hosp., LLC* v. *Cnty. of Chester Bd. of Assessment Appeals,* 293 A.3d 1248 (Pa. Commw. Ct. 2023); *Brandywine Hosp., LLC* v. *Cnty. of Chester Bd. of Assessment Appeals,* 291 A.3d 467 (Pa. Commw. Ct. 2023); *Jennersville Hosp., LLC* v. *Cnty of Chester Bd. of Assessment Appeals,* 293 A.3d 1248 (Pa. Commw. Ct. 2023); The Daily, *How Nonprofit Hospitals Put Profits Over Patients* (Jan. 5, 2023), *https://www.nytimes.com/2023/01/25/podcasts/the-daily/nonprofit-hospitals-investigation.html;* Gov't Accountability Off., *Tax Administration: Opportunities Exist to Improve Oversight of Hospitals' Tax-Exempt Status,* GAO–20–679 (Sept. 17, 2020), *https://www.gao.gov/products/gao-20-679;* Danielle Ofri, *Why Are Nonprofit Hospitals So Highly Profitable?,* N.Y. Times, Feb. 20, 2020, *https://www.nytimes.com/2020/02/20/opinion/nonprofit-hospitals.html;* Maya Miller & Beena Raghavendran, *Thousands of Poor Patients Face Lawsuits From Nonprofit Hospitals That Trap Them in Debt,* ProPublica (Sept. 13, 2019), *https://www.propublica.org/article/thousands-of-poor-patients-face-lawsuits-from-nonprofit-hospitals-that-trap-them-in-debt.*

[944] *See, e.g.,* Michael G. Vita & Seth Sacher, *The Competitive Effects of Not-For-Profit Hospital Mergers: A Case Study,* 49 J. Indus. Econ. 63 (2001), *http://onlinelibrary.wiley.com/doi/10.1111/1467-6451.00138/epdf* (finding substantial price increases resulting from a merger of nonprofit, community-based hospitals, and determining that mergers involving nonprofit hospitals are a legitimate focus of antitrust concern); Steven Tenn, *The Price Effects of Hospital Mergers: A Case Study of the Sutter-Summit Transaction,* 18 Int'l J. Econ. Bus. 65, 79 (2011), *http://www.tandfonline.com/doi/full/10.1080/13571516.2011.542956* (finding evidence of post-merger price increases ranging from 28%–44%, and concluding that ''[o]ur results demonstrate that nonprofit hospitals may still raise price quite substantially after they merge. This suggests that mergers involving nonprofit hospitals should perhaps attract as much antitrust scrutiny as other hospital mergers.'').

[945] *See, e.g., FTC* v. *OSF Healthcare Sys.,* 852 F. Supp. 2d 1069, 1081 (N.D. Ill. 2012) (''[T]he evidence in this case reflects that nonprofit hospitals do seek to maximize the reimbursement rates they receive.''); *FTC* v. *ProMedica,* No. 3:11 CV 47, 2011 WL 1219281 at *22 (N.D. Ohio Mar. 29, 2011) (finding that a nonprofit hospital entity ''exercises its bargaining leverage to obtain the most favorable reimbursement rates possible from commercial health plans.''); *United States* v. *Rockford Mem'l Corp.,* 898 F.2d 1278, 1284–87 (7th Cir. 1990) (rejecting the contention that nonprofit hospitals would not seek to maximize profits by exercising their market power); *FTC* v. *Univ. Health, Inc.,* 938 F.2d 1206, 1213–14 (11th Cir. 1991) (''[T]he district court's assumption that University Health, as a nonprofit entity, would not act anticompetitively was improper.''); *Hospital Corp. of America* v. *FTC,* 807 F.2d 1381, 1390–91 (7th Cir. 1986) (rejecting the contention that nonprofit hospitals would not engage in anticompetitive behavior). *See also* FTC & Dep't of Jusitce, *Improving Health Care: A Dose of Competition* 29–33 (2004), *https://www.ftc.gov/sites/default/files/documents/reports/improving-health-care-dose-competition-report-federal-trade-commission-and-department-justice/040723healthcarerpt.pdf* (discussing the significance of nonprofit status in hospital merger cases, and concluding that the best available empirical evidence indicates that nonprofit hospitals exploit market power when given the opportunity and that ''the profit/nonprofit status of the merging hospitals should not be considered a factor in predicting whether a hospital merger is likely to be anticompetitive'').

through this same mechanism because it is unlikely to lead to significant increases in healthcare nonprofits' market share, if at all.

Moreover, the Commission has other tools to address consolidation in healthcare markets and is committed to using them. The Clayton Act grants the Commission authority to enforce compliance with, *inter alia,* section 7 of the Clayton Act. The Clayton Act does not include any carveout for entities that are nonprofit or otherwise do not operate for profit—and the FTC's jurisdictional limit based on the definition of ''corporation'' in the FTC Act does not apply in this context.[946] Accordingly, the Commission has authority under the Clayton Act to review and challenge mergers and acquisitions involving healthcare entities or hospitals regardless of nonprofit status.[947] Thus, even if the jurisdictional limitations of the final rule were to somehow incentivize some hospitals and other healthcare entities claiming non-profit status to consolidate, the Commission will continue to scrutinize those mergers and work with State partners to vigorously defend competition.[948] For the same reason, the Commission disagrees with commenters who contended that the effects of consolidation and staffing shortages will be worse in areas highly saturated with nonprofits claiming tax-exempt status.

Finally, the Commission disagrees with commenters that stated the Commission must further study the final rule's effect on healthcare workers and entities. The Commission has specific, long-time expertise in the healthcare market as anticompetitive mergers and conduct in healthcare markets have long been a focus of FTC law enforcement, research, and advocacy.[949] This work includes economic analyses of the effects of mergers involving nonprofit hospitals and studies of the impacts of hospital mergers.[950] Accordingly, given this expertise and the extensive record in the rulemaking, the Commission finds it has sufficient understanding of healthcare markets and that the evidence supports the final rule's application to the healthcare industry.

6. Coverage of Franchisors Vis-à-Vis Franchisees

a. The Proposed Rule

The Commission proposed to exclude franchisees from the definition of ''worker'' and requested comment on whether and to what extent the rule should cover non-competes between franchisors and franchisees (''franchisor/franchisee non-competes'').[951] The Commission explained that it proposed to exclude franchisees from the definition of ''worker'' because, in some cases, the relationship between a franchisor and franchisee may be more analogous to the relationship between two businesses than the relationship between an employer and a worker.[952] The Commission also noted that the evidentiary record relates primarily to non-competes that arise out of employment. However, the Commission stated that, in some cases, franchisor/franchisee non-competes may present concerns under section 5 similar to the concerns presented by non-competes between employers and workers and sought comment on coverage of franchisor/franchisee non-competes.[953]

b. Comments Received

Many commenters requested that the final rule cover franchisor/franchisee non-competes. Numerous commenters contended the franchisee-franchisor relationship is closer to a relationship between a worker and an employer than a relationship between businesses. These commenters argued that franchisees are often individual business owners who, like workers, lack bargaining power to negotiate over non-competes. One commenter stated that the Commission acknowledged in the Franchise Rule that franchisees generally lack bargaining power.[954] Several commenters, including industry commenters representing franchisees, argued that franchisees tend to suffer even greater power imbalances than workers because many risk significant personal assets to start their franchises. According to these commenters, this risk places acute strain on franchisees' bargaining leverage when negotiating to renew franchise agreements because, if they choose to reject a new agreement, they not only lose the opportunity to continue working in the same field due to their non-compete, but also the value of their investment.

Commenters seeking coverage of franchisor/franchisee non-competes also stated that these non-competes do not protect legitimate interests because franchisors generally do not entrust franchisees with trade secrets or details about their broader commercial strategy. These commenters stated that, even if franchisees do receive such information, franchisors have less restrictive alternatives for protecting it, including NDAs and trade secret law. Some commenters also stated that non-competes have anticompetitive effects because franchisors may degrade the quality of inputs or raise input prices without fearing that their existing franchisees will leave for a competitor.

Many franchisee commenters also stated their desire to compete after exiting their franchise relationships. Franchisees also stated that their non-competes harm their negotiating position in bargaining over franchise renewal terms. These franchisees stated that franchisors can impose higher royalty rates or other less favorable terms over time as the franchisees feel powerless to refuse or make effective counteroffers, due to their non-competes. Many franchisees asserted that their non-competes are overbroad because they restrain individual owners' spouses and other close relatives from competing in the same industry. Some franchisees stated that their non-competes include penalties for choosing

[946] 15 U.S.C. 18; 15 U.S.C. 45; *Univ. Health, Inc.,* 938 F.2d at 1214–16.

[947] *Id.*

[948] *See, e.g., In the Matter of RWJ Barnabas Health and Saint Peters Healthcare Sys.,* Docket No. 9409 (Jun. 2, 2022) (complaint); *FTC* v. *Advoc. Health Care,* No. 15 C 11473, 2017 WL 1022015, at *1 (N.D. Ill. Mar. 16, 2017); *FTC* v. *Penn State Hershey Med. Ctr.,* 838 F.3d 327, 332 (3d Cir. 2016).

[949] *See, e.g.,* FTC, *Competition in the Health Care Marketplace, https://www.ftc.gov/tips-advice/competition-guidance/industry-guidance/health-care; FTC, Overview of FTC Actions in Health Care Services and Products* (2022), *https://www.ftc.gov/system/files/ftc_gov/pdf/2022.04.08%20Overview%20Healthcare%20%28final%29.pdf;* Joseph Farrell et al., *Economics at the FTC: Retrospective Merger Analysis with a Focus on Hospitals,* 35 Rev. Indus. Org. 369 (2009), *http://link.springer.com/content/pdf/10.1007%2Fs11151-009-9231-2.pdf;* FTC, *Examining Health Care Competition* (Mar. 20–21, 2014), *https://www.ftc.gov/news-events/events-calendar/2014/03/examining-health-care-competition;* FTC & Dep't of Justice, *Examining Health Care Competition* (Feb. 24–25, 2015), *https://www.ftc.gov/news-events/events-calendar/2015/02/examining-health-care-competition; Improving Health Care: A Dose of Competition, supra* note 945.

[950] *See, e.g.,* FTC, *FTC Policy Perspectives on Certificates of Public Advantage* (Aug. 15, 2022), *www.ftc.gov/copa;* FTC, *Physician Group and Healthcare Facility Merger Study* (ongoing, initiated Jan. 2020), *https://www.ftc.gov/enforcement/competition-matters/2021/04/physician-group-healthcare-facility-merger-study;* Christopher Garmon, *The Accuracy of Hospital Merger Screening Methods,* 48 RAND J. of Econ. 1068 (2017), *https://www.ftc.gov/system/files/documents/reports/accuracy-hospital-merger-screening-methods/rwp_326.pdf;* Joseph Farrell, et al., *Economics at the FTC: Hospital Mergers, Authorized Generic Drugs, and Consumer Credit Markets,* 39 Rev. Indus. Org. 271 (2011), *http://link.springer.com/content/pdf/10.1007%2Fs11151-011-9320-x.pdf;* Devesh Raval, Ted Rosenbaum, & Steve Tenn, *A Semiparametric Discrete Choice Model: An Application to Hospital Mergers,* 55 Econ. Inquiry 1919 (2017).

[951] NPRM at 3511, 3520.

[952] *Id.* at 3511.

[953] *Id.* at 3520.

[954] Trade Regulation Rule on Franchising and Business Opportunity Ventures, 43 FR 59614, 59625 (Dec. 21, 1978).

not to renew their contracts even if they do not compete.

Other commenters, primarily franchisors and trade organizations, stated that franchisor/franchisee non-competes should be excluded from the final rule. Many of these commenters argued that franchisor/franchisee non-competes are more similar to restrictive covenants between businesses than non-competes between employers and workers. Some of these commenters argued that franchisor/franchisee non-competes are more justified than non-competes in the employment context because, unlike employment relationships, entering into a franchise agreement is completely voluntary. Some commenters argued that, unlike non-competes in the employment context, franchisor/franchisee non-competes are only entered into by individuals with access to substantial capital and who therefore always have the option of starting their own businesses.

Many of these commenters argued that prohibiting non-competes for franchisees would threaten to severely disrupt or destroy the franchise business model, and that this would harm franchisors and franchisees alike, as franchising offers a unique opportunity for working people to become entrepreneurs with established brands. Commenters asserted non-competes are critical to the franchise business model because they offer both franchisors and franchisees confidence that existing franchisees will likely stay with a brand and refrain from using a franchise's trade secrets to unfairly compete against the franchisor. Commenters also asserted that franchisees are often exposed to proprietary information through training manuals and operational support and that non-competes help protect this information. In addition, commenters contended franchisor/franchisee non-competes protect investments made by other franchisees and maintain a franchise's goodwill.

Commenters supporting the exclusion of franchisor/franchisee non-competes from the final rule also asserted that the Commission lacked an evidentiary basis for covering such non-competes. These commenters also claimed no State has prohibited non-competes for franchisees, and the Commission would therefore lack data from natural experiments to justify extending a final rule to the franchise context.

c. The Final Rule

The Commission continues to believe that, as many commenters attested, franchisor/franchisee non-competes may in some cases present concerns under section 5 similar to the concerns presented by non-competes between employers and workers. The comments from franchisors, franchisees, and others provide the Commission with further information about non-competes in the context of the franchisor/franchisee relationship, but the evidentiary record before the Commission continues to relate primarily to non-competes that arise out of employment. Accordingly, the final rule does not cover franchisor/franchisee non-competes. Non-competes used in the context of franchisor/franchisee relationships remain subject to State common law and Federal and State antitrust laws, including section 5 of the FTC Act.

VI. Section 910.4: Relation to State Laws and Preservation of State Authority and Private Rights of Action

In proposed § 910.4, the Commission addressed State laws and preemption. Based on comments, the Commission adopts a modified provision clarifying and explaining that States may continue to enforce laws that restrict non-competes and do not conflict with the final rule, even if the scope of the State restrictions is narrower than the final rule.[955]

A. The Proposed Rule

The NPRM contained an express preemption provision, proposed § 910.4, that explained the proposed rule preempted State laws inconsistent with the rule and did not preempt State laws that offer greater protection than the rule. The NPRM explained that when a State law offers greater protection than the rule, employers would be able to comply with both the NPRM and the State law. Thus, the proposed rule would have established a regulatory floor, but not a ceiling. The NPRM provided two hypothetical examples, one of a State law that would be inconsistent with, and therefore preempted by, proposed § 910.2(a) and one that would not because it satisfied the savings clause by offering greater protection and was not inconsistent with proposed part 910.[956]

B. Authority for Preemption

Numerous commenters supported the preemption of inconsistent State laws. Some commenters asserted the Commission lacks the legal authority to preempt State laws, including State common law, on non-competes because Congress allegedly did not confer the necessary authority to the Commission or because of federalism principles. They argued there must be clear Congressional intent to preempt State laws relating to non-competes.[957] Numerous commenters asserted the Commission lacks clear authority from Congress to preempt State laws on non-competes, arguing the FTC's statutory authority neither expressly nor impliedly authorizes preemption of non-competes. Commenters made similar points based on cases about the preemptive force of the Commission's UDAP regulations. For example, one commenter asserted the FTC may not have the authority to preempt less restrictive State laws, citing *American Optometric Association* v. *FTC,* in which the court noted the need for congressional authorization for the Commission to preempt an entire field of State laws that arise from the State's police powers.[958]

The Commission finds it has the authority to promulgate regulations that preempt inconsistent State laws under section 6(g), together with section 5, of the FTC Act. Even without an express preemption provision, Federal statutes and regulations preempt conflicting State laws. Under the Supreme Court's conflict preemption doctrine, a Federal statute or regulation impliedly preempts State laws when it is impossible for the regulated parties to comply with both the Federal and the State law, or when a State law is an obstacle to achieving the full purposes and objectives of the Federal law.[959] ''Federal regulations have no less pre-emptive effect than Federal statutes.'' [960] Indeed, even commenters who questioned the FTC's authority to preempt State laws agreed that if a Federal agency promulgates a rule pursuant to its Congressionally conferred authority, the rule preempts conflicting State laws.

As discussed in Parts II.A, II.B, and II.C, the Commission has the authority to promulgate this final rule. Accordingly, the final rule preempts conflicting State laws. To provide a clear explanation of the Commission's intent and the scope of preemption effected by the final rule, the final rule includes an express preemption

[955] State statutes, regulations, orders, or interpretations, including State common law, are referred to as ''State laws'' for ease of reference.

[956] NPRM at 3515.

[957] Comments on the Commission's authority to promulgate this final rule, separate from the issue of preemption of State law, are summarized in Part II.

[958] *Am. Optometric Ass'n* v. *FTC,* 626 F.2d 896, 910 (1980).

[959] *See, e.g., Federal Preemption: A Legal Primer,* Cong. Rsch. Serv., 23 (May 18, 2023) (Report R45825), *https://crsreports.congress.gov/product/pdf/R/R45825/3.*

[960] *Fid. Fed. Sav. & Loan Ass'n* v. *de la Cuesta,* 458 U.S. 141, 153 (1982).

provision at § 910.4.[961] As discussed in Part VI.D, the Commission has modified proposed § 910.4 to make clear that even when the scope of non-compete prohibitions under a State law is less than that of the final rule, State authorities and persons may enforce the State law by, for example, bringing actions against non-competes that are illegal under the State law.

C. The Benefits of Preemption

Numerous commenters stated that variations in State laws chill worker mobility and expressed support for a uniform Federal standard. Some commenters explained that a preemption clause could bring clarity to the law's effect.

The U.S. Department of Justice commented that, due to the patchwork of State laws, a worker may be free to switch jobs in one jurisdiction but subject to a non-compete in another, creating uncertainty as to the non-compete's enforceability for both firms and workers.[962] In another commenter's view, the variation in State non-compete laws creates competitive disadvantages for companies in States that ban such clauses, necessitating a Federal ban.

Another commenter pointed out that most States have not passed statutes that ban or restrict non-competes, and that existing statutes cover different categories of workers and different wage levels, making it difficult for workers to know whether employers can enforce a particular non-compete. The commenter stated that variations in the legal authority of State attorneys general to take action on the public's behalf also limit the effectiveness of State restrictions on non-competes. A number of commenters explained that the difficulties arising from variations in State non-compete laws are exacerbated by the increase in remote and hybrid work, and workers who travel to work across State lines. Accordingly, many commenters favored a uniform Federal standard that would promote certainty for employers and workers. Even some commenters who generally opposed banning non-competes favored preemption to eliminate the patchwork of State laws that makes it difficult for workers to know the applicable law and encourages forum shopping by employers who want to bring suits in sympathetic jurisdictions.

Other commenters opposed preemption, asserting that State legislatures and courts are best situated to address non-competes and that the States have historically regulated this area. They contended States should be allowed to continue adjusting the scope of restrictions on non-competes including applicability to different types of workers, time span, and geographic scope.

The Commission finds that preemption of State laws, including State common law, that conflict with the final rule best mitigates the negative effects of the patchwork of State laws, including chilling worker mobility and undercutting competitive conditions in labor and product and services markets.[963] Preempting this patchwork with a Federal floor is particularly important given the increase in work across State lines, and remote and hybrid work, since the COVID–19 pandemic.

Moreover, as discussed in Part IX.C, preemption furthers a primary goal of the final rule: to provide a uniform, high level of protection for competition that is easy for both employers and workers to understand and makes it less likely that employers will subject workers to illegal non-competes or forum shop. Indeed, some commenters who otherwise opposed the proposed ban on non-competes regarded the patchwork itself burdensome to employers as well as workers and noted the rule would reduce burden by eliminating uncertainty and confusion caused by State law variations.[964] As described in Part IX.C, the Commission has determined that declining to issue this final rule and continuing to rely solely on State laws and case-by-case adjudication would be less effective than issuing a clear national standard. The Commission concludes, however, that supplementing the final rule with additional State authority and resources, so long as the State laws are not inconsistent with the final rule, will assist in protecting both workers and competition.

D. The Extent of Preemption

Some commenters strongly supported the NPRM but expressed concern that the preemption provision as proposed could undermine States' efforts to curb non-competes and would thereby undercut the final rule's effectiveness. These commenters stated that under one interpretation, proposed § 910.4 could preempt State laws that prohibit non-competes for workers earning less than a specified income because the law as a whole may not be deemed to provide greater protection than the final rule. In their view, such an interpretation would not further the final rule's goals, because States with income-based restrictions on non-competes rather than complete bans may offer covered workers protections against non-competes that the FTC's proposed rule would not provide, such as State enforcement, private rights of action, and certain financial penalties.[965]

These commenters also asserted that in many cases, State agencies and residents could be better positioned to respond to unlawful non-compete use specific to a particular State, but they would be unable to do so and dependent on the Commission if their laws were fully preempted. To enable concurrent enforcement of State laws that restrict the use of non-competes, thereby increasing the enforcement resources devoted to the issue, they recommended a ''savings clause'' that would exempt from preemption State laws that provide workers with protections substantially similar to or greater than those afforded by the

[961] Many FTC regulations, including regulations promulgated under section 6(g) of the FTC Act, include provisions addressing State laws and preemption. *See, e.g.,* Funeral Rule, 16 CFR 453.9 (exempting from preemption State laws that ''afford an *overall* level of protection that is *as great as, or greater than,* the protection afforded by'' the FTC's Rule) (emphasis added); Concerning Cooling Off Period for Sales Made at Homes or at Certain Other Locations, 16 CFR 429.2(b) (exempting laws and ordinances that provide ''a right to cancel a door-to-door sale that is *substantially the same or greater* than that provided in this part'') (emphasis added); Business Opportunity Rule, 16 CFR 437.9(b) (''The FTC does not intend to preempt the business opportunity sales practices laws of any [S]tate or local government, except to the extent of any conflict with this part. A law is not in conflict with this Rule if it affords prospective purchasers *equal or greater protection*[.]'') (emphasis added); Mail, internet, or Telephone Order Merchandise Rule, 16 CFR 435.3(b) (''This part does supersede those provisions of any State law, municipal ordinance, or other local regulation which are inconsistent with this part to the extent that those provisions do not provide a buyer with rights which are *equal to or greater* than those rights granted a buyer by this part.'') (emphasis added); Franchise Rule, 16 CFR 436.10(b) (''The FTC does not intend to preempt the franchise practices laws of any [S]tate or local government, except to the extent of any inconsistency with part 436. A law is not inconsistent with part 436 if it affords prospective franchisees *equal or greater protection*[.]'') (emphasis added); Labeling and Advertising of Home Insulation, 16 CFR 460.24(b) (preemption of ''State and local laws and regulations that are inconsistent with, or frustrate the purposes of this regulation''). *See also* Part II.B.

[962] Comment of Dep't of Justice Antitrust Div., FTC–2023–0007–20872 at 7.

[963] *See* Part IX.C.

[964] *See, e.g.,* Comment of Mech. Contractors Ass'n of Am., FTC–2023–0007–18218 (although opposed to the proposed rule, MCCA's position supports a single Federal rule and some level of preemption).

[965] *See* Comment of the Attys. Gen. of 17 States and DC, FTC–2023–0007–21043, at 14–15 (''jurisdictions like Colorado, Illinois, Washington, and the District of Columbia have passed laws that ban non-competes for workers making under a specified income threshold and also include remedies provisions that authorize [S]tate agencies and residents to enforce the law''); *id.* at 9–11 (discussing State enforcement, private action, and damages in several State non-compete laws).

rule.[966] They also recommended that the rule not preempt State antitrust and consumer protection laws that may protect workers against non-competes and other restrictive employment arrangements as those laws can provide another enforcement avenue for State agencies and residents.

Another commenter recommended including a narrow reverse preemption provision so that relevant State laws in States that enact the Uniform Restrictive Employment Agreement Act[967] would not be preempted.[968] The comment asserted that by doing so, a final rule would preserve a role for the States and encourage their cooperation with the Commission, and also provide greater protections for employees than the proposed rule provided in several ways, such as allowing for greater enforcement and including classes of employers that the final rule would not cover.[969] The uniform law would ban non-competes for workers earning at or below the State's annual mean wage and would allow non-competes for those earning more, but apply limits and require disclosures for any non-compete.

Based on comments, the Commission has modified the final rule's preemption provision to clarify and explain that State laws that restrict non-competes and do not conflict with the final rule are not preempted. Section 910.4 also expressly references State common law, antitrust law, and consumer protection law, so that the intended scope of preemption is clear. State common law is expressly referenced because many States do not have a general non-compete statute, and the common law varies considerably.

Section 910.4(b) reflects the Commission's intent that States may continue to enforce in parallel laws that restrict non-competes and do not conflict with the final rule, even if the scope of the State restrictions is narrower than that of the final rule. That is, State laws cannot authorize non-competes that are prohibited under this final rule, but States may, for example, continue to pursue enforcement actions under their laws prohibiting non-competes even if the State laws prohibit a narrower subset of non-competes than this rule prohibits.

Accordingly, § 910.4(a) states that the final rule will not be construed to annul, or exempt any person from complying with, any State statute, regulation, order, or interpretation applicable to a non-compete, including, but not limited to, State antitrust and consumer protection laws and State common law. Rather, the final rule supersedes such laws to the extent, and only to the extent, that such laws would otherwise permit or authorize a person to engage in conduct that is an unfair method of competition under § 910.2(a) or conflict with the notice requirement in § 910.2(b).[970] These revisions provide that when States have restricted non-competes and their laws do not conflict with the final rule, employers must adhere to both provisions, and workers are protected by both provisions (including State restrictions and penalties that exceed those in Federal law).

For example, § 910.4 makes clear that the final rule does not preempt State law enforcement where a State bans non-competes only for workers earning below a certain amount and thus has a ban that is narrower than the final rule. Thus, if a State's law bars non-competes only for workers who earn less than $150,000 per year, the final rule and the law are different in scope of protection but not directly inconsistent. The State may continue to enforce its ban for workers earning less than $150,000, but all non-competes covered by the final rule, regardless of a worker's earnings, remain an unfair method of competition under the final rule and are therefore unlawful.

In response to concerns raised by commenters and to further bolster the consistent use of State laws, the Commission expressly recognizes State authority and the existence of private rights of action arising under State laws that restrict non-competes or bar unfair methods of competition. This is set forth in § 910.4, now titled ''Relation to State laws and preservation of State authority and private rights of action,'' and is detailed in § 910.4(b). That section provides that unless a State law conflicts with the final rule and is superseded as described in § 910.4(a), part 910 does not limit or affect the authority of State attorneys general and other State agencies or the rights of a person to bring a claim or regulatory action arising under State laws, including State antitrust and consumer protection laws and State common law. Section 910.4(b) also explains that persons retain the right to bring a claim or regulatory action under State laws unless the laws conflict with the final rule and have been superseded as described in § 910.4(a).

These modifications are consistent with many commenters' recommendations and recognize State-based enforcement as a potent force that supplements Federal enforcement. In addition, the modifications, particularly those that explain § 910.4 does not exempt any person from complying with State laws, are intended to curb the use of preemption as a defense against State restrictions of non-competes.[971] Under the final rule, States may continue to play a critical role in restricting the use of non-competes. In contrast to the FTC Act, which cannot be enforced by private persons or State authorities,[972] the non-compete laws of numerous States provide for such enforcement.[973] Non-competes that are outside the FTC's jurisdiction or otherwise outside the scope of the final rule may be covered by State non-compete laws.[974] State penalties can be substantial and may be particularly important as a deterrent.

The modifications also reflect the Commission's long history of working in concert with States and encouraging concurrent enforcement of State laws to pursue common goals. While the Commission recognizes this will leave some variation in the enforcement exposure covered persons face among States, that variation will be greatly reduced by the final rule, which sets a

[966] Another comment recommended a similar formulation, which would exempt from preemption State laws that offer workers protection that is equal to or greater than the protection provided by the final rule. This commenter asserted that this formulation would allow existing State law to stand.

[967] *See* Uniform Restrictive Employment Agreement Act, *supra* note 332 at sec. 5, sec. 8.

[968] *See* Comment of ULC, FTC–2023–0007–20940.

[969] *See also* Part II.E (discussing comments on the Commission's jurisdiction under the FTC Act).

[970] The effect of part 910 is limited to non-competes. It would not broadly preempt other uses of State antitrust and consumer protection law.

[971] *See, e.g., Sprietsma* v. *Mercury Marine,* 537 U.S. 51, 62–70 (2002) (finding Federal Boat Safety Act did not relieve defendant from liability for State common law tort claim because it did not expressly nor impliedly preempt State common law).

[972] *See, e.g.,* FTC, A Brief Overview of the Federal Trade Commission's Investigative, Law Enforcement, and Rulemaking Authority App. A (May 2021), *https://www.ftc.gov/about-ftc/mission/enforcement-authority; Holloway* v. *Bristol-Myers Corp.,* 485 F.2d 986, 997 (D.C. Cir. 1973).

[973] Comment of the Attys. Gen. of 17 States and DC, FTC–2023–0007–21043 at 7 (''jurisdictions like Colorado, Illinois, Washington, and the District of Columbia have passed laws that ban non-competes for workers making under a specified income threshold and also include remedies provisions that authorize state agencies and residents to enforce the law''). *See also* 2023 Cal. Legis. Serv. Ch. 157 (S.B. 699) West (adding Cal. Bus. & Prof. Code sec. 16600.5, Sept. 1, 2023) (providing for a private right of action in regard to California's non-compete statute).

[974] *See* Part II.E (discussing the Commission's jurisdiction under the FTC Act). *See, e.g.,* Cal. Bus. & Prof. Code secs. 16600–16602 (broad coverage); Minn. Stat. Ann. sec. 181.988, subdiv. 1 (b) (''''Employer' means any individual, partnership, association, corporation, business, trust, or any person or group of persons acting directly or indirectly in the interest of an employer in relation to an employee.'').

floor that applies nationally.[975] As it has done in the past, the Commission will ''share the field'' with States and partner with them in the battle against abusive non-competes.[976] As set out in Part IX.C, the Commission considered and rejected the alternative of relying on existing State laws alone. Consistent with that determination, the Commission declines to adopt the suggestion from a comment that relevant State laws in States that enact the Uniform Restrictive Employment Agreement Act not be preempted.

VII. Section 910.5: Severability

The Commission stated in the NPRM that it may adopt a severability clause[977] and it received a comment stating the Commission should adopt such a clause to protect the rights and securities of workers if one part of the rule or one category of workers were invalidated. The Commission adds § 910.5, together with this section, to clarify the Commission's intent.[978]

Section 910.5 states that if any provision of the final rule is held to be invalid or unenforceable either facially, or as applied to any person or circumstance, or stayed pending further agency action, such invalidity shall not affect the application of the provision to other persons or circumstances or the validity or application of other provisions. Section 910.5 also states that if any provision or application of the final rule is held to be invalid or unenforceable, the provision or application shall be severable from the final rule and shall not affect the remainder thereof. This provision confirms the Commission's intent that the remainder of the final rule remain in effect in the event that a reviewing court stays or invalidates any provision, any part of any provision, or any application of the rule—including, for example, an aspect of the terms and conditions defined as non-competes, one or more of the particular restrictions on non-competes, or the standards for or application to one or more categories of workers.

The Commission finds that each of the provisions, parts of the provisions, and applications of the final rule operate independently and that the evidence and findings supporting each provision, part of each provision, and application of each provision stand independent of one another. In this final rule, the Commission determines that certain conduct is an unfair method of competition in Part IV.B and Part IV.C and differentiates between senior executives and workers who are not senior executives with respect to existing non-competes. The final rule distinguishes between the two in both the final rule's operation and in the bases for adopting the final rule. The difference in restrictions among different workers, and the distinct bases for adopting the restrictions, is described in detail in Parts IV.B and IV.C. The Commission also estimates the effect of excluding senior executives entirely from the rule in Part X.F.11 and finds that the benefits of covering only those workers who are not senior executives justify the costs.

The Commission promulgates each provision, part of each provision, and application of each provision as a valid exercise of its legal authority. Were any provision, part of any provision, or any application of any provision of the final rule stayed or held inapplicable to a particular category of workers, to particular conduct, or to particular circumstances, the Commission intends the remaining elements or applications of the final rule to prohibit a non-compete between covered persons and covered workers as an unfair method of competition.

In Parts IV.B and IV.C, the Commission finds that the use of non-competes is an unlawful unfair method of competition under section 5 of the FTC Act because it is restrictive and exclusionary conduct that tends to negatively affect competitive conditions in several independent ways. In support of its finding that the use of non-competes is an unlawful unfair method of competition for workers who are not senior executives, the Commission additionally finds that the use of non-competes is exploitative and coercive in Part IV.B.2.b.

The Commission relies principally on empirical evidence regarding the effects of changes in non-compete enforceability, both when finding in Part IV.B.3.a and Part IV.C.2.c.ii that the use of non-competes tends to negatively affect competitive conditions in labor markets, and when finding in Part IV.B.3.b and Part IV.C.2.c.i that the use of non-competes tends to negatively affect competitive conditions in product and service markets. The Commission further analyzes and quantifies these effects in Part X.F.6, including sensitivity analyses that compare the estimated effects of smaller changes in enforceability and larger changes in enforceability.

Based on this empirical evidence and analysis, the Commission believes that more limited application of the rule—which might result were a court to render the final rule inapplicable in some way—may be equivalent to smaller changes in the enforceability of non-competes in the empirical literature. As described in Part IV.B.3.a and IV.B.3.b, smaller changes in enforceability change the magnitude, but not the directional nature, of the labor market and product and service market effects.[979] Accordingly, consistent with the findings related to the use of certain non-competes being an unfair method of competition in Part IV, the empirical evidence on the use of non-competes, the regulatory impact analysis in Part X, and its expertise, the Commission finds that any smaller reduction in enforceability resulting from circumstances in which a court stays or invalidates some application of the final rule would not impair the function of the remaining parts of the final rule nor would it undermine the justification or necessity for the final rule as applied to other persons, conduct, or circumstances. The Commission intends for any remaining application of the final rule to be in force because it is committed to stopping any and all unlawful conduct related to the use of certain non-competes and the Commission finds every use of a non-compete covered by the final rule to be an unlawful unfair method of competition under section 5 of the FTC Act.[980]

In Part X, the Commission conducts a regulatory impact analysis for the final rule as applied to all workers, as applied to all workers other than senior executives, and as applied to senior executives. The Commission finds that the asserted benefits of the use of non-competes do not justify the harms from the use of non-competes for any category of workers. The Commission's findings and differential analysis demonstrate that the asserted benefits from the use of non-competes do not justify the harms from the use of non-competes for higher- or lower-wage earners, including, for example, lower-wage workers defined as workers whose total annual compensation is less than $151,164.

[975] The Commission has taken this position in previous regulations. *See, e.g.,* Part 429—Cooling-Off Period for Door-to-Door Sales, 37 FR 22934 (Oct. 26, 1972).

[976] For a previous example, *see* Trade Regulation Rule; Funeral Industry Practices, 47 FR 42260, 42287 (Sept 24, 1982) (noting the purpose of the rule's provision addressing relation of the rule to State law is ''to encourage [F]ederal-[S]tate cooperation by permitting appropriate [S]tate agencies to enforce their own [S]tate laws that are equal to or more stringent than the trade regulation rule'').

[977] NPRM at 3518–19 & n.429.

[978] In the NPRM, proposed § 910.5 addressed the compliance date.

[979] *See also* Part X.F.6.

[980] *See* NPRM at 3518–19.

For instance, if, for any reason, a reviewing court were to stay or invalidate the final rule as applied to senior executives, the Commission would intend for the remainder of the final rule to apply to all workers other than senior executives. Likewise, if a reviewing court were to stay or invalidate the final rule to apply to workers other than senior executives, the Commission would intend for the remainder of the final rule to apply to senior executives. Additionally, if a reviewing court were to stay or invalidate the final rule as applied to some other subset of workers, the Commission would intend for the remainder of the final rule to apply to all but those workers. So, for example, if a reviewing court were to stay or invalidate the final rule as applied to workers other than lower-wage workers—defined as workers whose total annual compensation is less than $151,164—the Commission would intend for the remainder of the final rule to apply to those workers, and further notes the evidentiary record demonstrates that application of the rule to those remaining workers would be beneficial and achieve lawful objectives. In the same way, if a reviewing court were to stay or invalidate the provision of the final rule regarding enforcing an existing non-compete or the notice requirement, the Commission would intend for the remainder of the final rule to apply. As described in Part IX.C, although the Commission concludes that a national standard is most effective, a number of States currently apply different standards to different workers and States also apply a myriad of legal standards to non-competes generally. Accordingly, were a reviewing court to stay or invalidate a particular application of the final rule, a covered person could simply comply with the provisions, parts of provisions, or applications of the final rule that remain in effect.

The Commission's adoption of the final rule does not hinge on the same restrictions applying to all non-competes, on the final rule applying to all workers, or on joint adoption or operation of each provision. Accordingly, the Commission considers each of the provisions adopted in the final rule to be severable, both within each provision and from other provisions in part 910. In the event of a stay or invalidation of any provision, any part of any provision, or of any provision as it applies to certain conduct or workers, the Commission's intent is to otherwise preserve and enforce the final rule to the fullest possible extent.

VIII. Section 910.6: Effective Date

The Commission adopts a uniform effective date of 120 days after publication of the final rule in the **Federal Register**. The final rule will go into effect, and compliance with the final rule will be required, on that date. Based on comments urging the Commission to reduce the compliance period from the 180-day period proposed in the NPRM so that the benefits of the final rule may be obtained as soon as possible, the Commission's findings that the use of non-competes is exploitative and coercive for the vast majority of workers, and modifications in the final rule that reduce covered entities' compliance burden, the Commission modifies the date that compliance with the final rule is required from 180 days to 120 days after publication in the **Federal Register**.

A. The Proposed Rule

In the NPRM the Commission proposed a compliance date of 180 days after publication of the final rule in the **Federal Register**. The Commission stated that, during the compliance period, employers would need to: (1) assess whether to implement replacements for existing non-competes (such as NDAs), draft those covenants, and then negotiate and enter into those covenants with the relevant workers; (2) remove any non-competes from employment contracts that they provide to new workers; and (3) rescind, no later than the date that compliance is required, any non-competes that it entered into prior to the compliance date.[981] The Commission preliminarily found that 180 days would be enough time for employers to accomplish all of these tasks.[982] The NPRM would have also required employers to provide the notice specified in proposed § 910.2(b)(2) within 45 days of rescinding the non-compete.[983]

The Commission also stated that it proposed to establish an effective date of 60 days after the final rule is published in the **Federal Register** even though compliance would not be required for 180 days.

[981] *Id.* at 3483, 3515–16. In the NPRM and herein, the Commission refers to the period between the publication of the final rule and the date on which compliance with the final rule is required as the ''compliance period.'' *See id.* at 3515.

[982] *Id.* at 3516.

[983] *Id.* (addressing compliance with proposed § 910.2(b)(2)).

B. Comments Received

Many worker commenters urged the Commission to act as quickly as possible to bring the final rule into force, citing the current acute, ongoing harms to their earnings, mobility, quality of life, and other significant impacts and noting the final rule's potential for immediate relief if their non-compete was no longer in force. Representatives of many local governments from different States contended that the negative effects of non-competes and the anticipated benefits of the proposed rule justified allowing the Commission's rule to go into effect as soon as possible. Other commenters supported the compliance date as proposed or favored other measures to obtain the anticipated benefits of the final rule as soon as practicable. Another commenter contended that the 180-day compliance period was sufficient to allow businesses to ensure compliance and suggested that the Commission move the effective date back to the day or the day after the final rule is published.[984]

Several commenters suggested the Commission adopt a longer compliance period of one year, 18 months, or two years. These commenters generally stated that businesses need more time to adjust their compensation packages, contracting practices, and employee policies to comply with the rule and to protect their intellectual property. At least one commenter also argued the Commission should adopt a two-year compliance period to allow courts sufficient time to hear and resolve challenges to the final rule. One commenter asserted that the compliance period would be especially burdensome for smaller business. Another industry commenter argued application of the rule should be phased in over time.

C. The Final Rule

The Commission adopts a 120-day compliance period. As outlined in Parts IV.B and IV.C, based on both voluminous comments from the public as well as a significant body of empirical evidence, the Commission finds that the use of non-competes is coercive and exploitative for the vast majority of workers across different earnings levels and occupations and that for all workers it tends to negatively affect competitive conditions in labor markets and also tends to negatively affect competitive conditions in product and service markets—and that such actual harms are in fact currently ongoing. The Commission adopts a 120-

[984] The comment did not consider the limitations on the effective date imposed by the CRA.

day compliance period to stop these unfair methods of competition as soon as practicable. The Commission finds that a 120-day period appropriately balances the interests at hand.

The Commission has taken several steps in the final rule to make compliance as simple as possible for employers. These steps make it practicable and reasonable to require compliance within 120 days. The final rule allows regulated entities to enforce existing non-competes with senior executives, who commenters contended are most likely to have complex compensation arrangements that include non-competes. Accordingly, there is no need for a lengthy compliance period, as the most complex existing arrangements are left in place. The Commission also eliminated the rescission requirement for all workers. Under the final rule, employers will not need to rescind (*i.e.,* legally modify) existing non-competes for any workers; rather, employers will simply be prohibited from enforcing them after the effective date of the final rule and will be required to provide the notice in § 910.2(b)(1).[985] While employers are required to provide notice to workers with existing non-competes who are not senior executives, under § 910.2(b), the final rule provides model safe harbor language that satisfies the notice requirement.[986] The final rule gives employers several options for providing the notice—on paper, by mail, by email, or by text.[987] And employers are exempt from the notice requirement where the employer has no record of a street address, email address, or mobile telephone number for the worker.[988] Furthermore, as explained in Part IV.E, the Commission has simplified the notice requirement to facilitate employers' ability to comply by simply sending a mass communication such as a mass email to current and former workers.

Starting on the effective date of the final rule, employers will be prohibited from entering into new non-competes barred by this final rule and from enforcing non-competes that the employer entered into prior to that date with workers other than senior executives. Prior to the effective date employers will need to identify each of their workers with existing non-compete agreements and can assess which, if any, are senior executives and determine if they wish to maintain those non-competes. Employers will also need to assess and revise, if necessary, any employment policies or handbooks that purport to bind workers even after the effective date.

To the extent they have confidential business information, trade secrets, or other investments to protect with respect to a particular worker, employers will be able to assess their options to lawfully protect that information. However, new protections will be unnecessary in many cases, because, for example, 95.6% of workers subject to non-competes are already subject to an NDA.[989] In the rare case where compensation might be tied to a non-compete that is not with a senior executive, the employer and worker can determine whether to amend their original employment agreement. The Commission concludes that the 120-day compliance period gives employers more than sufficient time to complete these tasks. For example, firms routinely complete entire onboarding processes for new employees in much shorter timeframes than 120 days.

The Commission also finds that the 120-day compliance period gives small businesses enough time to comply with the final rule. Although small businesses may have limited staff and funds compared to larger firms, they also have fewer workers, and the exclusion for existing non-competes for senior executives will relieve the compliance burden altogether for those small firms that use non-competes only with those workers. Moreover, the steps the Commission has taken to reduce the compliance burden of § 910.2(b) will further simplify and streamline compliance for small businesses.

The Commission has also determined it is not necessary to extend the compliance period to give courts time to adjudicate pending non-compete litigation because, as described in Part V.C.3, the Commission has adopted § 910.3(b), which provides that the final rule does not apply where a cause of action related to a non-compete arose prior to the effective date. The Commission also finds that a longer compliance period is not needed to hear and resolve challenges to the final rule, especially given the ability of a challenger to seek a preliminary injunction.

In sum, the Commission finds that due to modifications reducing covered entities' burden to comply with the final rule, a compliance period of 120 days is sufficient time to comply with the final rule. Given these changes the longer compliance period proposed in the NPRM is no longer warranted and would allow the use of certain non-competes that are an unfair method of competition—and their related harms and costs—to continue for longer than necessary. The substantial benefits to competition and to workers of the final rule taking effect as soon as possible outweigh any concerns about potential difficulties in meeting an earlier compliance date.

The Commission also adopts a 120-day effective date. The Commission concludes that it would ease the burden of implementation and reduce possible confusion by having a uniform date for when the final rule goes into effect and when compliance under the final rule is required. A 120-day effective date complies with the requirements of the Congressional Review Act that a ''major rule'' may not take effect fewer than 60 days after the rule is published in the **Federal Register**.

IX. Alternative Policy Options Considered

The Commission proposed to ban non-competes categorically, with a limited exception for non-competes entered into by a person who is selling a business entity. In the NPRM, the Commission discussed and sought comment on potential alternatives to the proposed categorical ban, including discrete alternatives that would implement a rebuttable presumption of unlawfulness or apply different standards to different categories of workers.[990] The Commission also sought comment on whether a rule should apply a different standard to senior executives, and whether, in lieu of the proposed rule, the Commission should adopt a disclosure rule or reporting rule.[991] The Commission sought comment on all aspects of potential alternatives, including whether the Commission should adopt one of the identified alternatives or some other alternative instead of the proposed rule.[992] The Commission also sought comment on the extent to which a uniform Federal standard for non-competes would promote certainty for employers and workers.[993]

The Commission received many comments on these questions, as well as on the question of whether the Commission should issue a Federal standard for non-competes or continue relying on existing law and case-by-case litigation to address harms from non-

[985] *See* Part IV.E (describing why the Commission is not finalizing a rescission requirement).

[986] § 910.2(b)(4) and (5).

[987] § 910.2(b)(2)(ii).

[988] § 910.2(b)(3).

[989] Balasubramanian, Starr, & Yamaguchi, *supra* note 74 at 44.

[990] NPRM at 3516.

[991] *Id.* at 3519–21.

[992] *Id.* at 3521.

[993] *Id.* at 3497.

competes. In this section, the Commission discusses the comments received regarding these alternatives and the reasons it has decided not to adopt them. This Part IX addresses these comments but does not address alternatives related to the design of specific regulatory provisions, which are discussed in the Part addressing the relevant provision.

A. Categorical Ban vs. Rebuttable Presumption

1. The Rebuttable Presumption Alternative Generally

While preliminarily finding that a categorical ban would best achieve the proposed rule's objectives, the Commission nevertheless sought comment on the alternative of a rebuttable presumption, under which it would be presumptively unlawful for an employer to use a non-compete, but a non-compete would be permitted if the employer could meet a certain evidentiary burden or standard.[994] The Commission also sought feedback on the form any rebuttable presumption should take.[995]

Most commenters that addressed this issue, including those both supporting and opposing the proposed rule, discouraged the Commission from including a rebuttable presumption in the final rule. These commenters contended that a rebuttable presumption would add complexity and uncertainty to the rule.

Supporters of the proposed rule asserted that a rebuttable presumption would undermine the rule's effectiveness, failing to deter employers from imposing non-competes while making litigation too uncertain and costly for most workers to pursue. Some of these commenters contended that a rebuttable presumption would also do little to reduce the chilling effects of non-competes. They argued that employers would continue to impose non-competes that are unlikely to survive a rebuttable presumption.

Many commenters critical of the proposed rule opposed a rebuttable presumption for essentially the same reasons they opposed the rule in general. They contended that, in States where non-competes are generally enforceable, a rebuttable presumption would inappropriately shift the burden of proof from workers to employers. Many of these commenters specifically opposed a rebuttable presumption that would use a test similar to antitrust law's ''quick look'' analysis, contending that the Commission's analysis of empirical research on non-competes cannot substitute for the lengthy experience courts usually have with a particular restraint before giving it quick-look treatment. A few commenters contended that a rebuttable presumption would increase litigation and raise employers' compliance costs by complicating the determination of whether a given non-compete is likely valid, requiring more lawyer involvement in drafting clauses and more reliance on courts to determine a non-compete's validity.

A few commenters supported a rebuttable presumption, arguing the Commission's proposed ban on non-competes was too blunt an instrument. Some also contended that a rebuttable presumption would offer a more flexible approach akin to the majority of State law approaches. At least one commenter stated a rebuttable presumption would make the final rule more likely to survive judicial review. A few commenters stated a rebuttable presumption would provide more protections than most State laws by allowing only non-competes that the commenter contended are not unfair to the worker, such as where highly paid workers agree to narrow non-competes in exchange for bargained-for consideration. One commenter argued a rebuttable presumption would enable the Commission to accrue more experience adjudicating non-competes and assessing their impact on competition.

Commenters advocating for a rebuttable presumption generally preferred a test focusing on one or more factors, including: the non-compete's geographic scope and duration; the presence and amount of any liquidated damages or penalty provision; whether the clause is narrowly tailored to prevent competition with actual competitors; the restrained worker's duties and income; and the availability of less restrictive alternatives. A few commenters supported a ''preponderance'' (as opposed to a ''clear and convincing'') standard to permit as many non-competes as possible but acknowledged that such a rule may be so similar to the existing common law as to be redundant.

After carefully reviewing and considering the comments, the Commission concludes that a rule implementing a rebuttable presumption is not preferrable to the final rule as adopted. Based on the Commission's expertise, including careful review and consideration of the entire rulemaking record, the Commission finds that a rebuttable presumption would be less effective than the final rule for achieving the Commission's stated goals. A rebuttable presumption also presents administrability concerns that the final rule does not.

Overall, the comments reinforced the Commission's concerns that a rebuttable presumption would foster substantial uncertainty about the validity of a given non-compete and would do little to reduce the *in terrorem* effects of non-competes. Research demonstrates that employers maintain non-competes even where they likely cannot enforce them,[996] that many workers are not aware of the applicable law governing non-competes or their rights under those laws,[997] and that the degree to which non-competes inhibit worker mobility is affected not only by whether a non-compete is actually enforceable but also on whether a worker believes their employer may enforce it.[998] Accordingly, the Commission concludes that a rule implementing a rebuttable presumption would be inadequate to reduce the prevalence of non-competes, their chilling effect on worker mobility, or their tendency to negatively affect competitive conditions. Relatedly, the Commission believes a rebuttable presumption would increase litigation costs for workers and employers relative to the final rule as adopted.

The Commission also believes that, in important respects, a rebuttable presumption for non-competes is inconsistent with the Commission's findings in this final rule. As discussed in greater detail in Part IX.C, a rule that provides for case-by-case, individualized assessment of non-competes is unlikely to address the negative effects of non-competes on competition in the aggregate. In addition, by focusing on considerations specific to the worker and the employer, a rebuttable presumption is unlikely to address the external effects of non-competes (*i.e.,* the effects on persons other than the parties to the non-compete), including their negative effects on the earnings of workers who are not covered by non-competes.

The Commission recognizes there may be some benefits to a rebuttable presumption relative to the status quo. Because it puts the burden of proof on employers, a rebuttable resumption would be stricter than the current law in States where non-competes are allowed, and research suggests even a small decrease in enforceability would increase worker mobility, raise wages,

[994] *Id.* at 3517.

[995] *Id.* at 3517–19.

[996] *See* Part IV.B.2.b.

[997] *See* Prescott & Starr, *supra* note 413.

[998] Starr, Prescott, & Bishara, *supra* note 68 at 633, 652, 664.

and promote innovation.[999] But the categorical ban adopted in the final rule would have greater benefits in these respects without the drawbacks explained in this Part IX.A.1.

2. Discrete Alternatives Related to Rebuttable Presumptions

In the NPRM, the Commission also sought comment on four discrete alternatives to the proposed rule: Alternative #1 (categorical ban below some threshold, rebuttable presumption above); Alternative #2 (categorical ban below some threshold, no requirements above); Alternative #3 (rebuttable presumption for all workers); and Alternative #4 (rebuttable presumption below some threshold, no requirements above).[1000]

As explained in Part IX.A.1, the Commission finds a rebuttable presumption would be ineffective in addressing the harms to competitive conditions caused by non-competes. For the same reasons, the Commission declines to adopt Alternatives #1, #3, and #4, all of which contemplated a rebuttable presumption for some or all workers.

While the vast majority of commenters supported the Commission's proposal to ban non-competes categorically for all workers, a number of commenters suggested that the Commission permit non-competes with senior executives (or other highly skilled or highly paid workers) and other workers. The Commission addresses these comments in Part IV.C and V.D.1, where it finds that such non-competes tend to negatively affect competitive conditions in labor markets and in product and service markets, and that non-competes are also exploitative and coercive for workers other than senior executives. For these reasons, the Commission declines to adopt Alternative #2, which contemplated imposing no requirements on workers above a certain wage or other threshold.

B. Other Discrete Alternatives

1. Disclosure Rule

In the NPRM, the Commission sought comment on the potential alternative of adopting disclosure requirements related to non-competes.[1001] The Commission explained that the rule could, for example, require an employer to disclose to a worker prior to making an employment offer that the worker will be subject to a non-compete and/or to explain the terms of the non-compete and how the worker would be affected by signing it.[1002] The Commission noted that a 2021 study by Starr, Prescott, and Bishara finds that disclosure of non-competes to workers prior to the acceptance of a job offer was associated with increased earnings, rates of training, and job satisfaction.[1003] The authors of the study, however, cautioned that their analysis ''should not be interpreted causally,'' a point the Commission noted in explaining why it gave minimal weight to the study.[1004] The Commission preliminarily concluded in the NPRM that a disclosure requirement would not achieve the objectives of the proposed rule.[1005]

In general, commenters stated they agreed with the Commission's preliminary view that, while there may be some benefits to a disclosure rule, it would not achieve the objectives of the rule. Workers and worker advocacy groups stated that non-competes are often presented to workers on their first day on the job, or after they accept an employment offer. Although these commenters generally supported a comprehensive ban, they noted that if the Commission did not pursue a ban, a disclosure requirement may help improve workers' awareness of non-competes before accepting an offer. On the other hand, these commenters contended that a disclosure rule would do little to reduce the prevalence of non-competes, because workers have little choice but to accept non-competes, which are typically presented as ''take-it-or-leave-it'' terms and are ubiquitous in many fields.

Many trade organizations, advocacy groups, and academics who were generally supportive of the rule stated that a disclosure rule would fail to mitigate the competitive harms caused by non-competes in the aggregate. While acknowledging a disclosure rule may ameliorate some problems related to worker awareness of non-competes, these commenters contended that non-competes are unfair and coercive because employees generally lack adequate bargaining power to refuse to sign or bargain over non-competes even when they are presented at the time of an employment offer, and that a disclosure rule would therefore not have the effect of making non-competes less unfair or coercive. A few commenters opposed a disclosure rule generally but urged the Commission to adopt a disclosure requirement for any non-competes permitted by the final rule, including for any non-competes entered into by a person who is selling a business.

On the other hand, some trade organizations, advocacy groups, and businesses that generally opposed the rule advocated for the Commission to adopt a disclosure rule in lieu of the proposed categorical ban. These commenters contended that a disclosure rule would substantially mitigate the unfairness of non-competes that are entered into without adequate notice to the worker without drastically altering the legal status quo, thereby maintaining the protections for trade secrets, training expenditures, and intellectual property they contend that non-competes provide. They stated that eight States and the District of Columbia have statutory notice requirements for non-competes.

Most of the commenters who supported a disclosure rule also argued that rather than demonstrating that non-competes tend to negatively affect competitive conditions, the available evidence merely demonstrates opportunistic behavior by employers (such as presenting non-competes only after prospective workers have taken hard-to-reverse steps towards accepting employment) and workers (such as seeking to be excused from a non-compete after recognizing its impact on future job prospects). These commenters asserted that a disclosure rule would be better suited to address these types of opportunistic behaviors than a categorical ban.

Some commenters based their support for a disclosure rule on their contention that workers have sufficient bargaining power to negotiate over non-competes when they are provided with notice of them. One such commenter pointed to the cited research by Starr, Prescott, and Bishara finding that disclosure of non-competes to workers prior to acceptance of a job offer may increase earnings, increase rates of training, and increase job satisfaction.[1006] The commenter also referenced the study's finding that of those workers who did not attempt to negotiate a non-compete, 52% reported that they thought the terms were reasonable and 41% reported that they assumed the terms to be non-

[999] Johnson, Lavetti, & Lipsitz, *supra* note 388 (decreasing enforceability increases worker mobility and earnings); Johnson, Lipsitz, & Pei, *supra* note 526 at 2–5 (enforceability negatively impacts patent quantity and quality).

[1000] NPRM at 3519.

[1001] *Id.* at 3521 n.446 (noting certain provisions in the Commission's Franchise Rule (16 CFR part 436), such as § 436.5(i) and (q), require non-competes to be disclosed to a franchisee).

[1002] *Id.* at 3521.

[1003] *Id.,* citing Starr, Prescott, & Bishara, *supra* note 68 at 75.

[1004] *Id.* at 3487, citing Starr, Prescott, & Bishara, *supra* note 68 at 73.

[1005] *Id.* at 3521.

[1006] Starr, Prescott, & Bishara, *supra* note 68 at 75.

negotiable.[1007] The commenter contended that a disclosure rule would decrease the number of workers who assumed non-competes were non-negotiable.

A few commenters contended a disclosure rule may be more likely to withstand judicial review because the Commission could promulgate a disclosure rule in this context under its UDAP authority pursuant to the Magnuson-Moss Act. In addition, a few commenters requested the Commission adopt timing rules for when the disclosure must be provided, such as by requiring that employers disclose a non-compete in the job advertisement, at the time of the job offer, or at least five business days prior to the worker's deadline to sign an employment agreement.

The Commission declines to adopt a disclosure rule.[1008] The Commission finds that merely ensuring workers are informed about non-competes would not address the negative externalities non-competes impose on workers, rivals, and consumers. As described in Part IV.B.3.a.ii, non-competes suppress wages for workers across the labor force, including workers who are not subject to non-competes. Ensuring that a worker who enters into a non-compete is informed about the non-compete does not address the harm to these other workers. In addition, it does not address the ways in which non-competes harm consumers and the economy through reduced new business formation and innovation, described in Part IV.B.3.b. In other words, non-competes have negative spillover effects on workers, consumers, businesses, and the economy that disclosure cannot remediate.

The Commission also finds that a disclosure requirement would not be as effective as a categorical ban in addressing the exploitation and coercion of workers through non-competes. As described in Part IV.B.2.b.i, there is a significant imbalance in bargaining power between employers and most workers, which is particularly acute in the context of negotiating employment terms such as non-competes. And, as many comments from workers and worker advocacy groups attest, non-competes are often included in standard-form contracts and offered on a take-it-or-leave-it basis.[1009] As a result, workers have limited practical ability to negotiate non-competes even if they are notified of such clauses prior to accepting their employment offer. Indeed, as described in Part IV.B.2.b.i, the comment record reflects that very few workers (other than senior executives) bargain over their non-competes—whether the worker knew about the non-compete before the job offer and understood its terms, or not.

The Commission gives the findings of the Starr, Prescott, and Bishara study on the impacts of disclosure little weight because the study reflects only correlation, not causation, with respect to the effects of a disclosure rule (similar to the ''use'' studies the Commission gives little weight to, as described in Part IV.A.2). The study merely compares a set of workers whose firms disclosed the non-compete and workers whose firms did not, and any correlation may thus be attributable to confounding factors. This comparison—similar to comparisons of workers with and without non-competes—may be polluted by differences between firms that opt to disclose non-competes and those that do not, or differences between workers who are the beneficiaries of disclosure versus those who are not.[1010] For example, it is possible that firms that disclose non-competes are also more responsible employers in general that tend to pay their workers more, train their workers more, and have more satisfied workers. The Commission therefore does not find that this evidence represents a causal relationship between the disclosure of non-competes and earnings and other outcomes. Moreover, the weight of the evidence discussed in Parts IV.B and IV.C finding increased earnings, new business formation, and innovation from the final rule significantly surpass the potential effects of disclosing non-competes.

One commenter stated that the Starr, Prescott, and Bishara study suggests that a disclosure rule would decrease the number of workers who assume a non-compete with which they are presented is non-negotiable. The study suggests that the potential effects of a disclosure rule in this respect would be, at best, limited.[1011] For the reasons described in this Part IX.B.1, the Commission is skeptical that a disclosure requirement would meaningfully increase the share of workers who actually bargain over non-competes.

A disclosure rule may address some deceptive or misleading practices in connection with non-competes. However, considering that a disclosure rule is not likely to significantly reduce the negative competitive impacts of non-competes on labor markets and on product and service markets, this benefit is significantly outweighed by the limitations of a disclosure rule.[1012]

The Commission further concludes that a disclosure rule is not necessary for non-competes in the context of sales of a business entity. As described in Part V.A, persons selling a business entity tend to have bargaining power in the context of the transaction, and the Commission is unaware of evidence that deceptive and misleading practices in connection with non-competes (such as waiting to disclose a non-compete until after the job offer) are common with respect to business sales.

2. Reporting Rule

In the NPRM, the Commission sought comment on a reporting rule as a potential alternative to the proposed rule.[1013] The Commission stated that it could require employers to report certain information to the Commission relating to their use of non-competes; for example, employers that use non-competes could be required to submit a copy of the non-compete to the Commission.[1014] As the Commission explained, a reporting rule might enable the Commission to monitor the use of non-competes and could potentially discourage employers from using non-competes that are not clearly justified under existing law.[1015]

The Commission stated in the NPRM that it did not believe a reporting rule would achieve the objectives of the proposed rule. The Commission stated that merely requiring employers to report their non-competes to the Commission would not meaningfully reduce the prevalence of non-competes and would therefore fail to reduce the negative effects non-competes have on competitive conditions in labor markets and product and service markets.[1016] At the same time, the Commission stated that a reporting rule would impose

[1007] *Id.* at 72.

[1008] The Commission notes that the Franchise Rule requires franchisors to disclose any non-compete that franchisees must impose on managers. 16 CFR 436.5(o)(3). These non-competes are prohibited by the final rule. *See* Parts III.D and V.D.6.

[1009] *See* Part IV.B.2.b.i.

[1010] Indeed, the authors of this study note that ''unobservables may more plausibly account for these estimates.'' *See* Starr, Prescott, & Bishara, *supra* note 68 at 77 n.35.

[1011] *Id.* at 72. The study finds that 38% of workers asked to sign a non-compete before accepting a job offer assumed they could not negotiate, versus 48% of workers asked after accepting a job offer.

[1012] The Commission considered whether a disclosure rule would be appropriate for senior executives, but concludes that it is not because it would fail to address many of the ways in which non-competes are restrictive and exclusionary and tend to negatively affect competitive conditions.

[1013] *Id.* at 3521.

[1014] *Id.*

[1015] *Id.*

[1016] *Id.*

significant and recurring compliance costs on employers.[1017]

Most commenters addressing this topic agreed with the Commission's preliminary view that a reporting rule would not achieve the goals of the proposed rule. At least one business opposed any reporting requirement due to the cost of compliance and to avoid exposing any confidential information contained in employment agreements. At the same time, some commenters stated that a reporting rule may assist enforcement and provide quantitative data sets to measure compliance, while recognizing that such benefits would lose significance if the Commission were to adopt the proposed rule. One commenter suggested that, to improve the effectiveness of any reporting rule, any such rule should include a provision stating that any non-competes which were not properly disclosed to State and Federal authorities are null and void.

The Commission declines to adopt a reporting rule. A reporting rule would impose recurring compliance costs on employers, compared with the proposed rule, which largely imposes one-time costs. At the same time, a reporting rule would be inadequate to address the negative effects of non-competes on competitive conditions in labor markets and product and service markets, or the Commission's concerns about exploitation and coercion through the use of non-competes, since it would allow for the continued use of non-competes.

3. Limitations on Scope and Duration

In addition to those alternatives listed in the NPRM, a few commenters suggested adopting an alternative rule that allows non-competes but sets a limitation on their geographic scope and/or duration. Some commenters suggested a geographic limit of five, ten, or thirty miles and/or a temporal limit of six months or one, two, or three years, while others suggested a fact-specific requirement that the geographic scope or duration of a non-compete be ''reasonable.'' Many of these commenters cited State laws that take a similar approach.

A few commenters opposed this alternative. One worker advocacy group argued that any bright-line limit may end up serving as a default, encouraging employers to impose non-competes of the maximum allowable scope or duration even if that limit is longer or broader than they otherwise would have imposed. At least one academic commenter argued that setting geographic scope or duration limitations on non-competes is unlikely to have a substantial impact, pointing to the continued prevalence of overly broad non-competes despite State laws designed to set upper limits on geographic scope and duration.

The Commission declines to adopt a standard providing that the geographic scope or duration of non-competes must be ''reasonable.'' The Commission is concerned a reasonableness standard would foster significant uncertainty among workers and businesses about the enforceability of non-competes, for the same reasons a rebuttable presumption would. In addition, as described in Part II.C.1 of the NPRM, all States where non-competes are enforceable currently apply a reasonableness standard, so a Federal reasonableness standard would not mitigate the negative effects of non-competes that are presently occurring.

The Commission also declines to adopt the alternative of imposing limits on the scope and duration of non-competes. Such a rule would be insufficient to address the negative effects of non-competes on competitive conditions in labor markets or products and services markets. Although a non-compete that lasts for a shorter duration or within a smaller geographic area curtails job mobility for the individual worker it binds to a lesser degree, it nonetheless curtails the worker's job mobility and the ability of competing employers to recruit and access talent. Non-competes limited in duration and scope still tend to inhibit efficient matching between workers and employers, with spillover effects on new business formation and innovation through the mechanisms described in Parts IV.B and IV.C. Furthermore, limitations on the scope and duration of non-competes would not address the spillover effects from non-competes on other workers and consumers. In short, even if a non-compete applies only to a relatively delimited location or time period, it still—by design—cuts off free and fair competition in labor and product and service markets.

In addition, most of the commenters who stated that they were exploited and coerced by non-competes did not do so on the basis that the non-compete was overbroad in scope or duration. Instead, most of the commenters who described the terms of their non-competes described limits on scope and duration that were within the bounds of what is typically permissible under State law.[1018] Some of these commenters even stated expressly that they were subject to the non-compete that was standard or typical in their field. Even these commenters, however, explained how they were exploited and coerced in connection with non-competes because the non-compete was unilaterally imposed and because the non-compete trapped them in worse jobs or forced them to bear significant harms or costs. For these reasons, the Commission declines to adopt bright-line limits on the scope and duration of non-competes.

4. Compensation Requirement

Some commenters requested that the Commission adopt an alternative that would permit non-competes so long as the worker is compensated. Some commenters pointed to Massachusetts and Oregon law governing non-competes under which, for certain workers, non-competes may be enforced if, *inter alia,* they include a minimum level of compensation or consideration to the worker separate from compensation for employment.[1019]

The Commission declines to adopt a rule requiring compensation for non-competes. First, such a rule would not address the harms to competitive conditions that non-competes cause, which result in harm to other workers, to rivals of employers, and to consumers. The Commission finds in Parts IV.B.3.a.ii and IV.C.2.c.ii. that non-competes harm workers other than the workers who sign them, by reducing the number of job opportunities and thereby inhibiting efficient matching for all workers. The Commission further finds in Parts IV.B.3.b and IV.C.2.c.i that non-competes inhibit new business formation and innovation, which affects consumers. Therefore, even if a worker were fully compensated for a non-compete, the fact of that compensation would not redress these negative externalities. Second, this alternative would be ineffective or significantly less effective because of the *in terrorem* effect of non-competes, which the Commission finds to be grounded in empirical evidence and supported by the comment record described in Part IV.B.2.b. Third, such a rule would be difficult to administer and potentially easy to evade, as employers could suppress other wages or job quality while labeling some compensation as attributable to the non-compete.

5. Combination of Different Alternatives

Some commenters suggested the possibility of combining two or more of the alternatives discussed in this Part IX

[1017] *Id.*

[1018] *See* Part IV.B.2.b.

[1019] Mass. Gen. Laws Ann. ch. 149, sec. 24L; Or. Rev. Stat. Ann. sec. 653.295.

in place of a categorical ban. While a combination of these regulations or limitations might modulate some of the ways in which non-competes are exploitative and coercive, they would not be as effective as a comprehensive ban. In particular, a combination approach would lack the clarity of a comprehensive ban and thus would not be as effective as a categorical ban in addressing the exploitation and coercion of workers through non-competes. Moreover, as noted previously, the alternatives discussed would do little to address the tendency of non-competes to negatively affect competitive conditions and to cause spillover effects on other workers and on consumers. Accordingly, a combination of these alternative regulations or limitations would fail to remedy the aggregate and spillover effects of non-competes and thus would not achieve the Commission's stated goals.

C. The No-Action Alternative: Reliance on Existing Legal Frameworks Instead of a Clear National Standard

The Commission sought comment on whether a Federal standard for non-competes would promote certainty for employers and workers.[1020] The Commission finds that a clear national standard for non-competes will more effectively address non-competes' tendency to negatively affect competitive conditions than case-by-case adjudication or relying on existing law alone. The Commission also finds that declining to adopt the final rule, and instead relying on case-by-case adjudication or existing law alone, would not address the exploitation and coercion of workers through non-competes.

1. Comments Received

Many commenters expressed support for the NPRM because they viewed current laws as insufficient to protect all workers, rivals, or consumers, regardless of where they are located, from the negative effects of non-competes on competitive conditions in labor markets and markets for products and services. Numerous workers, businesses, and other commenters said the patchwork of State laws and confusion about those laws, particularly reasonableness tests, makes it difficult for workers and businesses to understand the law and in turn contributes to the use of unenforceable or overbroad non-competes and chills worker mobility. Several commenters also said that case-by-case adjudication and reasonableness tests make it difficult for parties to predict outcomes, which in turn raises litigation costs. Even some organizations opposed to the proposed rule or who supported a different policy believed that a Federal rule could be beneficial, such as to businesses operating in multiple jurisdictions.

In addition, according to commenters, case-by-case adjudication under State law cannot address the harms caused by non-competes through their use in the aggregate. Some commenters also asserted that the patchwork of State laws is complicated by remote and hybrid workers. Others argued that State laws are skewed in favor of employers or leave workers vulnerable to unreasonable agreements. Some argued that many workers, businesses, non-competes, and labor markets cross State lines, demonstrating the need for one standard. Several State Attorneys General also said that numerous complications arise when localities span more than one State and those States have different laws on non-competes; workers become confused and enforcement of non-competes can have spillover effects in another State.[1021]

In contrast, many commenters stated that case-by-case adjudication is preferable to a Federal rule because it allows individual facts to be considered. In addition, many commenters argued that existing State legislative and judicial decisions are sufficient to impose limitations on non-competes while recognizing legitimate business interests. Commenters also argued that States should be allowed to continue their natural experiments with non-competes; that non-competes historically have been and should remain an issue of State law; and that States are best suited to make policy judgments for their citizens.

Some commenters argued that unenforceable or overly broad non-competes are not a problem because courts can strike down or reform them. Some employers asserted that they specifically, or employers more generally, did not enter into unenforceable non-competes. Other commenters argued that employers did not use choice of law clauses to evade State laws, stating the clauses are the products of arms-length bargaining and provide certainty and predictability.

2. Responses to Comments and the Commission's Findings

a. The Value of Rulemaking

The Commission has the authority to make rules and regulations to carry out the FTC Act's prohibition on unfair methods of competition under sections 5 and 6(g) of the FTC Act as described in Parts II.A through II.C, and the Supreme Court has stated that agencies generally have discretion to choose between rulemaking and adjudication.[1022] Based on the empirical evidence, the comments, and the Commission's expertise, the Commission finds that rulemaking is the appropriate method of addressing non-competes.

The prevalence of non-competes across the economy, described in Part I.B.2, and the scale of the harms they cause, described in Parts IV.B and IV.C, show that it is more efficient to address the harms to competition from non-competes via rulemaking compared to case-by-case adjudication. As the D.C. Circuit stated in ruling that the Commission had the authority to promulgate unfair methods of competition rules, ''the availability of substantive rule-making gives any agency an invaluable resource-saving flexibility in carrying out its task of regulating parties subject to its statutory mandate.'' [1023] The Commission estimates that there are 2.92 million firms using non-competes in the U.S.[1024] Adjudicating individual cases against even just one-tenth of 1% of these employers would be slow, inefficient, and costly for the Commission, employers, and workers. Rulemaking provides notice of the application of section 5 to non-competes in a clearer and more accessible way than piecemeal litigation and avoids compliance delays.[1025] The final rule will provide all market participants greater clarity about their obligations under section 5 of the FTC Act, facilitating compliance. Additionally,

[1020] NPRM at 3497.

[1021] Comment of the Attys. Gen. of 17 States and DC, FTC–2023–0007–21043 at 11.

[1022] *SEC* v. *Chenery Corp.,* 332 U.S. 194, 203 (1947); *NLRB* v. *Bell Aerospace Co. Div. of Textron, Inc.,* 416 U.S. 267, 293 (1974); Wright & Miller, Federal Practice and Procedure sec. 8117 (2d ed. 2023).

[1023] *Nat'l Petroleum Refiners Ass'n* v. *FTC,* 482 F.2d 672, 681–82 (D.C. Cir. 1973); *see also id.* at 690 (stating that ''the historic case-by-case purely adjudicatory method of elaborating the Section 5 standard and applying it to discrete business practices has not only produced considerable uncertainty'' but has also spawned lengthy litigation).

[1024] *See* Part X.F.6 (estimating that 49.4% of the 5.91 million firms in the U.S. use non-competes).

[1025] *See* Wright & Miller, Federal Practice and Procedure sec. 8117 (2d ed. 2023); *Nat'l Petroleum Refiners,* 482 F.2d at 690 (''[W]hen delay in agency proceedings is minimized by using rules, those violating the statutory standard lose an opportunity to turn litigation into a profitable and lengthy game of postponing the effect of the rule on their current practice. As a result, substantive rules will protect the companies which willingly comply with the law against what amounts to the unfair competition of those who would profit from delayed enforcement as to them.'') (citation omitted).

the final rule will simplify enforcement proceedings by streamlining the proof required.[1026]

In addition, the principal harms from non-competes arise from their tendency to negatively affect competitive conditions in the aggregate. A single non-compete with a single worker may not do much to inhibit efficient matching between workers and employers across a labor market or suppress new business formation or innovation (and what effects it does have would be difficult to measure), but the Commission finds based on empirical evidence that the use of many non-competes across the labor market does have these aggregate net negative effects.[1027] For this reason, rulemaking is preferable to individual litigation for addressing the negative effects of non-competes. Past Commission experience has also illustrated that case-by-case enforcement, education, and other enforcement mechanisms are not always sufficient to stop widespread harms.[1028] A Federal rulemaking is the most efficient method to address the scale of harm to competitive conditions in labor, product, and service markets caused by non-competes.

Finally, ''utilizing rule-making procedures opens up the process of agency policy innovation to a broad range of criticism, advice and data that is ordinarily less likely to be forthcoming in adjudication.'' [1029] Rulemaking is particularly beneficial when, as here, ''a vast amount of data had to be compiled and analyzed, and the Commission, armed with these data, had to weigh the conflicting policies.'' [1030] Rulemaking also allows for more fulsome engagement from the public by providing for public comment on a complete regulatory scheme. The Commission greatly benefited from the submitted comments.

[1026] *See Nat'l Petroleum Refiners,* 482 F.2d at 690 (''With the issues in Section 5 proceedings reduced by the existence of a rule delineating what is a violation of the statute or what presumptions the Commission proposes to rely upon, proceedings will be speeded up.'').

[1027] *See* Part IV.B.3.a–b.

[1028] *See, e.g.,* Combating Auto Retail Scams Trade Regulation Rule, 89 FR 590, 600 (Jan. 4, 2024) (stating that rulemaking was necessary because certain unfair and deceptive acts and practices had persisted despite more than a decade of Federal and State enforcement, education, and other action in the motor vehicle dealer marketplace).

[1029] *Nat'l Petroleum Refiners,* 482 F.2d at 683 (citations omitted); *see also* Wright & Miller, Federal Practice and Procedure sec. 8117 (2d ed. 2023).

[1030] *Nat'l Petroleum Refiners,* 482 F.2d at 683 (citations omitted).

b. Case-by-Case Litigation Alone Cannot Address the Negative Effects of Non-Competes on Competition

The Commission finds that case-by-case litigation alone is insufficient to address the harms to competition from non-competes due to the cost of litigation, which deters many workers from challenging non-competes, and the limited resources of public enforcement agencies. In addition, individual litigation is not well-suited to redress the negative externalities non-competes impose on other workers, other employers, consumers, and the economy from their use in the aggregate.

Many commenters addressed the shortcomings of individual litigation as a means for addressing the harms of non-competes. Numerous commenters noted that litigation is costly and many workers cannot afford to litigate their non-competes.[1031] Many commenters, including workers, entrepreneurs, and employment attorneys, shared examples of five-figure and six-figure litigation costs related to non-compete lawsuits. Numerous commenters reported that the fear of litigation costs induced them to refrain from seeking or accepting other work or starting a business, even though they thought the non-compete was likely unenforceable. Many other commenters stated that they complied with a non-compete after they were threatened with enforcement, even though they were unsure about the non-compete's enforceability. One study finds that 53% of workers subject to non-competes are hourly workers,[1032] who are particularly unlikely to be able to afford a court challenge.

Commenters also noted some non-competes include liquidated damages clauses or fee-shifting provisions requiring the worker to pay the employer's attorney and other costs if the employer wins, further increasing the costs (and risks) of challenging a non-compete. In addition, commenters stated that litigation is time-consuming and could take as long or longer than the non-compete period. For example, one commenter shared a decision in the commenter's own case where the appellate court found the non-compete violated public policy by leaving an area with only one surgeon in a specialty—but reached that decision only after the two-year non-compete had already run its course.[1033] Commenters also said workers who sued their employer could experience reputational harm and difficulty finding work going forward.

Litigation can be even riskier if a court might reform a non-compete, which leaves the worker subject to some restrictions even if the initial non-compete was impermissibly broad. Several commenters cited a *Harvard Law Review* article that discusses the consequences of allowing courts to sever or reform overbroad non-competes:

> For every covenant that finds its way to court, there are thousands which exercise an *in terrorem* effect on employees who respect their contractual obligations and on competitors who fear legal complications if they employ a covenantor, or who are anxious to maintain gentlemanly relations with their competitors. Thus, the mobility of untold numbers of employees is restricted by the intimidation of restrictions whose severity no court would sanction. If severance is generally applied, employers can fashion truly ominous covenants with confidence that they will be pared down and enforced when the facts of a particular case are not unreasonable.[1034]

If there is no penalty for drafting overbroad non-competes (as is true in most States),[1035] employers have little incentive to draft non-competes narrowly, particularly if a court is likely to revise it rather than strike it down, or if a worker is unlikely to be able to litigate at all. An employment attorney commented it is particularly difficult to advise workers about whether their specific non-compete is enforceable when it is possible a court may modify the underlying non-compete.

Case-by-case litigation under other antitrust laws alone is also insufficient to address the harms from non-competes. Non-competes restrain trade and therefore are subject to the Sherman Act.[1036] While private litigants may bring private causes of action to enforce the Sherman Act,[1037] the Commission views private litigation under the Sherman Act as an ineffectual response in the context of non-competes based on the history of cases by private litigants arising under that Act, as explained in the NPRM.[1038] For an individual litigant, proving harm to competition in the relevant geographic and product markets is a resource-intensive task that

[1031] *See also* Part IV.B.2.b.ii (describing exploitative and coercive effects of the risk and cost of being subject to a non-compete suit).

[1032] Lipsitz & Starr, *supra* note 72 at 144 (analyzing data from the Starr, Prescott, & Bishara survey).

[1033] *Graham* v. *Cirocco,* 69 P.3d 194, 200 (Kan. App. 2003).

[1034] Blake, *supra* note 22 at 682–83 (noting that this may not be applicable if the worker has bargaining power and it may be inefficient to tailor non-competes to each worker, and recommending that courts only sever when they determine the employer acted fairly).

[1035] *See* NPRM at 3495.

[1036] *See* Part I.B.1.

[1037] *See* 15 U.S.C. 15.

[1038] NPRM at 3496.

typically requires expert testimony.[1039] This makes an already expensive proposition even less palatable for most workers and further tips the risk-versus-reward calculus away from litigation. In addition, to succeed on a Sherman Act claim, a plaintiff must show harm to competition as a whole, not just to themselves. It may be difficult or impossible for a worker to establish that their individual non-compete—or a single firm's use of a non-compete—adversely affected competition in a labor market or product/service market sufficiently to violate the Sherman Act.[1040] Section 5, on the other hand, is more inclusive than the Sherman Act.[1041] As outlined in Part II.F, section 5 requires a showing of indicia of unfairness and a tendency to negatively affect competitive conditions. It does not require a separate showing of market power or market definition—nor does it require proof of harm to competition by each non-compete.[1042]

Case-by-case litigation by public enforcers, such as the Commission or State attorneys general, is a potential alternative or supplement to private litigation under other antitrust laws. But the ability of public enforcers to engage in effective case-by-case litigation related to non-competes, absent a rule, is limited.

As cited in Parts I.B. and II.C.2, the FTC has previously secured consent orders premised on the use of non-competes being an unfair method of competition under section 5, and the Commission has the authority to determine that non-competes are unfair methods of competition through adjudication. However, FTC resource constraints limit the potential effectiveness of enforcement of section 5 on a purely case-by-case basis. The Commission is an independent agency that works to promote fair and open markets and protect the entire American public from unfair and deceptive business practices. The Commission has fewer than 1,500 employees for its entire body of work related to this mission,[1043] which includes investigating, challenging, and litigating anticompetitive mergers and conduct; processing and reviewing merger filings; and investigating and challenging a wide range of consumer protection issues.[1044]

Similarly, several State Attorneys General commented that the multi-factor common law approaches to non-compete law result in piecemeal decisions that do not address the non-compete problem in a uniform manner.[1045] These State Attorneys General also noted that some State enforcement agencies lack straightforward authority to enforce existing common law protections related to non-competes and argued that the challenges associated with common law enforcement underscore the need for a Federal rule.[1046] And the resource limitations to pursue non-competes comprehensively through enforcement limit States equally—if not more.

The Commission estimates that there are approximately 30 million individual non-competes in the U.S.[1047] In contrast to the large volume of non-competes, the resources of public enforcement agencies are limited. Public enforcers must balance competing demands for resources and priorities when they bring public enforcement actions. Public enforcers cannot conceivably investigate the specific details of every non-compete or initiate litigation concerning more than a small fraction of unlawful non-competes. A Federal rule provides clarity to market participants, engages all stakeholders in the development of the rule, and more effectively ceases an unfair method of competition.

The significant limitations on the ability of private and public litigants to challenge unlawful non-competes have practical implications. Courts cannot strike down an unenforceable non-compete that they never had the opportunity to review. Moreover, as detailed in Part IV.B.2.b, non-compete restrictions may still have significant *in terrorem* effects when workers are uncertain about the enforceability of their non-competes or lack the ability to challenge their use.

Furthermore, case-by-case litigation is insufficient to address negative externalities from non-competes (*i.e.,* harms non-competes cause to persons other than the parties to the non-compete). As described in Parts IV.B and IV.C, non-competes impose significant negative externalities on other workers, other firms, consumers, and the economy. Individual non-compete cases are not well-suited for redressing these harms. For example, while the precise reasonability test for non-competes differs from State to State, the test typically considers the business interest asserted by the employer; the harm to the worker; and the injury to the public from the loss of the worker's services.[1048] This test does not generally account for the harms experienced by other workers, other firms, consumers, and the economy resulting from the negative effects of non-competes on competition.

Furthermore, because the significant harms of non-competes result from their aggregate use, they are unlikely to be captured by an assessment of an individual worker's non-compete or an individual firm's use of non-competes. This is true regardless of whether those non-competes are challenged under State non-compete laws or under other antitrust laws. It is likewise true regardless of whether non-competes are challenged by private litigants or public enforcers. Accordingly, the Commission finds that case-by-case litigation alone is insufficient to address the negative externalities of non-competes.

The Commission, by contrast, is well-positioned to evaluate non-competes holistically. The Commission is an expert agency and has used its expertise to assess the weight of the empirical evidence and comment record to evaluate the aggregate effects of non-competes. The Commission here implements a clear national standard through notice-and-comment rulemaking to protect competition, based on the evidence that the use of non-competes in the aggregate negatively affects competition and harms workers and consumers.

For all these reasons, the Commission finds that case-by-case litigation is not a viable alternative to the final rule.[1049]

[1039] *See, e.g., U.S. Healthcare, Inc.* v. *Healthsource, Inc.,* 986 F.2d 589, 599 (1st Cir. 1993) (''In practice, the frustrating but routine question how to define the product market is answered in antitrust cases by asking expert economists to testify.'').

[1040] *See* NPRM at 3496–97 (discussing non-compete cases that have been brought under the antitrust laws).

[1041] *See* Part II.A.

[1042] *See* Part II.F.

[1043] FTC, *Congressional Budget Justification—Fiscal Year 2025,* at 8 (2024), *https://www.ftc.gov/system/files/ftc_gov/pdf/fy25-cbj.pdf.*

[1044] *Id.*

[1045] Comment of the Attys. Gen. of 17 States and DC, FTC–2023–0007–21043 at 7.

[1046] *Id.*

[1047] *See* Part I.B.2.

[1048] *See* NPRM at 3494–95.

[1049] A few commenters suggested that the Commission could create guidelines instead of a rule to explain what factors the agency would look at in an enforcement action. By definition, however, a guidance document would ''not have the force and effect of law.'' *Perez* v. *Mortg. Bankers Ass'n,* 575 U.S. 92, 97 (2015) (quoting *Shalala* v. *Guernsey Mem'l Hosp.,* 514 U.S. 87, 99 (1995)). Guidelines would not bind employers or courts and would not provide workers with the same clarity about the enforceability of their non-competes. Moreover, case-by-case litigation itself is not suited to address the negative externalities of non-competes, a concern the issuance of guidelines would not address. The Commission finds that the issuance of guidelines is not a viable alternative to the final rule for the same reasons that it finds that the no-action alternative generally is not a viable alternative to the final rule.

c. State Law Alone Cannot Address the Negative Effects of Non-Competes on Competition

The Commission appreciates that States have enacted legislation in recent years to ban or restrict non-competes and ameliorate their negative effects.[1050] The Commission has long recognized the value of concurrent enforcement of Federal and State law and believes States have an important role to play in restricting the use of non-competes. Indeed, in this final rule, the Commission has revised § 910.4 to ensure that States may continue to enforce laws that restrict non-competes and do not conflict with the final rule. However, the Commission believes that reliance on State law alone is insufficient to address the negative effects of non-competes on competition. The practical ability of States to address the harms to their residents from non-competes is limited by various factors, including employers' use of choice-of-law, forum-selection, and arbitration clauses; significant confusion among both employers and workers resulting from the patchwork of State law, which chills workers from engaging in competitive activity even where non-competes are likely unenforceable under State law and also increases employers' compliance costs, particularly given the increase in interstate remote work; spillover effects from other States' laws; and incentives for States to adopt permissive non-compete policies.

Many States have adopted statutory restrictions or compete bans on non-competes. Four States—California, Minnesota, North Dakota, and Oklahoma—have adopted statutes rendering non-competes void for nearly all workers.[1051] The majority of the remaining 46 States have statutory provisions or case law that ban or limit the enforceability of non-competes for workers in certain specified occupations.[1052] The general language of the test for whether a non-compete is reasonable is fairly consistent from State to State.[1053] However, the specifics of the application of the standard differ from State to State. For example, States vary in how narrowly or broadly they define legitimate business interests and the extent to which courts are permitted to modify an unenforceable non-compete. States also differ with respect to statutory restrictions on non-competes.[1054] As a result, among the 46 States where non-competes may be enforced, variation exists with respect to the enforceability of non-competes.[1055]

State law also differs with respect to the steps courts take when they conclude that a non-compete is unenforceable as drafted. As noted in the NPRM, the majority of States have adopted the ''reformation'' or ''equitable reform'' doctrines, which allow courts to revise the text of an unenforceable non-compete to make it enforceable.[1056]

Because the enforceability of non-competes and courts' positions with respect to unenforceable non-competes vary from State to State, the question of which State's law applies in a legal dispute can determine the outcome of a non-compete case. Non-competes often contain choice-of-law provisions designating a particular State's law for resolution of any future dispute.[1057] Furthermore, some non-competes include forum-selection provisions specifying the court and location where a dispute may be heard.[1058] The default rule under conflict-of-laws principles is that the court honors the parties' choice of law, meaning that the burden is typically on the worker—the vast majority of whom the Commission finds are exploited and coerced when entering into a non-compete—to negotiate for the law of a different forum to apply.[1059]

There is significant variation, however, in how courts apply choice of law rules in disputes over non-competes.[1060] As a result, it can be difficult for employers and workers to predict how disputes over choice of law (and, in turn, the enforceability of the non-compete) will be resolved.[1061] Several commenters agreed that a Federal rule would alleviate these problems.

Choice of law provisions may also mean that workers lose their own State's protections. For example, workers from States where non-competes are banned commented that they faced enforcement of non-competes that selected the law of another State. This raises the concern that choice of law clauses can be used to evade State bans or restrictions by forum shopping.[1062] As two scholars note, when ''the parties or issues involved have connections to multiple jurisdictions,'' the law ''confounds lawyers and commentators because of its complexity and unpredictability.'' [1063]

Employers may also impose arbitration clauses, which require that legal disputes with the employer—including disputes related to non-competes—be resolved through binding arbitration rather than in court.[1064] Where such clauses are valid, the Federal Arbitration Act requires that courts enforce them.[1065] Choice of law, forum selection, and arbitration clauses create opportunities for employers to forum-shop in ways that undermine any given State's ability to effectively regulate non-competes.

Numerous workers, businesses, and other commenters said the patchwork of State laws and confusion about those laws makes it difficult for workers and businesses to understand whether a particular non-compete would be enforceable. The lack of a clear national standard, and resulting confusion,

[1050] *See* NPRM at 3494 (summarizing recent State non-compete legislation).

[1051] *See* Cal. Bus. & Prof. Code sec. 16600; N.D. Cent. Code sec. 9–08–06; Okla. Stat. Ann. tit. 15, sec. 219A. Minnesota banned non-competes signed on or after July 1, 2023, after the comment period closed. Minn. Stat. Ann. sec. 181.988.

[1052] In most States, those limits apply to just one or two occupations (most commonly, physicians). *See* Beck Reed Riden LLP, *Employee Noncompetes: A State-by-State Survey* (Feb. 19, 2024), *https://beckreedriden.com/wp-content/uploads/2024/02/BRR-Noncompetes-20240219-50-State-Noncompete-Survey-Chart.pdf* (hereinafter ''Beck Reed Riden Chart'').

[1053] *See* NPRM at 3494–95.

[1054] *See, e.g.,* Beck Reed Riden Chart, *supra* note 1052.

[1055] NPRM at 3495.

[1056] *Id.*

[1057] Gillian Lester & Elizabeth Ryan, *Choice of Law and Employee Restrictive Covenants: An American Perspective,* 31 Comp. Lab. & Pol'y J. 389, 396–402 (2010).

[1058] *Id.* at 402–04.

[1059] *Id.* at 397 (''In general, courts defer to choice of law clauses because they are presumed to represent the express intention of the parties.''). *Cf.* Cal. Lab. Code sec. 925(a) (stating that employers shall not require an employee who primarily resides and works in California, as a condition of employment, to agree to a provision that would either (1) require the employee to adjudicate outside of California a claim arising in California or (2) deprive the employee of the substantive protection of California law with respect to a controversy arising in California).

[1060] Lester & Ryan, *supra* note 1057 at 394–95.

[1061] *Id.* at 395 (''The state of the law is perhaps characterized more by inconsistency than anything else, so much so that commentators lament the 'disarray' and 'mish-mash' of the law, and criticize courts for their 'post-hoc rationalizing of intuitions' or their use of a 'hodgepodge of factors, often with insignificant explanation of how they decide what weight to give each.''') (internal citations omitted).

[1062] *See generally* Timothy P. Glynn, *Interjurisdictional Competition in Enforcing Non-Compete Agreements: Regulatory Risk Management and the Race to the Bottom,* 65 Wash. & Lee L. Rev. 1381, 1386 (2008) (noting ''judicial attempts to preempt other courts from disregarding the parties' choice of law''). Some States have attempted to defend against this by enacting statutes banning selection of a different State's law for a non-compete. *See* Minn. Stat. Ann. sec. 181.988(3)(a) (Minnesota); Cal. Lab. Code sec. 925 (California); Colo. Rev. Stat. sec. 8–2–113(6) (Colorado); Mass. Gen. Laws ch. 149, sec. 24L(e) (Massachusetts); La. Rev. Stats. 23:921(2) (Louisiana). Many of these statutes are relatively recent, however, and it remains to be seen how effective they will be.

[1063] Lester & Ryan, *supra* note 1057 at 389.

[1064] *See, e.g.,* Alexander J.S. Colvin, Econ. Pol'y Inst., Report, *The Growing Use of Mandatory Arbitration* (Apr. 6, 2018).

[1065] *See, e.g., Nitro-Lift Techs.* v. *Howard,* 568 U.S. 17, 20–22 (2012).

contributes to non-competes being used in jurisdictions where they are unenforceable. Starr, Prescott, and Bishara find that employers frequently use non-competes even when they are unenforceable under State law.[1066] Similarly, Colvin and Shierholz find that 45.1% of workplaces in California use non-competes even though they are unenforceable there.[1067] Anecdotally, an economist commented that the Commission's *Prudential Security* case, in which the employer continued using non-competes after they were held unenforceable by a court, was an example of employers enforcing unenforceable non-competes.[1068]

While the Commission has no doubt that many employers aim to ensure their contracts comply with applicable law, the empirical evidence indicates that at least some employers are using unenforceable non-competes, and some workers are turning down jobs where their non-competes are likely unenforceable. Some commenters referenced Starr, Prescott, and Bishara's finding that workers frequently cite non-competes as a factor in turning down job offers in both States that enforce non-competes and in those that do not.[1069] The study also finds that workers are more likely to report that they would be willing to leave for a competitor when they did not believe their employer would attempt to enforce a non-compete in court.[1070] The study suggests that whether a worker's non-compete is enforceable may matter less than whether the employer is willing to try to enforce it.[1071] The Commission notes that this study does not necessarily indicate a causal relationship, but it does indicate that for many workers, the *in terrorem* effect of non-competes may outweigh any State protections.

Furthermore, the ability of States to address harms to their residents from non-competes is limited by spillover effects from other States. The economies of States are closely interconnected. Therefore, even where a State adopts a law that strictly regulates non-competes, such a law can be undermined by permissive non-compete laws in a nearby State.[1072]

Finally, several comments argued that State regulation of non-competes should continue by quoting Justice Brandeis's dissent in *New State Ice Co.* v. *Leibmann:* ''[i]t is one of the happy incidents of the [F]ederal system that a single courageous State may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country.'' [1073] The Commission disagrees that further laboratory testing by States is needed. States have been experimenting with non-compete regulation for more than a century, with laws ranging from full bans to notice requirements, compensation thresholds, bans for specific professions, reasonableness tests, and more.[1074] Past State experimentation and legal changes yielded a considerable body of empirical research, which as described in Parts IV.B and IV.C, demonstrates that non-competes negatively affect competitive conditions in labor markets and in product and service markets. This evidence supports the Commission's finding that non-competes are an unfair method of competition.

Individual States' non-compete policies can cause spillover effects that negatively affect competitive conditions in other States. Individual States' non-compete policies can also affect the operation of legal regimes in other States. Choice of law provisions cause confusion for workers even in States where non-competes are unenforceable. There are incentives for some States to adopt extremely permissive non-compete policies to attract employers that favor non-competes, and potentially even to enable employers to ''export'' those permissive policies to other States through choice-of-law provisions.[1075] In short, States are interconnected with respect to non-competes. Without a uniform standard through the final rule, States are forced to balance the benefit to their residents of laws regulating non-competes against the fear that some employers may shift jobs to States where non-competes are more enforceable. One benefit of the Commission's rulemaking is it resolves this problem. The rulemaking record shows banning non-competes will improve competitive conditions in all States and will benefit workers in all States.

X. Regulatory Analysis

A. Introduction

The Commission has examined the economic impacts of the final rule as required by section 22 of the FTC Act (15 U.S.C. 57b–3). Section 22 directs the Commission to issue a final regulatory analysis that analyzes the projected benefits and any adverse economic effects and any other effects of the final rule. The final regulatory analysis must also summarize and assess any significant issues raised by comments submitted during the public comment period in response to the preliminary regulatory analysis.[1076]

B. Preliminary Analysis

Pursuant to section 22 of the FTC Act, the Commission issued a preliminary regulatory analysis of its proposed rule.[1077] The preliminary regulatory analysis contained (1) a concise description of the need for, and objectives of, the proposed rule; (2) a description of any reasonable alternatives to the proposed rule that may accomplish the stated objective of the final rule in a manner consistent with applicable law; and (3) for the proposed rule and for each of the alternatives described, a preliminary analysis of the projected benefits and any adverse economic effects and any other effects.[1078]

In the preliminary regulatory analysis, the Commission described the anticipated effects of the proposed rule and quantified the benefits and costs to the extent possible. For each benefit or cost quantified, the analysis identified the data sources relied upon and, where relevant, the quantitative assumptions made. The preliminary analysis measured the benefits and costs of the proposed rule against a baseline in which the Commission did not promulgate a rule regarding non-competes and included in the scope of the analysis the broadest set of economic actors possible. Several of the benefits and costs were quantifiable, but not monetizable—especially with respect to differentiating between transfers, benefits, and costs. The Commission preliminarily found that others were not quantifiable. The

---

[1066] Starr, Prescott, & Bishara, *supra* note 68 at 53, 81.

[1067] Colvin & Shierholz, *supra* note 65 at 5–6.

[1068] *See* FTC, Analysis of Agreement Containing Consent Order to Aid Public Comment, *In re Prudential Sec., Inc. et al.,* Matter No. 211 0026 at 1, 5–7 (Dec. 28, 2022).

[1069] Starr, Prescott, & Bishara, *supra* note 68 at 633, 663.

[1070] *Id.* at 633, 652, 664.

[1071] *Id.*

[1072] *See, e.g.,* Johnson, Lavetti, & Lipsitz, *supra* note 388 (finding that increases in non-compete enforceability in one State have negative impacts on workers' earnings in bordering States, and that the effects are nearly as large as the effects in the State in which enforceability changed, but taper off as the distance to the bordering State increases).

[1073] *New State Ice Co.* v. *Leibmann,* 285 U.S. 262, 311 (1932) (Brandeis, dissenting).

[1074] *See* Beck Reed Riden Chart, *supra* note 1052.

[1075] *See, e.g.,* Glynn, *supra* note 1062 at 1385–86 (stating that ''because employers typically are the first movers in [non-compete] litigation, they often can litigate in a hospitable judicial forum,'' and noting a rise in interjurisdictional disputes related to non-compete enforcement and ''judicial attempts to preempt other courts from disregarding the parties' choice of law'').

[1076] 15 U.S.C. 57b–3(b)(2)(C), (E).

[1077] NPRM at 3521–31.

[1078] *See* 15 U.S.C. 57b–3(b)(1)(A) through (C).

preliminary analysis discussed any bases for uncertainty in the estimates.

The Commission preliminarily found substantial positive effects of the proposed rule: an increase in workers' earnings by $250–$296 billion annually (with some portion representing an economic transfer from firms to workers); an increase in new firm formation and competition; a reduction in health care prices (and prices in other markets may also fall); and an increase in innovation. The Commission noted that several of these benefits overlap (*e.g.,* increases in competition may fully or in part drive decreases in prices and increases in innovation). The Commission also preliminarily found some costs of the proposed rule. Direct compliance and contract updating would result in $1.02 to $1.77 billion in one-time costs, and firm investment in human capital and capital assets would fall.

The Commission preliminarily concluded that the substantial labor market and product and service market benefits of the proposed rule would exceed the costs. Furthermore, the Commission preliminarily found the benefits would persist over a substantially longer time horizon than most costs of compliance and contract updating.

C. Public Comments on the Preliminary Regulatory Impact Analysis

Based on the comments received, the final regulatory analysis reflects greater quantification where possible and includes sensitivity analyses to reflect different assumptions, including assumptions commenters suggested. The final regulatory analysis concludes, consistent with the preliminary analysis, that the benefits of the final rule justify the costs.

Some commenters urged the Commission to quantify the costs and benefits to a greater degree. In the final analysis, the Commission incorporates greater quantification where possible. That some effects cannot be quantified or monetized does not, however, undermine the Commission's conclusion that the benefits justify the costs.

Some commenters focused on the methodology used to estimate earnings effects in the preliminary analysis, stating that extrapolating estimated effects on earnings based on linear predictions may result in incorrect estimates. These commenters stated that linear predictions might be particularly unreliable outside the range observed in the data. While as a general matter, linear extrapolation may not be appropriate in all circumstances, especially in the absence of data supporting such an approach, the Commission notes the linear effect of non-compete enforceability on earnings was statistically tested in the economic literature.[1079]

Nevertheless, to test and confirm the robustness of the conclusions drawn in the preliminary analysis from the linear approach, in this final analysis, the Commission uses several estimation approaches. For its primary analysis, the Commission adopts an approach that does not rely on extrapolation. Specifically, the Commission assumes that the historical average change [1080] in non-compete enforceability observed at the State level represents the total change in enforceability that results from the rule. This approach is hereafter referred to as the ''average enforceability change approach.'' It likely underestimates the effects of the rule because the State-level changes that would occur under the rule (which adopts a near comprehensive ban) would be substantially larger than the changes observed historically. The Commission also conducted sensitivity analyses with two other approaches—described further in Parts X.C and X.F.6.a—that use linear extrapolation to scale up the effects estimated in the literature to estimate the effects of the final rule (*i.e.,* a near comprehensive ban).

Some commenters alleged the proposed rule would increase inflation. Some commenters also stated the proposed rule would harm shareholders by decreasing corporate profits. In response, the Commission notes that the regulatory analysis attempts to quantify and monetize real costs and benefits of the final rule as opposed to nominal costs and benefits. Therefore, net benefits are benefits that represent increased economic efficiency resulting from the final rule rather than increases in the dollar value of output that may be due to inflation. Additionally, earnings increases are due, at least in part, to increased economic efficiency, which would likely lower prices. Accordingly, the Commission does not expect that prices will rise because of the rule. Indeed, empirical evidence shows that in physician clinics, prices fall with decreased non-compete enforceability.[1081] Similarly, while the effect of the final rule on corporate profits is unclear,[1082] the Commission's analysis is focused on overall gains or losses in economic surplus—*i.e.,* the net benefits to society, not to individual corporations.

Some commenters stated that certain costs may be missing from the preliminary analysis, including costs related to worker misconduct and litigation over the validity of the final rule. The Commission finds no evidence or compelling arguments directly linking non-competes to worker misconduct and therefore does not consider such costs.[1083] Costs related to litigation over the validity of the rule are outside the scope of the regulatory analysis under section 22, which is concerned with costs and benefits should the final rule be implemented.

Some commenters stated the rule may have beneficial tax ramifications for businesses and workers with non-competes that are no longer enforceable, including based on changes in amortization schedules. In response, the Commission notes that any tax savings under the final rule represent transfers from the government to firms that previously used non-competes. Significantly, the Commission is allowing existing non-competes with senior executives, who may be most likely to have non-competes with tax implications, to remain in effect. This will mitigate the need for tax-related administrative work. In response to comments on the tax ramifications of clawed back pay, the final rule does not encourage or require firms to ''claw back'' compensation and given the exclusion for senior executives' existing non-competes in the final rule, situations in which a firm would be in a position to consider clawing back pay are likely to be extremely limited, if any.

Some commenters stated workers may be harmed if firms claw back workers' earnings, if workers lose long-term incentive payments, retention bonuses, and severance payments, or if workers must pay for training out of pocket in response to the rule. First, in Parts IV.B.3.a.iiv and X.F.6.a, the Commission finds earnings increases overall associated with decreases in non-compete enforceability. With respect to existing non-competes, non-competes

[1079] Johnson, Lavetti, & Lipsitz, *supra* note 388 at 17.

[1080] In other words, taking all changes in non-compete enforceability between 1991 and 2014 (the range studied in the relevant literature) into account, the Commission considers a change whose magnitude is equal to the average of the magnitudes of all those changes. *See* Johnson, Lavetti, & Lipsitz, *supra* note 388 for more details.

[1081] Hausman & Lavetti, *supra* note 590.

[1082] The evidence in the empirical literature is mixed. Younge & Marx (*supra* note 755) find an increase in firm value when non-competes became enforceable in Michigan. Hiraiwa, Lipsitz, & Starr (*supra* note 502) find no effect on firm value when non-competes were prohibited for the majority of workers in Washington.

[1083] *See* Part V.D.3.

with senior executives, which are most likely to be structured with incentive payments, bonuses, and severance, may remain in effect under the final rule. To the extent any other existing non-competes with such structures are not excluded from the final rule, as noted in Parts III.D and IV.D, deferred compensation and other structured payments generally have many material contingencies other than a non-compete, which means incentive payments and retention bonuses will continue to retain value for the employer. Going forward, under the final rule, agreements for deferred compensation and other structured payments may be permissible as long as they do not fall within the definition of non-compete clause in § 910.1. With respect to payments for training, the Commission notes evidence that worker-sponsored training is unaffected by legal enforceability of non-competes,[1084] and it is therefore unlikely that workers will incur costs related to training as a result of the final rule.

Some commenters disagreed with the Commission's use of patenting activity as a proxy for innovation in the preliminary analysis, stating that the value of innovation may not be captured in patenting, in part because employers may use patents as a substitute for non-competes. First, the Commission agrees that innovation likely has value above and beyond patenting. That patenting does not capture the full value of innovation is not a basis for dismissing its value as a proxy altogether. Second, while it is theoretically possible firms may substitute from the use of non-competes to the use of patents to protect intellectual property, the empirical literature shows increases in innovation do not follow from the simple substitution of protections between non-competes and patents. Specifically, the empirical literature confirms the innovations prompted by decreased non-compete enforceability are qualitatively valuable, and—examining the relationship between non-compete enforceability and patenting for drugs and medical devices, where patenting is ubiquitous [1085]—it shows the patents reflect true net increases in innovation (as opposed to substitutions). One commenter stated there can be difficulty ascertaining the value of patenting. The Commission finds that there are several estimates of the private value of a patent (*e.g.,* the value to the patenting firm) in the literature, but no estimates of the social value of a patent, as further discussed in Part X.F.6.b. The Commission therefore stops short of monetizing this benefit. The final analysis addresses effects on innovation in greater detail in Part X.F.6.b.

Some commenters asserted the research related to investment in human capital does not distinguish between two different types of training: core training, *i.e.,* training required to perform job duties, and advanced training, *i.e.,* training with potential to increase productivity beyond the baseline requirements for job performance.[1086] Commenters stated that when non-competes are more enforceable, workers may receive additional core training rather than advanced training. In other words, when non-competes are more enforceable, labor mobility decreases and workers may also move to new industries to avoid potentially triggering non-compete clause violations (as discussed in Part IV.B.3.b.ii), both of which make experienced workers less often available for hire. Firms therefore may need to train workers at a greater rate because they will hire inexperienced workers who require more core training. Research finding increases in training associated with increases in non-compete enforceability therefore may not imply increases in advanced training—*i.e.,* the kind of training that increases productivity of workers already able to perform job duties, with net benefits for society as a whole. In response, the Commission agrees that decreases in training under the final rule may represent decreases in core, rather than advanced, training. It is not possible to discern whether the observed effects on training in the literature represent core versus advanced training because evidence that would facilitate such an analysis does not exist. Importantly, a decrease in core training would be economically beneficial because it would reflect a more efficient use of the labor force. Therefore, to the extent a decrease in training reflects a change in core training, this would be a net benefit of the final rule—not a cost. On the other hand, to the extent a decrease in training is due to a change in advanced training, this would represent a net cost of the final rule. The Commission further discusses investment in human capital in Part X.F.7.a.

Some commenters stated that costs associated with rescinding existing non-competes and updating contractual practices may be greater than estimated in the NPRM and attributed the greater cost to the need for high-cost outside counsel. In response, the Commission finds it likely that many firms will not need to use costly outside counsel (or indeed, any counsel) to comply with the final rule. This is especially true since the final rule allows non-competes for senior executives to remain in effect, since it does not require rescission of any existing contracts, and since it provides a model safe harbor notice for other workers and makes other adjustments to simplify the notice process. In response to commenters stating that firms will need more time to implement than estimated in the NPRM, the Commission conducts an updated analysis in Part X.F.7.b. The Commission notes that the model language provided in the final rule and allowing employers to use the last known address, mail or electronic, will significantly simplify the notice process for employers. Additionally, the Commission performs two sensitivity analyses in Part X.F.7.b. The first assumes an attorney's time is more costly—it replaces the primary estimate of the average hourly productivity of an attorney ($134.62 per hour, based on BLS earnings data) with an estimated rate of the cost of outside counsel who is a tenth-year attorney ($483 per hour).[1087] The second makes different assumptions about the time spent by employers related to existing non-competes that will be no longer be enforceable and updating contractual practices. Finally, the Commission clarifies the definition of ''non-compete clause'' in Part III.D to reduce confusion and give employers and workers a clearer understanding of what is prohibited. This, in turn, will reduce compliance costs and potential litigation costs over what constitutes a non-compete.

One commenter from the retail industry claimed the cost of implementing the proposed rule could

[1084] Starr, *supra* note 445.

[1085] See Part IV.B.3.b.ii, discussing Johnson, Lipsitz, & Pei, *supra* note 526.

[1086] Commenters used the words ''requisite'' and ''discretionary'' in lieu of ''core'' and ''advanced,'' respectively.

[1087] This estimate is drawn from the Fitzpatrick Matrix, which is a fee schedule used by many U.S. courts for determining the reasonable hourly rates in the District of Columbia for attorneys' fee awards under Federal fee-shifting statutes. It is used here as a proxy for market rates for litigation counsel in the Washington, DC area, which likely represent the high end of rates for litigation counsel in the U.S. The estimate is therefore adjusted to reflect a national rate by multiplying by the ratio of the hourly wage of attorneys nationwide to the hourly wage of attorneys in the Washington, DC metro area, based on BLS Occupational Employment and Wage Statistics data. The Commission conservatively uses the rates of a tenth-year attorney—a much more experienced attorney than is likely to be needed (and indeed no attorney at all may be needed). *See* Fitzpatrick Matrix, *https://www.justice.gov/usao-dc/page/file/1504361/dl?inline. See* BLS Occupational Employment and Wage Statistics, *https://www.bls.gov/oes/data.htm.*

be $100,000 to $200,000 per firm but did not support this assertion with any evidence. The Commission disagrees with this assertion, which does not align with its careful estimates based on empirical evidence and significant expertise presented in Part X.F.7.b.ii. The Commission's estimates also acknowledge and account for potentially heterogeneous costs across firms.

Some commenters stated that employers would need to spend substantial resources to litigate trade secret disputes and violations of post-employment restrictions other than non-competes. One commenter stated that the cost of a trade secret case may range from $550,000 to $7.4 million, depending on the monetary value of the trade secret claim. The Commission analyzes costs of litigation in Part X.F.7.c. The Commission agrees with commenters that trade secret litigation, and litigation over post-employment restrictions other than non-competes, may be costly. However, the Commission notes that no evidence exists to support the hypothesis that litigation on these fronts will increase because of the final rule. Indeed, recent evidence suggests that trade secret litigation does not increase following bans on non-competes.[1088] Moreover, the final rule, with its clear and bright-line standard (as compared to the current patchwork of State laws), would likely decrease litigation attempting to enforce non-competes, including litigation initiated by former employers against workers who start their own business or who find a new employer. While the Commission does not have evidence on the frequency of these different types of litigation, it expects the decrease in non-compete litigation would likely offset potential increases in other litigation.

Positing that firms will be reluctant to share trade secrets with workers under the rule, some commenters also stated that the costs of lessened sharing of trade secrets should be taken into account. Since no data exists on the effect of non-competes on the monetary value of shared trade secrets, the Commission does not quantify or monetize this effect. Moreover, there is no evidence that employers will lessen the extent to which they share trade secrets under the final rule, much less that any change would be material. As detailed in Part IV.D, employers have less restrictive alternatives to non-competes that mitigate these concerns.

Some commenters reference the Starr, Balasubramanian, and Sakakibara study [1089] and the Commission's interpretation of it in the NPRM to assert that firms founded because of the rule may be of lower quality than existing firms in terms of average employment and survival rates, and adjustments should be made to the Commission's analysis to account for these differences. Upon further review, the Commission interprets the authors' findings to show that within-industry spinouts resulting from lessened non-compete enforceability tend to be lower quality than non-within industry spinouts resulting from lessened non-compete enforceability. However, both types of spinouts are better, on average, than spinouts that form under stricter non-compete enforceability. The study's results therefore suggest that, if anything, the Commission underestimates the final rule's benefits from new business formation, because the estimates do not adjust for quality.

Some commenters asserted that, because of the positive effects of the proposed rule on labor mobility, firms may face greater costs associated with turnover (especially firms that currently use non-competes) due to the cost of finding a replacement, the cost of training a replacement, and the cost of lost productivity. Based on Pivateau (2011),[1090] one commenter estimated that turnover costs 25% of the annual salary of a worker. Some commenters also argued that some firms may face decreased costs of turnover, because more plentiful availability of labor can reduce the cost of hiring. The Commission finds that there may be distributional effects of increased turnover—benefits for firms that face a lower cost of hiring and costs for firms losing workers who had been bound by non-competes—and assesses the same in Part X.F.9.c.

Some commenters offered additional empirical evidence not discussed in the NPRM that was not specific to the proposed regulatory analysis. The Commission responds to those comments in Part IV.

D. Summary of Changes to the Regulatory Analysis

In the final regulatory analysis presented in Part X.F, the Commission updates its analyses based on the parameters of the final rule, comments received, supporting empirical evidence raised by commenters, changes in the status quo regarding regulation of non-competes, and reanalysis of evidence presented in the NPRM.[1091] This includes the Commission's attempt to quantify and monetize, to the extent feasible, all costs and benefits of the final rule, as well as transfers and distributional effects. The Commission additionally analyzes hypothetical scenarios to assess what otherwise unmonetized benefits and costs would lead to a final rule that is net beneficial. Finally, the Commission elects to include an analysis of an alternative the Commission considered, namely an analysis of fully excluding senior executives.[1092]

Under the final rule, existing non-competes with senior executives may remain in effect. While this change likely affects some costs and benefits associated with the final rule temporarily, the Commission does not specifically quantify or monetize those effects. The effect on persistent costs and benefits would be temporary, as senior executives will eventually move out of their jobs and retire or move into new jobs, to which the final rule will apply. The Commission notes throughout its analysis, however, how different estimates may be affected by this differential treatment of senior executives even if it cannot quantify the precise effect.

E. Summary of Benefits and Costs

The Commission considered several effects of the final rule on economic outcomes: earnings, innovation, entrepreneurship, distributional effects on workers, investment in human capital, capital investment, legal and administrative costs, prices, labor mobility and turnover, and litigation costs.

The Commission describes the primary estimates of benefits, transfers, costs, and distributional effects associated with each of these outcomes in Table 1. Table 1 also reports whether the outcome for each effect is quantifiable or monetizable and

[1088] Greenwood, Kobayashi & Starr, *supra* note 757. The Commission notes that this study supplements—but is not necessary to support—its finding that no evidence supports the conclusion that litigation costs will increase under the final rule. That finding is based on the Commission's expertise and the rulemaking record, including relevant comments. This study was published after the close of the comment period.

[1089] Starr, Balasubramanian, & Sakakibara, *supra* note 518.

[1090] Griffin Toronjo Pivateau, *Preserving Human Capital: Using the Noncompete Agreement to Achieve Competitive Advantage,* 4 J. Bus. Entrepreneurship & L. 319 (2010).

[1091] As described in detail in this Part X, the Commission's final analysis, including its quantification and monetization of effects, therefore is not precisely the same as its preliminary analysis.

[1092] The Commission is not required to analyze costs and benefits of regulatory alternatives in its final regulatory analysis. *See* 15 U.S.C. 57b–3(b)(2)(B).

discusses important nuance or uncertainty.

TABLE 1

Category	Extent of characterization	Description of estimate	Discussion
Earnings	Quantified	The estimated ten-year present discounted value of increased worker earnings is $400-$488 billion. Effect on earnings partially represents a transfer and partially represents a benefit of the final rule.	The extent to which the estimated increase in worker earnings represents a benefit versus a transfer is unclear, though there is evidence to suggest that a substantial portion is a benefit.
Innovation	Quantified	Annual count of new patents estimated to rise by 3,111–5,337 in the first year, rising to 31,110–53,372 in the tenth year. Annual spending on R&D estimated to fall by $0-$47 billion. Effect on innovation represents a benefit of the final rule.	Estimates of the societal value of innovation are not available. The two effects on innovation together represent a benefit because more output (amount of innovation) is produced with less input (R&D spending).
Prices	Partially Quantified	The estimated ten-year present discounted value of decreases in spending on physician and clinical services is $74-$194 billion. Prices in other sectors may decrease as well but are not quantified. The effect on prices partially represents a transfer and partially represents a benefit of the final rule.	Price changes encompass transfers (from firms to consumers) and benefits (since price changes are likely due to increased competition); however, the exact split is not clear. Increased competition may also increase consumer quantity, choice, and quality. Prices outside of physician and clinical services may fall due to changes in competition because of new entrants; however, the literature has not quantified this effect.
Investment in Human Capital	Monetized	The estimated ten-year present discounted value of the net effect of the final rule on investment in human capital ranges from a benefit of $32 billion to a cost of $41 billion. The effect on investment in human capital may represent a cost or benefit of the final rule.	The range in estimates reflects uncertainty over whether decreased investment in human capital under the final rule reflects reductions in advanced investment (which the firms opt into to increase productivity) or core investment (which is no longer necessary if more experienced workers are hired) and uncertainty over the workers for whom investment in human capital (all workers or workers in occupations which use non-competes at a high rate) is affected.
Legal and Administrative Costs	Monetized	One-time legal and administrative costs are estimated to total $2.1–$3.7 billion. Legal and administrative costs represent a cost of the final rule.	
Litigation Effects	Not quantified or monetized	The final rule may increase or decrease litigation costs. Effects on litigation costs may represent a cost or benefit of the final rule.	Estimates of the effect of the final rule on total litigation costs are not quantifiable. Litigation costs may rise or fall depending on firms' subsequent use of other contractual provisions and trade secret law and how the costs of such litigation compare to the cost of non-compete litigation, as well as the decreased uncertainty associated with a bright-line rule on non-competes.

TABLE 1—Continued

Category	Extent of characterization	Description of estimate	Discussion
Firm Expansion and Formation	Quantified	The final rule is estimated to increase new firm formation by 2.7–3.2% and decrease capital investment at incumbent firms by 0–7.9%. These effects represent a shift in productive capacity from incumbent firms to new firms. The overall effect on firm expansion and formation represents a distributional effect of the final rule.	New firm formation is generally a benefit, but may also crowd out incumbent firms and is therefore not a pure benefit. Decreased capital investment at incumbent firms may be counterbalanced by increased capital investment at new firms or rebalancing across industries, and therefore may or may not be a cost in net.
Distributional Effects on Workers	Not quantified or monetized	The rule may reduce the gender and racial earnings gap, may disproportionately encourage entrepreneurship among women, and may mitigate legal uncertainty for workers, especially relatively low-paid workers. The differential effect on different groups of workers represents a distributional effect of the final rule.	
Labor Mobility	Partially Monetized	Some firms may save on turnover costs (due to easier hiring as more potential workers are available), while some firms may have greater turnover costs (due to lost workers newly free from non-competes). The latter is estimated to be no more than $131 per worker with a non-compete, while estimates are not available to monetize the former. While it is unclear whether labor mobility costs represent a net cost or benefit of the final rule, they likely represent a distributional effect (costing firms which use non-competes and helping firms which do not) of the final rule.	The estimate of the increase in turnover costs for firms using non-competes is an upper bound, since it encompasses effects on investment in workers' human capital, hiring workers, and lost productivity of workers, all of which are expected to diminish under the final rule.

Note: Present values are calculated using discount rates of 2%, 3%, and 7%.

The Commission finds that, even in the absence of a full monetization of all costs and benefits of the final rule, the final rule has substantial benefits that clearly justify the costs. While data limitations make it challenging to monetize all the expected effects of the final rule, the Commission believes it has quantified the effects of the final rule likely to be the most significant in magnitude, and thus, potentially drive whether and the extent to which the final rule is net beneficial. This includes both benefits and costs. Based on those quantifications, the Commission is able to make conservative assumptions, based on its expertise, under which the final rule would be net beneficial. In this context, by conservative assumption, the Commission means that it is presuming the benefits it quantifies to be relatively low in value for purposes of this analysis, *i.e.,* lower than it believes is likely the case. With respect to costs, the Commission assumes costs are on the higher end of the estimated range, which is higher than the Commission believes is likely to be the case. Through this analysis, provided in detail in Part X.F.10, the Commission further bolsters its finding that the benefits of the final rule justify the costs.[1093]

Specifically, the Commission finds that even if only 5.5% of the estimated $400–$488 billion increase in worker earnings represents increased productivity resulting from improved, more productive matches between workers and employers, the benefits will outweigh the costs. In Part X.F.6.a, the Commission explains that the economic literature does not provide a way to separate increased productivity from the total effect on earnings (*i.e.,* transfers versus benefits in the regulatory impact analysis sense). However, the Commission finds that based on the literature, some part of the increase in worker earnings represents increased productivity and believes that 5.5%, and likely more, represents increased productivity. Similarly, even presuming that no part of the effect on earnings is a benefit (as opposed to a transfer), the Commission finds that if the social value of a patent were at least $297,144, then the monetizable benefits will exceed monetized costs. Notably, the literature finds that the average private value of a patent may be as high

[1093] The Commission notes that it does not believe there is a likely scenario in which firm exit and lost capital investment, especially when balanced against firm entry and gained capital investment at new firms, would change this outcome. Firm exit and lost capital investment, which are not quantified and are discussed as distributional effects in Part X.F.9, would not, for example, result in costs large enough to overcome the break-even analyses (even if, for example, the value of earnings representing productivity increases or the social value of patents had to be marginally higher) or the finding that the benefits justify the costs.

as $32,459,680, again making this assumption regarding the social value of a patent quite conservative. Finally, even presuming none of the earnings are benefits (rather than transfers) and that the social value of a patent is zero (an implausibly low estimate), if all the lost investment in human capital is core, the monetized benefits would also exceed monetized costs. Notably, in conducting these analyses, in each instance, the Commission further makes the very conservative assumption that monetizable benefits other than the benefit being analyzed are zero. That is, the Commission assumes that patents have no social value and that no reduced investment in human capital is core when considering how much of earnings must represent increased productivity in order for the monetized benefits to exceed the monetized costs. This break-even analysis shows that while data limitations making it challenging to monetize all of the expected benefits of the rule, the Commission finds that the final rule can be shown to be net beneficial even under very conservative assumptions.

F. Final Regulatory Analysis

1. Background

As discussed in Part IV.B.3.a, non-competes inhibit worker mobility, creating worse matches between workers and firms and decreasing workers' productivity and therefore their earnings. Non-competes also prevent firms from hiring talented and experienced workers; inhibit new business formation; and reduce the flow of innovative workers between firms, harming innovation. The final rule increases competition in labor markets by allowing workers to move more freely between jobs and increases competition in product and service markets by ensuring that firms are able to hire appropriate workers, that workers are able to create new entrepreneurial ventures, and that worker flow between firms enhances innovation.

2. Economic Rationale for the Final Rule

The final rule addresses two primary economic problems. First, non-competes tend to harm competitive conditions in labor markets. Non-competes increase barriers to voluntary labor mobility and prevent firms from competing for workers' services, thus creating frictions and obstructing the functioning of labor markets. These frictions inhibit the formation of optimal and efficient matches in the labor market, resulting in diminished worker and firm productivity and in lower wages.

The second economic problem is that non-competes tend to harm competitive conditions in product and service markets. Non-competes create a barrier to new business formation and entrepreneurial growth, which negatively affects consumers by lessening competition in product and service markets. Non-competes also make it difficult for competitors to hire talented workers, which reduces these competitors' ability to effectively compete in the marketplace. Additionally, non-competes impede innovation by preventing the churn [1094] of innovative workers between firms, limiting the spread and recombination of novel ideas, which may negatively affect technological growth rates.

3. Purpose of the Final Rule

The final rule provides that, with respect to a worker other than a senior executive, it is an unfair method of competition—and thus a violation of section 5 of the FTC Act—for a person to enter into or attempt to enter into a non-compete; enforce or attempt to enforce a non-compete; or represent that the worker is subject to a non-compete.[1095] The final rule also provides that, with respect to senior executives, it is an unfair method of competition—and thus a violation of section 5 of the FTC Act—for a person to enter into or attempt to enter into a non-compete; enforce or attempt to enforce a non-compete entered into after the effective date; or represent that the worker is subject to a non-compete, where the non-compete was entered into after the effective date.[1096]

4. Baseline Conditions

a. Estimate of the Affected Workforce

As described in Part II.E, some workers may not be subject to the final rule to the extent they are employed by an entity or in a capacity that is exempted from coverage under the FTC Act. The Commission estimates the fraction of the workforce who would be covered under the final rule (the ''coverage rate'') by applying conservative assumptions to individual-level data on the characteristics of the workforce from the American Community Survey (ACS) for 2017 to 2021.[1097] Residents of four States (California, Minnesota, North Dakota, and Oklahoma) are excluded from the sample used for the computation, since these States already generally do not enforce non-compete agreements.

To estimate the coverage rate, workers are classified according to three criteria: (1) whether the individual is identified as working for the government; (2) whether the individual is identified as working for a non-profit organization; and (3) whether the individual works in an industry or in a capacity that is likely to be outside the jurisdiction of the FTC Act. Government employment consists of employment with local, State, and Federal governments, in addition to individuals on active duty in the U.S. Armed Forces or Commissioned Corps. Nonprofit status is self-reported by survey respondents. Industries are defined based on the North American Industry Classification System (NAICS).

Such a classification of workers is necessarily imperfect as the FTC's jurisdiction does not exclude all workers that may be identified in the data as government employees or map directly into the data on non-profit status or the NAICS classifications that are available within the ACS. For example, the FTC Act is likely to exempt some firms that are classified as non-profits but not others, as described in Part II.E. Also, in some instances, only a subset of a given NAICS category (and not the entire category) appeared likely to fall outside the jurisdiction of the FTC Act. When ambiguity arose, the Commission was overinclusive in excluding workers. For example, the Commission classified all nonprofits as outside the coverage of the final rule for the purposes of estimating the coverage rate. Moreover, in estimating the coverage rate, the Commission excluded entire industries in calculating the coverage rate when some subset of that industry appeared to be outside the Commission's jurisdiction. This over-inclusiveness has the effect of underestimating the coverage rate of the final rule, and thus the overall net effect of the final rule will be conservative.

Using data from the ACS and the assumptions detailed in Part X.F.4, the Commission estimates that the final rule is likely to cover 80% of the private U.S. workforce.

b. Non-Compete Enforceability

For regulatory analyses, the effects of the final rule are measured against a baseline representing conditions that would exist in the absence of the rule. The extent of the final rule's costs and benefits depends on the degree to which it will change the enforceability of non-competes relative to what it would be in the baseline. Currently, non-competes are broadly prohibited in four States:

[1094] Churn in this context means turnover that is neither job creation nor job destruction—essentially the movement of workers among jobs.

[1095] *See* § 910.2(a)(1).

[1096] *See* § 910.2(a)(2).

[1097] The preliminary analysis in the NPRM did not estimate or apply a coverage rate based on jurisdiction.

California, North Dakota, Oklahoma, and Minnesota. In some other States, non-competes are prohibited for some, but not all, workers. For non-competes that are not prohibited expressly by statute, some version of a reasonableness test is used under State law to determine whether a given non-compete is enforceable or not. These reasonableness tests examine whether the restraint is greater than needed to protect an employer's purported business interest. Non-competes can also be found unreasonable where the employer's need for the non-compete is outweighed by the hardship to the worker or the likely injury to the public. Because these cases arise in the context of individual litigation, courts focus the ''likely injury to the public'' inquiry on the loss of the individual worker's services and not on the aggregate effects of non-competes on competition in the relevant market or overall in the economy.[1098]

Researchers have used various scoring systems to capture the enforceability of non-competes State by State over time. As described in Part IV.A.2, the Commission gives greatest weight to studies that measure enforceability granularly (*i.e.,* not using a binary score but, for example, an integer scale) and along various dimensions (*e.g.,* the employer's burden of proof in non-compete litigation and the extent to which courts are permitted to modify unenforceable non-competes to make them enforceable). The scoring system which fits these criteria best [1099] has been used to study the effect of non-compete enforceability on several economic outcomes. This score, which varies across States and across years, measures non-compete enforceability along a scale which runs from zero to one.[1100] A score of zero indicates enforceability equal to that of the State which enforces non-competes least (North Dakota). A score of one indicates enforceability equal to that of the State which enforces non-competes most readily (Florida). The final analysis relies on this score heavily as a granular and reliable scoring system that allows the Commission to consider the effect of non-compete enforceability on several economic outcomes. The studies that use this score form much of the basis for the final regulatory analysis.

5. Estimating the Effect of the Rule on a State-Level Enforceability Metric

In the absence of the rule, the average State enforceability score—in States that do not broadly prohibit them—when measured on a scale of 0 (lowest enforceability) to 1 (highest enforceability), is 0.78. The final rule will result in State-level enforceability of non-competes falling from its level in the absence of the rule to zero (*i.e.,* an average decrease of 0.78, excluding States that broadly prohibit non-competes).[1101] Using data on scores from 1991 to 2014, researchers report that the average magnitude of a change in the score (*i.e.,* the size of the change, regardless of whether it was a score increase or decrease) from year to year was 0.081.[1102] In other words, when a State's score changed from one year to the next, the average magnitude of that change was 0.081, on a scale of zero to one. Since the decrease that will result from the final rule is significantly larger than the average decrease considered in the literature (0.78 v. 0.081), the Commission considered different methods for the primary estimate in this final analysis. Consistent with the NPRM, this final analysis could attempt to scale up, or extrapolate, estimated effects to account for this larger decrease. As discussed in Part X.C, some commenters criticized this approach, stating that it may result in unreliable estimates absent evidence that the economic effects the Commission is attempting to measure would scale up linearly.

The Commission notes in X.C that empirical studies show a linear extrapolation is appropriate for measuring earnings effects.[1103] However, similar evidence supporting the use of linear extrapolation is not available for all economic outcomes the Commission is measuring in this final analysis. To maintain consistent reporting across economic outcomes and to avoid extrapolation, the final analysis considers the effect of a change equal to 0.081 when possible.[1104] That is, for the purposes of the final analysis, the Commission conservatively assumes the projected effects on economic outcomes due to the final rule are equal to the effects the economic literature associates with an average magnitude change in the non-compete enforceability score from year to year. The economic literature reports enforceability changes as simply increases or decreases in some studies,[1105] and the magnitude of those legal changes in this final analysis is assumed to mirror the average magnitude change of 0.081. The Commission makes these assumptions to avoid the possibility of inadvertently inflating the effects of changes in the enforceability score. The final rule will result in greater changes in enforceability than the changes examined in empirical studies. There is a possibility that the magnitude of change for particular economic outcomes will not be the same in response to every reduction in enforceability. For example, it is possible that for some economic outcomes, as enforceability gets closer to zero, the changes in the outcome being measured will be lower with each change in enforceability.

At the same time, the Commission notes that this may result in underestimating benefits of the final rule—the average magnitude change of 0.081 is much smaller than the average 0.78 change it would take for enforceability to reflect the final rule. To reflect this possibility, the final analysis includes sensitivity analyses which extrapolate beyond an average magnitude change. In these sensitivity

[1098] *See* NPRM at 3493–97 (describing the law governing non-competes at the time the NPRM was published). Minnesota prohibited non-competes after the publication of the NPRM. *See* Minn. Stat. Ann. sec. 181.988.

[1099] Bishara, *supra* note 501 at 751.

[1100] Different researchers have rescaled this score in different ways (*e.g.,* from zero to 470, or scaled such that the mean score is zero and the standard deviation of the score is one). The Commission uses the scaling from zero to one because that is the way it is used in the majority of the studies which are relied on in the final analysis, as well as for easy interpretability and consistency across the final analysis.

[1101] Calculated using data from 2009, the most recent year with publicly available data, and rescaled to a zero to one scale. *See* Starr, *supra* note 445.

[1102] Changes of zero (*i.e.,* years in which the score in a given State was the same as the prior year) were excluded from this calculation. The Commission notes that the study which reports this average (Johnson, Lipsitz, & Pei, *supra* note 526) was released after publication of the NPRM. The Commission also notes that the data underlying this calculation were used in other studies discussed in the NPRM; Johnson, Lipsitz, & Pei report the average score in the most accessible fashion and is therefore used here. The average they report is the average change in the analysis sample they select, which is chosen for analytical reasons to ensure accuracy of their estimates. Use of the underlying data to re-calculate the average score or use of scores provided by other researchers would not change the overall outcomes, conditional on sample selection. Moreover, the Commission reports the estimates resulting from a full extrapolation in this final analysis, which does not use this average score change in its sensitivity analysis, and is the method used in the NPRM. As noted, the Commission believes that the full extrapolation method is a valid, but potentially less precise method. Accordingly, the use of this score supplements—but is not necessary to support—the Commission's ultimate finding that the benefits to the final rule justify the costs.

[1103] Johnson, Lavetti, & Lipsitz, *supra* note 388 at 17.

[1104] When considering studies which do not report the relationship between non-compete enforceability and economic outcomes based on a numeric score, the Commission is unable to scale the effect to reflect the average magnitude change of 0.081.

[1105] *See, e.g.,* Jeffers, *supra* note 450.

analyses, the estimated effects from the empirical literature are scaled up on a State-by-State basis (rather than taking the average) to account for the estimated size of the decrease in each State's score. The Commission notes that linear extrapolation provides a robust estimate of earnings changes based on the empirical literature, but for consistency, the Commission reports effects based on the average magnitude change as its primary analysis.

6. Benefits of the Rule

The Commission finds several benefits attributable to the final rule, as reflected in part by the effects of the rule on earnings and prices, and all the effects on output and innovation, as summarized in Table 1 in Part X.E.

a. Earnings

The Commission finds labor markets will function more efficiently under the final rule, which will lead to an increase in earnings or earnings growth. Specifically, in this regulatory analysis, the Commission finds that the estimated ten-year present discounted value of increased worker earnings is $400–$488 billion. The final rule will result in additional earnings stemming from improvements in allocative efficiency due to more productive matching between businesses, which are economic benefits. In other words, the increase in worker mobility will allow employers to hire workers who are a better, more productive fit with the positions they are seeking to fill, which in turn will increase productivity overall. A portion of the additional earnings are transfers from firms to workers resulting from more plentiful employment options outside the firm,[1106] as workers who are not bound by non-competes will be in a different bargaining position with their employer. To the extent other better opportunities with different employers exist for a given worker, their current employers will now be competing with those other employers and may increase worker compensation to keep those workers. The Commission finds that the economic literature does not provide a way to separate the total effect on workers' earnings into transfers and benefits.

The increase in worker earnings resulting from the final rule is calculated as follows:

*Increase in worker earnings = (% Increase in Earnings caused by the change in enforceability of non-competes) * (Total Affected Earnings)*

The primary approach in this analysis is to estimate the percentage increase in earnings assuming that the effect of the final rule will be the same as the effect of an average magnitude change in non-compete enforceability, as discussed in Part X.F.5. The Commission estimates the percentage increase in workers' earnings to be 0.86%.[1107] The Commission estimates total affected annual earnings to be $6.2 trillion (in 2023 dollars).[1108]

Multiplying the percentage effect (0.86%) by overall affected annual earnings ($6.2 trillion) results in an annual earnings effect of $53 billion. The ten-year effect on earnings, discounted separately by 2%, 3%, and 7%, is reported in the first row of Table 2.[1109]

This primary approach requires no extrapolation (*i.e.,* it does not scale the effect on economic outcomes to account for the fact that the effect of the rule on enforceability scores will be greater than the changes studied in the economic literature). However, it may understate the increase in workers' earnings resulting from the final rule. Thus, the Commission conducts two sensitivity analyses to assess how the estimated effect of the rule would change if effects are extrapolated to represent changes in enforceability scores greater than those examined in the literature.

The first sensitivity analysis, hereafter referred to as the ''full extrapolation'' approach, calculates the effect on worker earnings in an identical fashion to the primary analysis but relies on an estimate of the percentage increase in worker earnings which extrapolates to the effect of a complete prohibition on the use of non-competes. This results in an effect on worker earnings equal to 3.2% (instead of 0.86% in the primary analysis).[1110] For this estimate, total affected earnings are equal to $7.3 trillion in 2023 dollars.[1111] The estimated effect on earnings across the workforce for this first sensitivity analysis is therefore given by the percentage effect on earnings (3.2%) multiplied by the total annual wages in the U.S. for the affected population ($7.3 trillion). This results in an annual

[1106] By transfers, the Commission refers to ''a gain for one group and an equal-dollar-value loss for another group.'' *See* Off. of Mgmt. & Budget, *Circular A–4* (Nov. 9, 2023), 57, *https://www.whitehouse.gov/wp-content/uploads/2023/11/CircularA-4.pdf.*

[1107] Calculated as $-(e^{-0.107*0.081}-1)$, where -0.107 is the estimated coefficient of earnings on non-compete enforceability score in Johnson, Lavetti, & Lipsitz (*supra* note 388), and 0.081 represents the size of an average magnitude change calculated in Johnson, Lipsitz, & Pei (*supra* note 526) which scales the effect to represent the effect of an average sized change in the non-compete enforceability score.

[1108] This figure represents total annual earnings in the U.S. in the most recent year with data available (2022), adjusted to 2023 dollars: see *https://data.bls.gov/cew/apps/table_maker/v4/table_maker.htm#type=0&year=2022&qtr=A&own=5&ind=10&supp=0.* Earnings from California, North Dakota, Oklahoma, and Minnesota (States which broadly do not enforce non-competes) are subtracted out, since enforceability in those States will be broadly unaffected by the rule. The estimate is additionally adjusted to account for the proportion of the workforce the Commission estimates are currently covered by the Commission's jurisdiction (80%), as discussed in Part X.F.4.a. Numerically, $6.2 trillion is calculated as ($9.1 trillion − $1.6 trillion) * 80% = $6.0 trillion, adjusted to $6.2 trillion to adjust to 2023 dollars. $9.1 trillion is total private earnings in 2022 in the U.S. (the most recent year with data available), and $1.6 trillion is total private earnings in 2022 in CA, ND, OK, and MN.

[1109] For illustrative purposes, State-specific estimates are displayed in Appendix Table A.1. In this table, the estimated number of covered workers is calculated as 80% * (total employed population in the State); the estimated increase in total earnings is calculated as 0.86% * (estimated total covered earnings), where estimated total covered earnings is calculated as (estimated number of covered workers) * (average annual earnings); and the estimated increase in average earnings is calculated as 0.86% * (average annual earnings). Total employed population and average annual earnings are taken from the Census Bureau Quarterly Census of Employment and Wages for 2022 (see *https://www.bls.gov/cew/data.htm*).

[1110] The percentage effect, 3.2%, is reported by Johnson, Lavetti, & Lipsitz (*supra* note 388) as the lower end of a range of possible effects of a ban on non-competes, relative to non-compete enforceability in 2014. The estimate is constructed by calculating the change in the enforceability score in each State which would bring that State's score to zero (representing no enforceability of non-competes) and scaling the estimated effect on worker earnings by that amount. The Commission uses the low end of the reported range in order to exercise caution against extrapolation, since the estimate uses an out-of-sample approximation: the changes in most States necessary to arrive at a score of zero are greater than the changes examined in the study (though this approximation is consistent with the results of a test in Johnson, Lavetti, and Lipsitz which shows that the effect of enforceability on earnings is roughly linear: namely, a change in enforceability that is twice as large results in a change in earnings that is twice as large). The Commission also notes that the estimated range is based on enforceability in 2014. Since then, some changes in State law have made non-competes more difficult to enforce for subsets of their workforces so that a prohibition on non-competes today is likely to have a slightly lesser effect than a prohibition would have had in 2014.

[1111] This estimate differs from total affected earnings for the primary analysis because the estimate of 3.2% takes into account enforceability in California, North Dakota, and Oklahoma. Earnings in those States is therefore added back into total affected earnings. However, earnings in Minnesota are still omitted, since the prohibition in that State was enacted after the conclusion of the study period in Johnson, Lavetti, and Lipsitz (2023): see Minn. Stat. sec. 181.988. Total annual earnings in the U.S. for the affected population excluding MN are calculated as ($9.1 trillion − $0.2 trillion) * 80%, updated to adjust to 2023 dollars. $9.1 trillion is earnings for all workers in the US in 2022 (the most recent year with available data) and $0.2 trillion is earnings for workers in MN. *See https://data.bls.gov/cew/apps/table_maker/v4/table_maker.htm#type=0&year=2022&qtr=A&own=5&ind=10&supp=0.*

estimated earnings gain of $234 billion.[1112] The ten-year effect, discounted at 2%, 3%, and 7%, is displayed in the second row of Table 2.

The second sensitivity analysis, hereafter referred to as the ''partial extrapolation'' approach, uses the same formula as the other two analyses (% effect on earnings * total affected earnings) but is more conservative in its estimate of the percent effect on earnings than the full extrapolation estimate. The full extrapolation approach assumes that enforceability scores fall to zero. The partial extrapolation approach instead assumes that enforceability scores fall to the minimum observed enforceability score ignoring scores in States that broadly prohibit non-competes (a more moderate extrapolation). The minimum observed enforceability score excluding States that broadly prohibit non-competes is 0.53 (on a scale of zero to one), which is the enforceability score in New York.[1113] This analysis calculates the change in each State's score that would bring it to 0.53, and scales the effect on worker earnings estimated in the empirical literature by that amount.[1114] For example, West Virginia's enforceability score is 0.59. To change to New York's enforceability score would imply a decrease in West Virginia's score of 0.06 (calculated as 0.59—0.53). This implies a percent effect on earnings in West Virginia of 0.64%.[1115]

Total affected earnings in each State are calculated by multiplying total earnings in that State (adjusted to 2023 dollars) by the estimated percentage of covered workers (80%). For example, in West Virginia, total earnings are estimated to be $0.24 trillion.[1116]

Next, the percent increase in earnings in each State is multiplied by total affected earnings in that State. In West Virginia, this results in an earnings increase of 0.64% * $0.24 trillion = $152 million. Finally, the earnings increases are added across States. The overall estimated effect is an annual increase in earnings of $161 billion. The ten-year effect, discounted at 2%, 3%, and 7%, is displayed in the third row of Table 2.

TABLE 2

	Estimated ten-year increase in earnings ($ billions), assuming:		
	2% Discount rate	3% Discount rate	7% Discount rate
Primary estimate (average enforceability change)	$488	$468	$400
Estimate (full extrapolation)	2,148	2,060	1,762
Estimate (partial extrapolation)	1,488	1,427	1,221

The estimated effects on earnings in Table 2 are based on estimates of the percentage change in earnings from a study in the empirical literature that aligns with the metrics outlined in Part IV.A.2. Another study in the literature estimates earnings effects using a comparison between workers in occupations that use non-competes at a high rate versus a low rate.[1117] After adjusting the finding from that study to the average magnitude enforceability change, the estimated effect on worker earnings is 0.5%,[1118] or $31 billion annually.[1119]

The Commission notes that, as discussed in Part X.E, earnings of senior executives who continue to work under non-competes are included in the calculations in this Part X.F.6.a. If the Commission were able to identify those senior executives, their omission from the calculations would decrease the earnings effect of the final rule, since the earnings effect for those senior executives (and others, because of spillovers) would be pushed further into the future, causing steeper discounting. However, while senior executives are paid relatively highly, there are relatively few of them: for example, based on BLS data on earnings by occupation, Chief Executives' earnings comprise just 0.5% of all earnings.[1120] Therefore, the impact on the earnings calculations of omitting or pushing forward the earnings of senior executives who would continue to work under a non-compete is limited.

Discussion of Transfers Versus Benefits

It is difficult to determine the extent to which the earnings effects represent transfers versus benefits. Transfers, in this context, refer to ''a gain for one group and an equal-dollar-value loss for another group.'' [1121] Such transfers do not represent a net benefit or cost to the economy as a whole for purposes of regulatory impact analysis.

To the extent a prohibition on non-competes leads to greater competition in the labor market and a more efficient allocation of labor by allowing workers to sort into their most productive

[1112] This estimate is comparable to the estimate of $250 billion per year reported in the NPRM. *See* NPRM at 3523. The estimate in the NPRM was based on earnings in 2020 (as opposed to 2022 in this final regulatory analysis), included earnings in Minnesota (which has since passed a bill prohibition non-competes), and did not adjust for the estimate of the affected workforce discussed in Part X.F.4.a.

[1113] Enforceability score data come from Starr (2019), which reports scores for 2009 (the most recent data available). Scores are adjusted to a scale of zero to one.

[1114] In particular, for each State, the Commission calculates the percentage effect on earnings as $e^{(0.107*\Delta Enf)}-1$, where ΔEnf is equal to the enforceability score in that State minus the lowest observed enforceability score, excluding CA, ND, OK, and MN (0.53).

[1115] Calculated as $-(e^{-0.107*0.064}-1)$, where −0.107 is the estimated coefficient of earnings on non-compete enforceability score in Johnson, Lavetti, & Lipsitz (*supra* note 388), and 0.064 represents the scaling factor due to West Virginia's score change.

[1116] Calculated as $0.29 trillion * 80%, where $0.29 trillion is earnings in WV in 2022 (the most recent year with data available) adjusted to 2023 dollars. See *https://data.bls.gov/cew/apps/table_maker/v4/table_maker.htm#type=0&year=2022&qtr=A&own=5&ind=10&supp=0.*

[1117] For further discussion of this study, see the discussion in Part IV.B.3.a.ii of Starr, *supra* note 445.

[1118] The change in enforceability which generates the estimate in Starr (*supra* note 445) is a one standard deviation change, as measured using non-compete enforceability scores for all 50 States and the District of Columbia in 1991, which is a change on a scale of zero to one of approximately 0.17, calculated as 1/[1.60−(−4.23)]. Scaling the estimate, a change equal to 0.081 would result in an earnings effect of 0.5%, calculated as $e^{(0.0099*0.081/0.172)}-1$.

[1119] Calculated as $6.2 trillion * 0.5%.

[1120] Calculated as (199,240 * 246,440)/(147,886,000 * 61,900), where 199,240 and 147,886,000 are employment for Chief Executives and All Workers, respectively, and 246,440 and 61,900 are dollar earnings for Chief Executives and All Workers, respectively, in 2022. See Occupation Employment and Wage Statistics, BLS, *https://www.bls.gov/oes/tables.htm.* The Commission notes that Chief Executives are used as an illustrative example, and are an imperfect proxy for senior executives: some Chief Executives (as classified by BLS) may not be senior executives under the final rule, and some senior executives under the rule may not be Chief Executives.

[1121] Off. of Mgmt. & Budget, *Circular A–4* (Nov. 9, 2023) at 57.

matches with firms (including new firms that may be formed), then the resulting earnings increases may reflect higher productivity and so represent a net benefit to the economy. However, some increases in earnings when non-competes are prohibited may simply represent a transfer of income from firms to workers (or, if firms pass labor costs on to consumers, from consumers to workers).

Several pieces of evidence support the Commission's finding that at least part of the increase in earnings represents a social benefit or net benefit to the economy, rather than just a transfer. As described in Part IV.B.3.a.ii, two studies have sought to estimate the external effect of non-compete use or enforceability: that is, the effect of use or enforceability on individuals other than those directly affected by non-compete use or enforceability.

One study directly estimates the external effect of a change in non-compete enforceability.[1122] While use of non-competes is not observed in the study, the effects of changes in a State's laws are assessed on outcomes in a neighboring State. Since the enforceability of the contracts of workers in neighboring States are not affected by these law changes, the effect must represent a change related to the labor market which workers in both States share. The estimate suggests that workers in the neighboring State experience effects on their earnings that are 76% as large as workers in the State in which enforceability changed.[1123] In other words, two workers who share a labor market would experience nearly the same increase in their earnings from a prohibition on non-competes, even if the prohibition only affects one worker. While the study does not directly estimate the differential effects by use, the effects on workers unaffected by a change in enforceability may be similar to the effects on workers not bound by non-competes.

A second study demonstrates that when the use of non-competes by employers increases, wages decrease for workers who do not have non-competes but who work in the same State and industry. This study also finds that this effect is stronger where non-competes are more enforceable.[1124] Since the affected workers are not bound by non-competes themselves, the differential in earnings likely does not completely represent a transfer resulting from a change in bargaining power between a worker bound by a non-compete and their employer.

Overall, these studies suggest there are market-level dynamics governing the relationship between earnings and the enforceability of non-competes: specifically, restrictions on the enforceability of non-competes affect competition in labor markets by alleviating frictions and allowing for more productive matching. Changes in enforceability or use of non-competes have spillover effects on the earnings of those workers who should not be directly affected because they do not have non-competes or they work in nearby labor markets that did not experience changes in enforceability. If non-competes simply changed the relative bargaining power of workers and firms, without affecting market frictions or competition, then these patterns are less likely to be observed. Additionally, new business formation when non-competes are less enforceable (see Part IV.B.3.b.i for a discussion of the evidence) may create new productive opportunities for workers.

Due to the uncertainty related to earnings as transfers versus benefits, the Commission analyzes various scenarios that allocate the percent of the earnings effect to a benefit at different levels in Part X.F.10. This does not represent a finding that no part or only a small part of the effect on earnings is a benefit; rather, it is to ensure that the total estimated effect of the final rule is robust for the purposes of the regulatory impact analysis to the possibility that a small percentage of the effect on earnings represents a net benefit.[1125]

b. Innovation

The Commission finds that an additional benefit of the rule would be to increase the annual count of new patents by 3,111–5,337 in the first year, rising to 31,110–53,372 in the tenth year. By alleviating barriers to knowledge-sharing that inhibit innovation, and by allowing workers greater opportunity to form innovative new businesses, the final rule will increase innovation. Studies have sought to directly quantify this effect, primarily focused on patenting activity. The Commission therefore considers the effect on patenting in support of its findings related to innovation. Lacking an estimate of the social value of a patent, the Commission does not monetize this benefit. The Commission also finds that the rule will reduce expenditure on R&D by $0 to $47 billion per year. In light of the increase in overall innovation, this reduction is a cost savings for firms, but may not reflect a market-level effect because it does not measure potential expenditure on R&D by new firms formed as a result of the final rule. The change in patenting due to the rule for each year is calculated as follows:

*Increase in # of Patents = (% Increase in Patenting) * (Total # of Affected Patents)*

The Commission estimates the percentage increase in patenting to average 10.9%–18.7% annually over a ten-year period,[1126] which is the percentage effect on patenting of an average magnitude change in non-compete enforceability, as discussed in Part X.F.5. The Commission assumes that the full effect on patenting phases in over the course of a ten-year period, resulting in an effect of 2.0%–3.4% in the first year, increasing to 19.8%–34.0% by the tenth year.[1127] The total number of affected patents in each year is 156,976.[1128]

The results of the analysis, for the top and bottom end of the reported range of percentage increases in patenting, are displayed in Table 3.

As a sensitivity analysis, mirroring the analysis in Part X.F.6.a, the Commission assumes that enforceability scores in each State will fall to the lowest observed score among States which do not broadly prohibit non-competes. The Commission calculates the percentage change in patenting in each State by extrapolating the

[1122] Johnson, Lavetti, & Lipsitz, *supra* note 388.

[1123] *Id.* (note: a new version of this paper, posted in 2023 after the NPRM was published, revised this estimate slightly).

[1124] Starr, Frake, & Agarwal, *supra* note 469.

[1125] The Commission notes that Part IV.B.3.a.ii does not measure or consider whether earnings are transfers or benefits because to the extent that the earnings that are transfers represent firms' ability to suppress earnings using an unfair method of competition, the transfer of such earnings from firms to workers through the use of non-competes still reflect the tendency of non-competes to negatively affect competitive conditions in the labor market.

[1126] These values represent the range reported in Johnson, Lipsitz, & Pei, *supra* note 526, considering both raw patent counts and patent counts weighted by a measure of their quality: the number of citations received in the five years after the patent is granted. The findings by Johnson, Lipsitz, & Pei are qualitatively confirmed in the literature, with similar estimates generated by He (*supra* note 560)—a study discussed in the NPRM—and Rockall & Reinmuth (*supra* note 564).

[1127] This analysis assumes that the effect on patenting increases by an identical amount each year (2.0–3.4%), ensuring that the overall average annual change is equal to that reported in Johnson, Lipsitz, & Pei (*supra* note 526).

[1128] This is the number of granted utility patents, which are patents for new or improved innovation and are the types of patents studied by Johnson, Lipsitz, & Pei (*Id.*). The figure comes from 2020, which is the most recent data available from the U.S. Patent and Trademark Office. It excludes States in which non-competes are not enforceable (California, Oklahoma, North Dakota, and Minnesota). Data available at *https://www.uspto.gov/web/offices/ac/ido/oeip/taf/st_co_20.htm.*

percentage increase in patenting to reflect the size of the change in that State's enforceability score. For example, as noted in Part X.F.6.a, West Virginia's score would fall from 0.59 to 0.53 as a result of this analysis. The percentage change in patenting in West Virginia would therefore average 9.0%–16.6%,[1129] resulting in an increase of 1.9%–3.6% in the first year, rising to 19.2%–35.6% by the tenth year.

The annual State-specific percentage changes are multiplied by the number of annual patents granted in each State.[1130] Finally, the changes in patenting across States are combined across States for a national estimate. The results are reported in Table 3. As States have broadly decreased legal enforceability of non-competes in recent years, the changes necessary to move to lower enforceability are likely overestimated in this sensitivity analysis. This causes the values estimated by this method to likely overestimate the true extent of the benefit.

TABLE 3

Year relative to publication of the rule	Estimated annual count of additional patents using low estimate of innovation effect	Estimated annual count of additional patents using high estimate of innovation effect	Estimated annual count of additional patents using low estimate of innovation effect and extrapolation approach	Estimated annual count of additional patents using high estimate of innovation effect and extrapolation approach
1	3,111	5,337	8,927	19,306
2	6,222	10,674	17,853	38,611
3	9,333	16,012	26,780	57,917
4	12,444	21,349	35,706	77,222
5	15,555	26,686	44,633	96,528
6	18,666	32,023	53,560	115,833
7	21,777	37,360	62,486	135,139
8	24,888	42,697	71,413	154,444
9	27,999	48,035	80,339	173,750
10	31,110	53,372	89,266	193,055

The Commission is not aware of estimates that assess the overall social value of a patent and therefore the Commission does not monetize the estimated effects on innovative output. Estimates of the effect of a patent on a firm's value in the stock market exist in the empirical literature,[1131] as do estimates of the sale value of a patent at auction.[1132] However, those estimates do not include the effects on follow-on innovation, consumers (who may benefit from more innovative products), competitors, or the rents that are shared with workers, and instead reflect solely the private effect of a patent to the relevant firms.

The Commission notes that patent counts may not perfectly proxy for innovation. However, by using citation-weighted patents, as well as other measures of quality, the study by Johnson, Lipsitz, and Pei shows that patent quality, not just patent quantity, increase when non-competes become less enforceable.[1133] Similarly, the study by He shows that the value of patents also increases when non-competes become less enforceable.[1134]

The second effect of the final rule associated with innovation is a possible change in spending on R&D. The change in R&D spending due to the final rule is calculated as follows:

Reduction in R&D Spending = (% Reduction in Spending) * (Total Affected Spending)

The Commission estimates that the percentage reduction in spending is 0–8.1%, with the broad range reflecting disagreement in the empirical literature.[1135] Total affected spending is $575 billion (in 2023 dollars).[1136] Multiplying the percentage effect by total affected spending, the overall annual effect is a reduction of $0-$47 billion in R&D spending in 2023 dollars.

The Commission notes that, in light of the increases in innovation identified in this Part X.F.6.b, reductions in R&D spending represent a cost savings for firms. Put differently, reductions in R&D spending may cause commensurate reductions in innovative output. Insofar as reductions in R&D spending resulting from the rule could have countervailing effects on innovation, the estimated increase in innovative output represents the net effect, which would otherwise be even larger, if R&D spending were held constant.

Notably, empirical estimates of R&D spending are based on observed changes among incumbent firms and therefore may not reflect market-level effects. Decreased investment at the firm level (the level of estimation in the studies that report effects of enforceability on R&D spending) does not necessarily mean that investment would decrease at the market level, since new firms entering the market may contribute additional R&D spending not captured in the referenced studies. For these reasons, the Commission stops short of classifying the effect on R&D spending as a benefit of the final rule.

The Commission notes that, as discussed in Part X.E, the estimated effects on innovation do not take into account that some senior executives

[1129] Calculated as $e^{(1.43*0.06)}-1$ and $e^{(2.56*0.06)}-1$, where 1.43 and 2.56 represent the coefficients reported in Johnson, Lipsitz, & Pei (*Id.*) as the lower and upper bounds of the reported coefficient range, and 0.06 is the decline in the enforceability score in West Virginia.

[1130] Data available at *https://www.uspto.gov/web/offices/ac/ido/oeip/taf/st_co_20.htm.*

[1131] Leonid Kogan, Dimitris Papanikolaou, Amit Seru, & Noah Stoffman, *Technological Innovation, Resource Allocation, and Growth,* 132 The Quarterly J. of Econ. 665 (2017).

[1132] Ariel Pakes, *Patents as Options: Some Estimates of the Value of Holding European Patent Stocks,* 54 Econometrica 755 (1986).

[1133] Johnson, Lipsitz, & Pei, *supra* note 526.

[1134] He, *supra* note 560.

[1135] Johnson, Lipsitz, & Pei (*supra* note 526) find a negative effect on R&D spending of 8.1% due to an average magnitude change in non-compete enforceability, while Jeffers (*supra* note 450) finds no economically or statistically significant effect on R&D spending.

[1136] Total U.S. R&D spending was estimated by the NSF in 2019, the most recent available year with finalized estimates, excluding nonprofits, higher education, and nonfederal and Federal government. Nat'l Ctr. for Sci. and Engrg. Stats., *New Data on U.S. R&D: Summary Statistics from the 2019–20 Edition of National Patterns of R&D Resources* (Dec. 27, 2021), *https://ncses.nsf.gov/pubs/nsf22314;* Nat'l Ctr. for Sci. and Engrg. Stats., *U.S. R&D Increased by $51 Billion in 2020 to $717 Billion; Estimate for 2021 Indicates Further Increase to $792 Billion* (Jan. 4, 2023), *https://ncses.nsf.gov/pubs/nsf23320.* Note that the data are not broken out by State, and therefore the final analysis cannot exclude CA, ND, OK, and MN.

may continue to work under non-competes under the rule. The Commission is unable to separate the effects of senior executives' non-competes from other workers' non-competes on innovation. Some effects estimated in this Part X.F.6.b may occur further in the future than assumed in this analysis, based on the extent of continued use of non-competes for senior executives.

Overall, the Commission finds that the final rule will significantly increase innovation. Furthermore, the increase in innovation may be accompanied by a decrease in spending on R&D that would, thus, be a cost saving to firms.

c. Prices

The Commission finds that consumer prices may fall under the final rule because of increased competition. The only empirical study of this effect concerns physician practice prices. Based on this study, the Commission estimates the ten-year present value reduction in spending for physician and clinical services from the decrease in prices is $74–$194 billion. The Commission finds some of the price effects may represent transfers from firms to consumers and some may represent benefits due to increased economic efficiency. Some of the benefits may overlap with benefits otherwise categorized, such as benefits related to innovation.

The decrease in prices for physician services because of the final rule is calculated as follows:

*Decrease in Prices = (% Decrease in Prices) * (Total Affected Spending)*

The Commission estimates the percentage decrease in prices for physician services to be 3.5%.[1137] Total spending on physician and clinical services was $801 billion in 2023 dollars, excluding States that broadly do not enforce non-competes.[1138] The Commission separately multiplies spending by 35%, 61.9%, and 75% (estimates of the proportion of hospitals covered by the Commission's jurisdiction as a proxy for total physician and clinical services spending covered by the Commission's jurisdiction) to arrive at total affected spending.[1139] The ten-year sum of discounted spending decreases for these analyses are presented in Table 4.

As a sensitivity analysis, mirroring the analysis in Part X.F.6.a, the Commission assumes that enforceability scores in each State will fall to the lowest observed score among States which do not broadly prohibit non-competes. The Commission calculates the percentage change in prices in each State by extrapolating the percentage decrease in prices to reflect the size of the change in that State's enforceability score. As noted in Part X.F.6.a, West Virginia's score would fall from 0.59 to 0.53 as a result of this analysis. The percentage decrease in prices in West Virginia would therefore be 2.5%.[1140] This percentage decrease is multiplied by State-specific physician spending, adjusted by the relevant multiplier to account for the Commission's jurisdiction, and summed over States.

The ten-year present discounted value of the spending decreases estimated by this analysis are presented in Table 4.

TABLE 4

	Assumed percent of physicians covered (%)	Estimated spending reduction over ten years (billions of dollars) assuming:		
		2% Discount rate	3% Discount rate	7% Discount rate
Primary estimate (average magnitude enforceability change)	35	$90	$87	$74
	61.9	160	153	131
	75	194	186	159
Sensitivity analysis (partial extrapolation approach)	35	257	247	211
	61.9	455	437	373
	75	552	529	459

Several effects of the final rule, including changes in capital investment, new firm formation, and innovation, may possibly filter through to consumer prices. Prices, therefore, may act as a summary metric for the effects on consumers. The Commission notes, however, that prices are an imperfect measure for the effect on consumers. For example, increased innovation catalyzed by the final rule could result in quality increases in products, which might increase prices (all else equal), but nevertheless, consumers may be better off. New firm formation may result in a broader set of product offerings, even if prices are unaffected. Finally, some portion of this effect may represent a transfer from physician practices to consumers. For all these reasons, as well as to avoid double-counting (since prices may reflect changes in innovation, investment, market structure, wages, and other outcomes that are measured elsewhere), the Commission considers evidence on prices to be corroborating evidence, rather than a unique cost or benefit, though some portion of the total effect likely represents a standalone benefit of the rule. The Commission also notes increased competition brought about by the final rule will likely increase

[1137] 3.5% is calculated as $-(e^{(0.427 * 0.081)} - 1)$, where 0.427 is the coefficient relating non-compete enforceability and physician prices in Hausman & Lavetti (*supra* note 590), and 0.081 represents the average magnitude non-compete enforceability score, as described in Part X.F.5.

[1138] See *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsStateHealthAccountsProvider*. Spending in 2020, the most recent year with available data, was $679 billion, which is $801 billion adjusted to 2023 dollars. CA, ND, OK, and MN are omitted.

[1139] In the absence of data on the percentage of physician practices that are non-profit, the Commission uses a range of three different assumptions on the share of covered hospitals. In the first two scenarios, the Commission assumes that the set of covered hospitals is all hospitals that are not non-profit. The first scenario uses 2020 data from the American Hospital Association indicating that 65% of hospitals report that they are non-profits (based on data available at *https://www.ahadata.com/aha-dataquery*). The second scenario uses 2017–2021 data from the American Community Survey indicating that 38.1% of hospital employment is at non-profits (see *https://www.washingtonpost.com/business/2023/05/12/force-behind-americas-fast-growing-nonprofit-sector-more)*. Finally, consistent with the Commission's findings in Part V.D.4, the percentages of firms that report themselves as nonprofit in the data, which reflects registered tax-exempt status under IRS regulations, does not equate to the Commission's jurisdiction. It is likely the Commission may have jurisdiction over some hospitals and other healthcare organizations identified as nonprofits. Therefore, the third scenario assumes that 75% are covered.

[1140] Calculated as $e^{(0.427 * 0.06)} - 1$, where 0.427 is the coefficient reported in Hausman and Lavetti (*supra* note 590), and 0.06 is the decline in the enforceability score in West Virginia.

consumer quantity, choice, and quality. These effects are not quantified in the literature.

To draw inferences to other industries, the Commission notes that if the relationship between non-compete enforceability and prices observed in healthcare markets holds in other industries, then under the final rule prices would likely decrease, and product and service quality would likely increase. Insofar as such effects may be driven by increases in competition, as discussed in Part IV.B.3.b.iii, *e.g.,* because of new firm formation, it is likely output would also increase. However, the evidence in the literature addresses only healthcare markets and therefore the Commission cannot say with certainty that similar price effects would be present for other products and services.

In many settings, it is possible that increases in worker earnings from restricting non-competes may increase consumer prices because of higher firms' costs.[1141] There is no empirical evidence that enforceability of non-competes increase prices due to increased labor costs. Additionally, greater wages for workers freed from non-competes may result from better worker-firm matching, which could simultaneously increase wages and increase productivity, leading to lower prices.

The Commission notes that, as discussed in Part X.E, the estimates of the effect of the rule on prices do not separately account for the effect of senior executives who may continue to have non-competes under the rule. The Commission is unable to monetize or quantify these effects separately because there is no accounting in the applicable literature of why, nor to which groups of workers, the observed price effects occur. If such non-competes have a large impact, some of the effects estimated in this section may occur further in the future than described in this Part X.F.6.c.

7. Costs of the Final Rule

The Commission finds costs associated with the final rule, including legal and administrative costs, and possibly costs related to investment in human capital and litigation, as summarized in Table 1 in Part X.E. The Commission notes the final analysis includes effects on investment in human capital and litigation costs in this Part X.F.7 discussing costs associated with the final rule, though it is not clear whether effects associated with investment in human capital are costs or benefits, and it is not clear whether litigation costs would rise or fall under the final rule.

a. Investment in Human Capital

The Commission estimates the ten-year present discounted value of the net effect of the final rule on investment in human capital (*i.e.,* worker training) ranges from a benefit of $32 billion to a cost of $41 billion. The Commission notes that this wide range represents substantial uncertainty in the interpretation of the estimates that exist in the economic literature. The estimates contained in this Part X.F.7.a are separated along lines created by that uncertainty.

There are two primary sources of uncertainty. The first pertains to the extent to which lost investment in human capital is ''core'' versus ''advanced.'' As discussed in Part IV.B.3.b.ii, when non-competes are enforceable, fewer workers will be available due to decreased labor mobility, including workers who would be a good skills match for a particular job, as well as workers moving to new industries to avoid triggering a potential non-compete clause violation. This may require retraining of workers forced into a new field that would not otherwise be necessary for an experienced worker within the same industry. The departure of experienced workers from the industry also means firms will be required to invest in the human capital of inexperienced workers who replace them. This type of investment in training to address a skills mismatch—which is referred to as the ''core'' training scenario—contrasts with what is referred to as the ''advanced'' training scenario, which is investment in training that builds upon the productivity of workers who may already be experienced in an industry. Insofar as reductions in investment in human capital due to the final rule represent reductions in core investment, the rule will save firms money and will additionally not require workers to forgo time spent producing goods and services to train. Therefore, such reductions would represent a benefit of the final rule. However, insofar as reductions in investment in human capital from the final rule represent reductions in advanced investment, there may be productivity losses for workers. The estimates in the literature do not allow the Commission to distinguish between the types of forgone human capital investment in the final analysis. This final analysis therefore separately estimates the effects assuming lost investment in human capital is core and assuming it is advanced.

The second source of uncertainty pertains to the specific estimates of the effect of non-compete enforceability on investment of human capital. Starr (2019) estimates the differential effect of non-compete enforceability on training in occupations which use non-competes at a high rate versus those that use non-competes at a low rate but does not estimate the absolute effect on investment across the workforce. Therefore, this final analysis separately estimates the effects on training under two different assumptions—that the increase in training due to greater non-compete enforceability affects all workers, or only workers in high-use occupations—to demonstrate how this uncertainty affects the estimates.[1142]

The Commission notes that some of the estimates described in this Part X.F.7 may overlap with estimates reported in other sections of the regulatory analysis. For example, if decreased enforceability of non-competes decreases investment in workers' human capital, and this decreased investment would be reflected in lower wages for workers, then the estimate of the wage increase resulting from the final rule will already account for the extent to which decreased investment decreases wages. That is, if investment were held constant, the earnings increase associated with the final rule may be even larger.

i. Estimates Assuming Lost Investment in Human Capital Is Core Training

The first set of estimates assumes that all lost training is core. This results in estimated effects of the final rule that represent upper bounds on the benefits associated with the final rule's effect on investment in human capital. In these scenarios, the final rule will allow firms to hire experienced workers instead of needing to provide costly training to workers new to the industry or a position. The change in investment in core training brought about by the rule is calculated as follows:

Effect of Decreased Investment in Core Training = Additional Output of

[1141] Sebastian Heise, Fatih Karahan, & Ayşegül Şahin *The Missing Inflation Puzzle: The Role of the Wage-Price Pass-Through,* 54 J. Money, Credit & Banking 7 (2022).

[1142] Whether this assumption yields an overestimate or underestimate depends on what happens to training of workers in occupations with a low-rate of non-competes use when the enforceability of non-competes changes. If the effect of a change in non-compete enforceability on workers in occupations that use non-competes at a low rate is small, this assumption yields an overestimate of the overall effect on training. If the effect on those workers is large, it results in an underestimate.

Workers Resulting From Less Time Spent Training + Reduced Direct Outlays on Training

Additional Output of Workers Resulting From Less Time Spent Training

The first component is additional output of workers resulting from less time spent on otherwise unnecessary training if they were better matched with firm and industry. The change in the output of workers from less time spent training because of the final rule is calculated as follows:

*Additional Output of Workers Resulting From Less Time Spent Training = (Total # of Affected Workers) * (Percentage Point Decrease in Trained Workers) * (Average Hours Spent Training Per Worker) * (Average Hourly Output of Workers)*

The Commission estimates the total number of affected workers as 101.1 million workers, assuming all workers are affected, and 45.3 million workers, assuming only workers in high-use occupations are affected.[1143] The percentage point decrease in trained workers is estimated to be 0.4.[1144] Average hours spent training per worker is estimated to be 85 hours per year.[1145] Average hourly output of workers is estimated to be $60.77.[1146]

The total additional output due to forgone training time is therefore calculated as $1.9 billion per year when all workers are assumed to be affected, or $0.8 billion per year when only workers in high-use occupations are assumed to be affected.

Reduced Direct Outlays on Human Capital Investment

The second component of the economic effect calculated in the final analysis is reduced direct outlays on human capital investment—or the out-of-pocket cost to firms for training. The change in direct outlays on human capital investment resulting from the rule is calculated as follows:

*Reduced Direct Outlays = [(Total Direct Outlays)/(# of Workers Receiving Training)] * [(Total # of Affected Workers) * (Percentage Point Decrease in Trained Workers)]*

Total direct outlays on human capital investment are estimated to be $105 billion in 2023 dollars.[1147] The estimated number of workers receiving training is 23.5 million workers.[1148] The Commission estimates the total number of affected workers as 101.1 million workers, assuming all workers are affected, and 45.3 million workers, assuming only workers in high-use occupations are affected.[1149] The percentage point decrease in trained workers is estimated to be 0.4.[1150]

This calculation results in annual cost savings of $1.6 billion, assuming the training rates of workers in all occupations are affected and $0.7 billion assuming the training rates of workers only in high-use occupations are affected. The ten-year present value effects of the final rule on investment in human capital, assuming that lost investment is core investment, discounted at 2%, 3%, and 7% and separately assuming effects on workers in all occupations versus just workers in occupations that use non-competes at a high rate, are presented in the first two rows of Table 5.

ii. Estimates Assuming Lost Investment in Human Capital Is Advanced Training

The second set of estimates of the effects on human capital investment in the final analysis assumes all training is advanced. The Commission begins with the same approach (calculated in Part X.F.7.a.i) to estimate the direct gain in output of workers and reduced direct outlays from foregone advanced human capital investment because such investment is costly for firms and results in decreased time spent on productive activities by workers, regardless of whether the investment is core or advanced. The major difference is that the Commission nets out an additional component which represents lost long-term productivity of workers caused by lost investment in their human capital. The Commission nets out this additional component based on the assumption that advanced human capital investment results in some increased long-term productivity in workers (because it assumes that firms would not otherwise make such a costly investment). This results in estimated effects of the final rule that represent upper bounds on the costs associated with changes in investment in human capital. Therefore, the estimated effect of the rule on advanced human capital investment is calculated as follows:

Effect of Decreased Investment in Advanced Training = Additional Output of Workers Resulting from Less Time Spent Training + Reduced Direct Outlays on Training − Lost Output Resulting from Foregone Advanced Training

The first two components—additional output of workers due to less time spent training and reduced direct outlays on training—are calculated in Part X.F.7.a.i. The lost output of workers due to lost investment in their human

---

[1143] Excluding States which broadly prohibit non-competes (CA, ND, OK, and MN), the BLS reports employment of 126.4 million individuals in May 2022 (the most recent year with occupation-specific data available), 56.6 million of whom work in occupations that use non-competes at a high rate, as defined in Starr, *supra* note 445; see *https://www.bls.gov/oes/tables.htm*. The Commission estimates that 80% of employed individuals are covered by the Commission's jurisdiction (see Part X.F.4.a), resulting in 101.1 million covered workers, 45.3 million of whom work in high-use occupations. The Commission notes that these estimates include public employment, as data on occupation-specific employment at the State level are not available by firm ownership. Occupation-specific employment data are necessary to split workers into low- and high-use occupations. Workers including those estimated to be bound by non-competes and those who are not are included in this estimate, since the empirical estimate of the increase in training reflects a sample representative of the full workforce, not just those bound by non-competes.

[1144] The coefficient reported by Starr (*supra* note 445), 0.77%, corresponds to a one standard deviation increase on Starr's scale, and represents the percentage point effect on the percentage of workers trained (rather than the amount of training they receive). Rescaling to a scale of zero to one, a one standard deviation increase is equal to a change in the enforceability measure of 0.17. Since estimates for earnings and innovation use a mean enforceability change of 0.081 on a scale of zero to one, the coefficient in Starr is rescaled to 0.77 * (0.081/0.17) = 0.364%, which represents the change in the fraction of covered workers receiving training due to an average magnitude change of 0.081.

[1145] 85 hours per year is calculated as 5.7 weeks per year * 20.1 hours per week * 73.9%, where 73.9% is the percentage of training that is firm-sponsored (the type of training likely to be affected by the final rule). These three estimates (5.7 weeks per year, 20.1 hours per week, and 73.9% of training being firm sponsored) are estimated in Harley J. Frazis & James R. Spletzer, *Worker Training: What We've Learned from the NLSY79,* 128 Monthly Lab. Rev. 48 (2005).

[1146] The Commission assumes that the average hourly output of workers is twice their average earnings and estimates average earnings to be $30.38 per hour, which is the average hourly earnings for workers in training ages 22–64 currently holding one job in the Survey of Income and Program Participation for all waves from 1996 to 2008. The dollar value is adjusted to 2023 dollars.

[1147] 2022 Training Industry Report, Training Magazine (Nov. 2022) at 17.

[1148] Calculated as 15.8% * 148.9 million, where 15.8% is the percentage of workers who receive training, according to Frazis & Spletzer *supra* note 1145 at 48. 148.9 million is the estimated number of workers in the U.S. in May 2022 according to *https://www.bls.gov/oes/tables.htm*. Note that all workers are included in this estimate (not just workers in States which enforce non-competes) because the estimate of training expenditures also covers all workers.

[1149] Excluding States which broadly prohibit non-competes (CA, ND, OK, and MN), the BLS reports employment of 126.4 million individuals in May 2022 (the most recent year with occupation-specific data available), 56.6 million of whom work in occupations that use non-competes at a high rate, as defined in Starr (*supra* note 445) (*see https://www.bls.gov/oes/tables.htm*). The Commission estimates that 80% of employed individuals are covered by the Commission's jurisdiction (see Part X.F.4.a), resulting in 101.1 million covered workers, 45.3 million of whom work in high-use occupations. *See supra* note 1143.

[1150] As discussed in Part X.F.7.a.i.

capital due to the rule in each year is calculated as follows:

*Lost Output from Lost Investment in Human Capital = (Total # of Affected Workers) * (Percentage Point Decrease in Trained Workers) * (Average Hourly Output of Workers) * (Average Hours Worked per Year) * (% Productivity Loss)*

The Commission estimates the total number of affected workers as 101.1 million workers, assuming all workers are affected, and 45.3 million workers, assuming only workers in high-use occupations are affected.[1151] The percentage point decrease in trained workers is estimated to be 0.4.[1152] Average hourly output of workers is estimated to be $60.77.[1153] The average number of hours worked per year is 1,784.[1154] The Commission assumes the percent productivity loss to be 6.4%.[1155]

In the first year, this yields a total estimate of lost output from lost investment in human capital of $1.5 billion or $0.7 billion (under the separate assumptions of all workers being affected and only high-use occupation workers being affected). Since the returns to advanced training persist to some extent over time, in the second year, returns to advanced training from the first year are assumed to depreciate by 20%,[1156] and the calculation is redone according to the depreciated return to advanced training. In the third year, training from the first year again depreciates, and so on until the tenth year (the end of the horizon considered).

Additionally, in the second year, a new round of advanced training is forgone. An additional $1.5 billion or $0.7 billion in lost output is therefore incurred in the second year under the final rule, and the depreciation calculations are again repeated for the new round of advanced training until year ten. New rounds of advanced training are forgone in each year through the tenth. Lost output from lost advanced training in the tenth year is therefore the sum of a depreciated return to training from each of the prior nine years plus lost output from lost training in the tenth year itself.

To arrive at estimates of overall lost productivity due to lost advanced training, lost productivity in each year (separately due to lost training in each prior year) is added together. Finally, lost productivity due to lost advanced training is subtracted from the two components calculated in Part X.F.7.a.i (additional output of workers from less time spent training and reduced direct outlays). The ten-year discounted effects of the final rule on investment in human capital, assuming lost investment is advanced training investment, discounted at 2%, 3%, and 7%, and separately assuming workers in all occupations versus just workers in occupations that use non-competes at a high rate, are presented in the last two rows of Table 5.

TABLE 5

	2% Discount rate	3% Discount rate	7% Discount rate
Estimated discounted ten-year effect assuming lost training is core and workers in all occupations are affected	$32	$31	$27
Estimated discounted ten-year effect assuming lost training is core and workers in high-use occupations are affected	14	14	12
Estimated discounted ten-year effect assuming lost training is advanced and workers in all occupations are affected	−41	−39	−31
Estimated discounted ten-year effect assuming lost training is advanced and workers in high-use occupations are affected	−19	−17	−14

Note: All values in billions of 2023 dollars. Negative values represent net cost estimates, while positive values represent net benefit estimates.

As discussed in Part X.E, the Commission notes that the estimates in this Part X.F do not account for senior executives who continue to work under non-competes under the rule. If the effects on training are due to effects on such senior executives, then the effects discussed herein would occur further into the future than discussed.

b. Legal and Administrative Costs Related to Compliance

The Commission finds that firms with existing non-competes will have related legal and administrative compliance costs as a result of the final rule. The Commission quantifies and monetizes these costs and conducts related sensitivity analyses.

i. Legal Costs

The Commission finds one-time legal costs related to firms' compliance with the final rule are estimated to total $2.1-$3.7 billion. The Commission estimates two main components of legal costs: (1) updating existing employment agreements or terms to ensure new hire employment terms comply with the final rule; and (2) advising employers about potential operational or contractual changes for workers who will no longer have enforceable non-competes. The latter includes determination of workers whose non-competes are no longer enforceable

[1151] Excluding States which broadly prohibit non-competes (CA, ND, OK, and MN), the BLS reports employment of 126.4 million individuals in May, 2022 (the most recent year with occupation-specific data available), 56.6 million of whom work in occupations that use non-competes at a high rate, as defined in Starr (*Id.*) (see *https://www.bls.gov/oes/tables.htm*). The Commission estimates that 80% of employed individuals are covered by the Commission's jurisdiction (see Part X.F.4.a), resulting in 101.1 million covered workers, 45.3 million of whom work in high-use occupations. *See supra* note 1143.

[1152] As discussed in Part X.F.7.a.i.

[1153] The Commission assumes that the average hourly output of workers is twice their average earnings and estimates average earnings to be $30.38 per hour, which is the average hourly earnings for workers in training ages 22–64 currently holding one job in the Survey of Income and Program Participation for all waves from 1996 to 2008. The dollar value is adjusted to November 2023 dollars using *https://www.bls.gov/data/inflation_calculator.htm.*

[1154] See *https://fred.stlouisfed.org/release/tables?rid=50&eid=6462#snid=6449,* which reports average weekly hours and overtime of all employees on private nonfarm payrolls by industry sector, seasonally adjusted. The reported value, 34.3, is multiplied by 52 to get annual hours worked.

[1155] This figure is the midpoint of two estimates in the literature: Harley Frazis & Mark A. Loewenstein, *Reexamining the Returns to Training: Functional Form, Magnitude, and Interpretation,* 40 J. Hum. Res. 453 (2005) [3.7%] and Gueorgui Kambourov, Iourii Manovskii, & Miana Plesca, *Occupational Mobility and the Returns to Training,* 53 Can. J. of Econ. 174 (2020) [9.1%].

[1156] There is no perfect estimate of the rate of human capital depreciation in the economic literature. Studies typically make assumptions they deem reasonable to estimate this rate, with 20% representing neither the low end nor the high end of the range of such assumptions. *See, e.g.,* Rita Almeida & Pedro Carneiro, *The Return to Firm Investments in Human Capital,* 16 Lab. Econs. 97 (2009), who assume that the human capital depreciation rate may range from 5% to 100%.

under the rule, as opposed to those that fall under the exemption for senior executives.

For the first component, firms must consider what changes to their contractual practices are needed to ensure that incoming workers are not offered or subject to non-competes and what revisions to human resources materials and manuals are needed to ensure they are not misused on a forward-going basis. Firms may respond by removing specific non-compete language from standard contracts and human resources (H.R.) materials and manuals used for future employees. The second component involves strategic decisions and changes in response to the final rule. For example, firms may adjust other contractual provisions such as NDAs. This legal work is not mandated or required by the rule; it would be undertaken only by the subset of firms and workers for whom firms conclude that such alternatives would be desirable. Additionally, such adjustments are likely unnecessary for senior executives whose non-competes continue to be enforceable under the rule. Therefore, this component additionally involves identifying senior executives whose existing non-competes are unaffected. For any such legal work, firms may use in-house counsel or outside counsel.

Legal costs are therefore calculated as follows:

Legal Costs = Modify Standard Contract Language/H.R. Materials and Manuals Costs + Revise Contractual Practices Costs

One component of the legal cost will be due to the modification of standard contracts to remove prohibited language regarding non-competes which is calculated as follows:

*Modify Standard Contract Language/H.R. Materials and Manuals = (Average Hours Necessary for Modification) * (Cost per Hour) * (# of Affected Businesses)*

The Commission estimates that, on average, modifying standard contract language and H.R. materials and manuals would take the equivalent of one hour of a lawyer's time.[1157] The estimated cost per hour is $134.62 in 2023 dollars,[1158] and the number of affected businesses is 3.4 million.[1159] This results in a total one-time modification cost of $457 million.

Another component of legal costs relates to any firm-level revision to their contractual practices, including identification of senior executives, which is calculated as follows:

*Revise Contractual Practices Costs = (Average Hours Necessary to Update Contractual Practices) * (Cost per Hour) * (# of Affected Businesses)*

The Commission estimates the average firm employs the equivalent of four to eight hours of a lawyer's time to update its contractual practices and determine which employees may fall under the final rule's exemption.[1160] The Commission estimates the cost of a lawyer's time to be $134.62 as discussed in this Part X.F.7.b.i. The number of affected businesses is estimated to be 2.9 million.[1161]

Under the assumption that the average firm that uses a non-compete employs the equivalent of four to eight hours of a lawyer's time, the total one-time expenditure on revising contractual practices would range from $1.6 billion (assuming four hours are necessary) to $3.1 billion (assuming eight hours are necessary).

Some commenters indicated that some firms may use outside counsel, which is more costly to firms, to remove non-competes from contracts of incoming workers and to update contractual practices. While commenters did not provide data to support this assertion, as a sensitivity analysis, the Commission replaces the estimate of the hourly earnings of a lawyer with an estimate of the cost of outside counsel ($483 per hour), conservatively overestimating costs by using the estimated rate of a tenth-year lawyer.[1162] Under this sensitivity analysis, the Commission estimates the total cost of ensuring that incoming workers' contracts do not contain non-competes would be $1.6 billion and the cost of updating contractual practices would be $5.6-$11.3 billion. Some commenters stated that the hourly cost of lawyers' time may be even greater than the value assumed in the sensitivity analysis ($483 per hour). The Commission finds that the sensitivity analysis assuming a rate of $438 per hour provides a reasonable estimate of the costs under the assumption that outside counsel would be used, and that higher rates (*e.g.,* $749 per hour, as stated by one commenter) are unreasonably high, especially as an average across many firms.

The Commission believes the exclusion of existing non-competes with senior executives could result in lower net legal costs than the Commission's estimate. First, for senior executives who currently work under a non-compete, firms will have a longer time period during which they may update

---

[1157] This process would likely be straightforward for most firms (*i.e.,* simply not using non-competes or removing one section from a boilerplate contract). There may be firms for which it is more difficult and requires more time. This analysis uses an average time spent of one hour, which conservatively represents the *average* time spent to do so, and accounts for variation across firms.

[1158] According to BLS, the median wage for a lawyer was $65.26 per hour in 2022, or $67.31 in 2023 dollars. See *https://www.bls.gov/ooh/legal/lawyers.htm.* As in Part X.F.7.a, the Commission doubles this number to reflect the lost productivity of the worker.

[1159] Calculated as 6.88 million * 0.494. Here, 6.88 million is the number of establishments in the U.S. (excluding California, North Dakota, Oklahoma, and Minnesota, where non-competes are broadly unenforceable) in 2021 (the most recent year with data available): see *https://www.census.gov/data/tables/2021/econ/susb/2021-susb-annual.html.* This value is multiplied by 49.4%, the percentage of firms using non-competes in the U.S. according to Colvin & Shierholz (*supra* note 65).

[1160] The Commission emphasizes that this is an average to underscore there would likely be large differences in the extent to which firms update their contractual practices. Many firms, including those that use non-competes only with workers who do not have access to sensitive information, or those which are already using other types of restrictive employment provisions to protect sensitive information, may opt to do nothing. There is evidence indicating firms that use non-competes are already using other types of restrictive employment provisions: Balasubramanian et al. (2024) find that 95.6% of workers with non-competes are also subject to an NDA, 97.5% of workers with non-competes are also subject to a non-solicitation agreement, NDA, or a non-recruitment agreement, and that 74.7% of workers with non-competes are also subject to all three other types of provisions. See Balasubramanian, Starr, & Yamaguchi (*supra* note 74). Other firms may employ several hours or multiple days of lawyers' time to arrive at a new contract. The estimated range of four to eight hours represents an average taken across these different possibilities. For example, if two-thirds of firms that currently use non-competes opt to make no changes to their contractual practices (for example, because they are one of the 97.5% of firms which already implement other post-employment restrictions, or because they will rely on trade secret law in the future, or because they are using non-competes with workers who do not have access to sensitive information), and one-third of such firms spend (on average) the equivalent of 1.5 to 3 days of an attorney's time, this would result in the estimate of 4–8 hours on average.

[1161] Calculated as 5.91 million * 0.494. Here, 5.91 million is the number of firms in the U.S. (excluding California, North Dakota, Oklahoma, and Minnesota, where non-competes are broadly unenforceable) in 2021 (the most recent year with data available): *see https://www.census.gov/data/tables/2021/econ/susb/2021-susb-annual.html.* This value is multiplied by 49.4%, the percentage of firms using non-competes in the U.S. according to Colvin & Shierholz (*supra* note 65). The Commission notes that this analysis assumes that decisions regarding protection of sensitive information and contract updating are made at the firm (a collection of establishments under shared ownership and operational control), rather than establishment, level, since sensitive information is likely shared across business establishments of a firm. This explains the difference between the number of businesses used here (2.9 million) versus the number used to calculate the cost of contract revision (3.4 million).

[1162] This estimate is drawn from the Fitzpatrick Matrix. *See supra* note 1087 and accompanying text. Note that the Commission does not double this number to reflect productivity, since the cost of outside counsel's time likely already reflects the productivity of that worker.

contractual practices. For example, for a senior executive who does not change jobs for 5 years after the compliance date of the final rule, the firm will have 5 years to determine how it wants to update contractual practices for an incoming senior executive who replaces the current one. Delaying costs in this way reduces their economic effect due to discounting. Additionally, if a senior executive remains in their job for over ten years, then the cost of updating contractual practices would fall outside the scope of the Commission's estimates altogether.

At the same time, when the final rule goes into effect, firms will need to identify senior executives whose existing non-competes are not covered by the final rule in order to determine which contractual practices they may need to update immediately. The Commission does not include a separate legal cost for identifying senior executives and estimates the range of attorney time for revising contractual practices under the final rule, which encompasses identifying senior executives, to be the same as the estimate for the proposed rule—4 to 8 hours. This is in part because the strategic considerations involved in revision of contractual practices will likely include such identification. Moreover, the Commission believes the identification of such workers will not be difficult or time consuming. Firms can use the compensation threshold to rule out the vast majority of workers from the exemption and the definition of senior executive in § 910.1 includes clear duties to determine whether any executives who meet the compensation threshold are senior executives under the final rule. It also provides that the CEO and/or president of a firm is a senior executive without the need to conduct any duties analysis.

Another reason the Commission does not add to its estimate of 4 to 8 hours to account for identification of senior executives is that excluding existing non-competes with senior executives would otherwise decrease this estimate, likely to a greater degree than the cost of identifying senior executives. As noted, a significant amount of time spent by attorneys as estimated in the NPRM was intended to account for revising contractual practices for more complex agreements. Commenters noted that employment terms with senior executives are often individualized so that attorney and firm time would be spent on their agreements regardless of whether a non-compete may be included. Since firms use non-competes for senior executives at a high rate,[1163] revising contractual practices for senior executives may constitute a significant portion of the overall estimate of the cost of revising contractual practices, and given their exclusion, the Commission finds that the cost estimate for revising contractual practices likely represents an overestimate overall. The Commission does not, however, reduce its final cost estimates to account for this change. As noted in Part X.D, this final analysis generally does not account for the temporal difference in coverage of non-competes for senior executives. The same is true here and, to be consistent across the estimates in this final regulatory analysis, the Commission does not estimate a reduction in legal cost but notes potential bases for differences in estimates where relevant.

Overall, the Commission acknowledges that there may be substantial heterogeneity in the costs for individual firms; however, these numbers may be overestimates. For firms whose costs of removing non-competes for incoming workers is greater, the work of ensuring that contracts comply with the law would overlap substantially with the costs of updating contractual practices.

ii. Administrative Costs for Notification Requirement

The Commission finds the total one-time costs for implementing the notification requirement are estimated to be $94 million. These costs relate to the provision of notice to workers other than senior executives as required by § 910.2(b). Notably, firms may use the model notice language provided by the Commission, and the form of this model notice enables firms to choose to send the notice to workers regardless of whether they have non-competes as described in Part IV.E. The notice provision cost is calculated as follows:

Notice Provision Cost = Digital Notice Provision Costs + Mailed Notice Provision Costs

The first component, digital notice provision costs, are calculated as follows:

*Digital Notice Provision Costs = (Average Hours Necessary to Compose and Send Notice) * (Cost per Hour) * (# of Affected Businesses)*

The Commission estimates that 20 minutes (⅓ of one hour) are necessary for a human resources specialist to compose and send this notice in a digital format to all of a firm's workers who are not senior executives [1164] and applicable former workers, on average.[1165] The cost per hour is estimated to be $63.70.[1166] The estimated number of affected businesses is 3.4 million.[1167] The digital notice provision cost is therefore estimated to be $72 million.

Businesses may not have digital contact information for some workers. The cost of mailed notice provision would include the cost of postage and the cost of a human resource professional's time. Mailed notice provision costs are therefore calculated as follows:

*Cost of Mailed Notice Provision = Number of Workers with Non-competes Receiving Physical Notice * (Cost of One Printed Page + Mailing Cost + Cost of Human Resource Professional's Time)*

The number of workers with non-competes receiving physical notice is the total number of covered workers (101.1 million; see Part X.F.7.a.i) times the percentage of workers who have non-competes (18.1%) times the percentage of workers who require mailed notice (assumed to be 66% of workers [1168]), for a total of 12.3 million workers. The Commission notes that the percentage of workers who require mailed notice is likely a substantial overestimate, since it is estimated based on the percentage of individuals who receive health information digitally. The Commission believes employers are more likely to have digital means of providing the notice to their current workers especially, but also to their

[1163] More than 60%; *see* Part I.B.2.

[1164] The Commission notes that identification of such workers is accounted for in revision of contract costs calculated in Part X.F.7.b.i.

[1165] *See, e.g.,* the supporting statement for the Notice of Rescission of Coverage and Disclosure Requirements for Patient Protection under the Affordable Care Act (CMS–10330/OMB Control No. 0938–1094) at 5, which estimates time spent customizing and sending similar notice. Available at *https://www.reginfo.gov/public/do/DownloadDocument?objectID=119319401.*

[1166] According to BLS, the median wage for a human resources specialist was $30.88 per hour in 2022, which is equivalent to $31.85 in November 2023 dollars, updated for inflation using *https://www.bls.gov/data/inflation_calculator.htm.* See *https://www.bls.gov/ooh/business-and-financial/human-resources-specialists.htm.* As in Part X.F.7.a, the Commission doubles this number to reflect the lost productivity of the worker.

[1167] As calculated in Part X.F.7.b.i., the Commission conservatively assumes that each establishment—a physical location of a business—must engage in its own communication, and that each establishment has digital contact information for at least one worker, and will therefore engage in digital notice provision.

[1168] See *infra* note 1165 (CMS Supporting Statement assumes 66% of workers require mailed notice from their health insurance companies).

former workers. The Commission adopts this estimate as an upper bound.

The cost per worker is estimated as 5 cents for one printed page plus mailing cost of 70 cents plus one minute of an HR professional's time, at $63.70 per hour, for a total of $1.81 per notice. The overall cost of mailed notice provision is therefore estimated to be $22 million. The total cost of the notice provision is therefore $94 million.

Commenters stated that it may take two hours of a legal professional's time to provide notice. The Commission finds this estimated time to be a substantial overestimate and reiterates that this analysis incorporates a legal professional's time necessary to identify senior executives and to strategize updates to firm contractual practices into its estimate of legal costs in X.F.7.b.i. The model notice language alleviates the need for a legal professional's time and the Commission finds it unreasonable to assume such a notice would need to actually be sent by a legal professional. While firms may opt to use original language drafted by an attorney to notify workers, the Commission notes that the model language satisfies the notification requirement and therefore does not include the cost of original language as a regulatory cost estimate in the final analysis. However, under these assumptions, the cost of providing the notice is estimated at $5.2 billion.

The Commission notes that communication is conducted at the establishment level and time costs do not vary based on the number of existing senior executives with non-competes that the final rule does not cover. While establishments with only senior executives with non-competes would not incur any notification costs because the final rule does not cover existing non-competes with senior executives, without an estimate of the percentage of firms for which this is true, the Commission conservatively assumes that all establishments estimated to use non-competes engage in this notification.

Legal and administrative costs are summarized in Table 6. The Commission notes that, since all costs are assumed to be borne in the first year, there is no discounting applied and therefore only one estimate for each analysis is presented.

TABLE 6

	$ billions
Cost of modifying standard contract language/H.R. materials and manuals	
Primary	$0.5
Sensitivity analysis (outside counsel cost of $483)	1.6
Cost of reviewing and revising contractual practices	
Primary, four hours	1.6
Primary, eight hours	3.1
Sensitivity analysis (four hours, outside counsel cost of $483)	5.6
Sensitivity analysis (eight hours, outside counsel cost of $483)	11.3
Administrative Costs for Notification Requirement	
Primary	0.09

c. Litigation Effects

Theoretically, under the final rule, certain litigation costs may fall. Litigation related to non-competes may decrease because the final rule creates bright line rules, reducing uncertainty about the enforceability of non-competes. On the other hand, litigation costs may rise if firms turn to litigation to protect trade secrets and if that litigation is more expensive than enforcing (or threatening to enforce) non-competes, and/or if firms elect to litigate over what constitutes a non-compete.

The Commission finds there are plausible but directionally opposite theoretical outcomes for the different types of litigation that may be affected by the final rule. In fact, some recent evidence suggests trade secret litigation falls as a result of bans on non-competes taking effect.[1169] The Commission finds no evidence increased litigation will result in increased costs associated with the final rule. The Commission cannot quantify or monetize the overall effect as a cost or benefit, but estimates the magnitude of any change would be sufficiently small as to be immaterial to the Commission's assessment of whether the benefits of the rule justify its costs.

8. Transfers

As discussed in Part X.F.6.a, some portion of the earnings effect associated with the final rule represents a transfer: while workers may earn more with greater productivity resulting from the rule, some of their earnings increase may result from enhanced bargaining power, which constitutes a transfer from firms to workers.

Similarly, some portion of the price effects associated with the final rule represents a transfer: while consumers may achieve greater surplus with increased competition, the price decrease itself is partially a transfer from firms to consumers.

9. Distributional Effects

The Commission finds several distributional effects associated with the final rule, including those associated with firm expansion and formation, distributional effects on workers, and labor mobility, as summarized in Table 1 in Part X.E.

a. Firm Expansion and Formation

When non-competes are prohibited, new firms may enter the market but incumbent firms may opt to invest less in capital, leaving the overall effect on total capital investment unclear. Similarly, while new firms may enter the market, it is theoretically possible that incumbent firms may exit the market without the ability to use non-competes (though no evidence of this

[1169] Greenwood, Kobayashi, & Starr, *supra* note 757. The Commission notes that this study supplements—but is not necessary to support—its finding that no evidence supports the conclusion that litigation costs will increase under the final rule. That finding is based on the Commission's expertise and the rulemaking record, including relevant comments. This study was published after the close of the comment period.

effect exists) or contract. Research finds that decreased non-compete enforceability increases new firm formation by 2.7% and may have no effect on capital investment or may decrease capital investment at incumbent firms by up to 7.9%. To the extent there may be a decrease in capital investment at incumbent firms as a result of the final rule, it may represent a shift in productive capacity from incumbent firms to new firms. As discussed in Part IV.D, another purported justification for non-competes is that they allow firms to protect trade secrets, which in theory might allow firms to share those trade secrets more freely with workers, and so improve productivity. However, no empirical evidence substantiates this claim or would allow quantification or monetization of this effect.

Empirical evidence has studied parts, but not all, of the contrasting effects on capital investment and new firm formation. Studies have examined effects of non-competes on capital investment by large, publicly traded firms, who are likely incumbents.[1170] However, no study examines the effect of capital investment economy-wide, nor does any study specifically examine capital investment for new firms. Similarly, studies have examined new firm formation, but no studies look at firm exit among incumbents.

It is thus not possible to measure the benefit and costs of the full economy-wide effects on firm expansion and formation. The calculations that may be performed using available data will necessarily omit components of the tradeoff. The final analysis therefore quantifies the effects that the literature has examined but does not monetize those effects.

i. Capital Investment

Research finds that capital investment for incumbent firms at the firm level may decrease under the final rule for the economy as a whole, though effects for high-tech industries may be positive, negative, or close to zero. The Commission notes that the capital investment discussed in this Part X.F.9 relates to tangible capital, does not reflect capital investment by newly-formed firms, and is distinct from R&D spending, which is discussed in Part X.F.6.b.

One estimate of the overall effect of non-compete enforceability on capital investment by incumbent firms, which some commenters pointed to, is estimated with substantial uncertainty and is statistically indistinguishable from zero (*i.e.,* statistically insignificant): a decline in capital investment of 7.9% for the average incumbent publicly-traded firm.[1171] Another study finds no effect on capital investment, but includes the use of non-competes in its estimating procedure, leading to concerns that the finding does not support a causal interpretation, as explained in Part IV.A.2.[1172]

The Commission notes two additional estimates specific to high-tech or knowledge firms: a decline in capital investment among incumbent publicly-traded firms of 34%–39% (an estimate which corresponds to the estimate of a decline of 7.9% when all publicly traded firms are examined),[1173] and an increase in capital investment of 3.1% for the average publicly-traded high-tech firm (an estimate that is statistically insignificant).[1174] The Commission notes the study finding an increase in capital investment of 3.1% uses a more granular measure of non-compete enforceability than the study finding a decrease of 34%–39%, and the Commission therefore gives it more weight.[1175]

The Commission reiterates that any change in investment at the firm level does not necessarily mean investment would change at the market level, since increased firm entry may also increase the employed capital stock and investment in that capital stock, which may offset any possible decreases in investment for incumbent firms. These potential positive offsetting effects are not captured in the estimates herein.

ii. New Firm Formation

Research finds that new firm formation increases by 2.7% across the economy due to decreases in non-compete enforceability.[1176] The Commission also notes an estimate specific to high-tech industries: that decreases in non-compete enforceability led to a 3.2% increase in the establishment entry rate.[1177]

The benefits associated with new firm entry may include added surplus for consumers (*e.g.,* from increased competition) or workers (from expanded labor demand). However, the Commission is unable to quantify those beneficial effects, though some may be captured by the effect on prices discussed in Part X.F.6.c. Nor is it able to quantify whether existing firms might exit or contract in response to this new firm entry (*i.e.,* whether the new firms' output would be wholly additive or crowd out some amount of existing firms' output). New firm entry may also drive some of the innovative effects of the final rule if new firms are engaging in substantial innovation.

Overall, the Commission finds that the rule will likely result in a 2.7% increase in new firm formation and is unable to quantify the net effects of this on the productive capacity of the economy. Benefits from new firm entry and possible costs from decreased capital investment may offset each other but the degree to which this happens is not quantifiable. The effect of the final rule on firm expansion and formation likely results in productive capacity shifting from incumbent firms to new firms. Consistent with findings in Part IV.B.3.b.iii, productive capacity shifting from incumbent to new firms may decrease concentration, possibly contributing to decreases in prices, as discussed in Part X.F.6.c.

[1170] Jeffers, *supra* note 450; Johnson, Lipsitz, & Pei, *supra* note 526.

[1171] The increase, 7.9%, is calculated as 0.00317/0.04, where 0.00317 is the reported coefficient (Table 4, Panel A, Column 1), and 0.04 is the mean investment per million dollars of assets ratio, across all firms (Table 2, Panel C). Due to statistical uncertainty, the estimate cannot rule out (with 95% confidence) values ranging from a *gain* in capital investment equal to 6.7% to a *loss* in capital investment equal to 22.5% for the average firm. See Jeffers, *supra* note 450.

[1172] Shi, *supra* note 84.

[1173] Jeffers, *supra* note 450. The estimate pertains to firms in Technology and Professional, Scientific, and Technical Services.

[1174] Johnson, Lipsitz, & Pei, *supra* note 526. The estimate pertains to firms classified as high-technology by the National Science Foundation: see *https://nsf.gov/statistics/seind14/index.cfm/chapter-8/tt08-a.htm.*

[1175] The two studies are otherwise identical in the extent to which they satisfy the criteria for assessing empirical research laid out in Part IV.A.2.

[1176] Jeffers (*supra* note 450) does not report an effect for the economy as a whole. However, Jeffers reports coefficients of −0.103 for the effect of increased non-compete enforceability on firms founded per million people in knowledge-sector industries and 0.008 for non-knowledge sector industries, with respective sample sizes of 78,273 and 190,665 (Table 9, Panel A, Columns 1 and 2). Using the sample sizes as weights, the Commission estimates a weighted average of these coefficients of −0.024. Applying this estimate to the average number of firms founded per million people (Table 2, Panel B) results in an estimated increase in new firm formation of 2.7%. The Commission did not calculate the effect for the economy as a whole in the NPRM. The NPRM reported that increases in non-compete enforceability decreased new firm entry by ''0.06 firms per million people (against a mean of 0.38) for firms in the knowledge sector,'' NPRM at 3526, which was consistent with the version of the Jeffers study cited in the NPRM. The final rule cites the updated version of the Jeffers study, published in 2024. The Commission notes that estimation of the uncertainty in the combined estimate requires information on the covariance of the estimated coefficients, which is not reported in Jeffers' study. See Jeffers, *supra* note 450.

[1177] Johnson, Lipsitz, & Pei, *supra* note 526. The estimate pertains to firms classified as high-technology by the National Science Foundation: see *https://nsf.gov/statistics/seind14/index.cfm/chapter-8/tt08-a.htm.*

b. Distributional Effects on Workers

The Commission finds that the final rule may reduce gender and racial earnings gaps, may especially encourage entrepreneurship among women, and may mitigate legal uncertainty for workers, especially relatively low-paid workers.

Specifically, the Commission finds gender and racial wage gaps may close significantly under a nationwide prohibition on non-competes, according to economic estimates.[1178] Another estimate indicates that the negative effect of non-compete enforceability on within-industry entrepreneurship is significantly greater for women than for men.[1179]

The Commission finds the rule may be especially helpful for relatively low-paid workers, for whom access to legal services may be prohibitively expensive. Workers generally may not be willing to file lawsuits against deep-pocketed employers to challenge their non-competes, even if they predict a high probability of success. The Commission finds that the bright-line prohibition in the final rule, which the Commission could enforce, may mitigate uncertainty for workers.[1180]

c. Labor Mobility

The Commission finds the overall effect of the final rule on turnover costs due to increased labor mobility is ambiguous and represents a distributional effect of the rule. The Commission finds turnover costs for firms seeking new workers may fall with a greater availability of experienced labor. For firms losing workers newly freed from non-competes, the Commission estimates the effect of the final rule to be $131 per worker with a non-compete. The Commission therefore finds the effect on turnover costs represents a distributional effect of the final rule because it costs firms that use non-competes to constrain workers and benefits firms that do not.

To calculate the potential $131 increase in turnover costs for workers whose non-competes are no longer enforceable after the rule, this final analysis calculates:

*Additional Turnover Cost per Worker with a Non-compete = (Baseline Turnover Rate) * (% Increase in Turnover) * (Rate of Use of Non-competes in Affected Industries) * (Overall Earnings of Affected Workers) * (Cost of Turnover as % of Earnings)/(Number of Workers in Affected Industries with Non-competes)*

The Commission estimates the baseline turnover rate, *i.e.,* the turnover rate in the status quo, to be 47% annually.[1181] The estimated percent increase in turnover from the final rule is 1.0%.[1182] The estimated rate of use of non-competes in affected industries is 23.9%.[1183] Estimated overall earnings of affected workers is $5.25 trillion.[1184] The estimated cost of turnover as a percentage of earnings is 25%.[1185] Finally, the estimated number of workers in affected industries with non-competes is 11.8 million.[1186]

The annual estimated increase in turnover costs per worker with a non-compete is $131.

The Commission notes the actual costs of turnover to businesses may be substantially lower under the final rule than this estimate reflects. This is because the specific components of turnover costs—finding a replacement, training, and productivity—are likely to be affected by the final rule. An increased availability of experienced workers results when non-competes no longer constrain those workers, and finding replacements will be less costly to firms. Additionally, training should not be counted in the costs of turnover presented in this Part X.F.9.c, since it is separately accounted for in Part X.F.7.a, but is nevertheless included in the 25% estimate used to arrive at the estimate of $131 per worker with a non-compete, since there is no reliable way to remove training costs from that estimate; it is thus double-counted. Finally, because the Commission finds increased labor mobility will likely increase worker productivity due to better matching between workers and firms, the cost of lost productivity will be lower. The cost of lost productivity will also be lessened because the pool of workers available to firms may be more talented or experienced, since such workers would no longer be bound by non-competes (relative to new entrants to the workforce, who are not experienced and also are not bound by non-competes). This would allow firms to recruit workers who are more likely to be highly productive upon entry at a new job.

The Commission reiterates its finding that the costs of turnover for many firms may diminish due to a more plentiful supply of available labor. Without estimates of the effect of the final rule on the cost of recruiting a worker, the net effect of the final rule on turnover costs is not quantified.

10. Break-Even Analysis

The Commission believes it has quantified the effects of the final rule that are likely to be the most significant in magnitude, but data limitations make it challenging to monetize all the expected effects of the final rule, *i.e.,* to numerically estimate the impact of particular effects on the economy as a whole. Most of the estimated costs of the final rule are monetized in Part X.F.7. However, the Commission is unable to monetize the estimated benefits of the final rule without additional assumptions. Two of the major benefits—innovation and earnings—are quantified but they are not monetized because a particular parameter or data point that would allow the Commission to estimate their effect in dollars is unavailable. For earnings, this parameter is an estimate of the percentage of the effect on earnings that represents a benefit versus a transfer.[1187] For innovation, this parameter is an estimate of the social value of a patent. Making an assumption about these parameters allows the Commission to monetize the benefits associated with the effect on earnings and innovation. A break-even analysis based on such assumptions confirms the Commission's finding that the benefits of the rule clearly justify the costs.

The analysis in this Part X.F.10 calculates the sum of the monetizable costs of the rule, separately under the assumption that lost investment in human capital is core training (in which case monetizable costs are direct

[1178] Johnson, Lavetti, & Lipsitz, *supra* note 388 at 38.

[1179] Marx (2022), *supra* note 524 at 8.

[1180] NPRM at 3531.

[1181] Based on annual worker mobility rates (separations divided by employment) in 2022 as calculated using the Job Openings and Labor Turnover Survey, conducted by BLS.

[1182] Calculated as $-e((-0.241+0.112)*0.081) - 1)$, where $-0.241+0.112$ represents the estimated effect in Johnson, Lavetti, and Lipsitz (*supra* note 388) on workers in high use industries. The corresponding estimate for other industries is statistically indistinguishable from zero and those industries are therefore omitted from calculations. The multiplier 0.081 is the average magnitude change in non-compete enforceability, as discussed in Part X.F.5.

[1183] Calculated as the average usage rate in high-use industries in Starr, Prescott & Bishara (*supra* note 68).

[1184] Based on data from BLS for industries classified as high-use in Starr, Prescott & Bishara (*supra* note 68), excluding CA, ND, OK, and MN. See *https://data.bls.gov/cew/apps/data_views/data_views.htm#tab=Tables.*

[1185] See Pivateau, *supra* note 1090.

[1186] Calculated as 49.4 million * 23.9%. 49.4 million is equal to 0.8 * 61.8 million, where 0.8 is the coverage rate (see Part X.F.4.a) and 61.8 million is the number of workers in high-use industries (*https://data.bls.gov/cew/apps/data_views/data_views.htm#tab=Tables*). 23.9% is the average usage rate in high-use industries in Starr, Prescott, & Bishara (*supra* note 68).

[1187] Though the estimated effect on earnings is presented in dollars, the Commission considers this value to be quantified, but not monetized, since some part of the estimate may represent a transfer and not a benefit.

compliance costs and the cost of updating contractual practices), and under the assumption that lost investment in human capital is advanced training (in which case monetizable costs are the net cost of lost productivity from decreased human capital investment, direct compliance costs, and the cost of updating contractual practices). The analysis conservatively assumes that training for all workers is affected (versus just those in high-use occupations, as described in Part X.F.7.a).

If the Commission assumes the decrease in human capital investment is a decrease in core training, the final rule results in net benefits without monetizing or counting any positive effects on the economy from earnings or innovation. The savings or benefit to the economy from reduced core training would be greater than the combined monetized costs of the final rule in X.F.7.b. In other words, even if the benefit to the economy from earnings and innovation were assumed to be zero (an implausible and extremely conservative assumption), the final rule would be net beneficial under the assumption that estimates of reduced training reflect better matching of workers and firms and therefore a reduced need to provide workers with core training.

Under the assumption that lost human capital investment is advanced, the Commission calculates values of the social value of a patent and the benefit percentage of the earnings effect that would fully offset the net monetizable costs of the final rule.

a. Estimate of Net Benefit Assuming Lost Human Capital Investment Is Core Training

Under the assumption that lost human capital investment is core, the sum of the present discounted value of direct compliance costs and the cost of contractual updating (the monetizable costs of the rule), using a 3% discount rate, is $3.7 billion. In this case, the final rule is net beneficial even ignoring the benefits associated with innovation and earnings. This is because the net monetized cost ($3.7 billion) is less than the monetized benefit associated with investment in human capital ($31 billion or $13.9 billion, when all occupations are assumed to be affected versus just high-use occupations, respectively). The net monetizable benefit of the final rule—even ignoring benefits associated with innovation and earnings—is therefore $27.3 billion or $10.2 billion, respectively.

b. Estimate of Net Benefit Assuming Lost Human Capital Investment Is Advanced Training

In this Part X.F.10.b, the Commission calculates the net monetizable costs and benefits of the final rule assuming that lost human capital investment is advanced training, and under varying assumptions about the values of the two monetization parameters identified (the social value of a patent and the percentage of the earnings effect that represents a benefit). Then, the Commission calculates break-even points: values for the monetization parameters which would fully offset the net monetizable costs of the final rule.

Break even points are calculated by finding the values of the social value of a patent and the benefit percent of the earnings increase such that:

*(Net Costs Associated with Investment in Human Capital) + (Direct Compliance Costs) + (Costs of Updating Contracts) = (Earnings Increase) * (Benefit % of Earnings Increase) + (Patent Increase) * (Social Value of Patent)*

As calculated in Part X.F.7, assuming a 3% discount rate, the net cost associated with investment in human capital is $39.0 billion.[1188] Direct compliance costs plus the cost of updating contracts are estimated to be $3.7 billion.[1189] Net monetizable costs therefore total $42.7 billion.

The estimated earnings increase of the final rule over ten years, discounted at 3% is $468 billion. The estimated effect of the rule on innovation (using the low end of the primary estimate) ranges from an additional 3,111 patents per year to 31,110 patents per year, increasing as time goes on.[1190]

The Commission presents estimates that demonstrate break-even points by making an assumption for the value of one of the two monetization parameters, and calculating the value of the other which implies equal monetized costs and benefits. Based on estimates of the private value of a patent, the Commission separately assumes that the social value of a patent is $94,886, $234,399, $5,865,833, or $32,459,680.[1191] In addition to spanning a wide range of possible valuations, these values all represent the private value of a patent to certain actors (*e.g.,* the purchaser or seller of a patent, or shareholders of a patenting company). These values do not account for innovative spillovers (*e.g.,* follow-on innovation) or product market spillovers to competitors (who may lose business to innovating firms), and therefore do not necessarily represent the social value of a patent. However, they serve as benchmarks against which to assess the breakeven points of the analysis of the final rule.

No studies have assessed what percentage of the earnings effect of non-compete enforceability is a benefit versus a transfer. The Commission separately assumes that the percentage is equal to 0%, 5%, 10%, and 25%.

The computed breakeven points are reported in Table 7, under the assumption that lost investment in human capital is advanced. Panel A reports necessary benefit percentages, under each of the four assumed social values of a patent, that would cause the rule to result in zero net monetized benefit. A reported value of 0% indicates that the assumed value of a patent itself covers the net monetized costs of the final rule. Panel B reports the necessary social value of a patent, under each of the four assumed benefit percentages, that would cause the rule to result in zero net monetized benefit. A reported value of $0 indicates that the benefits associated with earnings cover the net monetized costs of the final rule on their own.

TABLE 7

Assumed social value of a patent	Necessary benefit percentage on earnings
Panel A	
$94,886	5.5
$234,399	1.7
$5,865,833	0.0

[1188] Note that this calculation considers the net cost of lost investment in human capital (*i.e.,* the cost of lost productivity, minus the savings on direct outlays and gained output due to less time spent training). The Commission reiterates that this calculation assumes that lost human capital investment is advanced, rather than core.

[1189] This calculation assumes that updating contractual practices takes, on average, eight hours per firm.

[1190] The estimates presented here conservatively assume zero effect on R&D spending.

[1191] The Commission points out that the economic literature has not explored the *social* value of a patent, but has explored the *private* value of a patent, with highly varied conclusions (all reported here adjusted to 2023 dollars). Serrano estimates the average value of a patent (in terms of its sale price at auction) to be between $234,399 and $289,022. Pakes estimates the average value of a patent (in terms of stock market reactions to announcements) to be $5,865,833. Kogan et al. estimate the average value of a patent (also in terms of stock market reactions to announcements) to be $32,459,680. Outside of the academic literature, a Richardson Oliver Insights report notes that the average sale price of U.S. issued patents on a brokered market was $94,886. *See* Carlos J. Serrano, *Estimating the Gains from Trade in the Market for Patent Rights,* 59 Int'l Econ. Rev. 1877 (2018); Pakes, *supra* note 1132; Kogan, et al., *supra* note 1131; Richardson Oliver Insights Report (2022): *https://www.roipatents.com/secondary-market-report.*

TABLE 7—Continued

Assumed social value of a patent	Necessary benefit percentage on earnings
$32,459,680	0.0
Assumed benefit percentage on earnings	**Necessary patent value**
Panel B	
0%	$297,144
5%	134,202
10%	0
25%	0

Panel A shows that, even assuming a value of patenting ($94,886) that is substantially lower than the estimates in the economic literature, only 5.5% of the earnings effect must be an economic benefit (as opposed to a transfer) for the benefits associated with innovation and earnings to outweigh the monetized costs of the rule. Panel B shows that, even if no part of the earnings effect of the final rule reflects an economic benefit (which the Commission finds to be unlikely, in light of the evidence discussed in Part IV.B.3.a.ii), the social value of a patent would need to be only $297,144 in order to cover the monetized costs of the rule—well within the range of (private) values of a patent found in the literature.

The Commission additionally notes that Table 7 omits other benefits of the rule. The estimated benefits do not include the benefits arising from decreased consumer prices or increased workforce output. The estimates also omit possible changes in litigation costs associated with the rule. The Commission finds it likely that the omitted benefits substantially exceed the omitted costs, and additionally reiterates that the estimated values in Table 7 assume that lost investment in human capital is fully advanced. Therefore, the Commission views the values reported in Table 7 as conservative estimates of the breakeven points of the rule under those scenarios.

11. Analysis of Alternative Related to Senior Executives

The Commission elects to provide an analysis of the effects of an alternative with more limited coverage. Specifically, the Commission provides an analysis of a rule that would cover—and therefore ban—non-competes with all workers except senior executives. As compared to the final rule, under this alternative, it would not be an unfair method of competition to enter into non-competes with senior executives after the effective date. The Commission finds that excluding all non-competes with senior executives from coverage under the rule (as opposed to the final rule, which excludes only existing non-competes with senior executives) would diminish both costs and benefits, but would still result in substantial benefits on net.

a. Analysis of Lost Benefits and Costs if Senior Executives Are Excluded

Several costs and benefits may be affected if senior executives are excluded from coverage by the final rule. The Commission now discusses each of those costs and benefits relative to the final rule.

The Commission finds that some benefits related to labor market competition and workers' earnings would be lost if senior executives were entirely excluded from the final rule. This is especially true because those workers have high earnings, meaning that a given percentage increase in their earnings yields a greater overall effect compared with relatively lower earning individuals. However, those workers make up a small portion of the workforce—approximately 0.75% of the workforce, based on data from the American Community Survey.[1192] The overall change in the earnings benefit is therefore limited, but would exceed senior executives' share of the workforce. Support for this finding is discussed in Part IV.C. Garmaise (2011) finds that earnings of senior executives are negatively affected by non-competes. Countervailing evidence exists, but it is based on evaluation of the use of non-competes, which the Commission gives less weight.[1193] The Commission notes the definition of senior executive used in Garmaise (2011) does not map perfectly to the definition of senior executives in this final rule, though there is likely substantial overlap.

The Commission is unable to quantify the lost benefits related to innovation if senior executives were excluded from coverage under the final rule but finds their exclusion would diminish the innovation benefits of the final rule. Senior executives are involved in determination of the strategic path of the firm and its execution, which likely has a substantial effect on innovation. The Commission cannot quantify what percentage of the innovation effect is due to senior executives versus other workers, though it is likely shared by both groups.

The Commission finds that benefits related to consumer prices would fall significantly if senior executives were excluded from coverage. By increasing competition, increases in new firm formation and increased ability to hire talented workers may be key drivers of the effect of the final rule on consumer prices. As discussed in Part IV.C, senior executives have the knowledge and skills necessary to found new firms, or to be key members of other firms. Therefore, if senior executives are excluded from the final rule, some benefits associated with new firm foundation and innovation would be lost, though the exact proportion cannot be estimated. The Commission notes that benefits associated with lower prices through increased competition might also be lost but cannot be quantified.

Turning to costs, the Commission finds that costs associated with investment in human capital may fall if senior executives were excluded from the rule. The productivity of senior executives may benefit from investment in their human capital.[1194] The precise monetary contribution of investment in senior executives' human capital to the productivity of firms has not been estimated, nor has the empirical literature separately assessed the effect of non-competes on human capital investment for senior executives. If senior executives benefit from advanced, rather than core, training investment (as described in Part X.F.7.a), their exclusion will reduce costs. Because senior executives are a small part of the workforce and must be highly skilled, locking them up with non-competes could theoretically mean that firms would need to invest in relatively more core training for senior executives if they were excluded from the final rule.

The Commission finds that the direct costs of compliance with the final rule may be partially affected if senior executives were categorically excluded. The final rule allows employers to enforce existing non-competes for senior executives, so there are no notice and re-negotiation costs for senior executives. However, in this scenario, costs associated with ensuring incoming

[1192] In particular, 0.75% represents the percentage of employed individuals from 2017–21 ages 22–64, excluding residents of CA, ND, OK, and MN, and excluding workers reporting working for non-profits or the government, whose earnings are above the inflation-adjusted threshold and who are coded as having occupation ''Top Executive.'' The Commission notes that this estimate may not exactly match the definition in the final rule but the Commission believes that this provides a reasonable estimate.

[1193] *See* Part IV.A.2 (explaining the Commission's concerns with these types of studies).

[1194] Solomon Akrofi, *Evaluating the Effects of Executive Learning and Development on Organisational Performance: Implications for Developing Senior Manager and Executive Capabilities,* 20 Int'l. J. of Training and Dev. 177 (2016).

senior executives' contracts do not have non-competes would be substantially reduced. Because senior executives' contracts are generally more complex than other workers' contracts, this reduction may be relatively large, even though there are relatively few senior executives in the workforce (approximately 0.75%). With respect to the costs of updating contractual practices, commenters noted the costs of updating senior executives' contracts may be greater than for other workers because of the complexity of their contracts. Therefore, excluding senior executives categorically might reduce costs associated with updating contractual practices substantially. At the same time, senior executives' contracts may already be bespoke and individualized to such an extent that removing a non-compete would not considerably raise the costs associated with revising contractual practices. Moreover, these contracts may be even more likely than other workers to already include NDAs and other similar provisions.

Finally, the Commission finds exclusion of senior executives may reduce litigation costs from the final rule, though the overall effect is unclear. Senior executives are highly likely to have access to sensitive business information. To the extent costs associated with trade secret litigation or litigation over other restrictive covenants increase under the final rule, though no evidence supports this possibility, then exclusion of senior executives may substantially reduce these costs. Litigation related to whether a worker meets the definition of a senior executive may also increase if senior executives are categorically excluded.

Overall, excluding senior executives from the final rule would substantially reduce the benefits of the rule—especially those associated with new firm formation, innovation, and prices—but would also likely reduce costs, especially those associated with investment in human capital and updating contractual practices. The Commission finds that the benefits of a rule excluding senior executives would justify the costs of such a rule.

b. Analysis of Benefits and Costs to Workers Other Than Senior Executives

Now, the Commission turns to an analysis of the benefits and costs that remain if senior executives are excluded from the rule.

The Commission finds there would be substantial benefits to labor market competition and workers' earnings even if senior executives were categorically excluded. The evidence on earnings discussed in Part IV.B.3.a.ii does not exclude senior executives, but based on the percentage of the population that represents senior executives, the evidence largely pertains to workers other than senior executives. Therefore, while studies focused on senior executives (largely) do not apply, studies of the entire workforce mostly reflect the effects of non-competes on other workers. In addition to the broader evidence on earnings discussed in Part IV.B.3.a.ii, one study analyzes a population exclusively comprised of hourly workers, nearly all of whom are highly likely not to be senior executives, supporting the finding that even with senior executives excluded from a rule, there would be substantial benefits to labor market competition and workers' earnings.[1195]

The Commission is unable to quantify to what extent the estimated effects on innovation are driven by senior executives versus other workers, but still finds that a final rule excluding these senior executives would result in substantial benefits to innovation. First, there is evidence that productivity of inventors decreases when they take career detours because of non-competes.[1196] Second, insofar as effects on innovation are driven by increased idea recombination, having access to those ideas (which innovators actively engaged in R&D must) implies that moving to new firms would increase innovation. Empirical studies have not quantified the size of these effects relative to the overall effect of banning non-competes for workers including senior executives on innovation, however.

The Commission finds that a rule excluding senior executives would still yield substantial benefits with respect to consumer prices. Many entrepreneurs were not formerly senior executives, meaning that encouraging entrepreneurship among workers who are not senior executives by prohibiting non-competes will yield more business formation. That business formation increases competition, which may lead to lower prices. Additionally, firms will not be foreclosed access to talent (which is likely important across the spectrum of workers, though evidence only specifically exists for senior executives), which may also lead to lower prices. In the absence of empirical evidence demonstrating which workers' non-competes affect consumer prices, the Commission cannot estimate how much of the effect is due to coverage of which workers.

The Commission finds that a rule excluding senior executives would result in decreased levels of investment in workers' human capital. The empirical literature has not separately assessed the effect of non-competes on investment in human capital for senior executives versus other workers, though the study finding that training decreases with greater non-compete enforceability includes both workers who are and are not senior executives. The Commission therefore believes that some or much of any cost or benefit of the rule from changing investment in human capital would pertain to workers who are not senior executives. However, the Commission notes that, as discussed in Part X.F.7.a, if lost training under the rule is lost ''core'' (as opposed to ''advanced'') training, then the final rule will cause a cost *savings* for firms, which will have greater access to experienced workers and will therefore spend less on ''core'' training.

The Commission finds that the direct costs of compliance with the final rule may be partially diminished if senior executives were excluded. First, the Commission reiterates that notice is not required for senior executives under the final rule. Therefore, that component of the direct costs of compliance would not be affected. However, even with those senior executives excluded, costs associated with ensuring incoming workers' contracts do not have non-competes would still be present. Insofar as senior executives' contracts may be more complex than other workers' contracts, this cost may be substantially diminished, however. Similarly, with respect to the costs of updating contractual practices, as noted by commenters, these costs may be substantially greater for the contracts of senior executives due to the complexity of their contracts and the sensitivity of the information they possess. Therefore, while some costs associated with updating contractual practices would survive if senior executives were excluded, their exclusion may reduce costs associated with the rule disproportionately to their (relatively low) share of the workforce.

Finally, some litigation costs may still be present if senior executives are excluded. Litigation costs associated with non-competes would still likely fall for workers other than senior executives due to the bright-line coverage in the rule. Costs associated with litigation other than non-compete litigation may rise if firms turn to those methods, though no evidence suggests they will.

Overall, a rule that excludes senior executives will likely result in

[1195] Lipsitz & Starr, *supra* note 72.

[1196] Mueller, *supra* note 569.

substantial benefits, as well as some costs. While the Commission largely cannot quantify the extent to which benefits and costs would fall if senior executives were excluded from coverage under the rule, the Commission finds that the benefits quantified and monetized elsewhere in this impact analysis would likely be diminished relative to the final rule as adopted, especially those associated with innovation and prices, but costs would also be diminished, especially those associated with investment in human capital and updating contractual practices. The Commission finds that, even in the absence of a full monetization of all costs and benefits of the final rule, the final rule has substantial benefits that clearly justify the costs, which remains true even if senior executives were excluded from coverage.

XI. Regulatory Flexibility Act

The Regulatory Flexibility Act (''RFA''), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, requires an agency to provide an Initial Regulatory Flexibility Analysis (''IRFA'') and Final Regulatory Flexibility Analysis (''FRFA'') of any final rule subject to notice-and-comment requirements, unless the agency head certifies that the regulatory action will not have a significant economic impact on a substantial number of small entities.[1197] In the NPRM, the Commission provided an IRFA, stated its belief that the proposal will not have a significant economic impact on small entities, and solicited comments on the burden on any small entities that would be covered.[1198] In addition to publishing the NPRM in the **Federal Register**, the Commission announced the proposed rule through press and other releases,[1199] as well as through other outreach including hosting a public forum on the proposed rule [1200] and attending the U.S. Small Business Administration Office of Advocacy's (''SBA Advocacy'') roundtable on the proposed rule with small entities,[1201] in keeping with the Commission's history of small business guidance and outreach.[1202]

The Commission thereafter received over 26,000 public comments, many of which identified themselves as being from small businesses, industry associations that represent small businesses, and workers at small businesses.[1203] The Commission greatly appreciates and thoroughly considered the feedback it received from such stakeholders in developing the final rule. The Commission made changes from the proposed rule in response to such feedback and will continue to engage with small business stakeholders to facilitate implementation of the final rule. Further, the Commission is publishing compliance material to assist small entities in complying with the final rule.

Specifically, based on the Commission's expertise and after careful review and consideration of the entire rulemaking record—including empirical research on how non-competes affect competition and over 26,000 public comments—the Commission adopts this final rule, including with changes relative to the proposal to reduce compliance burdens on small business and other entities. For example, the Commission allows existing non-competes with senior executives to remain in force,[1204] amends the safe harbor notice requirement to ease compliance,[1205] removes the requirement to rescind existing non-competes, and removes the ownership threshold from the sale of business exception.[1206] In light of the comments, the Commission has carefully considered whether to certify that the final rule will not have a significant impact on a substantial number of small entities. The Commission continues to believe the final rule's impact will not be substantial in the case of most small entities, and in many cases the final rule will likely have a positive impact on small businesses. However, the Commission cannot fully quantify the impact the final rule will have on such entities. Therefore, in the interest of thoroughness and an abundance of caution, the Commission has prepared the following FRFA with this final rule.

Although small entities across all industrial classes—*i.e.,* all NAICS codes—would likely be affected, the estimated impact on each entity would be relatively small. The Small Business Administration (''SBA'') states that, as a rule of thumb, the impact of a rule could be significant if the cost of the rule (a) eliminates more than 10% of the businesses' profits; (b) exceeds 1% of the gross revenues of the entities in a particular sector; or (c) exceeds 5% of the labor costs of the entities in the sector.[1207] As calculated in Part XI.F, the Commission estimates that legal and administrative costs would result in costs on average of $712.45 to $1,250.93 for single-establishment firms with 10 workers.[1208] These costs would exceed the SBA's recommended thresholds for significant impact only if the average profit of regulated entities with 10 workers is $7,125 to $12,509, average revenue is $71,245 to $125,093, or average labor costs are $14,249 to $25,019, respectively. Furthermore, while there are additional nonmonetizable costs associated with the final rule, there are also nonmonetizable benefits which would at least partially offset those costs, as explained in Part X.F.6.

A. Reasons for the Rule

The Commission describes the reasons for the final rule in Parts IV.B and IV.C.

B. Statement of Objectives and Legal Basis

The Commission describes the objectives and legal basis for the final rule in Part IV.B and IV.C and the legal authority for the final rule in Part II.

[1197] 5 U.S.C. 603–605.

[1198] NPRM at 3531.

[1199] FTC, Press Release, *FTC Proposes Rule to Ban Noncompete Clauses, Which Hurt Workers and Harm Competition* (Jan. 5, 2023), *https://www.ftc.gov/news-events/news/press-releases/2023/01/ftc-proposes-rule-ban-noncompete-clauses-which-hurt-workers-harm-competition.*

[1200] FTC, FTC Forum Examining Proposed Rule to Ban Noncompete Clauses (Feb. 16, 2023), *https://www.ftc.gov/news-events/events/2023/02/ftc-forum-examining-proposed-rule-ban-noncompete-clauses.*

[1201] Commission staff attended the February 28, 2023, roundtable. *See also* Comment from SBA Off. of Advocacy, FTC–2023–0007–21110 at 2.

[1202] Each year since FY2002, the Small Business Administration (SBA) Office of the National Ombudsman has rated the Federal Trade Commission an ''A'' on its small business compliance assistance work. *See, e.g.,* SBA Office of the Nat'l Ombudsman, 2021 Annual Report to Congress at 47.

[1203] The Commission received over 26,000 comment submissions in response to its NPRM. *See Regulations.gov, Non-Compete Clause Rule* (Jan. 9, 2023), *https://www.regulations.gov/document/FTC-2023-0007-0001.* To facilitate public access, 20,697 such comments have been posted publicly at *www.regulations.gov. Id.* (noting posted comments). Posted comment counts reflect the number of comments that the agency has posted to *Regulations.gov* to be publicly viewable. Agencies may redact or withhold certain submissions (or portions thereof) such as those containing private or proprietary information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. Gen. Servs. Admin., *Regulations.gov* Frequently Asked Questions, *https://regulations.gov/faq.*

[1204] *See* Part IV.C.3.

[1205] *See* Part IV.E.

[1206] *See* Part V.A.

[1207] SBA, *A Guide for Government Agencies: How to Comply With the Regulatory Flexibility Act,* at 19 (Aug. 2017) *https://advocacy.sba.gov/resources/the-regulatory-flexibility-act/a-guide-for-government-agencies-how-to-comply-with-the-regulatory-flexibility-act/* (hereinafter ''RFA Compliance Guide'').

[1208] Ten workers is chosen as an illustrative example. For this example, the Commission calculates the cost of notification based on 10 workers and applies legal costs consistent with the average per establishment cost calculated in X.F.7.

C. Issues Raised by Comments, the Commission's Assessment and Response, and Any Changes Made as a Result

1. Comments [1209] on Benefits to Small Businesses and the Commission's Findings [1210]

a. Comments

Numerous small businesses and small business owners generally supported the proposed rule and shared two primary reasons, among others, that the rule may uniquely benefit small business owners. First, because non-competes are expressly designed to prevent workers from starting new businesses within the industry and geographic market that worker is experienced in, commenters said non-competes prevent new business formation and threaten new small businesses. Thus, consistent with the empirical evidence,[1211] commenters said a ban on non-competes will drive small business creation as entrepreneurial employees will be free to compete against their former employers. Second, commenters said non-competes harm small businesses by preventing them from hiring experienced workers. The Commission considered all comments related to small businesses and addresses many of them in Parts IV.B and IV.C and throughout this document.

Many comments from small businesses align with the findings in Part IV.B.3.b.i, namely that non-competes inhibit new business formation. A vast majority of such new businesses will be small businesses. For example, Kang and Fleming find that when Florida made non-competes more enforceable, larger businesses entered the State and increased employment while small businesses entered less frequently, and employment for them did not change.[1212] An economist stated the NPRM's findings show that non-competes harm small business formation and that firms struggle to hire and grow in States that are more likely to enforce non-competes. Another commenter identified an additional study showing that Hawaii's ban on non-competes in the technology industry increased the number of technology startups.[1213]

Some commenters cited the Small Business Majority's polling data on non-competes. The survey finds that 67% of small businesses that currently use non-competes support the proposed ban [1214] and 46% of small business owners have been subject to a non-compete that prevented them from starting or expanding their own businesses.[1215] Additionally, 35% of small business respondents reported that they have been prevented from hiring an employee because of a non-compete.[1216] The survey also finds that of the 312 small businesses that responded, 59% expressed agreement that NDAs could likely protect confidential information or trade secrets as effectively as a non-compete.[1217] The online survey had a small sample size of 312 small business owners and decision-makers, and had a margin of error of +/−6%.[1218] An economist commented that these survey findings provide specific evidence underlying the mechanisms identified in the empirical studies finding that non-competes decrease new business formation and prevent new firms from hiring and growing. While the survey has too small of a sample size to be fully representative of small businesses, the survey illustrates that non-competes have prevented or delayed small businesses from starting or expanding.

Small businesses stated non-competes hindered their small business, including through costly lawsuits from former employers. Many commenters said non-competes were preventing them from starting a business.[1219] One technology startup organization cited the thousands of startups formed by alumni of five leading tech companies as well as key within-industry spinoffs in the aerospace industry and suggested the number of spinoffs could be greater with a nationwide ban on non-competes. The commenter stated that even delays in founding a startup slow innovation. The commenter looked at the employment history of these aerospace startup founders and stated that, while it could not determine whether they had non-competes, their work history suggested they were not constrained in the labor market.

Many small businesses commented that non-competes prevented them from hiring the right talent and harmed their businesses, often because small businesses could not afford a lawsuit or even the legal costs of determining whether a non-compete with a perspective employee was unenforceable.[1220] A technology startup organization stated that startups are much more likely to survive with experienced counselors and mentors.[1221] A policy organization stated that non-competes favor established and large companies, because they can use non-compete litigation strategically to chill movement of experienced executives to startups and smaller firms that lack the resources to contest the non-competes in court. The policy organization also stated workers with non-competes often go to an established competitor that has the resources to protect them in case of a suit rather than a small firm, meaning small firms are disadvantaged in hiring. Similarly, a law firm commenter stated that small firms are less able to compensate new hires who have forfeiture-for-competition clauses compared to larger firms.

Commenters made several other arguments in favor of the rule covering small businesses. Several commenters pointed out that small businesses have not struggled to thrive in States where non-competes have long been prohibited, including California, Oklahoma, and North Dakota. A startup organization agreed with data cited in the NPRM indicating non-competes disproportionately reduce entrepreneurship for women, and argued that disproportionate financial challenges for women mean women entrepreneurs have fewer resources to withstand other harms from non-competes, including lack of access to talent.[1222] A law firm stated that a small business exception to the rule would lead to an inefficient ''cliff'' effect, where small businesses who previously fell within the exception would need to

[1209] The U.S. SBA publishes a Table of Small Business Size Standards based on the North American Industry Classification System (NAICS), determining the maximum number of employees or annual receipts allowed for a concern and its affiliates to be considered small. 13 CFR 121.201; *see also* Small Bus. Admin., *Table of Size Standards, https://www.sba.gov/document/support-table-size-standards.* Because commenters did not provide their NAICS number or annual receipts, and many did not provide the number of workers, the Commission is unable to determine whether each individual commenter meets the SBA's definition of a small business. Instead, for purposes of considering comments from small businesses, the Commission relies on the commenter's self-description of being a small business or start-up.

[1210] This section captures comments related to the potential benefits of the final rule for small businesses. These comments do not directly address the IRFA. Comments on the IRFA are captured in Part XI.G. Many comments and issues concerning small businesses are also discussed in Part IV.B.3.b.i.

[1211] *See* Part IV.B.3.b.i.

[1212] Kang & Fleming, *supra* note 536.

[1213] *See* Glasner, *supra* note 528.

[1214] Sm. Bus. Majority, Opinion Poll, *Small Business Owners Support Banning Non-Compete Agreements* 2 (Apr. 13, 2023). The survey also finds that 51% of small businesses that do not use non-competes support the proposed ban.

[1215] *Id.*

[1216] *Id.*

[1217] *Id.* at 3 (finding that 24% strongly agreed and 35% somewhat agreed).

[1218] *Id.* at 2.

[1219] *See* Part IV.B.3.b.i (summarizing these comments).

[1220] *Id.*

[1221] *Id.*

[1222] *See also* Marx (2022), *supra* note 519.

rescind their existing non-competes after surpassing a threshold. Finally, and importantly, numerous workers at small businesses reported substantial harms from non-competes consistent with the harms cited in Part IV.B.2 and IV.B.3.a, just as workers for large employers did.

b. Responses to Comments

As the Commission explained in Parts IV.B.3.b and IV.C.2.c, the weight of the empirical evidence supports the conclusion that non-competes inhibit new business formation and foreclose small and other businesses from accessing the talent they need to grow and succeed. Most new businesses are small, and non-competes are expressly designed to prevent workers from starting new businesses in the fields they know best. The Commission appreciates the small businesses and entrepreneurs who shared their experiences in the comments. These comments and the many comments discussed in Parts IV.B.2 and IV.B.3 from small businesses align with and bolster the empirical evidence. The comments illustrate the real-world impacts of non-competes on entrepreneurs and would-be entrepreneurs, both before and after formation of a business. Moreover, the labor market effects—including reducing labor mobility and artificially suppressing wages and job quality—are not different or mitigated when a worker works for a small business rather than a large one. Studies finding harm from non-competes examined both large and small businesses, and the Commission believes that small businesses' use of non-competes causes the same harms set forth in Parts IV.B and IV.C, including harm to other small businesses.

Based on these and other comments, the Commission believes that many small businesses are blocked from hiring workers that could help their business grow and have fewer resources than larger businesses to evaluate the risk of hiring a worker subject to a non-compete, to pay to ''release'' a worker they want to hire from a non-compete, such as a forfeiture-for-competition clause, and defend themselves from a non-compete suit.

In response to the comments on small business successes in States where non-competes are banned, the Commission notes that it recognizes that there are many successful small businesses in States that ban non-competes, but is not aware of any empirical evidence considering success rates of small businesses based on enforceability of non-competes.

In response to the comment discussing startups in the aerospace industry, the Commission notes that the conclusions of the commenter align with the empirical evidence that the most successful startups are within-industry spinoffs.[1223] However, the Commission notes that according to the data presented in the comment, some of the founders the comment described as being unrestrained in the labor market have significant gaps in their work history, though the Commission cannot determine the cause of any gaps.

As explained in Part IV.C, the Commission adopts a partial exception in § 910.2(a)(2) for senior executives under which their existing non-competes—non-competes entered into before the effective date—are not covered by the final rule. Employers cannot, however, enter into new non-competes with senior executives as of the effective date. The evidence and comments describing the importance of freeing senior executives from non-competes with respect to founding and supporting new and small businesses contributed to the Commission's decision to ban future non-competes for senior executives instead of excepting senior executives entirely from the final rule. The Commission is aware that existing non-competes with senior executives will reduce some of the benefits for new and small businesses as fewer senior executives will be free to join or found those businesses beginning on September 4, 2024. However, senior executives are a small, narrowly defined group, meaning there will still be numerous experienced workers freed from non-competes that can found or support small businesses, and senior executive non-competes will eventually become phased out. In addition, the Commission expects small businesses to receive the other anticipated benefits of the final rule.

2. Comments Arguing the Rule Will Harm Small Businesses and the Commission's Findings [1224]

a. Comments

Some small businesses and industry groups stated they believe a ban on non-competes would harm small businesses. Several commenters requested an exception for small businesses or certain types of small businesses, such as independent medical practices. The Commission addresses these comments in this Part XI.C.2 and addresses direct potential costs in Part XI.E. The Commission appreciates the small businesses and entrepreneurs who shared their experiences in the comments.

Commenters raised concerns that eliminating non-competes for all businesses would allow larger businesses and incumbents to easily hire away talent from smaller competitors and startups. Other small businesses said they had been harmed in the past by former workers competing against them, including by recruiting clients and other workers, or by large competitors hiring their workers. Similarly, some industry associations and small businesses said non-competes protect independent businesses, including medical practices, from dominant consolidators, as high recruitment, retention, and other costs may induce small businesses to sell their business to consolidators. Relatedly, some healthcare organizations argued a ban that does not cover nonprofit hospitals and health systems would provide those large nonprofits with an unfair advantage over independent medical practices.

Some small businesses offered the same justifications as other businesses for using non-competes but emphasized the heightened potential damage to smaller businesses less able to bear costs, including being forced to close or sell.[1225] Many of these comments asserted that small businesses relying on legitimate trade secrets would be especially harmed if a worker took that information to a competitor or new business, particularly because they would be least equipped to detect theft or retain sophisticated legal counsel to litigate potential trade secrets or NDA claims, thus reducing investment and innovation.[1226] A law firm argued that trade secrets litigation often costs millions, and few attorneys are willing to work on contingency, so startups would struggle to litigate against larger well-financed firms, especially as large firms can drive costs up to force the startup out of the litigation. SBA Advocacy asserted that if competitive information is not protected, some small businesses could face a serious risk of loss or potential closure and could not afford alternative means of protection.

One industry organization stated more generally that protecting information is a high priority for emerging growth companies. Some small businesses

[1223] *See* Part IV.B.3.b.i.

[1224] This section captures comments that do not directly address the IRFA but that are related to the potential costs of the final rule for small businesses. Comments directly addressing the IRFA are captured in Part XI.G. Many comments concerning small businesses are also discussed in Part IV.B.3.b.i.

[1225] *See, e.g.,* SBA Off. of Advocacy, FTC–2023–0007–21110 at 3.

[1226] *Id.*

stated if non-competes are banned, they might silo workers and information to limit the potential harm from a worker leaving for a larger competitor and would harm the business. One business stated that while banning non-competes might allow more market entrants, those new entrants will be more likely to fail without the protection of non-competes for worker retention and confidential information. Some business associations stated small business owners often rely on independent contractors and sole proprietors such as marketers to build their businesses and share proprietary information with them (meaning contractors may have access to information from multiple competitors) and covering such groups under the rule would harm their growth.

Small businesses also stated they use non-competes to protect investments, including in training, to prevent workers from taking clients or customers, and to increase retention and stability. For example, some small businesses shared that they started using non-competes after workers they had trained extensively went to a larger competitor or started their own business. One small business organization stated the proposed requirement to relate ''costs incurred'' to TRAPs would be harder for small businesses who are more likely to train on the job. A physician practice stated a partner leaving for a hospital would destabilize and increase costs for the practice, but a non-compete that is bought out helps practices afford those extra costs or otherwise prevents destabilization.

Commenters provided additional reasons small businesses use non-competes. A business stated that they could not afford to pay workers as much as larger businesses, so will be unable to find workers. A small business association stated that banning non-competes would exacerbate the labor shortage for small businesses by decreasing investment in training, when there are already insufficient qualified applicants. A commenter stated that the NPRM did not provide any examples of small businesses using non-competes in an unfair way. SBA Advocacy also stated that some small business employment contracts compensate workers for non-competes. One business stated small businesses may not be able to afford to fight larger businesses using borderline *de facto* non-competes.

A banking association stated new businesses that cannot protect their business would be less able to attract capital than more established businesses, while a community bank similarly said it may be unable to lend to small businesses that cannot protect their workers, customers, and proprietary information with non-competes. A small business stated that NDAs and non-solicitation clauses were too difficult to enforce, as it was told by judges that in order to win a non-solicitation suit against a former worker who purportedly took clients, the business would need to subpoena its own former clients to testify, which would damage the business's reputation.

A physician said they were able to start an independent practice while complying with a non-compete and hire others in compliance with their non-competes. One small business said they were able to work out solutions when hiring a worker subject to a non-compete to avoid violating it.

SBA Advocacy relayed the concern of one 8(a) [1227] small business that feared if entities in the 8(a) business development program cannot control their talent, the money the Federal government has spent helping these companies would be wasted. Accordingly, SBA Advocacy asserted that the proposed rule conflicted with the Congressional law creating the 8(a) program.[1228]

A small Federal contractor stated that larger companies could poach workers who are skilled and/or who are already cleared by the government to work on projects from small businesses, potentially putting them out of business, and would damage contractors' ability to provide stability to the agencies.

Some commenters expressed concern that the proposed 25% threshold [1229] for the sale of business exception would cause small businesses to lose value when acquired because owners and key workers are critical contributors to the business and non-competes are intangible assets, making buyers less likely to buy. Some commenters requesting a small business exception suggested various definitions of ''small business,'' including based on the number of employees.

Finally, SBA Advocacy encouraged the Commission to adopt an approach addressing the different concerns of small entities and consider, analyze, and tailor alternatives to the size and type of entity to minimize adverse impacts to small entities.[1230] It stated that a categorical ban was inappropriate given the range of industries and nature of economic impacts.[1231] One business requested an exception for highly paid workers at small businesses, to create a predictable bright-line rule while leveling the playing field for small businesses. An industry association asked for an exception for newly formed businesses to encourage capital formation among start-up entities.

b. Responses to Comments

First and foremost, the Commission finds, based on its expertise, the empirical evidence, and the record before it, that non-competes tend to negatively affect competitive conditions in both labor and product and service markets, including by inhibiting new business formation.[1232] The Commission is not aware of any empirical research on existing firm closures—including small business closures—being correlated with decreased non-compete enforceability. The Commission is also not aware of empirical research on specific business closure patterns. Rather, the empirical evidence shows that non-competes overall increase new business formation and decrease concentration, indicating that the final rule will likely increase the overall number of small businesses. The Commission is focused on the aggregate effects of non-competes on competitive conditions and here considers the overall effect on small businesses. While an individual small business may benefit from prohibiting one of its workers from joining a competitor or from keeping a competitor from entering the market, non-competes have a substantial net negative aggregate impact on competitive conditions in both labor markets and product and services markets, including negative spillover effects on other small businesses that do not use non-competes.[1233]

The Commission has assessed the evidence on protection of trade secrets and proprietary information in Part IV.D and finds that businesses have sufficient, less restrictive alternatives to protect such information. These options, such as NDAs, protection under trade secrets law, and importantly, competing

[1227] Sections 7(j)(10) and 8(a) of the Small Business Act (15 U.S.C. 636(j)(10) and 637(a)) authorize the SBA to establish a business development program, which is known as the 8(a) Business Development program. The 8(a) program is a robust nine-year program created to help firms owned and controlled by socially and economically disadvantaged individuals. SBA, *8(a) Business Development Program* (last updated Jan. 25, 2024), *https://www.sba.gov/federal-contracting/contracting-assistance-programs/8a-business-development-program.*

[1228] SBA Off. of Advocacy, FTC–2023–0007–21110 at 3.

[1229] NPRM, proposed § 910.1(e).

[1230] SBA Off. of Advocacy, FTC–2023–0007–21110 at 3.

[1231] *Id.*

[1232] *See* Parts IV.B and IV.C.

[1233] *See id.*

on the merits to retain workers, are also accessible to small businesses. On the latter, small businesses have potentially distinct options from larger firms because of their greater ability to be flexible and responsive to their workers' preferences. Moreover, the Commission notes that no evidence exists to support the hypothesis that trade secret litigation will increase after the final rule takes effect. Recent evidence suggests trade secret litigation does not increase following bans on non-competes.[1234] With a bright-line rule banning non-competes, small businesses, like other business, will not face or have to undertake litigation related to non-competes, which may partially offset other litigation costs if firms do substitute other litigation. In fact, the purported dynamic where small firms are outspent and outmatched by large firms that drive up the cost of trade secrets litigation, is the exact dynamic many small businesses face when sued over a non-compete, which can also force small businesses to close.[1235] While the Commission does not have data on the frequency of each type of litigation or how often it forces small businesses to close, these comments indicate that this alleged legal threat is already present in a different form. Moreover, the overbreadth of non-competes that employers cite as the source of their benefits for reducing litigation costs is also the source of the negative effects of non-competes on competitive conditions, and pecuniary benefits to a firm engaged in an anticompetitive practice are not a cognizable justification for an anticompetitive practice.[1236]

Additionally, the Commission is unaware of any evidence that small businesses in States where non-competes are less enforceable are more likely to experience trade secret misappropriation, or evidence that small businesses are at a distinct disadvantage in these States. Finally, the Commission notes that despite claims that using non-competes to protect trade secrets supports innovation, the empirical evidence shows increased enforceability of non-competes on net in the aggregate harms innovation. Again, the Commission considers the overall effect on all business, including small businesses, and finds that the final rule will not reduce innovation by small business.

In response to the comments that businesses would limit sharing confidential information with their workers or that a small business's inability to protect confidential information would cause new businesses to fail, the Commission notes that use of less restrictive alternatives, including, for example, NDAs, fixed term contracts, and worker retention policies, would allow small businesses to maintain the same or near same level of protection for the confidential information they might share and want to protect. Accordingly, to the extent it is productive for a small business to protect such information or share it with a worker, the firm would adopt these alternatives and be able to continue to operate with the same or similar use of confidential information. Moreover, the Commission is not aware of any empirical evidence supporting the conclusion that firms would share less confidential information or be less able to protect it. In fact, the evidence shows that both within-industry and non-within industry spinouts are better quality, on average, when non-competes are less enforceable, which reinforces the conclusion that small businesses do not rely on non-competes to thrive.[1237] Indeed, no empirical evidence shows new businesses fail at a higher rate when (or because) non-competes are less enforceable. To the extent some businesses may choose to limit information sharing (as some individual comments suggest), the Commission concludes that the benefits of the final rule with respect to earnings, new business formation, and innovation justify any limited resulting negative effect.

In Parts IV.D.1 and X.F.7.a, the Commission examines the evidence on human capital investment and other investment and finds uncertainty regarding whether the effects on training and other investment will be benefits or costs under the final rule. The Commission distinguishes between core training and advanced training, finding that businesses may be able to spend less on core training under the final rule to the extent businesses are able to better match workers with their needs. The Commission similarly finds that new business formation under the final rule could result in an increase in overall capital investment or serve to offset any decreased capital investment in incumbent firms. As noted in comments from small businesses, non-competes limit their ability to hire experienced, productive workers. While it may be true in some cases that large businesses will be able to ''poach'' workers from smaller business, smaller businesses would also be better able to hire talent from large (or other) businesses under the final rule. In fact, theoretically, the final rule would be more beneficial to smaller businesses because they would no longer be hamstrung by the threat of non-compete litigation by large firms when hiring experienced workers from those firms. To the extent large firms can afford to pay out a worker non-compete or to litigate or threaten litigation to secure talent they want from a small firm, a ban on non-competes will better level the playing field between small and large firms competing for talent. While as stated by one commenter, some small businesses may be successful if they are able to use non-competes, the empirical evidence supports the conclusion that new business formation will increase overall under the final rule, and the Commission is not aware of any evidence of small business closure patterns. Businesses also have other alternatives to retain workers.[1238] Finally, the empirical evidence demonstrates ways in which non-competes advantage large businesses against smaller ones.[1239]

In response to comments that argued non-competes were needed to promote stability and worker retention, the Commission notes there is no evidence that stability and worker retention are economically productive in and of themselves. The overall evidence on the harms from non-competes demonstrates that retention of workers through non-competes has considerable costs to both labor markets and product and service markets. Importantly, businesses also have other, less restrictive alternatives—that do not tend to negatively affect competitive conditions—to retain workers as discussed in this Part and in Part IV.D.2. In response to the comment that small businesses will be less likely to afford retaining workers than large businesses that can pay more, the Commission notes that increases in innovation are likely to make small businesses more productive and successful, allowing them to better compete with their larger competitors. Moreover, the Commission notes that, in addition to those retention alternatives, many workers commented that their non-competes prevented them from seeking jobs with better working

[1234] Greenwood, Kobayashi, & Starr, *supra* note 757. The Commission notes that this study supplements—but is not necessary to support—its finding that no evidence supports the conclusion that litigation costs will increase under the final rule. That finding is based on the Commission's expertise and the rulemaking record, including relevant comments. This study was published after the close of the comment period.

[1235] *See* Parts IV.D and X.F.7.c.

[1236] *See* Part II.F.

[1237] *See* Part X.F.9.a.

[1238] *See* Part IV.D.2.

[1239] *See* Part IV.B.3.b.

conditions, shorter commutes, more flexible hours, or more career advancement opportunities, among others.[1240] Small businesses have ways to compete for workers beyond wages alone.

Many of the comments from small businesses, as well as from other commenters, appear to confuse non-competes with other types of agreements, such as non-solicitation agreements or NDAs, and argue that non-competes are needed to prevent former workers from taking the employer's customers or clients or disclosing confidential information. The final rule does not ban non-solicitation clauses unless they meet the definition of non-compete clause.[1241] While one commenter argued that non-solicitation clauses may be more difficult to enforce than non-competes, the Commission weighs the cost of this potential increased difficulty against the harms from non-competes and finds that any marginal benefit compared to a non-solicitation clause does not justify the costs of non-competes. And as explained previously, pecuniary benefits to a firm from an anticompetitive practice are not a cognizable defense.[1242]

In response to comments that small businesses are more reliant on independent contractors and without non-competes independent contractors might have access to confidential information for multiple competitors, the Commission first notes that the final rule does not prohibit agreements preventing a worker from working for two firms simultaneously.[1243] Many alternatives to non-competes allow businesses working with independent contracts to protect their confidential information, including maintaining security of confidential information as well as NDAs and other such agreements, as described in Part IV.D. There is no evidence that independent contractors are more likely to use or share confidential business information and, in fact, they are likely to be working under an agreement detailing their responsibilities and to be more familiar with ways to assure clients that any confidential business information shared with them will remain confidential.

In response to comments that banks might decrease lending without non-competes, the Commission notes that there is no indication that small businesses in States that have banned or limited non-competes have been unable to obtain financing and commenters provide no related evidence. Again, small businesses will have less restrictive alternatives as a means of protecting confidential information. Moreover, with respect to new business formation, workers seeking to start their own businesses will be able to reassure banks that their business will not face the threat of litigation or a court enjoining them from continuing with their business because of a non-compete.

In response to SBA Advocacy's comment on compensation for non-competes, the Commission considered this issue in Part IV.C. and decided to allow existing non-competes with senior executives, which the Commission finds are most likely to have involved consideration, to remain in force.

In response to the comment on the 8(a) business development program, the Commission notes that there are likely program participants in States where non-competes are banned or partially banned and, thus, are not able to use non-competes. Moreover, the program aims to help firms owned and controlled by socially and economically disadvantaged individuals with various supports and assistance to improve their success in securing government contracts. There is no basis to believe such assistance hinges on these small businesses being able to use non-competes with their workers. Like other firms, program participants have viable, less restrictive alternatives that do not tend to negatively affect competitive conditions. The evidence presented in this Part shows that on the whole, small businesses—including 8(a) participants—are expected to benefit from the ban on non-competes by, for example, having a larger pool of talent from which to hire workers.

In response to the comment that large businesses may use borderline *de facto* non-competes, the Commission notes that it provides greater clarity on the definition of non-compete clause in Part III.D, which the Commission believes will reduce both confusion and evasion. To the extent the commenter is raising the possibility that such other restrictive employment terms may tend to negatively affect competitive conditions, the Commission notes that section 5 and the other antitrust laws apply to those terms and govern whether such terms might be unlawful.

In response to comments on the proposed sale of business threshold, as explained in Part V.A, the Commission is eliminating the 25% threshold, meaning more small businesses will be able to utilize non-competes for more owners when they are selling their business. While individual businesses might see decreased value in a sale from being unable to use non-competes for workers, any decrease is justified by the net aggregate benefits of freeing labor markets and product and service markets from non-competes. Again, pecuniary benefits to a firm engaged in an anticompetitive practice is not a cognizable defense.[1244]

In response to the proposed definitions of ''small business,'' first, as explained in Part X.H, the Commission declines to create an exception for small businesses. Second, the SBA already defines ''small business'' based on size standards set forth in 13 CFR 121.201, and agencies are prohibited from deviating from this definition without following the procedures set out in 13 CFR 121.903.[1245]

In response to the comments arguing that the Commission's jurisdiction does not extend to tax-exempt nonprofit hospitals and healthcare organizations and that the final rule would, thus, give large nonprofits an unfair advantage over small practices, the Commission addresses this question in Parts II.E.2 and V.D.4. In response to the comment on difficulties in using TRAPs under the proposed rule, the Commission notes the final rule does not ban TRAPs, but covers terms and conditions of employment that meet the definition of non-compete clause as delineated in § 910.1 and described in Part III.D.

The commenter asserting that the final rule would exacerbate a labor shortage for small businesses did not provide evidence to support this claim. The Commission, however, finds that a ban on non-competes will increase labor mobility and enable skilled workers who are currently trapped by non-competes to work for others in the industry.

Finally, the Commission notes that numerous workers at small businesses have shared how non-competes have harmed them.

The Commission has carefully considered all of SBA Advocacy's and other stakeholders' comments, including those requesting a small business exception. The Commission has made the following changes, which the Commission believes will benefit small entities: adding an exception for existing senior executive non-competes; amending the notice requirement to ease compliance; and eliminating the sale of

[1240] *See* Part IV.B.3.a.iii.

[1241] *See* Part III.D.

[1242] *See* Part II.F.

[1243] *See* Part III.D.

[1244] *See* Part II.F.

[1245] RFA Compliance Guide, *supra* note 1207 at 14. One business suggested that the SBA definition is prone to confusion and litigation but did not provide any additional information to explain why or how.

business ownership threshold. The Commission believes that the final rule will benefit small businesses overall. The Commission notes that no State has exempted small businesses from any State statutes regulating non-competes.[1246] There is no empirical evidence that a small business exception is necessary or appropriate. Further, the evidence indicating that a ban on non-competes will benefit the economy accounts for non-competes used by both large and small businesses. In sum, the evidence indicates the final rule will, in the aggregate, benefit both small businesses and workers who work for small businesses—not to mention the consumers who in turn benefit. More small businesses are expected to enter the market, and the final rule will remove barriers to their growth.

D. Comments by the Chief Counsel for Advocacy of the SBA, the Commission's Assessment and Response, and Any Changes Made as a Result

The Commission received and carefully reviewed the comment from the SBA.[1247] The issues raised by the SBA and the Commission's responses are included in Parts XI.C and XI.F.

E. Description and Estimated Number of Small Entities to Which the Rule Will Apply

The final rule will impact all small businesses, across all industry classes, that use non-competes. It may also impact some small businesses that do not use non-competes but are impacted by other businesses' use of non-competes. The Commission does not expect that there are classes of businesses which will face disproportionate impacts from the final rule.

For the vast majority of industries, there is no nationwide granular data regarding the percentage of firms that use non-competes, which would facilitate calculating the number of small entities in a given industry using non-competes. Because of this data limitation and given the relatively stable percentage of firms using non-competes across the size distribution,[1248] the Commission estimates the total number of small firms across all industries in the U.S. economy. The Commission then calculates the number of firms estimated to use non-competes by applying an estimate of the percentage of firms using non-competes to that total. Using the size standards set by the SBA,[1249] the Commission calculates that there are 5.25 million small firms and 5.48 million small establishments in the U.S.[1250] Assuming that 49.4% of firms or establishments use non-competes,[1251] an estimated 2.59 million small firms, comprising 2.71 million small establishments, would be affected by the final rule. These calculations—the counts of businesses and the percentage of businesses that use non-competes—are based on small businesses with employees, since sole proprietorships are unlikely to use non-competes. Since the estimate cannot account for differential use of non-competes across industries, these firms span all industries and various sizes below the standards set in the SBA's size standards.

The Commission sought comments on all aspects of the IRFA, including the description and estimated number of small entities to which the rule would apply. A business association claimed the IRFA estimated the number of small businesses solely based on one incomplete study, the Colvin and Shierholz study, which it argued counted only firms with no union members who said all employees signed non-competes, risking significantly undercounting the number of impacted businesses. This comment misreads the study. The cited statement explained that when tabulating the share of businesses where all employees sign non-competes, the study counted only firms with no union members as it did not have information on whether union members signed non-competes.[1252] That does not mean that only firms with no union members where all employees signed non-competes were included in the study. In fact, the study divided its results between the share of workplaces where all employees and only some employees were subject to non-competes.[1253] The comment cites to only one component of the study results. Moreover, the study states that anecdotal evidence indicates it is rare for unions to agree to non-competes,[1254] and comments the Commission received align with that anecdotal evidence.

F. Projected Reporting, Recordkeeping, and Other Compliance Requirements

To comply with the final rule, small entities must do three things. First, to comply with §§ 910.2(a)(1)(i) and 910.2(a)(2)(i), which state it is an unfair method of competition to enter into a non-compete with a worker, small entities can no longer enter into new non-competes with incoming workers, including senior executives. This may include revising human resources materials and manuals and template or form contracts to ensure they are not misused on a forward-going basis, and making strategic decisions regarding workers' employment terms. Second, to comply with § 910.2(a)(1)(ii) and (iii), small entities cannot enforce (or make misrepresentations about) existing non-competes for workers other than senior executives after the effective date. That is, businesses must refrain from suing or threatening to sue workers other than senior executives regarding a non-compete after the effective date; but formal contract rescission is not required. Third, businesses must provide notice to workers other than senior executives that the worker's non-compete will not be enforced against the worker. The Commission provides a safe harbor notice that must be provided only to workers with known contact information. These foregoing steps entail some potential legal and administrative costs.

As calculated in Parts X.D.1.a and X.D.2.a, the Commission estimates the legal and administrative costs would

[1246] *See generally* Beck Reed Riden Chart, *supra* note 1052. In 2023, Maryland increased its non-compete compensation threshold to $19.88 per hour and set a slightly lower threshold for small employers at $19.20 per hour. Md. Lab. & Empl. Code sec. 3–716.

[1247] SBA Off. of Advocacy, FTC–2023–0007–21110.

[1248] *See* Colvin & Shierholz, *supra* note 65 at 5. The Commission emphasizes that, since smaller firms generally use non-competes at a lower rate, based on the numbers reported in Table 1, the estimate of the number of affected small entities is likely larger than is true in practice.

[1249] *See* Small Bus. Admin., *Table of Size Standards, https://www.sba.gov/document/support-table-size-standards.*

[1250] The Commission uses the latest data available from the Census Bureau's Statistics of U.S. Businesses database, available based on firm revenue and firm size. Census Bureau, *Statistics of U.S. Businesses (SUSB)* (last revised Nov. 17, 2023), *https://www.census.gov/programs-surveys/susb.html.* Values are deflated to current dollars using *https://www.bls.gov/data/inflation_calculator.htm.* As used in this analysis, per the Census Bureau, ''a firm is a business organization consisting of one or more domestic establishments in the same geographic area and industry that were specified under common ownership or control.'' On the other hand, ''an establishment is a single physical location at which business is conducted or services or industrial operations are performed.'' *See* Census Bureau, *Glossary, https://www.census.gov/programs-surveys/susb/about/glossary.html.* The number of small firms calculated here has decreased compared to the IRFA based on the updated Census Bureau data and SBA size standards.

[1251] *See* Colvin & Shierholz, *supra* note 65. The Commission notes that the estimated percentage of firms which use non-competes is based on a survey of businesses with employees. In addition, the Small Business Majority's recent survey of small businesses finds that 48% of respondents use non-competes. Sm. Bus. Majority Opinion Poll, supra note 1214. The Commission does not find that this survey has a sufficiently representative sample size to be considered definitive but notes that it aligns with the Colvin & Shierholz estimate.

[1252] *See* Colvin & Shierholz, *supra* note 65.

[1253] *See generally id.*

[1254] *Id.*

total $538.48 to $1,076.96 for each small firm, plus an additional $155.85 for each establishment owned by that firm, plus an additional $1.81 per worker. A single-establishment firm with 10 workers, for example, would bear estimated costs of $712.45 to $1,250.93.[1255] Only a small portion of the average cost estimated for each small firm—$155.85 per establishment, plus $1.81 per worker—is required under the rule. The remainder of the estimated cost is attributable to legal costs which firms may (but are not required to) undertake to revise their contractual practices. The FRFA assumes that the value of human resource professionals' times and legal professionals' time is equal to twice their average wages, which results in updated estimates.[1256] In an abundance of caution, the Commission has erred on the side of overestimating costs.

As described in greater detail in Part X.F.7.a, the Commission also finds that firm investment in human capital may increase or decrease under the final rule, depending on the type of training affected. Given the evidence available, the Commission is unable to fully monetize the estimates of firm investment in human capital. It concludes, however, that even in the absence of a full monetization of all costs and benefits of the final rule, the final rule has substantial benefits that clearly justify the costs.

1. Legal Costs

To ensure that incoming workers' contracts do not include non-competes and that they fully comply with the final rule, firms may employ in-house counsel, outside counsel, or human resource specialists (depending on the complexity of the relevant non-compete). For many firms, this process would likely be straightforward (*i.e.,* simply not using non-competes or removing one section from a boilerplate contract). Other firms may have more complex agreements or choose to use more time. The Commission assumes that, on average, ensuring that contracts for incoming workers do not have non-competes would take the equivalent of one hour of a lawyer's time (valued at $134.62),[1257] resulting in a total cost of $134.62*2.71 million = $364.8 million. There may be substantial heterogeneity in the costs for individual firms; however, the Commission believes this number is conservative. For firms whose costs of removing non-competes for incoming workers is greater, the work of ensuring that contracts comply with the law would overlap substantially with the costs of updating contractual practices, described in Part X.F.7.b.

For each establishment of each firm, estimated direct compliance costs total $21.23 + $134.62 = $155.85, plus $1.81 per worker with a non-compete.

Some business commenters have indicated that they may add or expand the scope of NDAs or other contractual provisions. This legal work is not mandated or required by the rule; it would be undertaken only by the subset of firms and workers for whom firms conclude that such alternatives would be desirable. Additionally, such adjustments are likely unnecessary for senior executives whose non-competes continue to be enforceable under the final rule. Therefore, this component additionally involves identifying senior executives whose existing non-competes are unaffected. For any such legal work, firms may use in-house counsel or outside counsel. To do so, firms may use in-house counsel or outside counsel to revise current contracts or enter into new, different contracts with workers.

The Commission is not aware of empirical evidence on how much it costs firms to revise their contractual practices when they can no longer use non-competes, and commenters did not provide evidence on costs. However, there is evidence indicating that firms that use non-competes are already using other types of restrictive employment provisions. Balasubramanian et al. find that 95.6% of workers with non-competes are also subject to an NDA, 97.5% of workers with non-competes are also subject to a non-solicitation agreement, NDA, or a non-recruitment agreement, and that 74.7% of workers with non-competes are also subject to all three other types of provisions.[1258] Firms that are already using multiple restrictive covenants may not need to expand the scope of existing restrictive employment provisions or enter into new ones.

Among the approximately one half of firms that use non-competes,[1259] the Commission assumes that the average firm employs the equivalent of four to eight hours of a lawyer's time to revise its contractual practices.[1260] The Commission emphasizes that this is an average to underline the fact that there would likely be large differences in the extent to which firms update their contractual practices. Many firms, including those that use non-competes only with workers who do not have access to sensitive information, or those that are already using other types of restrictive employment provisions to protect sensitive information, may opt to make no changes. Other firms may employ several hours or multiple days of lawyers' time to arrive at a new contract.[1261] The estimated range of four to eight hours represents an average taken across these different possibilities. For example, if two-thirds of firms that currently use non-competes opt to make no changes to their contractual practices (for example, because their workers are among the 97.5% of workers that already have other post-employment restrictions, or because they will rely on trade secret law in the future, or because they are using non-competes with workers who do not have access to sensitive information), and one-third of such firms spend (on average) the equivalent of 1.5 to 3 working days of an attorney's time, this would result in the estimate of 4–8 hours on average.

The Commission further emphasizes this estimate is an average across all employers that would be covered by the final rule. There is likely substantial heterogeneity in the amount of time firms would use to revise contractual practices; very large firms that use non-competes extensively would likely incur greater costs.

Under the assumption that the average firm that uses a non-compete employs the equivalent of four to eight hours of a lawyer's time, this analysis calculates the total expenditure on updating contractual practices to range from $134.62*4*2.59 million = $1.4 billion to $134.62*8*2.59 million = $2.8 billion. Note that this assumes decisions regarding protection of sensitive information and contract updating are

[1255] "Ten workers" is chosen as an illustrative example.

[1256] See Part X.F.7.b for a detailed description of the calculation and assumptions. The Commission notes that a typographical error in the IRFA resulted in the Commission reporting preliminary figures that were substantially larger than the comparable calculations in the preliminary section 22 analysis, which accounts for some of the differential between the preliminarily reported figures in the IRFA and the final estimates here.

[1257] BLS, *Occupational Outlook Handbook, Lawyers* (last modified Sept. 6, 2023), *https://www.bls.gov/ooh/legal/lawyers.htm* (updated for inflation to 2023 dollars and based on updated BLS data). Assumed lost productivity is twice the median wage.

[1258] Balasubramanian, Starr, & Yamaguchi, *supra* note 74. The value 97.5% is calculated as (1–0.6%/24.2%), where 0.6% represents the proportion of workers with only a non-compete, and no other post-employment restriction, and 24.2% represents the proportion of workers with a non-compete, regardless of what other post-employment restrictions they have.

[1259] Colvin & Shierholz, *supra* note 65 at 1.

[1260] Part X.F.7.b.i.

[1261] These estimates are derived from outreach to employment attorneys active in assisting firms in writing their non-competes. Commenters did not provide additional information or data that could be used to update these estimates.

made at the firm, rather than establishment, level, since sensitive information is likely shared across business establishments of a firm.

For each affected small business, the estimated cost of updating contractual practices is $134.62*4 = $538.48 to $134.62*8 = $1,076.96.

2. Administrative Costs for Notification Requirements

To reduce compliance costs and increase compliance certainty, § 910.2(b)(5) provides that an employer complies with the notice requirement in § 910.2(b)(1) where it provides notice to a worker pursuant to § 910.2(b)(4). Furthermore, § 910.2(b)(4) includes model language that constitutes notice to the worker that the worker's non-compete is no longer in effect. The Commission estimates that composing and sending this message in a digital format to all of a firm's workers and applicable former workers for whom digital contact information is available would take 20 minutes of a human resources specialist's time.[1262] According to BLS, the median wage for a human resources specialist was $31.85 per hour in 2023.[1263] The cost of compliance for currently employed workers with digital contact information available is therefore ($31.85*2)/3 = $21.23 per establishment. As estimated in Part XI.E, there are 2.59 million small firms, comprising 2.71 million small establishments, in the U.S. that use non-competes.[1264] Conservatively assuming that each establishment must engage in its own communication (*i.e.,* that a firm's headquarters does not have the ability to send a company-wide email, for example), this means that the total direct compliance cost for workers who are already employed and for whom digital contact information is available is $21.23*2.71 million = $57.5 million.

Each small firm must additionally mail notice to workers with non-competes for whom a physical address is available, but digital contact information is not. The cost per notice is estimated as 5 cents for one printed page plus mailing cost of 70 cents plus one minute of an HR professional's time, at $63.70 per hour, for a total of $1.81 per notice. Given an estimated count of affected workers with non-competes at small businesses of 584,843,[1265] the overall cost of mailed notice provision is therefore estimated to be $1.1 million.

G. Comments and Responses to Comments on the IRFA

The IRFA explained the Commission's preliminary assessment of the direct compliance costs for employers, both for rescinding non-competes for workers who are already employed as well as the costs of an attorney to ensure contracts for incoming workers do not have non-competes.[1266] The IRFA also explained the Commission's assessment of the costs of updating contractual practices, if the employer seeks to do so, by expanding the scope of other contractual provisions to protect trade secrets and other valuable investments.[1267] The Commission sought comment on all aspects of the IRFA.[1268]

In support of the proposed rule, one employment law firm said there are no significant recurring compliance costs to the final rule that would create an undue burden for small employers compared to larger employers. The Commission agrees. The final rule is designed to require only a one-time action and no recurring compliance requirements in order to minimize compliance costs for employers. A technology startup organization said the rule would save small businesses significant legal costs from the complex legal analysis currently necessary when trying to hire a worker subject to a non-compete, particularly when trying to assess the patchwork of State laws, ''reasonableness'' tests, and choice-of-law issues, which startups have few resources to pay.

Some commenters raised concerns about the preliminary assessment of direct compliance costs, primarily concerning unsubstantiated costs of consulting with counsel. Some commenters said small businesses would need to consult with outside counsel to ensure they properly comply with the final rule, though they did not explain why. Another business association said most small businesses do not have the organizational development required to issue the notice and would need to hire outside counsel. A group of industry associations said the estimated costs of $317.68 to $563.84 were not realistic and did not reflect the cost of discussions with outside counsel on its existing agreements and contracts and its contract negotiation practices, but the comment did not provide information to support a different estimate. Some commenters argued that small businesses lacking internal counsel or employment lawyers on retainer would face substantial unplanned expenses when seeking outside counsel on whether other restrictive covenants violated the proposed *de facto* non-compete provision. These commenters did not provide cost estimates.

First, in response to the proposed rule's Preliminary Regulatory Impact Analysis, commenters discussed that the estimated compliance costs and costs of contractual updating may underestimate true costs for the broader business community and provided alternative estimates of the time employers might spend complying with the rule and updating contractual practices, as well as the charged rates of outside counsel. These comments are addressed in the sensitivity analyses presented in Part X.F.7. The Commission has also updated the estimated legal costs in this Part. Commenters also argued that small businesses would face greater costs associated with the use of outside counsel but did not quantify those costs for small businesses. Again, the Commission provides a sensitivity analysis reflecting the cost of experienced outside counsel for all firms in Part X.F.7.b.i. Moreover, as the Commission notes, the estimate reflects significant heterogeneity, so that it is likely that some firms will simply be able to remove the paper or electronic copy of the non-compete from their website or workplace manual—requiring no attorney time—while others, like the commenter, may spend more time consulting with counsel.

Second, in response to these and other comments and as explained in Part III.D, the definition of non-compete clause has been revised to reduce confusion and give employers and workers a clearer understanding of what is prohibited, which will in turn reduce compliance costs. Third, the FRFA includes updated compliance costs to reflect any remaining need to assess contracts under § 910.2(a). Fourth, the Commission has made the notice

[1262] *See* Part X.F.7.

[1263] *See* BLS, *Occupational Outlook Handbook, Human Resources Specialists, https://www.bls.gov/ooh/business-and-financial/human-resources-specialists.htm* (last modified Sept. 6, 2023) (updated for inflation to 2023 dollars).

[1264] The dataset is available at Census Bureau, *2021 SUSB Annual Data Tables by Establishment Industry,* Industry (Feb. 2022) (last revised Sept. 15, 2023), *https://www.census.gov/data/tables/2021/econ/susb/2021-susb-annual.html.*

[1265] Estimated as 80% * 18.1% * 66% * (33,271,644–27,151,987), where 80% is the percentage of covered workers (see Part X.F.4.a), 18.1% is the estimated percentage of workers with non-competes (see Starr, Prescott, & Bishara, *supra* note 68), 67% is the assumed percent of workers without digital contact information, and 6,119,657 = 33,271,644–27,151,987 is the count of workers at small businesses (see *https://advocacy.sba.gov/wp-content/uploads/2023/11/2023-Small-Business-Economic-Profile-US.pdf*).

[1266] *See* NPRM at 3532.

[1267] *See id.* at 3532–33.

[1268] *See id.* at 3531.

requirement as simple as possible by providing model language for the notice in § 910.2(b)(4) and a safe harbor allowing employers to use a last known address and an exception for employers who do not have a workers' contact information. Employers can provide the notice by hand or through the mail, email, or a text message,[1269] and employers are not required to provide notice if they have no method of contacting a worker by paper or digital format.[1270] An employer is required only to notify workers that existing non-competes are no longer in effect and refrain from including non-competes in future contracts. This process is designed to be as easy as possible for employers. Employers should rarely need to seek outside legal assistance for complying with the notice requirement, and commenters do not provide an explanation of why legal assistance would be a necessary part of this process, though the cost of any such legal assistance (to identify senior executives for whom notice is not required) is accounted for in Part XI.F.1. Finally, the Commission will provide guidance materials for small entities to explain how to comply with the final rule.

The estimated compliance costs do not directly include any costs or savings from the senior executive exception, because the number of workers the exception might apply to is such a small portion of workers overall that any effect is *de minimis.* At an individual firm level, small businesses might not be impacted by the exception (if no workers earn above the total compensation threshold). Others might face increased compliance costs if they choose to use the exception and need to evaluate whether a worker meets the definition of senior executive (as accounted for in Part XI.F.1). However, the total compensation threshold included in the final rule's definition of ''senior executive'' is designed to ensure that employers and workers do not need to conduct a job duties assessment for every worker, only workers making above the threshold. In addition, in many cases it may be clear that a worker does or does not meet the test for whether a worker is a ''senior executive'' without a detailed assessment. For example, CEOs and Presidents are presumed to be in a policy-making position under § 910.1 and will not be otherwise subject to a job duties test, while highly paid workers in a non-executive role such as many physicians will not. Other small businesses might see decreased or eliminated direct and indirect compliance costs if they can maintain existing senior executive non-competes.

Many commenters also stated there are other indirect costs. SBA Advocacy suggested that the IRFA did not account for additional potential costs, including the costs of services, including higher legal fees to protect information, potential increased training, hiring and retention costs, and process changes.[1271] Similarly, a business association argued small businesses could face additional costs for finding alternatives to protect assets and to alter hiring, training, and retention processes. Some business associations argued that the cost of updating contractual practices would be higher because businesses would need to consult counsel, and many small businesses may be unable to afford to do so. A business organization stated that the Commission should consider the costs from a small business diminishing in value to potential buyers because it cannot record the value of its non-competes.

Another business organization said costs to small businesses are not limited to updating contractual agreements, mentioning the use of non-competes to protect assets and investments. A law firm suggested that trade secrets litigation often costs unspecified millions in attorney and expert fees and investigations costs. A business association commented that the rule would likely trigger additional litigation costs for trade secret protection and satisfying standards for injunctive relief, as well as unspecified additional costs related to lost business relationships and ideas. The business association cited an article from the biotech industry as saying a ban will force biotech companies to find other ways to protect themselves, likely through increased trade secret litigation, and recognizing that non-competes are critical to startups in the industry.

Two comments requested that the Commission publish a supplemental IRFA to account for the rule's potential impact.

The Commission notes that agencies are generally not required to consider indirect costs, though it is considered a best practice.[1272] While commenters raised categories of indirect costs that may be implicated (and it is not clear exactly what potential costs may fit into those categories), commenters did not provide any data or information that could enable the Commission to estimate any indirect costs. Some of these costs are also attenuated and speculative. Many of these concerns are also addressed in Parts IV.D and XI.C. The commenters also misunderstand the calculations in the IRFA and RIA; the estimates are an average across employers using non-competes, and there is likely to be substantial heterogeneity. The calculations account for the assumption that some firms may spend more than this amount. In response to comments on hiring costs, some firms may save on hiring costs from easier hiring, while others might have increased turnover costs.[1273] Businesses also have other options to compete on the merits besides raising wages, as many commenters indicated they sought jobs with better hours, more flexible schedules, shorter commutes, career opportunities, and other benefits.[1274] Businesses will be better able to hire workers experienced in their field who require less training than workers new to an industry.[1275]

Even if commenters' unsupported assertions that trade secret litigation and NDA enforcement may be more costly for businesses, including small businesses, are correct, such costs are justified by the benefits of the rule and in any event pecuniary benefits to a firm from an anticompetitive practice are not a cognizable justification.[1276] The Commission estimates that the final rule may increase or decrease overall litigation costs, and there is no evidence in the literature to allow the Commission to quantify those costs or benefits.[1277]

The comment citing an article on the biotech industry overstates the article's statements. The article said the existing increase in trade secrets litigation was likely to continue if the rule were adopted, did not cite any evidence for this prediction other than that non-competes are often used to protect trade secrets, and noted that companies may also use NDAs or restrict access to sensitive information.[1278] The article

[1269] § 910.2(b)(2).

[1270] § 910.2(b)(3).

[1271] SBA Off. of Advocacy, FTC–2023–0007–21110 at 3.

[1272] *Mid-Tex Elec. Co-op., Inc.* v. *FERC,* 773 F.2d 327, 342 (D.C. Cir. 1985) (''[I]t is clear that Congress envisioned that the relevant 'economic impact' was the impact of compliance with the proposed rule on regulated small entities[,]'' and the court inferred that ''Congress did not intend to require that every agency consider every indirect effect that any regulation might have on small businesses in any stratum of the national economy.''); *see also* RFA Compliance Guide, *supra* note 1207 at 22–23, 64–68.

[1273] *See* Part X.F.9.

[1274] *See* Part XI.C.2.b.

[1275] *See* Part X.F.7.a.

[1276] *See* Parts IV.D.3, X.F.5–6, II.F.

[1277] *See* Part X.F.7.c.

[1278] Rosemary Scott, *FTC's Non-Compete Law Could Propel Rise in Trade Secrets Lawsuits,*

Continued

did not say that non-competes are critical to biotech startups.[1279]

The commenter asking the Commission to consider small business valuation changes did not provide any potential estimates of such a cost, nor did the commenter demonstrate that such costs exist. It is unclear whether this commenter was referring to the value of non-competes for owners or for workers, but some such non-competes may fall within the exceptions for existing senior executive non-competes or for owners in a sale of business.[1280] To the extent there are any remaining non-competes that increase the value of a business in a sale, the Commission finds that any marginal decrease is justified by the substantial overall benefits of the rule.

In response to the requests for a supplemental IRFA, one is not required by law, and this FRFA responds to all comments on the IRFA. A supplemental IRFA would not provide the public with additional relevant information that the IRFA did not.

H. Discussion of Significant Alternatives

The RFA requires that agencies include a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected.[1281] Statutory examples of ''significant alternatives'' include different requirements or timetables that take into account the resources available to small entities; the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for small entities; the use of performance rather than design standards; and an exemption from coverage of the rule, or any part thereof, for small entities.[1282]

In Part IX, the Commission discusses significant alternatives to the final rule. Part IX also includes an assessment determining that each of the significant alternatives would not accomplish the objectives of the final rule. The Commission did incorporate some of the alternatives proposed in the NPRM and in comments into the final rule, namely the exception for existing senior executive non-competes, simplifying notice requirements, eliminating rescission requirements, and eliminating the 25% threshold for the sale of business exception. In addition, the Commission's analysis of benefits and costs in Part X includes an assessment of the benefits and costs of excluding senior executives. The Commission notes that it has designed the final rule to minimize compliance costs for all businesses and that the final rule does not include any reporting requirements. As stated in Part X.F.7.b, the Commission estimates that direct compliance costs and the costs of updating contractual practices would result in costs of $538.48 to $1,076.96 for each firm. As previously noted, the Commission does not believe the final rule imposes a significant economic impact on a substantial number of small entities. The Commission has also described how the final rule will benefit and increase the number of small businesses.

After careful consideration, the Commission is not creating an exception for small entities or different regulatory requirements for small entities. The final rule provides that for workers other than senior executives, it is an unfair method of competition for a person to enter into or attempt to enter into a non-compete, enforce or attempt to enforce a non-compete, or represent that the worker is subject to a non-compete.[1283] For senior executives, the final rule provides that it is an unfair method of competition for a person to enter into or attempt to enter into a non-compete, enforce or attempt to enforce a non-compete entered into after the effective date, or represent that the worker is subject to a non-compete, where the non-compete was entered into after the effective date.[1284] Based on the available evidence, the Commission does not believe that the analysis in Parts IV.B and IV.C is fundamentally different for non-competes that are imposed by small entities. For this reason, the Commission is not creating an exception for small entities or different regulatory requirements for small entities.

The Commission is not delaying the effective date of the final for small entities. Under § 910.6, the final rule is effective 120 days after publication in the **Federal Register** on September 4, 2024. One small business asked that the final rule's effective date be delayed for two years to give the business time to silo its intellectual property and implement safeguards to protect its information. In the Commission's view, the rule's effective date of September 4, 2024 will afford small entities a sufficient period of time to comply with the final rule, and commenters have not provided evidence that more time is necessary.[1285]

XII. Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (''PRA''),[1286] Federal agencies must obtain approval from the Office of Management and Budget (''OMB'') for each collection of information they conduct or sponsor. The term ''collection of information'' includes any requirement or request for persons to obtain, maintain, retain, report, or publicly disclose information.[1287] Under the PRA, the Commission may not conduct or sponsor, and, notwithstanding any other provision of law, a person is not required to respond to, an information collection unless the information collection displays a valid control number assigned by OMB.[1288]

A. The Proposed Rule

In the NPRM, the Commission stated that it believed the proposed rule would contain a disclosure requirement that would constitute a collection of information requiring OMB approval under the PRA. The Commission stated that this disclosure requirement was proposed § 910.2(b)(2), which would have required employers to provide notice to a worker with an existing non-compete—*i.e.,* a non-compete that was entered into prior to the effective date—that the non-compete is no longer in effect and may not be enforced against the worker.[1289] Conservatively assuming that each establishment must engage in its own communication—*i.e.,* a firm's headquarters does not have the ability to send a company-wide email, for example—the Commission estimated that covered employers would incur an estimated labor cost burden of 1,310,747 hours to comply with this requirement (3,932,240 establishments × 20 minutes). The Commission estimated the associated labor cost for notifying affected workers who are already employed is $9.98 × 7.96 million × 0.494 = $39,243,755.[1290]

The Commission stated that the proposed rule would impose only *de minimis* capital and non-labor costs.

BioSpace (Feb. 8, 2023), *https://www.biospace.com/article/ftc-s-non-compete-law-could-propel-rise-in-trade-secrets-lawsuits-/.*

[1279] *Id.*

[1280] *See* § 910.3.

[1281] 5 U.S.C. 604(a)(6).

[1282] *See* 5 U.S.C. 603(c)(1)–(4).

[1283] *See* § 910.2(a)(1).

[1284] *See* § 910.2(a)(2).

[1285] *See* Part VIII.

[1286] 44 U.S.C. 3501 *et seq.*

[1287] 44 U.S.C. 3502(3); 5 CFR 1320.3(c).

[1288] 44 U.S.C. 3506(c)(1)(B); 5 CFR 1320.5(a)(3).

[1289] NPRM at 3533.

[1290] *Id.* at 3534.

The Commission anticipated that covered employers would already have in place existing systems to communicate with and provide employment-related disclosures to workers. While the proposed rule would require a one-time disclosure to some workers subject to a rescinded non-compete, the Commission anticipated that this one-time disclosure would not require substantial investments in new systems or other non-labor costs. The Commission noted that, moreover, many establishments are likely to provide the disclosure electronically, further reducing total costs.[1291]

The Commission sought comment on all aspects of its PRA analysis, including (1) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information would have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of these information collections on respondents.

B. Comments Received

No commenters specifically addressed the PRA analysis in the NPRM. However, the Commission received extensive comments on its Preliminary Regulatory Impact Analysis and Initial Regulatory Flexibility Act Analysis, and many of these commenters addressed the Commission's estimates related to the cost of compliance. These comments are summarized in Parts X (the Commission's Final Regulatory Analysis) and XI (the Commission's Final Regulatory Flexibility Act Analysis). The Commission also received comments on the proposed notice requirement itself. These comments are summarized in Part IV.E.

C. Final PRA Analysis

The Commission finalizes the proposed rule's notice requirement largely as proposed, with some adjustments to even further ease compliance. In the final rule, § 910.2(a)(1)(ii) prohibits employers from enforcing existing non-competes—*i.e.,* non-competes entered into prior to the effective date—with respect to workers other than senior executives. Section 910.2(b)(1) as finalized states further that for each existing non-compete that it is an unfair method of competition to enforce or attempt to enforce under § 910.2(a)(1)(ii)—*i.e.,* non-competes entered into with workers other than senior executives—the person who entered into the non-compete with the worker must provide clear and conspicuous notice to the worker by the effective date that the worker's non-compete will not be, and cannot legally be, enforced against the worker.

Pursuant to § 910.2(b)(2), the notice must (i) identify the person who entered into the non-compete with the worker and (ii) be on paper delivered by hand to the worker, or by mail at the worker's last known personal street address, or by email at an email address belonging to the worker, including the worker's current work email address or last known personal email address, or by text message at a mobile telephone number belonging to the worker.

Section 910.2(b)(3) provides an exception to the notice requirement in § 910.2(b)(1) where the person that would otherwise be required to provide the notice has no record of a street address, email address, or mobile telephone number.

Section 910.2(b)(4) provides model language that employers may use to comply with the notice requirement. Section 910.2(b)(5) states that an employer presumptively complies with the notice requirement in § 910.2(b)(1) where the employer provides a notice to the worker pursuant to § 910.2(b)(4). And § 910.2(b)(6) allows but does not require employers, in addition to providing the required notice in English, to provide the notice in another language (or languages). Section 910.2(b)(6) also permits employers to use any Commission-provided translation of the model language in § 910.2(b)(4).

The notice requirement has changed in two important respects from the proposed rule. First, employers are no longer required to provide the notice to senior executives with existing non-competes. Second, as long as employers provide the notice in English, they are permitted to provide the notice in a language other than English. However, neither of these changes significantly affects the burden of complying with the notice. Senior executives are only 0.75% of workers, so the cost savings to employers of not needing to provide the notice to senior executives are minimal. No employer is required to provide the notice in a different language, so the rule does not require employers to incur any compliance costs for doing so.

The Commission estimates that composing and sending the notice in a digital format to workers for whom digital contact information is available would take 20 minutes of a human resources specialist's time. According to BLS, the median wage for a human resources specialist in 2022 was $31.85 per hour in 2023 dollars.[1292] The cost of compliance for currently employed workers is therefore ($31.85*2)/3=$21.23 per establishment.[1293] According to the Census Bureau's Statistics of U.S. Businesses database, in 2021 (the most recent year for which data are available), there were 5.91 million firms and 6.88 million establishments in the U.S.[1294] The Commission estimates the percentage of firms using non-competes in the U.S. at 49.4%.[1295] The Commission conservatively assumes that each establishment must engage in its own communication—*i.e.,* that a firm's headquarters does not have the ability to send a company-wide email, for example. This yields an estimated 3,397,545 covered establishments which would incur an estimated labor cost burden of 1,132,515 hours to comply with this requirement (3,397,545 establishments × 20 minutes). The Commission estimates the associated labor cost for notifying affected workers who are already employed and for whom digital contact information is available is $21.23 × 6.88 million × 0.494 = $72,141,201.

Businesses may not have digital contact information for workers. The number of workers with non-competes who must therefore receive physical notice is the total number of covered workers (101.1 million; see Part X.F.7.a.i) times the percentage of workers who have non-competes (18.1%) times the percentage of workers who require mailed notice (assumed to be 66% of workers [1296]), for a total of 12.1 million workers. The Commission notes that the percentage of workers who require mailed notice is likely a substantial overestimate, since it is estimated based on the percentage of individuals who receive health information digitally. The Commission believes that employers are more likely to have digital means of providing the notice to their current workers

[1291] *Id.*

[1292] BLS, *Occupational Outlook Handbook: Human Resources Specialists, https://www.bls.gov/ooh/business-and-financial/human-resources-specialists.htm.* The value in 2022 was $30.88, which was updated to 2023 dollars.

[1293] The lost productivity of workers is assumed to be twice the median wage. *See* Part X.F.7.b.ii.

[1294] Census Bureau, *2021 SUSB Annual Data Tables by Establishment Industry* (December 2023), *https://www.census.gov/data/tables/2021/econ/susb/2021-susb-annual.html.*

[1295] *See* Colvin & Shierholz, *supra* note 65 at 4.

[1296] *See supra* note 1165 (CMS Supporting Statement assumes 66% of workers require mailed notice from their health insurance companies).

especially, but also to their former workers. The Commission conservatively adopts this estimate as an upper bound. The cost of mailed notice provision includes some capital costs (the cost of postage and mailing materials) and the cost of a human resource professional's time. The cost per worker is estimated as 5 cents for one printed page plus mailing cost of 70 cents plus the cost of one minute of an HR professional's time, at $63.70 per hour, for a total of $1.81 per notice. The overall cost of mailed notice provision is therefore estimated to be $22 million.

As the Commission stated in the proposed rule, the Commission anticipates that covered employers already have in place existing systems to communicate with and provide employment-related disclosures to workers. While the final rule requires a one-time disclosure to some workers, the Commission anticipates this one-time disclosure will not require substantial investments in new systems or other non-labor costs. Moreover, many establishments are likely to provide the disclosure electronically, further reducing total costs.

XIII. Other Matters

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this final rule as a ''major rule,'' as defined by 5 U.S.C. 804(2).

List of Subjects in 16 CFR Part 910

Antitrust.

■ For the reasons set forth above, and under the authority of Sections 5 and 6(g) of the Federal Trade Commission Act, the Federal Trade Commission adds subchapter J, consisting of parts 910 and 912, to chapter I in title 16 of the Code of Federal Regulations to read as follows:

Subchapter J—Rules Concerning Unfair Methods of Competition

PART 910—NON-COMPETE CLAUSES

PART 912—[RESERVED]

PART 910—NON-COMPETE CLAUSES

Sec.

Authority: 15 U.S.C. 45 and 46(g).

PART 910—NON-COMPETE CLAUSES

§ 910.1 Definitions.

As used in this part:

Business entity means a partnership, corporation, association, limited liability company, or other legal entity, or a division or subsidiary thereof.

Employment means work for a person.

Non-compete clause means:

(1) A term or condition of employment that prohibits a worker from, penalizes a worker for, or functions to prevent a worker from:

(i) Seeking or accepting work in the United States with a different person where such work would begin after the conclusion of the employment that includes the term or condition; or

(ii) Operating a business in the United States after the conclusion of the employment that includes the term or condition.

(2) For the purposes of this part, term or condition of employment includes, but is not limited to, a contractual term or workplace policy, whether written or oral.

Officer means a president, vice president, secretary, treasurer or principal financial officer, comptroller or principal accounting officer, and any natural person routinely performing corresponding functions with respect to any business entity whether incorporated or unincorporated.

Person means any natural person, partnership, corporation, association, or other legal entity within the Commission's jurisdiction, including any person acting under color or authority of State law.

Policy-making authority means final authority to make policy decisions that control significant aspects of a business entity or common enterprise and does not include authority limited to advising or exerting influence over such policy decisions or having final authority to make policy decisions for only a subsidiary of or affiliate of a common enterprise.

Policy-making position means a business entity's president, chief executive officer or the equivalent, any other officer of a business entity who has policy-making authority, or any other natural person who has policy-making authority for the business entity similar to an officer with policy-making authority. An officer of a subsidiary or affiliate of a business entity that is part of a common enterprise who has policy-making authority for the common enterprise may be deemed to have a policy-making position for purposes of this paragraph. A natural person who does not have policy-making authority over a common enterprise may not be deemed to have a policy-making position even if the person has policy-making authority over a subsidiary or affiliate of a business entity that is part of the common enterprise.

Preceding year means a person's choice among the following time periods: the most recent 52-week year, the most recent calendar year, the most recent fiscal year, or the most recent anniversary of hire year.

Senior executive means a worker who:

(1) Was in a policy-making position; and

(2) Received from a person for the employment:

(i) Total annual compensation of at least $151,164 in the preceding year; or

(ii) Total compensation of at least $151,164 when annualized if the worker was employed during only part of the preceding year; or

(iii) Total compensation of at least $151,164 when annualized in the preceding year prior to the worker's departure if the worker departed from employment prior to the preceding year and the worker is subject to a non-compete clause.

Total annual compensation is based on the worker's earnings over the preceding year. Total annual compensation may include salary, commissions, nondiscretionary bonuses and other nondiscretionary compensation earned during that 52-week period. Total annual compensation does not include board, lodging and other facilities as defined in 29 CFR 541.606, and does not include payments for medical insurance, payments for life insurance, contributions to retirement plans and the cost of other similar fringe benefits.

Worker means a natural person who works or who previously worked, whether paid or unpaid, without regard to the worker's title or the worker's status under any other State or Federal laws, including, but not limited to, whether the worker is an employee, independent contractor, extern, intern, volunteer, apprentice, or a sole proprietor who provides a service to a person. The term worker includes a natural person who works for a franchisee or franchisor, but does not include a franchisee in the context of a franchisee-franchisor relationship.

§ 910.2 Unfair methods of competition.

(a) *Unfair methods of competition*—(1) *Workers other than senior executives.* With respect to a worker other than a senior executive, it is an unfair method of competition for a person:

(i) To enter into or attempt to enter into a non-compete clause;

(ii) To enforce or attempt to enforce a non-compete clause; or

(iii) To represent that the worker is subject to a non-compete clause.

(2) *Senior executives.* With respect to a senior executive, it is an unfair method of competition for a person:

(i) To enter into or attempt to enter into a non-compete clause;

(ii) To enforce or attempt to enforce a non-compete clause entered into after the effective date; or

(iii) To represent that the senior executive is subject to a non-compete clause, where the non-compete clause was entered into after the effective date.

(b) *Notice requirement for existing non-compete clauses*—(1) *Notice required.* For each existing non-compete clause that it is an unfair method of competition to enforce or attempt to enforce under paragraph (a)(1)(ii) of this section, the person who entered into the non-compete clause with the worker must provide clear and conspicuous notice to the worker by the effective date that the worker's non-compete clause will not be, and cannot legally be, enforced against the worker.

(2) *Form of notice.* The notice to the worker required by paragraph (b)(1) of this section must:

(i) Identify the person who entered into the non-compete clause with the worker;

(ii) Be on paper delivered by hand to the worker, or by mail at the worker's last known personal street address, or by email at an email address belonging to the worker, including the worker's current work email address or last known personal email address, or by text message at a mobile telephone number belonging to the worker.

(3) *Exception.* If a person that is required to provide notice under paragraph (b)(1) of this section has no record of a street address, email address, or mobile telephone number, such person is exempt from the notice requirement in paragraph (b)(1) of this section with respect to such worker.

(4) *Model language.* For purposes of paragraph (b)(1) of this section, the following model language constitutes notice to the worker that the worker's non-compete clause cannot legally be enforced and will not be enforced against the worker.

BILLING CODE 6750–01–P

Figure 1 to Paragraph (b)(4)—Model Language

A new rule enforced by the Federal Trade Commission makes it unlawful for us to enforce a non-compete clause. As of [DATE EMPLOYER CHOOSES BUT NO LATER THAN EFFECTIVE DATE OF THE FINAL RULE], [EMPLOYER NAME] will not enforce any non-compete clause against you. This means that as of [DATE EMPLOYER CHOOSES BUT NO LATER THAN EFFECTIVE DATE OF THE FINAL RULE]:

- You may seek or accept a job with any company or any person—even if they compete with [EMPLOYER NAME].
- You may run your own business—even if it competes with [EMPLOYER NAME].
- You may compete with [EMPLOYER NAME] following your employment with [EMPLOYER NAME].

The FTC's new rule does not affect any other terms or conditions of your employment. For more information about the rule, visit [*link to final rule landing page*]. Complete and accurate translations of the notice in certain languages other than English, including Spanish, Chinese, Arabic, Vietnamese, Tagalog, and Korean, are available at [URL on FTC's website].

BILLING CODE 6750–01–C

(5) *Safe harbor.* A person complies with the requirement in paragraph (b)(1) of this section if the person provides notice to a worker pursuant to paragraph (b)(4) of this section.

(6) *Optional notice in additional languages.* In addition to providing the notice required in paragraph (b)(1) of this section in English, a person is permitted to provide such notice in a language (or in languages) other than English or to include internet links to translations in additional languages. If providing optional notice under this paragraph (b)(6), a person may use any Commission-provided translation of the model language in paragraph (b)(4) of this section.

§ 910.3 Exceptions.

(a) *Bona fide sales of business.* The requirements of this part shall not apply to a non-compete clause that is entered into by a person pursuant to a bona fide sale of a business entity, of the person's ownership interest in a business entity, or of all or substantially all of a business entity's operating assets.

(b) *Existing causes of action.* The requirements of this part do not apply where a cause of action related to a non-compete clause accrued prior to the effective date.

(c) *Good faith.* It is not an unfair method of competition to enforce or attempt to enforce a non-compete clause or to make representations about a non-compete clause where a person has a good-faith basis to believe that this part is inapplicable.

§ 910.4 Relation to State laws and preservation of State authority and private rights of action.

(a) This part will not be construed to annul, or exempt any person from complying with any State statute,

regulation, order, or interpretation applicable to a non-compete clause, including, but not limited to, State antitrust and consumer protection laws and State common law, except that this part supersedes such laws to the extent, and only to the extent, that such laws would otherwise permit or authorize a person to engage in conduct that is an unfair method of competition under § 910.2(a) or conflict with the notice requirement in § 910.2(b).

(b) Except with respect to laws superseded under paragraph (a) of this section, no provision of this part shall be construed as altering, limiting, or affecting the authority of a State attorney general or any other regulatory or enforcement agency or entity or the rights of a person to bring a claim or regulatory action arising under any State statute, regulation, order, or interpretation, including, but not limited to, State antitrust and consumer protection laws and State common law.

§ 910.5 Severability.

If any provision of this part is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, the provision shall be construed so as to continue to give the maximum effect to the provision permitted by law and such invalidity shall not affect the application of the provision to other persons or circumstances or the validity or application of other provisions. If any provision or application of this part is held to be invalid or unenforceable, the provision or application shall be severable from this part and shall not affect the remainder thereof.

§ 910.6 Effective date.

This part is effective September 4, 2024.

PART 912—[RESERVED]

By direction of the Commission, Commissioners Holyoak and Ferguson dissenting.

April J. Tabor,

Secretary.

Note: The following appendix will not appear in the Code of Federal Regulations.

APPENDIX A—TABLE A.1

State	Estimated number of covered workers	Estimated increase in total annual worker earnings	Estimated increase in average annual worker earnings
Alabama	1,620,882	$822,829,396	$508
Alaska	251,167	145,317,588	579
Arizona	2,460,342	1,410,771,964	573
Arkansas	999,178	478,239,544	479
California	.....	.....	.....
Colorado	2,251,980	1,484,772,427	659
Connecticut	1,314,029	945,571,637	720
Delaware	367,291	220,637,013	601
District of Columbia	598,990	604,415,889	1,009
Florida	7,486,582	4,229,047,004	565
Georgia	3,764,270	2,188,893,667	581
Hawaii	495,988	270,123,206	545
Idaho	656,688	315,487,683	480
Illinois	4,735,066	3,051,620,266	644
Indiana	2,490,735	1,280,797,352	514
Iowa	1,229,598	624,937,405	508
Kansas	1,112,654	553,683,941	498
Kentucky	1,536,365	759,416,081	494
Louisiana	1,492,474	747,953,455	501
Maine	501,216	258,101,666	515
Maryland	2,112,817	1,378,702,305	653
Massachusetts	2,876,506	2,288,111,777	795
Michigan	3,440,754	1,946,978,052	566
Minnesota	.....	.....	.....
Mississippi	916,362	384,971,511	420
Missouri	2,256,955	1,184,012,673	525
Montana	396,982	191,696,465	483
Nebraska	787,174	399,373,568	507
Nevada	1,177,510	646,371,090	549
New Hampshire	536,516	343,360,391	640
New Jersey	3,307,696	2,301,979,408	696
New Mexico	666,290	326,156,344	490
New York	7,411,689	5,879,334,118	793
North Carolina	3,759,643	2,105,343,963	560
North Dakota	.....	.....	.....
Ohio	4,314,090	2,330,837,261	540
Oklahoma	.....	.....	.....
Oregon	1,560,619	916,694,759	587
Pennsylvania	4,690,586	2,795,472,689	596
Rhode Island	385,074	220,004,925	571
South Carolina	1,745,274	858,798,497	492
South Dakota	354,502	169,742,169	479
Tennessee	2,526,310	1,389,744,066	550
Texas	10,599,295	6,535,957,999	617
Utah	1,320,994	715,807,809	542
Vermont	241,017	127,248,043	528
Virginia	3,166,902	1,995,480,948	630

APPENDIX A—TABLE A.1—Continued

State	Estimated number of covered workers	Estimated increase in total annual worker earnings	Estimated increase in average annual worker earnings
Washington	2,809,814	2,090,953,114	744
West Virginia	539,026	253,817,680	471
Wisconsin	2,301,874	1,207,149,373	524
Wyoming	217,787	108,650,236	499
Full US, excluding CA, ND, OK, MN	101,785,552	53,291,058,349	524

Note: The estimated number of covered workers is calculated as 80% * (total employed population in the state); the estimated increase in total earnings is calculated as 0.86% * (estimated total covered earnings), where estimated total covered earnings is calculated as (estimated number of covered workers) * (average annual earnings); and the estimated increase in average earnings is calculated as 0.86% * (average annual earnings). Total employed population and average annual earnings are taken from the U.S. Census Bureau Quarterly Census of Employment and Wages for 2022 (see *https://www.bls.gov/cew/data.htm*). National totals may not equal the sum of state-specific estimates due to rounding.

[FR Doc. 2024–09171 Filed 4–30–24; 8:45 am]

BILLING CODE 6750–01–P

Federal Trade Commission

600 Pennsylvania Avenue NW | Washington, D.C. 20580 | ftc.gov

Fact Sheet on the FTC's Noncompete Rulemaking

On April 23, 2024, the FTC voted to finalize a new rule to prohibit employers from enforcing noncompetes against workers.

- The Commission determined that noncompetes are an unfair method of competition and therefore violate Section 5 of the Federal Trade Commission Act ("FTC Act").
- The final rule prohibits employers from entering into new noncompetes with workers on or after the effective date. The rule also prohibits employers from enforcing existing noncompetes with workers other than senior executives.
- The rule is set to go into effect on September 4, 2024.

Noncompetes restrict the freedom of American workers and suppress wages.

- Noncompetes restrict workers' fundamental freedom to leave for a better job or to start their own business.
- In many cases, noncompetes are take-it-or-leave-it contracts that exploit workers' lack of bargaining power and coerce workers into staying in jobs they would rather leave, or force workers to leave a profession or even relocate.
- By restricting workers from moving freely, noncompetes prevent workers from accepting higher-paying jobs.
- Noncompetes even reduce the wages of workers who aren't subject to noncompetes.

Noncompetes stifle new businesses and new ideas.

- Noncompetes prevent workers from starting their own firms and block new businesses from hiring qualified workers.
- Noncompetes restrict the flow of knowledge between firms, and studies have found that noncompetes reduce innovation. This affects not just workers but also consumers by

depriving consumers of better products and lower prices that result from competition and innovation.

Noncompetes are widespread throughout the U.S. economy.

- Roughly one in five Americans, totaling nearly **30 million people**, are subject to noncompetes.
- The Commission received over **26,000 comments**, with thousands of workers describing how noncompetes blocked them from taking a better job, negotiating better pay, or starting their own business.
- The Commission also heard from entrepreneurs and small businesses who said noncompetes prevented them from starting new ventures or hiring knowledgeable workers to help grow their businesses.

By banning noncompetes, the FTC estimates that:

- Over **25,000 commenters** supported a categorical ban on noncompetes.
- New business formation will grow by **2.7%**, creating over **8,500 new businesses** each year.
- American workers' earnings will increase by **$400-$488 billion** over the next decade, with workers' earnings rising an estimated **$524** a year on average.
- Health care costs will be reduced by **$74-$194 billion** over the next decade in reduced spending on physician services.
- Innovation will increase, with an average estimated increase of **17,000-29,000** more patents each year over the next decade.

The Noncompete Rule

- **The rule states that noncompetes are an unfair method of competition**.
    - As a result, the rule prohibits employers from entering into new noncompetes with workers as of the effective date, set to be on September 4, 2024.
- **The rule prohibits employers from enforcing noncompetes with workers other than senior executives as of the effective date, set to be on September 4, 2024.**
    - Less than 1% of workers are estimated to be senior executives under the final rule.
    - Specifically, the final rule defines the term "senior executive" as workers earning more than $151,164 who are in a "policy-making position."

- **The rule requires employers to notify workers whose noncompetes are no longer enforceable that their noncompetes are no longer in effect and will not be enforced.**
    - The FTC provides model language that employers can use to notify employees.

- **The rule includes an exception that allows noncompetes between the seller and buyer of a business.**

- **The final rule differs from the proposed rule in several respects**.
    - The rule does not ban existing noncompetes with senior executives.
    - The rule simplifies the notice and compliance requirements for employers.
    - The rule expands the sale of business exception.

How to Report a Violation of the Noncompete Rule

- Once the rule becomes effective, set to be on September 4, 2024, you can submit information about a suspected violation of the rule to the Bureau of Competition by sending an email to noncompete@ftc.gov.

- Complaints may also be sent by mail to:
  Office of Policy and Coordination
  Bureau of Competition
  Federal Trade Commission
  600 Pennsylvania Avenue, NW
  Washington, DC 20580

Please note that the FTC cannot provide legal advice, take action on behalf of private individuals, or answer questions about its investigations.

- NOTE: Confidential information should be marked “Confidential” and sent via regular mail. To learn how we may use the information you provide, please read our Privacy Policy.

- RESPONSES: All incoming messages are forwarded to the appropriate division within the Bureau of Competition. The FTC may use these reports to investigate and bring enforcement actions for violations of the rule, but it can’t respond to each message or resolve reports on behalf of individuals.

August 22, 2024

Texas Federal Judge Blocks FTC Non-Compete Ban

Sean Gallagher, Scott Gilbert, Arindam Kar, Eric Packel, Emma Schuering, Jason Weber, Ross Weimer

Polsinelli

This week, Judge Ada E. Brown of the U.S. District Court for the Northern District of Texas in *Ryan v. The Federal Trade Commission* upheld a challenge by business groups to the FTC's non-compete ban. In addition to confirming her earlier ruling that the FTC non-compete ban was not a valid exercise of agency power, the judge also expanded the limited, temporary injunction entered on July 3, 2024 to hold unlawful and set aside the noncompete-ban in a ruling with a "nationwide effect" that is not limited to the parties in the lawsuit. In other words, **the FTC's non-compete ban will not take effect on September 4 for anyone.**

The Court concluded that: (1) the FTC lacked statutory authority to promulgate substantive rules concerning unfair methods of competition, *i.e.* the non-compete ban; and (2) the non-compete ban is arbitrary and capricious because it is "unreasonably overbroad without a reasonable explanation." As a result, the Court found the non-compete ban to be an unlawful agency action. In deciding the appropriate relief, the Court relied on recent precedent from the Fifth Circuit to conclude its ruling must have a "'nationwide effect,' is 'not party-restricted,' and 'affects persons in all judicial districts equally.'" Thus, the Court's ruling prevents (1) the FTC from taking *any* action to enforce the non-compete ban against *anyone*; and (2) the FTC non-compete ban from taking effect on September 4, 2024—effectively vacating it.

What happens next? In the wake of the ruling, the FTC's spokesperson stated, "[The FTC is] seriously considering a potential appeal." If the FTC decides to appeal, the decision would be reviewed by the U.S. Court of Appeals for the Fifth Circuit in New Orleans. Any decision rendered by the Fifth Circuit would likely be appealed to the U.S. Supreme Court—meaning the final fate of the FTC's non-compete will be revisited and could change.

Importantly, even though the FTC non-compete ban will likely not go into effect in the immediate future, the FTC still has the power in the interim under Section 5 of the FTC Act to pursue enforcement actions on a case-by-case basis. In reacting to the ruling, an FTC spokesperson stated, "Today's decision does not prevent the FTC from addressing noncompetes through case-by-case enforcement actions." If the FTC is to be taken at its word, it appears ready to amplify such enforcement actions in the future. The FTC's posture could change after the November election depending upon the policies of the next administration.

How should employers approach non-competes? Notwithstanding this week's ruling, employers should still be mindful of the enforceability of their non-competes now and in the future. Several states have limited or outright banned the use of non-competes. The move by the FTC could spark additional state legislatures to revisit state-level restrictions as they return from recess and begin new legislative sessions this Fall. The U.S. Congress could also decide to enact legislation of its own; and, it's conceivable that this week's ruling will serve as a catalyst for Congress to revisit such legislation.

Polsinelli attorneys are continually monitoring the evolving landscape of restrictive covenant law.

MissionCare
COLLECTIVE

THE STATE OF THE

Direct Care Workforce

2025 REPORT

2119

Executive Summary

The direct care workforce is in urgent need of attention. Over half of direct care workers (DCWs) rely on public assistance, and they face anxiety and depression at three times the national average. Home care workers often experience social isolation, further impacting their well-being.

Although other professions offer higher wages, many DCWs are drawn to caregiving by a profound sense of purpose and mission. However, their primary interactions are often with recruiters or schedulers, leading to a disconnection from their employers. This lack of direct engagement fosters mistrust, while providers contend with high turnover, workforce shortages, and regulatory pressures.

These issues have significant consequences: families increasingly struggle to access necessary care, a problem set to escalate as the population ages.

We must act decisively. Supporting our direct care workforce is essential for delivering high-quality care and achieving optimal outcomes. A healthy workforce benefits the ecosystem.

MissionCare COLLECTIVE

BRANDI KURTYKA
CEO, MissionCare Collective

The Workforce Why

For many direct care workers, caregiving transcends the boundaries of a mere job. It is a profound calling driven by a deep-seated desire to positively impact the lives of those they assist. This role goes beyond providing basic help; it involves building meaningful connections, sharing in the narratives of their clients, and becoming an essential part of their journey. Each day brings a new opportunity to make a difference, to touch lives, and to be touched in return. The role offers unparalleled freedom, not just through daily routines but through the rewarding experience of witnessing the direct impact of their service. Motivated by an unwavering passion, these caregivers embody the essence of true service, showcasing the immense power of compassion, commitment, and human connection.

> Each day brings a new opportunity to make a difference, to touch lives, and to be touched in return.

CALLING.
CONNECTION.
CLIENTS.
CAREER.

The Power of Human Connection

Dedicated home care workers illuminate the profound motivations behind their roles.

"My clients are family - they take care of me as well!"

Monica H.

Financial Health

"... we love our work, but we can't pay our bills."

2124

America's fastest growing profession pays poverty wages.

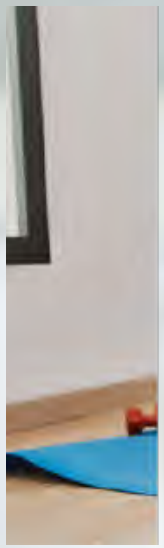
15%
LACK HEALTH INSURANCE

42%
LOW INCOME HOUSEHOLDS

90%
DO NOT HAVE AN ACTIVE CREDIT CARD

55%
ANY PUBLIC ASSISTANCE

Accessing Public Assistance[2]



31%
FOOD

32%
MEDICAID

15%
CASH ASSISTANCE

Struggling Financially

Juggling multiple jobs to make ends meet, often needing to work outside of care to pay bills.

2125


21%
of direct care workers self report poor mental health.[3]

Emotional Health

The emotional health of direct care workers (DCWs) is a significant concern, with 21% reporting poor mental health. DCWs are three times more likely to struggle with anxiety and depression. Financial instability, with many being single mothers juggling multiple jobs, further compounds these issues. Role misunderstandings and expectations to perform tasks beyond their training, often being mistaken for housekeepers, add to their stress. Working in unfamiliar and potentially unsafe environments exposes them to risks like drug activity, violence, and sexual assault. Social isolation from working in the homes of those they care for, coupled with the high physical and emotional demands of the job, leads to elevated stress levels.

3X more likely to struggle with anxiety & depression

Physical Health[4]

350%

MORE LIKELY TO SUFFER FROM MUSCULOSKELETAL DISORDERS

150%

MORE LIKELY TO EXPERIENCE OBESITY

200%

MORE LIKELY TO HAVE CARDIOVASCULAR DISEASE

19%

MORE LIKELY TO HAVE OR DEVELOP DIABETES

200%

MORE LIKELY TO HAVE SLEEP DISORDERS

250%

MORE SUSCEPTIBLE TO INFECTIOUS DISEASES

180%

MORE LIKELY TO HAVE HIGH BLOOD PRESSURE

160%

MORE LIKELY TO EXPERIENCE SUBSTANCE ABUSE

Training, Development, and Education

Professionalize the Role

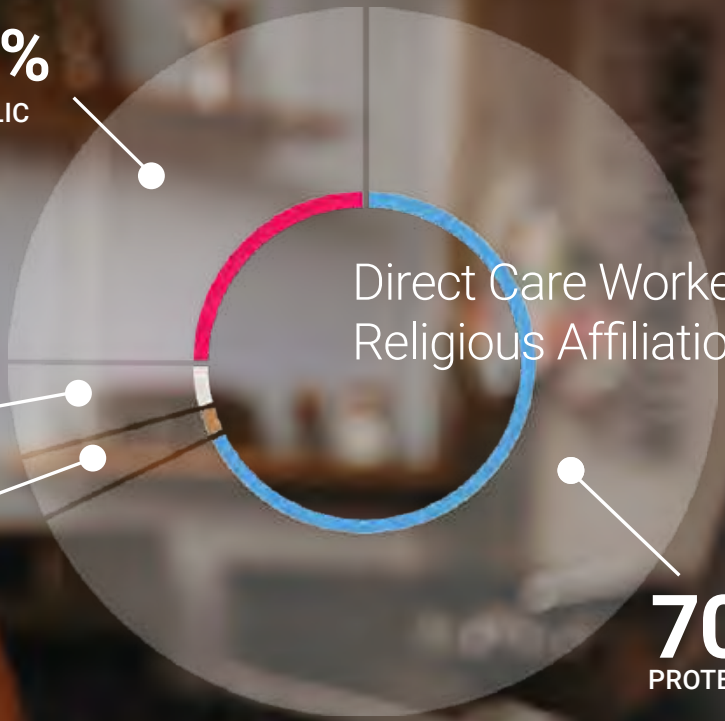
The call to professionalize caregiving resonates as direct care workers seek recognition and yearn for respect.

2129

Educational Attainment[5]

70%
desire more training
2130

Religion[6]

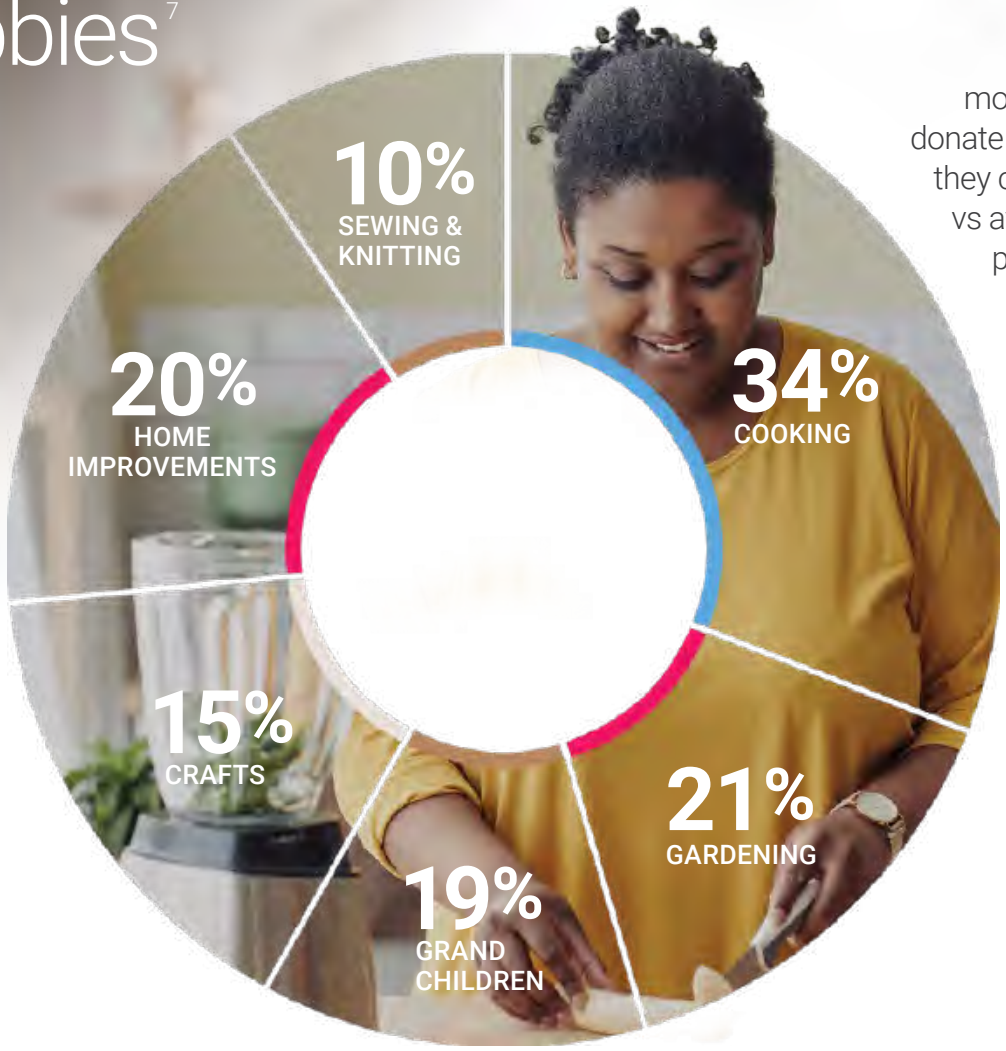


Care is a Calling

The driving force behind serving people is God.

2131

Hobbies[7]



2X

more likely to donate to causes they care about vs average US population.

Shared Passions Drive Connection

The diverse hobbies of direct care workers often translate into enriching activities they share with both their own families and the clients they serve.

Workforce Data By State[8]

	Active # DCWs	DCW Job Openings 2020-2030	Median Wage	Wage Competitiveness	People of Color	Immigrants	Uninsured	Low Income Household
ALABAMA	39,950	61,800	$12.15	-$3.50	61%	3%	16%	42%
ALASKA	8,080	11,800	$17.92	-$2.60	49%	33%	14%	20%
ARIZONA	80,080	190,400	$15.18	-$2.90	62%	25%	17%	34%
ARKANSAS	34,740	61,500	$13.25	-$2.63	44%	2%	11%	41%
CALIFORNIA	873,280	1,414,200	$15.44	-$4.66	78%	47%	9%	28%
COLORADO	56,620	92,600	$16.73	-$2.89	44%	19%	13%	28%
CONNECTICUT	60,620	92,900	$16.65	-$2.72	67%	34%	8%	28%
DELAWARE	13,340	22,500	$14.94	-$2.81	74%	20%	5%	33%
FLORIDA	158,160	234,900	$14.56	-$2.05	74%	46%	18%	31%
GEORGIA	74,800	129,100	$13.35	-$2.91	74%	18%	20%	39%
HAWAII	11,620	21,500	$16.46	-$2.94	87%	50%	9%	20%
IDAHO	24,860	35,400	$14.25	-$2.74	22%	11%	14%	40%
ILLINOIS	156,830	221,100	$16.09	-$2.82	58%	21%	11%	35%
INDIANA	68,800	112,400	$14.78	-$2.90	31%	6%	11%	34%

Workforce Data By State

	Active # DCWs	DCW Job Openings 2020-2030	Median Wage	Wage Competitiveness	People of Color	Immigrants	Uninsured	Low Income Household
IOWA	43,890	73,400	$15.76	-$1.84	20%	7%	5%	32%
KANSAS	47,250	66,400	$13.51	-$3.71	28%	8%	18%	36%
KENTUCKY	42,170	68,700	$14.43	-$2.28	20%	6%	8%	35%
LOUISIANA	52,550	82,000	$10.78	-$4.84	84%	1%	11%	54%
MAINE	23,780	35,500	$16.47	-$1.92	10%	8%	11%	25%
MARYLAND	51,200	129,400	$16.38	-$2.28	81%	42%	9%	25%
MASSACHUSETTS	143,920	216,400	$17.04	-$3.57	59%	40%	5%	30%
MICHIGAN	123,280	182,100	$14.94	-$2.93	40%	5%	11%	35%
MINNESOTA	131,500	208,400	$15.83	-$3.71	38%	26%	9%	32%
MISSISSIPPI	26,670	52,300	$11.57	-$3.38	73%	1%	20%	53%
MISSOURI	108,380	152,500	$13.30	-$4.09	35%	4%	22%	40%
MONTANA	13,290	21,100	$15.17	-$2.21	22%	4%	8%	31%
NEBRASKA	24,850	37,400	$15.88	-$1.62	31%	12%	12%	33%
NEVADA	21,770	45,400	$14.58	-$2.46	67%	37%	12%	25%
NEW HAMPSHIRE	15,100	24,400	$16.83	-$1.77	13%	10%	7%	18%
NEW JERSEY	123,790	158,400	$16.21	-$3.47	82%	54%	12%	27%
NEW MEXICO	40,180	59,400	$12.01	-$4.50	80%	12%	13%	49%
NEW YORK	584,260	1,069,900	$16.88	-$3.67	77%	58%	6%	33%

Workforce Data By State

	Active # DCWs	DCW Job Openings 2020-2030	Median Wage	Wage Competitiveness	People of Color	Immigrants	Uninsured	Low Income Household
NORTH CAROLINA	113,060	182,400	$13.62	-$2.62	60%	6%	16%	37%
NORTH DAKOTA	13,980	21,900	$17.57	-$2.34	22%	19%	15%	31%
OHIO	149,950	229,800	$14.61	-$2.78	41%	8%	12%	38%
OKLAHOMA	33,070	62,700	$12.75	-$3.10	45%	6%	27%	38%
OREGON	44,620	64,900	$17.70	-$1.46	32%	15%	11%	31%
PENNSYLVANIA	260,730	376,800	$14.41	-$3.36	46%	16%	11%	32%
RHODE ISLAND	16,300	24,800	$17.04	-$1.78	50%	36%	5%	22%
SOUTH CAROLINA	47,950	78,900	$13.17	-$2.79	67%	3%	17%	40%
SOUTH DAKOTA	9,770	14,100	$14.82	-$1.91	17%	9%	9%	30%
TENNESSEE	52,600	102,200	$13.65	-$2.86	38%	4%	18%	38%
TEXAS	387,490	653,100	$11.42	-$5.29	79%	25%	36%	44%
UTAH	25,610	49,000	$15.45	-$2.24	26%	11%	12%	27%
VERMONT	9,840	16,900	$15.30	-$3.52	16%	7%	9%	28%
VIRGINIA	95,500	153,500	$13.44	-$4.09	63%	19%	14%	35%
WASHINGTON	126,000	176,000	$18.55	-$2.69	47%	35%	11%	24%
WEST VIRGINIA	25,480	38,000	$12.56	-$3.03	11%	1%	11%	44%
WISCONSIN	102,950	153,100	$14.98	-$3.19	31%	6%	9%	32%
WYOMING	5,760	10,500	$15.48	-$3.13	16%	4%	17%	31%

Pipeline Expansion

In a comprehensive study of 67,000 direct care workers, seven distinct personas were identified that illuminate their diverse motivations and workplace values. Each persona represents a unique opportunity for recruitment pipeline expansion and workforce stabilization. The report offers targeted strategies to reduce turnover, incentivize staff effectively, and optimize recruitment efforts. It also provides practical engagement tips and career pathway considerations, serving as a crucial resource for healthcare organizations aiming to attract and retain a dedicated workforce.

Career Caregivers

Spanning various ages and with over 3 years of professional experience, they typically work exclusively within the care field. Most often seeking full-time hours, ensuring a strong client match is of utmost importance.

Caring on the Siders

Middle-aged women, often without children, working hourly jobs. They are transient in their work, heavy internet users, and enjoy donating to liberal and cultural causes. They also have a passion for R&B music.

Young and on the Move

Young adults, aged 18-24, a mix of students and working professionals. Living on a limited income and unlikely to have children, they seek jobs that allow for personal growth that don't interfere, but enhance their lifestyle.

2136

Single Moving Mommas

Single moms who move frequently, have below-average discretionary income, and are most likely renting. They value discount stores and often worry about making ends meet and lack of job flexibility.

Still Going Strong Retirees

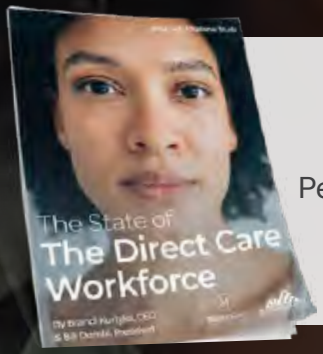
Females in their 60s who enjoy spending time with their grandchildren and getting out of the house. Living on a limited income, they are somewhat concerned about having enough money to retire.

Oodles of Offspring

Young female households with multiple children, comprising a mix of renters and homeowners with limited income. They prioritize family over work and enjoy spending time and money on their kids.

Empty Nesters

Young or near-retirees who enjoy spending time with their grandchildren, watching daytime television, and sewing. Living on a limited income, they love helping others and getting out of the house.



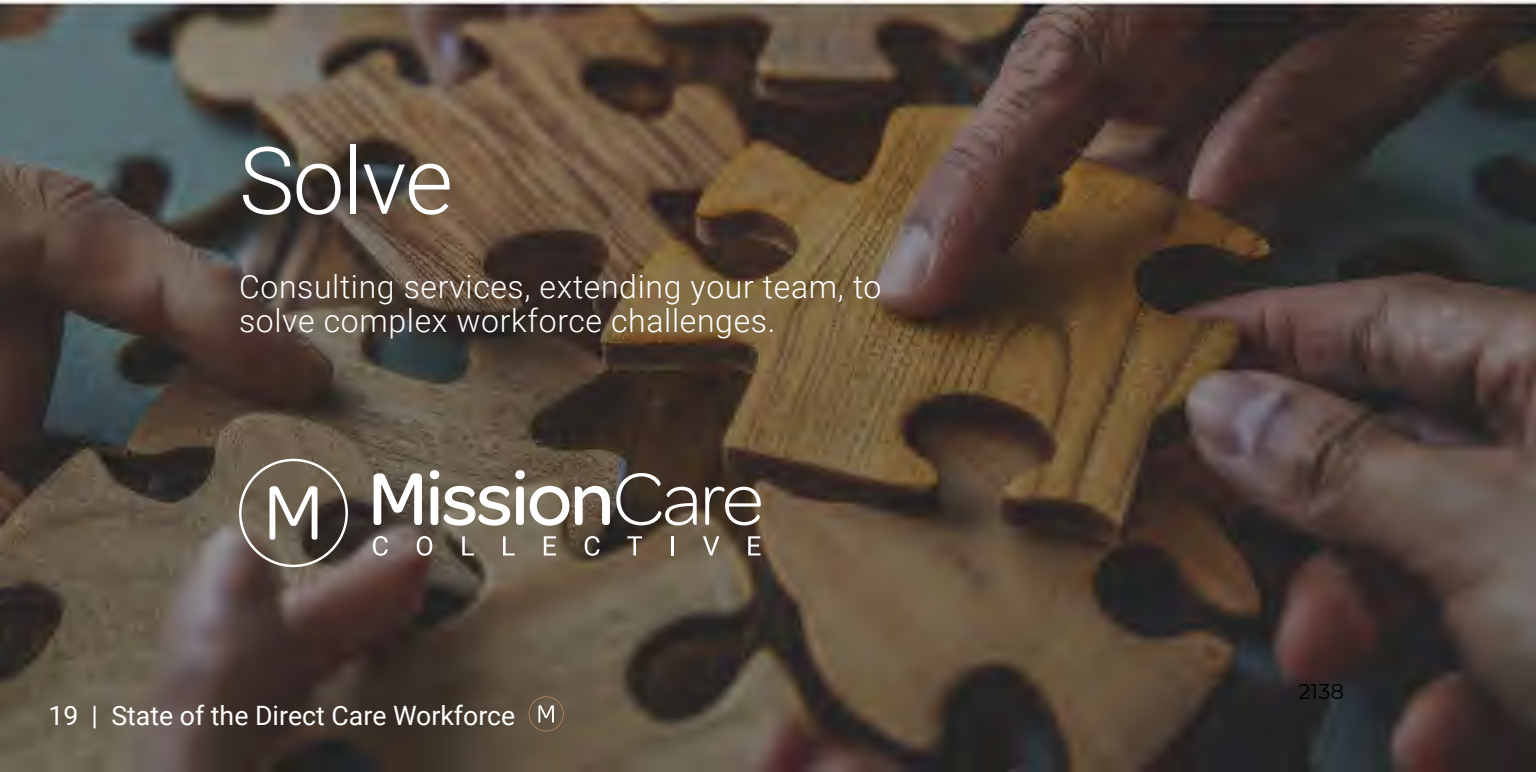
Download Report

Personas are the foundation to pipeline expansion.

MissionCare COLLECTIVE

About Us

Everything we do is about building a stronger workforce.



Solve

Consulting services, extending your team, to solve complex workforce challenges.

MissionCare COLLECTIVE

2138

Recruit

A recruitment engine that taps into the largest network of caregivers, CNAs, and HHAs in the nation. “The LinkedIn for Caregivers.”

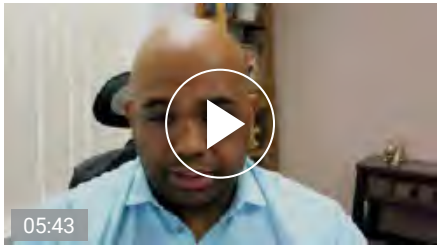
Retain

An engagement platform that helps turn your workforce into a community, increasing retention, profitability, and operational efficiencies.

2139

Data Into Action

MissionCare Collective is honored to support thousands of companies nationwide, transforming data and insights, like those found in this report, into actionable strategies that drive impactful results. Here are a few stories from our trusted partners who have turned workforce challenges into opportunities, enhancing employee engagement, retention, and revenue to ultimately deliver superior care.



Boosting Retention and Reducing Workforce Chaos for Leading Home Care Agency

Scan to watch video

Reducing Unfilled Shifts and Increasing Care Capacity for Premier Home Care Brand

Scan to watch video

Building Employee Connections to Drive Bottom Line Results for Multi-State Skilled Nursing Network

Scan to watch video

COACHUP CARE

20-200%
RETENTION INCREASE

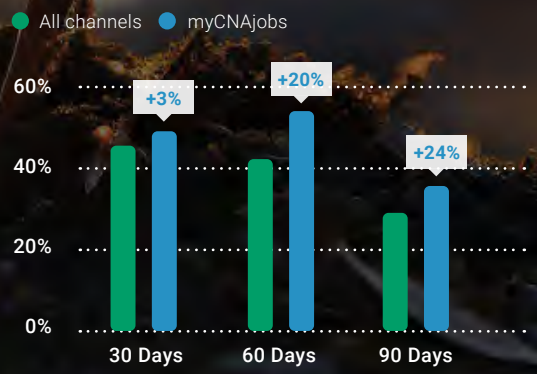
1-3 POINTS
eNPS INCREASE

10-50%
UNFILLED SHIFT REDUCTION

20-50%
RECRUITMENT $ REDUCTION

myCNAjobs

Caregiver, CNA, and Home Health Aide hires made from myCNAjobs are **24%** more likely to be retained after 90 days versus hires made from other channels.



2141

MissionCare
COLLECTIVE

THE STATE OF THE

Direct Care Workforce

2025 REPORT

References

1, 2, 5. PHI. "Direct Care Workers in the United States Key Facts 2023."
3. American Journal of Public Health
4. Brookings.edu
6, 7. MissionCare Collective. "2022-2023 Direct Care Workforce Report."
8. PHI. "The Direct Care Workforce State Index." Accessed Aug 2024.

Genworth Cost of Care Survey 2023

Summary and Methodology

131168 07/11/24

Genworth®

Summary of 2023 Survey Findings

To help families plan for potential long-term care needs, Genworth has conducted its Cost of Care Survey since 2004. This comprehensive data-gathering effort compiles current rates charged by long-term care service providers across all 50 states and makes them easily accessible through an interactive digital tool on Genworth's website.

Following the 2021 survey, the United States continued to grapple with the COVID-19 pandemic, and we saw shifts in the long-term care space. Genworth made the decision to recalibrate our Cost of Care Survey and methodology to align with consumer needs and the current state of the industry.

Keeping the best of the past with a fresh lens for the future, we share the key findings of Genworth's Cost of Care Survey 2023.

Cost of care

The national median costs associated with all long-term care service providers increased in 2023. From 2021 to 2023, Assisted Living Facilities have increased an average of 18.89%, but the increase from 2022 to 2023 was only 1.36%. The annual national median for a private, one-bedroom arrangement at these facilities reported to be $64,200 a year in 2023. The national median cost for a private, one bedroom in a Nursing Home is $116,800 a year and a semi-private room is $104,025 a year, representing average increases of 4.92% and 4.40%, respectively since 2022. The national median price of Adult Day Services increased an average 5.56% since 2022, reportedly costing $95 a day in 2023.

The 2023 Cost of Care data reveals high year-over-year increases in homecare services which includes both homemaker services – assistance with "hands off" everyday tasks such as cooking, cleaning, etc. and general companionship – as well as home health aides who provide "hands on" assistance with activities like bathing, eating, and getting dressed. The reported national median cost in 2023 for homemaker services is $30 per hour and $33 per hour for home health aide services, although significant variance exists across regions and actual pricing depends on the severity of one's need. These prices represent an average increase of 10.00% and 7.14%, respectively, year-over-year compared to the 2022 dataset. If we compare that to our 2021 survey, the hourly cost for homemaker services has risen by 15.38% and home health aide services have risen by 22.22%.

Cost Drivers

Inflation and a shortage of workers are seen as equal contributors to the increases in long-term care costs. Inflation was the number one driver for assisted living facilities and adult day care, while worker shortages was the number one driver for home care and nursing homes.

Person-Centered Care

This year's survey included a new focus on person-centered care. Person-centered care is safe, high-quality health care that puts a high value on respecting and responding to the preferences, needs and values of patients and their families. **All respondents, regardless of facility type, said the idea of person-centered care was very important to them.** The top barriers that impact the ability to offer person-centered care are staff training and cost.

The following report provides additional details around the 2023 national median rates for the various types of care settings as well as the methodology used for the survey.[1]

[1] Genworth Cost of Care Survey, September through December 2023

To learn more, visit Genworth.com/CostofCare

Genworth Cost of Care Survey 2023 | **Summary**

HOME

Homemaker Services: Services providing help with household tasks that cannot be managed alone. Homemaker services includes "hands-off" care such as cooking, cleaning and running errands.

NATIONAL MEDIAN HOURLY RATE 2023	NATIONAL MEDIAN HOURLY RATE 2022	YEAR-OVER-YEAR PERCENT CHANGE
$30	$28	7.14%

Home Health Aide Services: Home health aides offer services to people who need more extensive care. It is "hands-on" personal care, but not medical care. The rate listed here is the rate charged by a non-Medicare certified, licensed agency.

NATIONAL MEDIAN HOURLY RATE 2023	NATIONAL MEDIAN HOURLY RATE 2022	YEAR-OVER-YEAR PERCENT CHANGE
$33	$30	10%

COMMUNITY

Adult Day Health Care (ADC): Provides social and support services in a community-based, protective setting. Various models are designed to offer socialization, supervision and structured activities. Some programs may provide personal care, transportation, medication management and meals.

NATIONAL MEDIAN DAILY RATE 2023	NATIONAL MEDIAN DAILY RATE 2022	YEAR-OVER-YEAR PERCENT CHANGE
$95	$90	5.56%

Assisted Living Facility (ALF): Residential arrangements providing personal care and health services. The level of care may not be as extensive as that of a nursing home. Assisted living is often an alternative to a nursing home, or an intermediate level of long term care.

NATIONAL MEDIAN MONTHLY RATE 2023	NATIONAL MEDIAN MONTHLY RATE 2022	YEAR-OVER-YEAR PERCENT CHANGE
$5,350	$5,278	1.36%

FACILITY

Nursing Home Care: These facilities often provide a higher level of supervision and care than Assisted Living Facilities. They offer residents personal care assistance, room and board, supervision, medication, therapies and rehabilitation, and on-site nursing care 24 hours a day.

Semi-Private Room

NATIONAL MEDIAN DAILY RATE 2023	NATIONAL MEDIAN DAILY RATE 2022	YEAR-OVER-YEAR PERCENT CHANGE
$285	$273	4.40%

Private Room

NATIONAL MEDIAN DAILY RATE 2023	NATIONAL MEDIAN DAILY RATE 2022	YEAR-OVER-YEAR PERCENT CHANGE
$320	$305	4.92%

Methodology

About

This year, 176,807 providers were contacted resulting in 11,867 completed surveys of nursing homes, assisted living facilities, adult day health facilities and home care providers. Potential respondents were selected from CareScout's nationwide database of providers, supplemented with additional providers in each category of long-term care services. CareScout is a wholly owned subsidiary of Genworth Financial, Inc. that helps older adults and their families navigate the aging journey and find quality care.

Respondents representing all 50 states and the District of Columbia completed the survey by either phone or online between September and December 2023. Survey respondents were informed that the survey data provided would be included in the Genworth Cost of Care Survey 2023 results. Rates were collected for 2023 and 2022, and survey questions varied based on the type of care provided.

One of the most comprehensive surveys of its kind, the Genworth Cost of Care Survey publishes costs in 429 regions based on 382 U.S. Metropolitan Statistical Areas (MSAs). MSA definitions are established by the U.S. Office of Management and Budget. The survey also includes some counties outside of the MSA regions. Data collection attempted for all provider types in all regions, the following results in this document represent the number of regions where data collection was successful.

Home Care (HC)[2]

Surveyors completed 3,593 interviews with licensed home health care providers representing 18 percent of home care agencies.[3] The agencies surveyed provided home health care and homemaker services where a skilled nurse does not need to be present. A home health aide will typically help with bathing, dressing, transferring and toileting, but not with catheters or injections. Most of these agencies also provide homemaker services that typically include assistance with shopping, finances, cooking, errands and transportation. Homemaker services may also be employed for the purpose of providing companionship.

Annual rates are based on 44 hours of care per week, multiplied by 52 weeks. Where a rate range was provided, the midpoint was used. The survey excludes holiday rates.

Adult Day Health Care (ADC)

Surveyors polled 6 percent of adult day health care facilities, resulting in 600 completed surveys. ADC is designed to meet the needs of adults who are functionally and/or severely cognitively impaired. Programs are intended to be structured and comprehensive, and to take place in a protective setting that promotes well-being through a variety of health, social and other support services. These services are intended to help enable individuals live more independently in the community and may also be used to provide relief for family caregivers.

[2] Various provider categories used in the survey may not be the same as the definitions used in a long term care insurance policy.

[3] Not all states require a license for home care. Data includes certain states where unlicensed providers are included because the state does not offer or does not have HH license requirements.

ADC facility rates are structured in a variety of ways: Some charge by the hour, some by the half-day and others for the full day, regardless of utilization. All rates used in Genworth's survey were extrapolated to a daily (6–8 hours) rate.

ADC facility rates may be subsidized by the government or the community. A government subsidy is based on the individual's ability to pay. However, a community subsidy is available to individuals regardless of their income level. This survey captures the full private pay rates or, where applicable, the community subsidy rates. This survey does not capture the government subsidy rates.

Annual rates are based on the daily rate multiplied by five days per week, then multiplied by 52 weeks.

Assisted Living Facilities (ALF)[4]

Surveyors polled 15 percent of licensed assisted living facilities, resulting in 3,739 completed surveys. Surveyors also determined whether the facility charges a non-refundable community or entrance fee. This study shows that approximately 61 percent of assisted living facilities charge a one-time, non-refundable fee.

Unlike nursing homes, there is no uniform regulatory standard for assisted living facilities. As a consequence, states have instituted licensing standards that vary from state to state. The assisted living facilities polled were licensed according to the licensure requirements of the state in which the assisted living facility was located.

Currently, there are more than 70 different names or designations for facilities licensed as some form of an assisted care facility. Generally, fewer than 40 percent of these care facilities use the term "assisted living facility" as a part of their formal name or licensure designation. For example, some facilities may be identified as "residential care facilities." Because of variations in licensing requirements by state, both small group homes and large multi-service facilities qualified as assisted living facilities for the purposes of this study.

Surveyors collected the monthly private pay rates as they ranged from basic care to more substantial care for a one-bedroom unit in an assisted living facility. Where a rate range was provided, the average of the high and low was used in the annual cost calculation.

Annual rates are based on the monthly fee multiplied by 12 months.

Nursing Homes (NH)

Surveyors polled 13 percent of certified and licensed nursing homes, resulting in 3,935 completed surveys.

Surveyors collected the daily rates for private rooms (single occupancy) and semi-private rooms (double occupancy) in Medicare-certified nursing facilities. Medicare-certified nursing homes represent more than 90 percent of all nursing homes in the U.S.[5] The daily room charge usually includes services beyond rent, such as three meals a day, laundry, sundries, basic nurse supervision and generic non-prescription pharmaceuticals.

Annual rates are based on the daily fee multiplied by 365.

[4] Assisted Living Facilities are referred to as Residential Care Facilities in California.

[5] Nursing Home Data Compendium 2015 Edition, Centers for Medicare and Medicaid Services (https://www.cms.gov/Medicare/Provider-Enrollment-and-certification/CertificationandComplianc/Downloads/nursinghomedatacompendium_508-2015.pdf), site accessed 03/06/24.

Region Definitions

State	Region
Alaska	State Median
	Anchorage
Alabama	State Median
	Anniston, Oxford, Jacksonville
	Birmingham, Hoover
	Daphne, Fairhope, Foley
	Decatur
	Dothan
	Florence, Muscle Shoals
	Gadsden
	Huntsville
	Mobile
	Montgomery
	Tuscaloosa
Arkansas	State Median
	Fayetteville, Springdale, Rogers
	Fort Smith
	Hot Springs
	Little Rock, North Little Rock, Conway
Arizona	State Median
	Lake Havasu City, Kingman
	Phoenix, Mesa, Scottsdale
	Prescott
	Sierra Vista, Douglas
	Tucson
	Yuma
California	State Median
	Bakersfield
	Chico
	Fresno
	Los Angeles, Long Beach, Anaheim
	Madera
	Merced
	Modesto
	Napa
	Oxnard, Thousand Oaks, Ventura
	Redding
	Riverside, San Bernardino, Ontario
	Sacramento, Roseville, Arden, Arcade
	Salinas
	San Diego, Carlsbad
	San Francisco, Oakland, Hayward
	San Jose, Sunnyvale, Santa Clara
	San Luis Obispo, Paso Robles, Arroyo Grande
	Santa Cruz, Watsonville
	Santa Maria, Santa Barbara
	Santa Rosa
	Stockton, Lodi
	Vallejo, Fairfield
	Visalia, Poterville
Colorado	State Median
	Boulder
	Colorado Springs
	Denver, Aurora, Lakewood
	Fort Collins
	Grand Junction
	Greeley
	Pueblo
Connecticut	State Median
	Bridgeport, Stamford, Norwalk
	Hartford, West Hartford, East Hartford
	New Haven, Milford
	Norwich, New London
District of Columbia	State Median
	Washington, Arlington, Alexandria
Delaware	State Median
Florida	State Median
	Cape Coral, Fort Myers
	Crestview, Fort Walton Beach, Destin
	Deltona, Daytona Beach, Ormond Beach
	Gainesville
	Homosassa Springs

State	Region
	Jacksonville
	Lakeland, Winter Haven
	Miami, Fort Lauderdale, West Palm Beach
	Naples, Immokalee, Marco Island
	North Port, Sarasota, Bradenton
	Ocala
	Orlando, Kissimmee, Sanford
	Palm Bay, Melbourne, Titusville
	Panama City
	Pensacola, Ferry Pass, Brent
	Port St. Lucie
	Punta Gorda
	Sebastian, Vero Beach
	Sebring
	Tallahassee
	Tampa, St. Petersburg, Clearwater
Georgia	State Median
	Albany
	Athens, Clarke County
	Atlanta, Sandy Springs, Roswell
	Augusta, Richmond County
	Brunswick
	Columbus
	Dalton
	Gainesville
	Macon
	Rome
	Savannah
	Valdosta
	Warner Robins
Hawaii	State Median
	Urban Honolulu
Iowa	State Median
	Ames
	Cedar Rapids
	Davenport, Moline, Rock Island
	Des Moines, West Des Moines
	Dubuque
	Iowa City
	Sioux City
	Waterloo, Cedar Falls

State	Region
Idaho	State Median
	Boise City
	Coeur d'Alene
	Idaho Falls
	Lewiston
	Pocatello
Illinois	State Median
	Bloomington
	Carbondale, Marion
	Champaign, Urbana
	Chicago, Naperville, Elgin
	Decatur
	Kankakee
	Peoria
	Rockford
	Springfield
Indiana	State Median
	Bloomington
	Columbus
	Elkhart, Goshen
	Evansville
	Fort Wayne
	Indianapolis, Carmel, Anderson
	Kokomo
	Lafayette, West Lafayette
	Michigan City, La Porte
	Muncie
	South Bend, Mishawaka
	Terre Haute
Kansas	State Median
	Lawrence
	Manhattan
	Topeka
	Wichita
Kentucky	State Median
	Bowling Green
	Elizabethtown, Fort Knox
	Lexington, Fayette
	Louisville/Jefferson County
	Owensboro

State	Region
Louisiana	State Median
	Alexandria
	Baton Rouge
	Hammond
	Houma, Thibodaux
	Lafayette
	Lake Charles
	Monroe
	New Orleans, Metairie
	Shreveport, Bossier City
Massachusetts	State Median
	Barnstable Town
	Boston, Cambridge, Nashua
	Pittsfield
	Springfield
	Worcester
Maryland	State Median
	Baltimore, Columbia, Towson
	Cumberland
	Hagerstown, Martinsburg
	Salisbury
Maine	State Median
	Bangor
	Lewiston, Auburn
	Portland, South Portland
Michigan	State Median
	Ann Arbor
	Battle Creek
	Bay City
	Detroit, Warren, Dearborn
	Flint
	Grand Rapids, Wyoming
	Jackson
	Kalamazoo, Portage
	Lansing, East Lansing
	Midland
	Monroe
	Muskegon
	Niles, Benton Harbor
	Saginaw

State	Region
Minnesota	State Median
	Duluth
	Mankato, North Mankato
	Minneapolis, St. Paul, Bloomington
	Rochester
	St. Cloud
Missouri	State Median
	Cape Girardeau
	Columbia
	Jefferson City
	Joplin
	Kansas City
	Springfield
	St. Joseph
	St. Louis
Mississippi	State Median
	Gulfport, Biloxi, Pascagoula
	Hattiesburg
	Jackson
Montana	State Median
	Billings
North Carolina	State Median
	Asheville
	Burlington
	Charlotte, Concord, Gastonia
	Durham, Chapel Hill
	Fayetteville
	Goldsboro
	Greensboro, High Point
	Greenville
	Hickory, Lenoir, Morganton
	Jacksonville
	New Bern
	Raleigh
	Rocky Mount
	Wilmington
	Winston, Salem
North Dakota	State Median
	Bismarck

State	Region
	Fargo
	Grand Forks
Nebraska	State Median
	Grand Island
	Lincoln
	Omaha, Council Bluffs
New Hampshire	State Median
	Manchester, Nashua
New Jersey	State Median
	Atlantic City, Hammonton
	Ocean City
	Trenton
	Vineland, Bridgeton
New Mexico	State Median
	Albuquerque
	Farmington
	Las Cruces
	Santa Fe
Nevada	State Median
	Carson City
	Las Vegas, Henderson, Paradise
	Reno
New York	State Median
	Albany, Schenectady, Troy
	Binghamton
	Buffalo, Cheektowaga, Niagara Falls
	Glens Falls
	Kingston
	New York, Newark, Jersey City
	Poughkeepsie, Newburgh, Middletown
	Rochester
	Syracuse
	Utica, Rome
	Watertown, Fort Drum
Ohio	State Median
	Akron
	Canton, Massillon
	Cincinnati
	Cleveland, Elyria
	Columbus
	Dayton
	Lima
	Mansfield
	Springfield
	Toledo
	Youngstown, Warren, Boardman
Oklahoma	State Median
	Enid
	Lawton
	Oklahoma City
	Tulsa
Oregon	State Median
	Albany
	Bend, Redmond
	Eugene
	Grants Pass
	Medford
	Portland, Vancouver, Hillsboro
	Salem
Pennsylvania	State Median
	Allentown, Bethlehem, Easton
	Altoona
	Bloomsburg, Berwick
	Chambersburg, Waynesboro
	Erie
	Gettysburg
	Harrisburg, Carlisle
	Johnstown
	Lancaster
	Lebanon
	Philadelphia, Camden, Wilmington
	Pittsburgh
	Reading
	Scranton, Wilkes-Barre, Hazleton
	State College
	Williamsport
	York, Hanover
Rhode Island	State Median
	Providence, Warwick

State	Region
South Carolina	State Median
	Charleston, North Charleston
	Columbia
	Florence
	Greenville, Anderson, Mauldin
	Hilton Head Island, Bluffton, Beaufort
	Myrtle Beach, Conway, North Myrtle Beach
	Spartanburg
	Sumter
South Dakota	State Median
	Rapid City
	Sioux Falls
Tennessee	State Median
	Chattanooga
	Clarksville
	Jackson
	Johnson City
	Kingsport, Bristol
	Knoxville
	Memphis
	Morristown
	Nashville, Davidson, Murfreesboro, Franklin
Texas	State Median
	Abilene
	Amarillo
	Austin, Round Rock
	Beaumont, Port Arthur
	Brownsville, Harlingen
	College Station, Bryan
	Corpus Christi
	Dallas, Fort Worth, Arlington
	El Paso
	Houston, The Woodlands, Sugar Land
	Killeen, Temple
	Laredo
	Longview
	Lubbock
	McAllen, Edinburg, Mission
	Midland
	Odessa
	San Antonio, New Braunfels
	Sherman, Denison
	Tyler
	Victoria
	Waco
Utah	State Median
	Logan
	Ogden, Clearfield
	Provo, Orem
	Salt Lake City
	St. George
Virginia	State Median
	Blacksburg, Christiansburg, Radford
	Charlottesville
	Harrisonburg
	Lynchburg
	Richmond
	Roanoke
	Staunton
	Virginia Beach, Norfolk, Newport News
	Winchester
Vermont	State Median
	Burlington, South Burlington
Washington	State Median
	Bellingham
	Bremerton, Silverdale
	Kennewick, Richland
	Mount Vernon, Anacortes
	Olympia, Tumwater
	Seattle, Tacoma, Bellevue
	Spokane, Spokane Valley
	Walla Walla
	Yakima
Wisconsin	State Median
	Appleton
	Eau Claire
	Fond du Lac
	Green Bay
	Janesville, Beloit
	La Crosse, Onalaska

State	Region
	Madison
	Milwaukee, Waukesha, West Allis
	Oshkosh, Neenah
	Racine
	Wausau
West Virginia	State Median
	Beckley
	Charleston
	Huntington, Ashland
	Morgantown
	Parkersburg, Vienna
	Weirton, Steubenville
Wyoming	State Median
	Casper

Genworth Cost of Care regions are based on Metropolitan Statistical Areas (MSAs) as defined by the Office of Management and Budget (OMB) (census.gov).

In February 2013, the OMB refined its MSA delineations, thereby impacting some of our region definitions. All 2023 Cost of Care data reflects survey results based on the new delineations.

About Genworth Financial

Genworth Financial, Inc. (NYSE: GNW) is a Fortune 500 company focused on empowering families to navigate the aging journey with confidence, now and in the future. Headquartered in Richmond, Virginia, Genworth provides guidance, products, and services that help people understand their caregiving options and fund their long-term care needs. Genworth is also the parent company of publicly traded Enact Holdings, Inc. (Nasdaq: ACT), a leading U.S. mortgage insurance provider. For more information on Genworth, visit genworth.com, and for more information on Enact Holdings, Inc. visit enactmi.com.

About CareScout

CareScout helps older adults and their families navigate the aging journey and find quality care. Inspired by a mission to simplify and dignify the aging experience, we're building an integrated ecosystem of care and funding solutions. To learn more about CareScout, visit www.CareScout.com. CareScout, LLC (CareScout) is a wholly owned subsidiary of Genworth Financial, Inc. (NYSE: GNW).

Visit genworth.com/costofcare to:

- Compare daily, monthly and annual costs across locations
- Calculate future costs of care
- Get more information about the Cost of Care Survey

Insurance and annuity products:	**Are not deposits.**	**Are not guaranteed by a bank or its affiliates.**
May decrease in value.	**Are not insured by the FDIC or any other federal government agency.**	

DIRECT CARE WORKERS IN THE UNITED STATES

KEY FACTS
2023

PHI
QUALITY CARE THROUGH QUALITY JOBS

2156

TABLE OF CONTENTS

INTRODUCTION

Direct care workers assist older adults and people with disabilities with essential daily tasks and activities across a range of long-term care settings. This report explores the three primary segments of this workforce:

- **Home Care Workers** are the nearly 2.8 million personal care aides and home health aides (and in some cases, nursing assistants) who support individuals in private homes.
- **Residential Care Aides** are the 718,840 personal care aides, home health aides, and nursing assistants who support individuals in group homes, assisted living communities, and other residential care settings.
- **Nursing Assistants in Nursing Homes** are the 447,940 workers who provide services to individuals living in skilled nursing homes.[1]

The growing population of older adults continues to drive up demand for direct care workers. Over the past decade, the direct care workforce added nearly 1.6 million new jobs, growing from 3.2 million workers in 2012 to 4.8 million in 2022.[2] This trend is projected to continue, with the direct care workforce expected to add just over 1 million new jobs from 2021 to 2031—more new jobs than any other single occupation in the country.[3] When also accounting for jobs that must be filled when existing workers transfer to other occupations or exit the labor force, there will be an estimated 9.3 million total job openings in direct care from 2021 to 2031.[4]

This job growth is occurring primarily in the home and community-based services (HCBS) sector, with the home care workforce projected to increase by 35 percent in the next decade.[5] The number of residential care aides is also projected to increase by 13 percent, although a recent drop in residential care employment makes these growth projections less certain.[6] In contrast, the nursing assistant workforce is expected to continue decreasing in size, with a projected reduction of 3 percent over the next decade.[7] These diverging trends across long-term care industries largely result from consumer preference for home care and public policies that have expanded HCBS funding and access.[8]

In the past 10 years, the direct care workforce has seen incremental wage growth (even after accounting for worsening inflation[9]), largely due to state and federal investments in Medicaid programs and the long-term care workforce. Much of this investment occurred in response to the COVID-19 pandemic.[10] However, this wage growth has slowed dramatically with the reduction of federal pandemic supports. After increasing by $0.68 per hour in 2020, the median hourly wage for direct care workers increased by just $0.07 per hour in 2021 and by $0.02 per hour in 2022, adjusting for inflation.[11] Median wages for home care workers actually declined by $0.72 per hour from 2021 to 2022, as many sources of pandemic-related funding were phased out. These trends mean that direct care wages remain low—the median hourly wage for all direct care workers was just $15.43 in 2022—with home

care workers earning the least. As a result, long-term care employers continue to experience acute recruitment and retention challenges in a persistently competitive labor market.[12]

Low wages combined with a high rate of part-time work make it challenging for direct care workers to financially support themselves and their families. Median annual earnings for direct care workers are just $23,688.[13] Thirty-nine percent of direct care workers live in low-income households (defined as subsisting at less than 200 percent of the federal poverty level), and 46 percent rely on public assistance, such as Medicaid, food and nutrition assistance, or cash assistance.[14] These trends both reflect and perpetuate the racial and gender inequities faced by direct care workers, who are majority women and people of color.[15]

This annual research report begins by describing how the growing, changing population of older adults is impacting demand for direct care, then provides a comprehensive update on three key segments of the direct care workforce: home care workers, residential care aides, and nursing assistants in nursing homes. Each of the workforce sections focuses on demographics, occupational roles, job quality challenges, and projected job openings. Throughout, we highlight the ongoing impact and implications of the COVID-19 pandemic on the long-term care industry and this workforce. Taken together, these analyses underscore the pressing need for job quality interventions across long-term care settings—building on recent investments and progress—to improve the lives of direct care workers and the older adults and people with disabilities they support.

DIRECT CARE WORKER

EMPLOYMENT BY INDUSTRY, 2022

Home Care Workers	58%
Residential Care Aides	15%
Nursing Assistants in Nursing Homes	9%
Direct Care Workers in Other Industries	18%

WAGES BY INDUSTRY, 2012 TO 2022

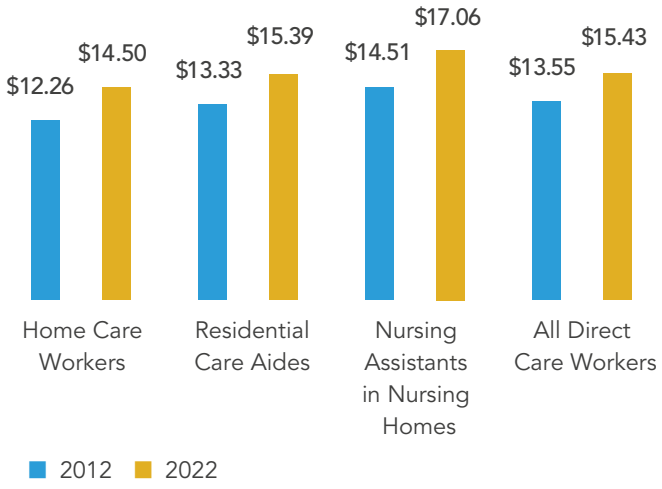


Chart Sources: Other industries employing direct care workers include hospitals and numerous others. U.S. Bureau of Labor Statistics (BLS), Division of Occupational Employment and Wage Statistics (OEWS). 2023. *May 2012 to May 2022 National Occupational Employment and Wage Estimates.* https://www.bls.gov/oes/current/oes_nat.htm; BLS OEWS. 2023. *May 2012 to May 2022 National Industry-Specific Occupational Employment and Wage Estimates.* https://www.bls.gov/oes/current/oessrci.htm; analysis by PHI (June 2023).

U.S. POPULATION PROJECTIONS

From 2020 to 2060, the population of adults age 65 and older in the U.S. is projected to increase dramatically from 56.1 million to 94.7 million.[16] The number of adults age 85 and older is expected to nearly triple over the same period from 6.7 million to 19 million. This demographic shift is the primary driver of job growth in the direct care workforce.

In contrast to the rapid expansion of the older adult population, the population of adults age 18 to 64 is expected to remain relatively stable, which means that there will be fewer potential paid and unpaid caregivers available to support older adults. Currently, the ratio of adults age 18 to 64 to adults age 85 and older is 30 to 1, but that ratio is projected to drop to 12 to 1 by 2060.

PROJECTED POPULATION GROWTH BY AGE GROUP, 2020 TO 2060

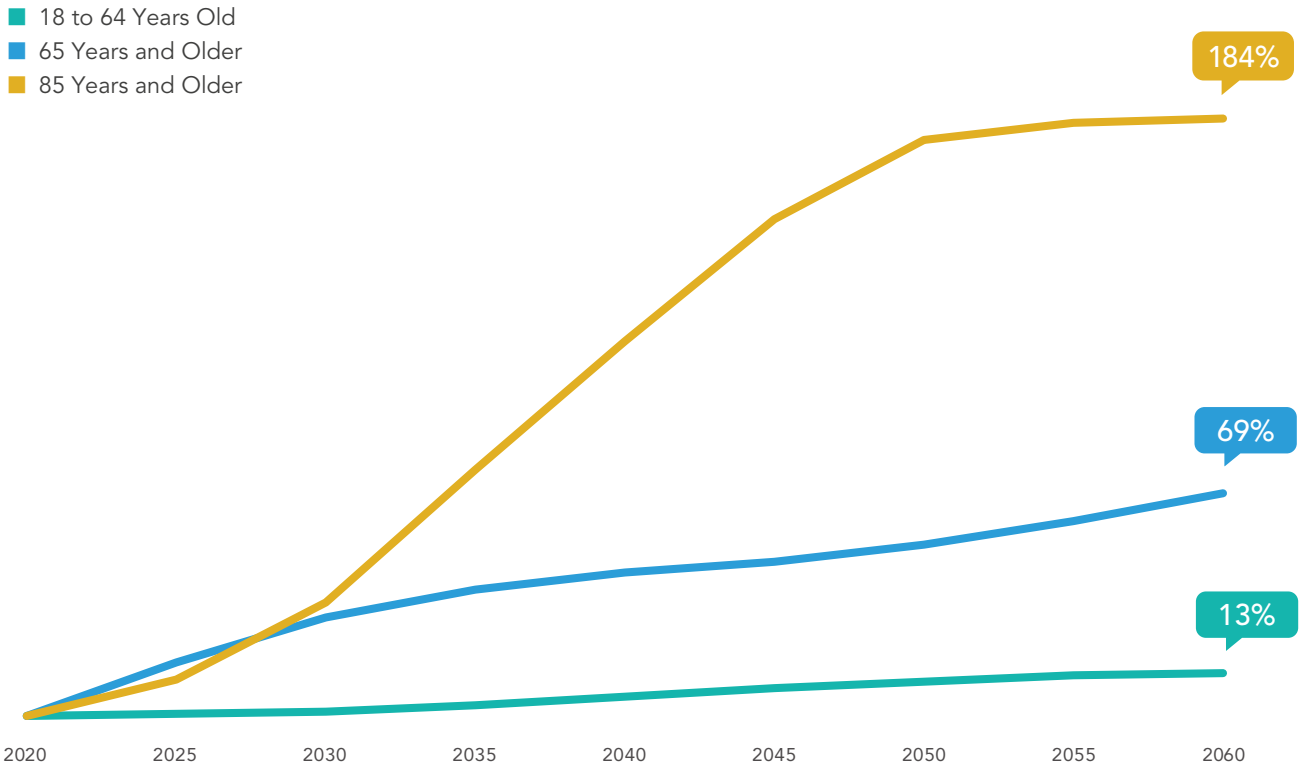


Chart Source: U.S. Census Bureau. 2017. *2017 National Population Projections Datasets, Projected Population by Single Year of Age, Sex, Race, and Hispanic Origin for the United States: 2016 to 2060.* https://www.census.gov/data/tables/2017/demo/popproj/2017-summary-tables.html; analysis by PHI (June 2023).

Growing diversity and acuity among older adults will also shape future demand for direct care workers.[17]

The population of adults age 65 and over will become more diverse by 2060. From 2020 to 2060, the proportion of older adults of color will increase from 24 percent to 45 percent, and the proportion of older adults who are immigrants will increase from 14 percent to 23 percent.

Demographic changes among older adults will likely influence overall long-term care needs and service utilization patterns. These changes also highlight the need to promote cultural and linguistic competency within the direct care workforce, while recognizing workers' own diverse backgrounds, experiences, and barriers.[18]

Individuals are also living longer with complex chronic conditions, such as Alzheimer's disease and other forms of dementia (among other conditions).

About 1 in 9 people age 65 and over are currently living with Alzheimer's disease, the most common form of dementia.[19] As our population grows older, the number of older adults with Alzheimer's disease is expected to more than double, from 6.7 million in 2023 to 13.8 million in 2060.[20] This trend will drive up demand for direct care workers since more than a third of individuals across all long-term care settings are living with Alzheimer's disease or another form of dementia.[21]

OLDER ADULT POPULATION BY RACE / ETHNICITY AND NATIVITY, 2020 AND 2060

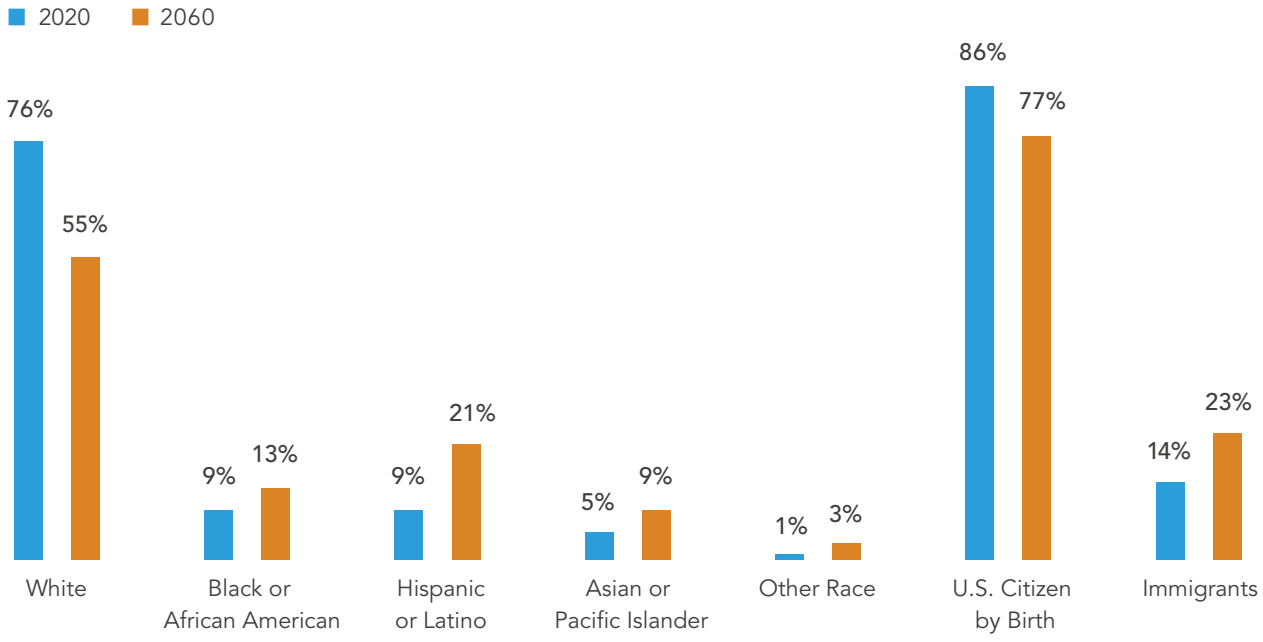


Chart Sources: The percentages shown in the chart do not total 100 percent because they are rounded to the nearest whole percentage. U.S. Census Bureau. 2017. 2017 *National Population Projections Datasets, Projected Population by Single Year of Age, Sex, Race, and Hispanic Origin for the United States: 2016 to 2060.* https://census.gov/data/tables/2017/demo/popproj/2017-summary-tables.html; U.S. Census Bureau. 2017. *2017 National Population Projections Datasets, Projected Population by Single Year of Age, Sex, Race, Hispanic Origin and Nativity for the United States: 2016 to 2060.* https://census.gov/data/tables/2017/demo/popproj/2017-summary-tables.html; analysis by PHI (July 2023).

HOME CARE WORKERS

Home care workers (primarily personal care aides and home health aides, as well as some nursing assistants) assist more than 9.8 million older adults and people with disabilities living at home.[22] The home care workforce is one of the largest and fastest growing occupations in the U.S. due to a combination of factors, including the rapidly expanding population of older adults, consumer preferences for aging and receiving care in place, and the increasing provision of home and community-based services (HCBS).[23] After incrementally increasing in recent years, home care worker wages dropped substantially from 2021 to 2022 when adjusted for inflation, and a large number of workers live in low-income households. In the context of persistently high turnover and a historically tight labor market, home care employers are struggling more than ever to recruit and retain enough workers to meet escalating demand.[24]

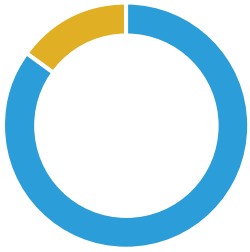
WHO ARE HOME CARE WORKERS?

Home care workers are primarily women, people of color, and immigrants, and therefore face heightened risks of discrimination throughout their lives in areas including housing, education, employment, health care, and more.[25] Gender, racial, and other forms of equity are central concerns for this workforce.[26]

- **Eighty-five percent of home care workers are women.**[27]
- **Home care workers have a median age of 48.** Thirty-five percent of the home care workforce is age 55 and over, compared to 23 percent of the U.S. labor force overall.[28]
- **While people of color make up 40 percent of the total U.S. labor force,[29] they constitute 66 percent of all home care workers.** Twenty-six percent of home care workers are Black or African American and 26 percent are Hispanic or Latino (any race).

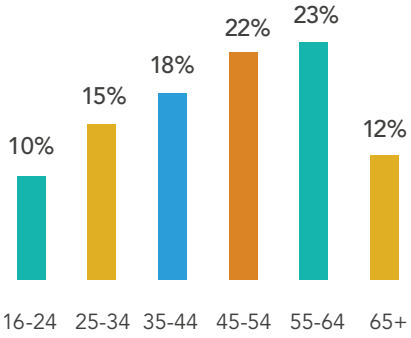
HOME CARE WORKERS BY

SEX, 2021



- Female 85%
- Male 15%

AGE, 2021



RACE AND ETHNICITY, 2021

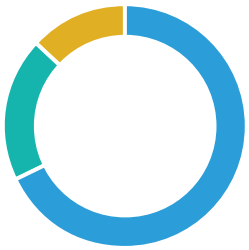
- White 34%
- Black or African American 26%
- Hispanic or Latino (Any Race) 26%
- Asian or Pacific Islander 9%
- Other 5%

Chart Source: "Hispanic or Latino" refers to people of any race who identify as Hispanic or Latino; these individuals are excluded from all other race/ethnicity categories. Ruggles, Steven, Sarah Flood, Matthew Sobek, Danika Brockman, Grace Cooper, Stephanie Richards, and Megan Schouweiler. 2023. *IPUMS USA: Version 13.0. American Community Survey, 2021*. https://doi.org/10.18128/D010.V13.0; analysis by PHI (June 2023).

- **Immigrants constitute 32 percent of the home care workforce, compared to 17 percent of the total U.S. labor force.**[30]
- **Twenty-eight percent of home care workers have at least one child under age 18 living at home, and 8 percent have one or more children under the age of five living at home.**
- **Nearly 30 percent of home care workers provide unpaid family caregiving for one or more older adults** as compared to 19 percent of workers in the U.S. labor force overall.[31]
- **Forty-five percent of home care workers have pursued education beyond high school.**

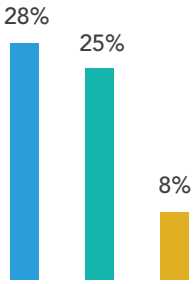
HOME CARE WORKERS BY

CITIZENSHIP STATUS, 2021



- U.S. Citizen by Birth 68%
- U.S. Citizen by Naturalization 19%
- Not a Citizen of the U.S. 13%

PARENTAL STATUS, 2021



- Any Child(ren) Under Age 18
- Child(ren) Age 5 to 17
- Child(ren) Under Age 5

UNPAID FAMILY CAREGIVING STATUS, 2021

- Provides Unpaid Family Caregiving for an Older Adult 29%
- Does Not Provide Unpaid Family Caregiving for an Older Adult 71%

EDUCATIONAL ATTAINMENT, 2021

- Less than High School 19%
- High School Graduate 36%
- Some College, No Degree 24%
- Associate's Degree or Higher 21%

Chart Source: Ruggles, Steven, Sarah Flood, Matthew Sobek, Danika Brockman, Grace Cooper, Stephanie Richards, and Megan Schouweiler. 2023. *IPUMS USA: Version 13.0. American Community Survey, 2021.* https://doi.org/10.18128/D010.V13.0; analysis by PHI (June 2023). Flood, Sarah M., Liana C. Sayer, and Daniel Backman. *American Time Use Survey Data Extract Builder: Version 3.1. American Time Use Survey, 2011-2021.* https://doi.org/10.18128/D060.V3.1; analysis by PHI (June 2023). This estimate draws on ten years of pooled data from the American Time Use Survey.

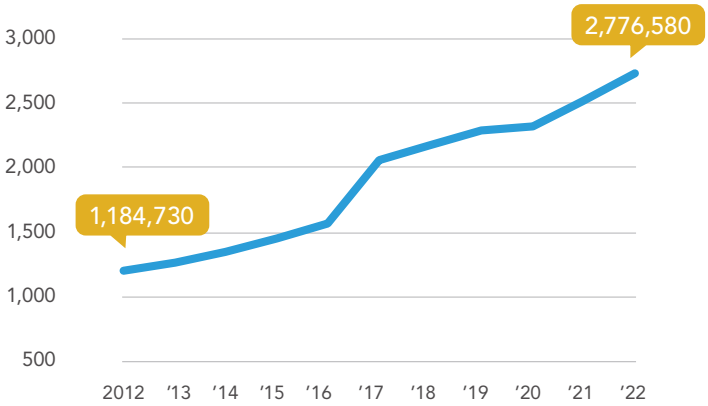
THE ROLE OF HOME CARE WORKERS

Home care workers assist older adults and people with disabilities living at home with activities of daily living (ADLs), which include eating, dressing, toileting, mobility, and bathing.[32] Other responsibilities differ across occupational groups within the home care sector. **Personal care aides** also provide other household assistance and/or social support to help individuals remain engaged in their communities. **Home health aides** (and in some cases, **nursing assistants**[33]) also perform certain clinical tasks under the remote or intermittent onsite supervision of a licensed professional. Although formally classified as personal care aides in most cases, **direct support professionals** constitute a distinct occupational group within this workforce that provides habilitation services, employment assistance, and other supports to people with intellectual and developmental disabilities.[34] *(See Occupational Titles and Industry Classifications on page 28 for more details.)*

- **The home care workforce more than doubled in size over the past 10 years, from nearly 1.2 million in 2012 to nearly 2.8 million in 2022.**
- PHI estimates that **at least 1.2 million home care workers are employed as "independent providers" through Medicaid-funded consumer-direction programs,** based on 2019 survey data on consumer enrollment in these programs.[35]

  It is very difficult to accurately estimate the number of independent providers, however. Due to a 2017 methodological change, a proportion of these workers hired through consumer-direction programs are now captured by the Bureau of Labor Statistics (BLS) Occupational Employment and Wage Statistics (OEWS) program.[36] However, the accuracy of these data varies by state and many independent providers are likely excluded. More broadly, the OEWS data do not include self-employed home care workers who are hired directly and paid out-of-pocket by consumers through the "gray market."[37]
- **Home care workers constitute 58 percent of the total direct care workforce,** which also includes workers who are employed in residential care, nursing homes, and other settings.

HOME CARE WORKER EMPLOYMENT, 2012 TO 2022



DIRECT CARE WORKER EMPLOYMENT BY INDUSTRY, 2022

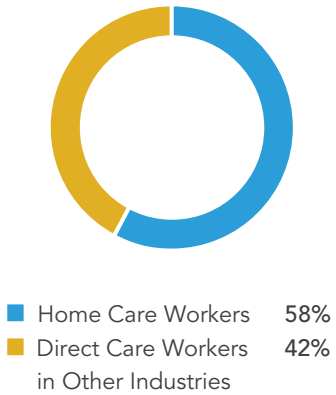
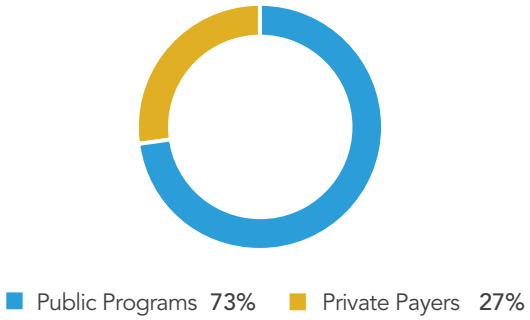


Chart Sources: U.S. Bureau of Labor Statistics (BLS), Division of Occupational Employment and Wage Statistics (OEWS). 2023. May 2012 to May 2022 *National Occupational Employment and Wage Estimates*. https://www.bls.gov/oes/current/oes_nat.htm; BLS OEWS. 2023. *May 2012 to May 2022 National Industry-Specific Occupational Employment and Wage Estimates*. https://www.bls.gov/oes/current/oessrci.htm; analysis by PHI (June 2023).

- Home care jobs are predominantly government funded. **Payments from public programs (primarily Medicaid and Medicare) constitute 73 percent of the home care industry's $123.4 billion in total annual revenue.**[38]

Chart Source: U.S. Census Bureau. 2021. *Economic Census of the United States, Health Care and Social Assistance: Sales, Value of Shipments, or Revenue by Type of Payer for the U.S. and States: 2017.* https://data.census.gov/cedsci/table?q=EC1762TYPEPAYER&n=6216%3A6231%3A6232%3A6233&tid=ECNTYPEPAYER2017.EC1762TYPEPAYER; analysis by PHI (June 2022).

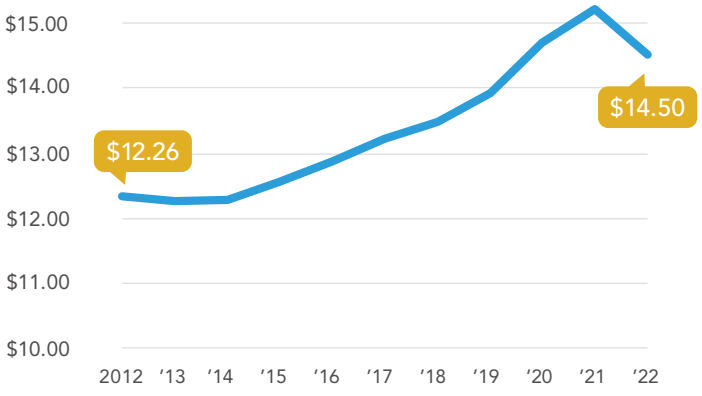
HOME CARE INDUSTRY REVENUE BY SOURCE, 2017



CHALLENGES FOR HOME CARE WORKERS

- **Home care workers' wages have risen somewhat over the past 10 years:** inflation-adjusted median hourly wages rose from $12.26 in 2012 to $14.50 in 2022. Recent wage growth was largely driven by COVID-19 pandemic-related funding measures, **but this growth trend is slowing and may even be reversing** as these funding measures wind down: inflation-adjusted median hourly wages for home care workers declined from $15.22 in 2021 to $14.50 in 2022.

HOME CARE WORKER MEDIAN HOURLY WAGES, ADJUSTED FOR INFLATION, 2012 TO 2022



- **In addition to experiencing a decrease in median hourly wages, more home care workers are working part-time hours. Forty-three percent of home care workers work part time,** defined as fewer than 35 hours per week.[39] Thirty-six percent work part time for "non-economic reasons," which include personal or family obligations and health issues, among other reasons. Seven percent work part time for "economic reasons," which means they cannot find full-time work due to economic conditions at their workplaces or in the broader labor market.

HOME CARE WORKERS BY EMPLOYMENT STATUS, 2022

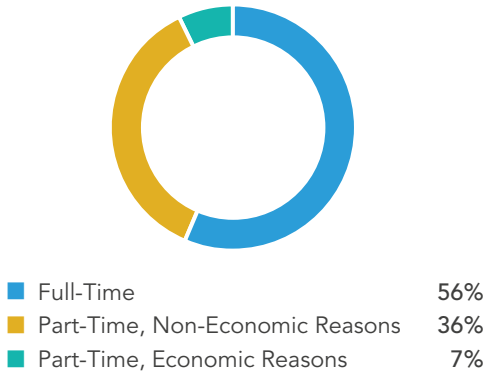
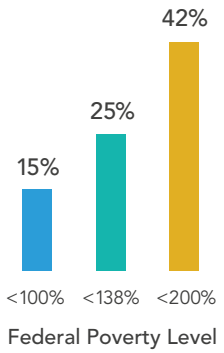


Chart Source: U.S. Bureau of Labor Statistics (BLS), Division of Occupational Employment Statistics (OEWS). 2023. *May 2012 to May 2022 National Industry-Specific Occupational Employment and Wage Estimates.* https://www.bls.gov/oes/current/oessrci.htm; analysis by PHI (June 2023).
The percentages shown in the employment status chart do not total 100 percent because they are rounded to the nearest whole percentage. Flood, Sarah M., Miriam King, Renae Rodgers, Steven Ruggles, J. Robert Warren, and Michael Westberry. 2023. *IPUMS USA: Version 9.0. Current Population Survey, 2022.* https://doi.org/10.18128/D030.V10.0; analysis by PHI (June 2023).

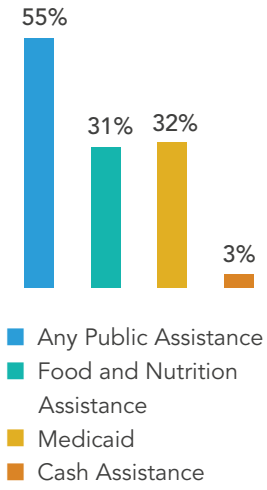
- **Sixteen percent of home care workers typically work more than 40 hours per week.**[40]
- Because of low wages and part-time hours, **home care workers earn a median annual income of $20,599.**[41]
- Low incomes lead to high poverty rates among home care workers: **15 percent live in a household below the federal poverty level and 42 percent live in low-income households.**[42]
- Because of high poverty rates, **more than half of home care workers receive some form of public assistance.**
- **Thirty-seven percent of home care workers are housing cost-burdened,** meaning that their housing costs—including rent or mortgage payments—exceed 30 percent of their household income.
- **Fifteen percent of home care workers lack health insurance,** while 43 percent rely on public coverage, most commonly Medicaid.

HOME CARE WORKERS

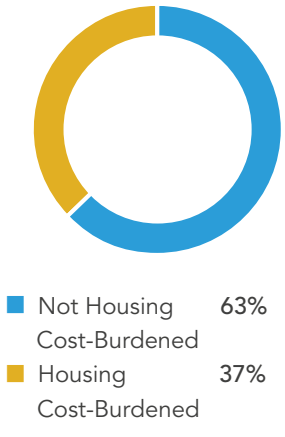
BY POVERTY LEVEL, 2021



ACCESSING PUBLIC ASSISTANCE, 2021



HOUSING COST-BURDENED, 2021



BY HEALTH INSURANCE STATUS, 2021

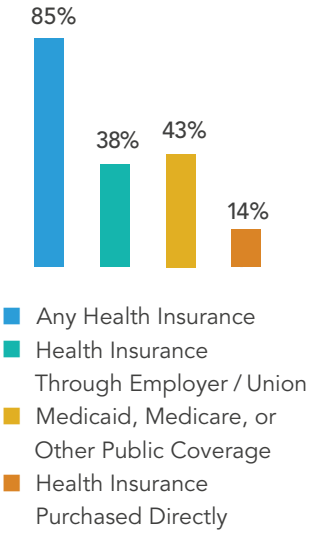


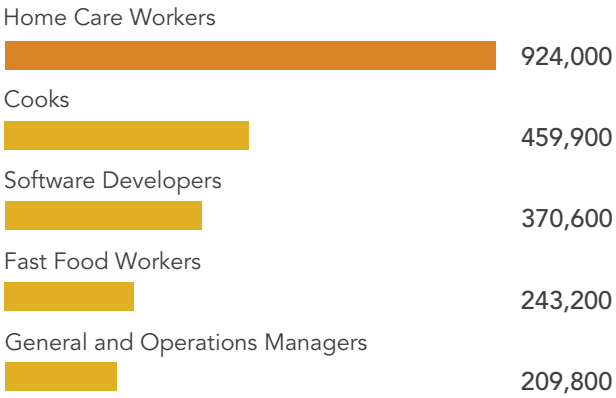
Chart Source: Ruggles, Steven, Sarah Flood, Matthew Sobek, Danika Brockman, Grace Cooper, Stephanie Richards, and Megan Schouweiler. 2023. *IPUMS USA: Version 13.0. American Community Survey, 2021*. https://doi.org/10.18128/D010.V13.0; analysis by PHI (June 2023). Ruggles, Steven, Sarah Flood, Matthew Sobek, Danika Brockman, Grace Cooper, Stephanie Richards, and Megan Schouweiler. 2023. *IPUMS USA: Version 13.0. American Community Survey, 2021*. https://doi.org/10.18128/D010.V13.0; analysis by PHI (June 2023). The percentages for specific forms of coverage in the health insurance chart do not total 85 percent because workers may have more than one source of coverage.

FUTURE DEMAND FOR HOME CARE WORKERS

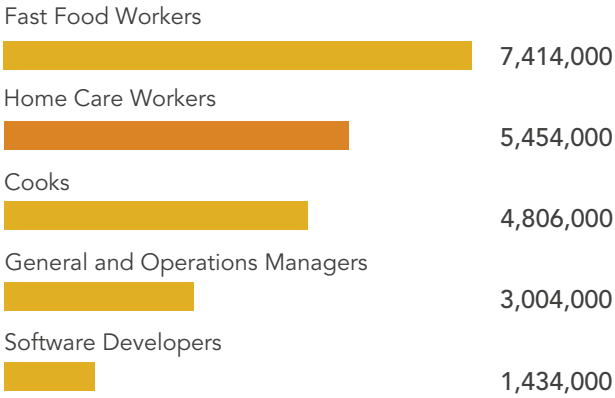
- **The home care workforce is projected to add over 900,000 new jobs from 2021 to 2031—more new jobs than any other occupation in the U.S.** The occupation with the second-largest projected growth, which is cooks, will add nearly 500,000 fewer jobs than the home care workforce.

- **From 2021 to 2031, the home care workforce will have nearly 5.5 million total job openings.** This figure includes 924,000 new jobs created by growth in demand, 2.3 million job openings caused by workers moving into other occupations, and 2.3 million job openings due to workers leaving the labor force altogether.[43] The home care workforce ranks second among all U.S. occupations for total projected job openings.

OCCUPATIONS WITH MOST JOB GROWTH, 2021 TO 2031



OCCUPATIONS WITH THE MOST TOTAL JOB OPENINGS, 2021 TO 2031



CONCLUSION

While minimum wage increases, Medicaid policy changes, and COVID-19-related funding helped boost wages for home care workers in recent years, this wage growth reversed in 2022—and a growing number of home care workers work part-time hours. Low wages and part-time hours mean that a large proportion of home care workers are still living in low-income households and relying on public assistance to make ends meet. In turn, inadequate compensation and other job quality concerns continue to drive high turnover and cause widespread job vacancies.[44] The ongoing impacts of the COVID-19 pandemic have slowed some of the projected growth in new home care jobs as compared to previous years' employment projections; however, this workforce is still expected to add more new jobs than any other occupation in the years ahead. At the same time, *total* projected job openings in home care have increased significantly compared to earlier estimates, reflecting the persistent job quality and retention challenges in the sector.

Chart Sources: U.S. Bureau of Labor Statistics (BLS), Employment Projections Program (EPP). 2022. *National Employment Matrix - Industry*. https://data.bls.gov/projections/nationalMatrixHome?ioType=i; BLS EPP. 2022. *EP Data Tables, Table 1.10 Occupational Separations and Openings, Projected 2021–2031*. https://www.bls.gov/emp/tables.htm; analysis by PHI (June 2023).

RESIDENTIAL CARE AIDES

Residential care aides support more than 1.2 million individuals living in residential care settings in the U.S., which range from small group homes to assisted living and life plan communities (i.e., senior living communities with tiered levels of care).[45] The number of residential care aides dropped somewhat in 2021, then recovered in 2022, but projected employment growth has slowed overall.[46] Despite these fluctuations, residential care aides play a prominent role in the nation's long-term care system but—like other direct care workers—continue to work in poor-quality jobs.

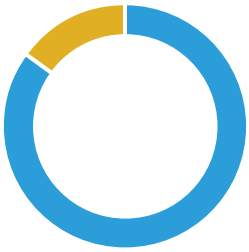
WHO ARE RESIDENTIAL CARE AIDES?

Residential care aides are majority women and people of color, and disproportionately immigrants, and therefore face heightened risks of discrimination throughout their lives in areas including housing, education, employment, health care, and more.[47] Gender, racial, and other forms of equity are central concerns for this workforce.[48]

- **Eighty-five percent of residential care aides are women.**[49]
- **Residential care aides have a median age of 40.** Twenty percent of residential care aides are age 16 to 24, compared to 13 percent of the total U.S. labor force.[50]
- **While people of color make up 40 percent of the total U.S. labor force,**[51] **they constitute 60 percent of residential care aides.** Thirty-three percent of residential care aides are Black or African American.

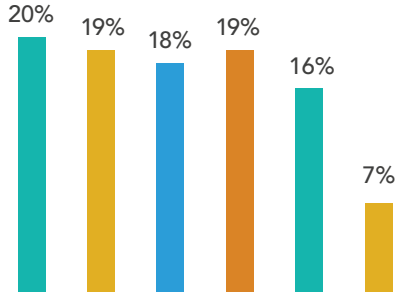
RESIDENTIAL CARE AIDES BY

SEX, 2021



- Female 85%
- Male 15%

AGE, 2021



RACE AND ETHNICITY, 2021

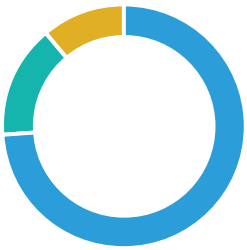
- White 41%
- Black or African American 33%
- Hispanic or Latino (Any Race) 14%
- Asian or Pacific Islander 7%
- Other 6%

Chart Source: Ruggles, Steven, Sarah Flood, Matthew Sobek, Danika Brockman, Grace Cooper, Stephanie Richards, and Megan Schouweiler. 2023. *IPUMS USA: Version 13.0. American Community Survey, 2021.* https://doi.org/10.18128/D010.V13.0; analysis by PHI (June 2023). The percentages shown in the charts do not total 100 percent because they are rounded to the nearest whole percentage. "Hispanic or Latino" refers to people of any race who identify as Hispanic or Latino; these individuals are excluded from all other race/ethnicity categories.

- **Immigrants constitute 26 percent of the residential care aide workforce, compared to 17 percent of the total U.S. labor force.**[52]
- **Thirty percent of residential care aides have at least one child under age 18 living at home, and 11 percent have one or more children under the age of five living at home.**
- **Thirty-one percent of residential care aides provide unpaid family caregiving for one or more older adults** as compared to 19 percent of workers in U.S. labor force overall.[53]
- **Over half of residential care aides have pursued education beyond high school.**

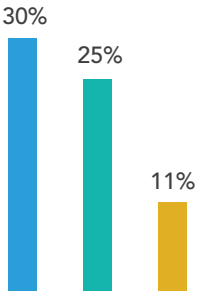
RESIDENTIAL CARE AIDES BY

CITIZENSHIP STATUS, 2021



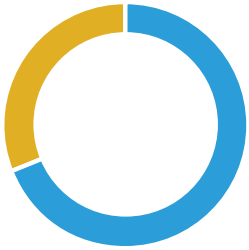
- U.S. Citizen by Birth 74%
- U.S. Citizen by Naturalization 15%
- Not a Citizen of the U.S. 11%

PARENTAL STATUS, 2021



- Any Child(ren) Under Age 18
- Child(ren) Age 5 to 17
- Child(ren) Under Age 5

UNPAID FAMILY CAREGIVING STATUS, 2021



- Provides Unpaid Family Caregiving for an Older Adult 31%
- Does Not Provide Unpaid Family Caregiving for an Older Adult 69%

EDUCATIONAL ATTAINMENT, 2021

- Less than High School 11%
- High School Graduate 37%
- Some College, No Degree 31%
- Associate's Degree or Higher 20%

Chart Source: Ruggles, Steven, Sarah Flood, Matthew Sobek, Danika Brockman, Grace Cooper, Stephanie Richards, and Megan Schouweiler. 2023. *IPUMS USA: Version 13.0. American Community Survey, 2021.* https://doi.org/10.18128/D010.V13.0; analysis by PHI (June 2023). Flood, Sarah M., Liana C. Sayer, and Daniel Backman. *American Time Use Survey Data Extract Builder: Version 3.1. American Time Use Survey, 2011-2021.* https://doi.org/10.18128/D060.V3.1; analysis by PHI (June 2023). This estimate draws on a decade of pooled data from the American Time Use Survey. The percentages shown in the educational attainment chart do not total 100 percent because they are rounded to the nearest whole percentage.

THE ROLE OF RESIDENTIAL CARE AIDES

Residential care aides assist individuals with daily tasks and activities in community-based residential care settings. These roles are filled by **personal care aides, home health aides,** and **nursing assistants,** depending on state-level regulations and employers' hiring practices. Although formally classified as personal care aides in most cases, **direct support professionals** specifically support residents with intellectual and developmental disabilities in residential care settings. *(See Occupational Titles and Industry Classifications on page 28 for more details.)*

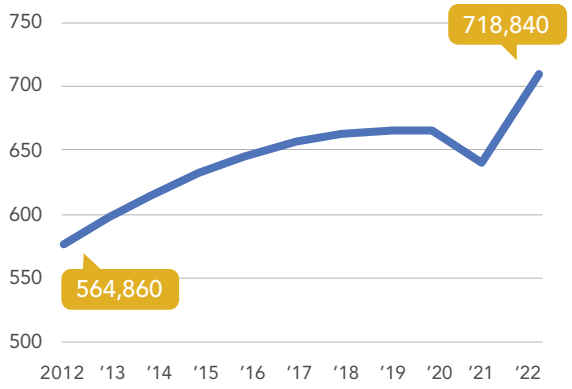
- **The residential care aide workforce added 153,980 jobs in total over the past 10 years, increasing in size from 564,860 workers in 2012 to 718,840 in 2022.**[54] After losing over 27,000 jobs from 2020 to 2021, the residential care aide workforce gained back over 71,000 jobs in 2022.

- **Residential care aides constitute 15 percent of the total direct care workforce,** which also includes workers who are employed in home care, nursing homes, and other settings.

- Of the residential care industry's $136 billion in total annual revenue, **40 percent comes from public programs**, primarily Medicaid and Medicare, and **36 percent comes from private sources**, including long-term care insurance and out-of-pocket payments.[55]

Revenue sources vary across residential care. Public sources constitute 66 percent of revenue in residential care homes for people with intellectual and developmental disabilities, versus 16 percent of revenue in assisted living and continuing care retirement communities.[56]

RESIDENTIAL CARE AIDE EMPLOYMENT, 2012 TO 2022



DIRECT CARE WORKER EMPLOYMENT BY INDUSTRY, 2022

Residential Care Aides	15%
Direct Care Workers in Other Industries	85%

RESIDENTIAL CARE REVENUE BY SOURCE, 2021

Public Programs	40%
Out-of-Pocket Payments	27%
Private Insurance	9%
Other	24%

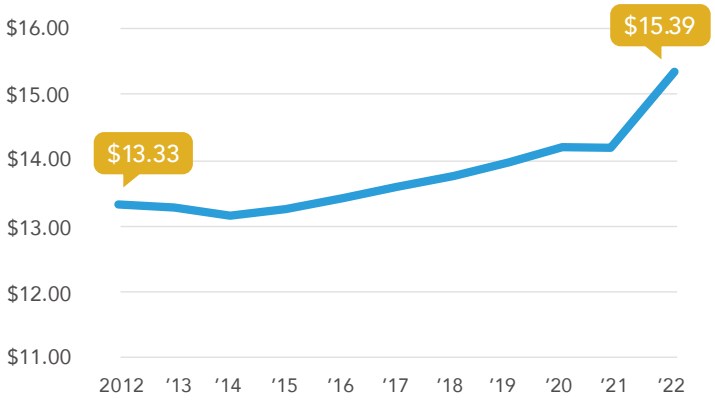
Chart Sources: U.S. Bureau of Labor Statistics (BLS), Division of Occupational Employment and Wage Statistics (OEWS). 2023. *May 2012 to May 2022 National Occupational Employment and Wage Estimates.* https://www.bls.gov/oes/current/oes_nat.htm; BLS OEWS. 2023. *May 2012 to May 2022 National Industry-Specific Occupational Employment and Wage Estimates.* https://www.bls.gov/oes/current/oessrci.htm; analysis by PHI (June 2023). U.S. Census Bureau. 2022. *Service Annual Survey, Estimated Sources of Revenue for Employer Firms: 2013 through 2021.* https://www.census.gov/data/tables/2021/econ/services/sas-naics.html (July 2023). Other sources of revenue include other healthcare providers; contributions, gifts, and grants; investment and property income; property, auto, and casualty insurances; and all other non-classifiable sources of revenue.

CHALLENGES FOR RESIDENTIAL CARE AIDES

- **Residential care aides' wages have risen somewhat over the past 10 years:** inflation-adjusted median hourly wages were $13.33 in 2012 and $15.39 in 2022. This trend means that residential care aides' wages have increased slightly faster than the costs of goods and services over the past decade.
- **More than one in four residential care aides work part time,** defined as fewer than 35 hours per week. The proportion of residential care aides working part time has increased from about one in five in the previous year. Twenty-four percent work part time for "non-economic reasons," which include personal or family obligations and health issues, among other reasons. Four percent work part time for "economic reasons," which means they cannot find full-time work due to economic conditions at their workplaces or in the broader labor market.
- **Fifteen percent of residential care aides typically work more than 40 hours per week.**

RESIDENTIAL CARE AIDE(S)

MEDIAN HOURLY WAGES, ADJUSTED FOR INFLATION, 2012 TO 2022



BY EMPLOYMENT STATUS, 2022

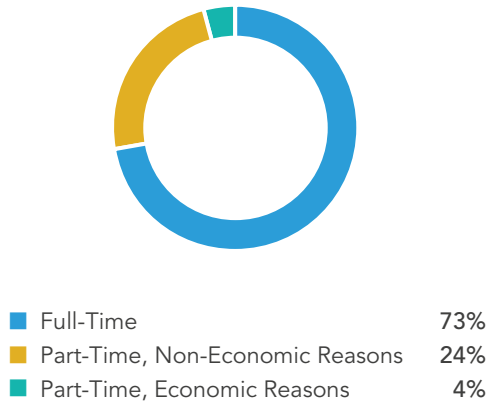
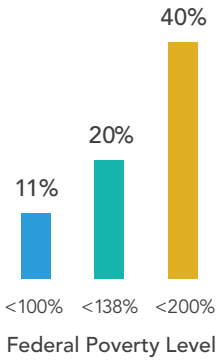


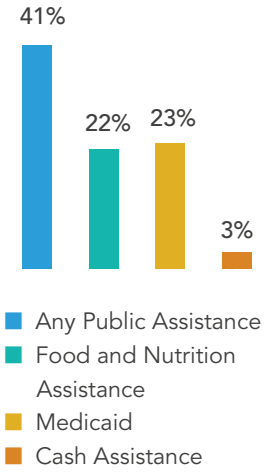
Chart Source: U.S. Bureau of Labor Statistics (BLS), Division of Occupational Employment Statistics (OEWS). 2023. May 2012 to May 2022 National Industry-Specific Occupational Employment and Wage Estimates. https://www.bls.gov/oes/current/oessrci.htm; analysis by PHI (June 2023). Flood, Sarah M., Miriam King, Renae Rodgers, Steven Ruggles, J. Robert Warren, and Michael Westberry. 2023. Integrated Public Use Microdata Series, Current Population Survey, 2022: Version 9.0. https://doi.org/10.18128/D030.V10.0; analysis by PHI (June 2023). The percentages shown in the employment status chart do not total 100 percent because they are rounded to the nearest whole percentage.

RESIDENTIAL CARE AIDES

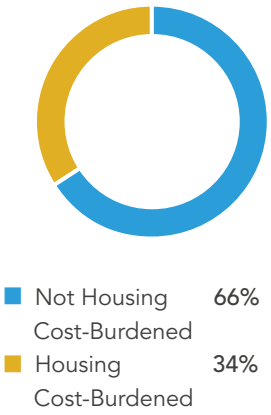
BY POVERTY LEVEL, 2021



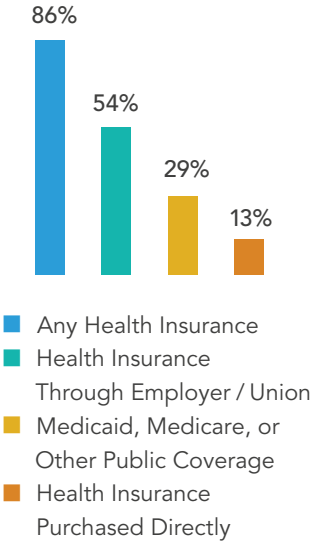
ACCESSING PUBLIC ASSISTANCE, 2021



HOUSING COST-BURDENED, 2021



BY HEALTH INSURANCE STATUS, 2021



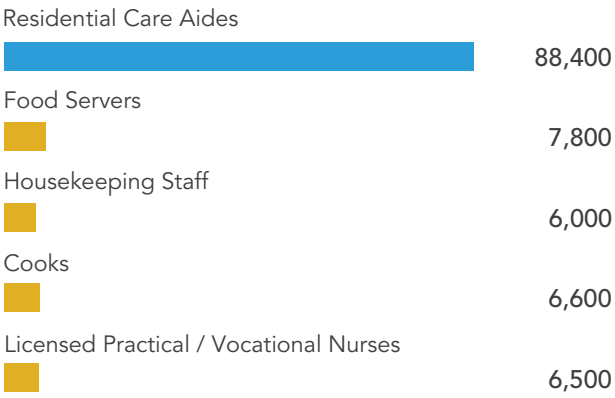
- Because of low wages and a prevalence of part-time hours, **residential care aides earn a median annual income of $24,718.**
- Low incomes lead to high poverty rates among residential care aides: **11 percent live in a household below the federal poverty level and 40 percent live in low-income households.**
- Because of high poverty rates among residential care aides, **41 percent receive some form of public assistance.**
- **Thirty-four percent of residential care aides are housing cost-burdened, meaning that their housing costs**—including rent or mortgage payments—exceed 30 percent of their household income.
- **Fourteen percent of residential care aides lack health insurance.** Fifty-four percent receive insurance through an employer or union (including insurance through their spouses), while 29 percent rely on public coverage, most commonly Medicaid.

Chart Source: Ruggles, Steven, Sarah Flood, Matthew Sobek, Danika Brockman, Grace Cooper, Stephanie Richards, and Megan Schouweiler. 2023. *IPUMS USA: Version 13.0. American Community Survey, 2021.* https://doi.org/10.18128/D010.V13.0; analysis by PHI (June 2023). The percentages for specific forms of coverage in the health insurance chart do not total 86 percent because workers may have more than one source of coverage.

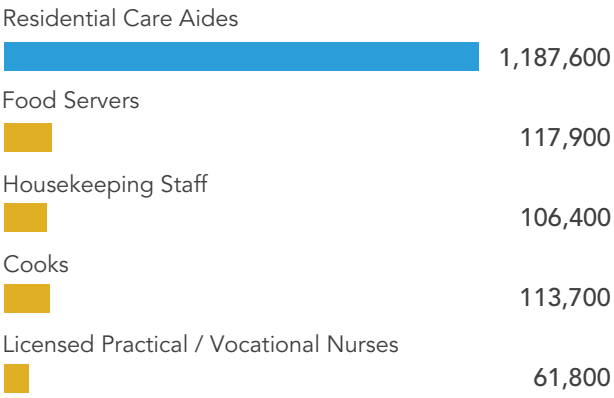
FUTURE DEMAND FOR RESIDENTIAL CARE AIDES

- **The residential care aide workforce, which is the largest occupational group within residential care settings by far, is projected to add 88,400 new jobs from 2021 to 2031.**
- **From 2021 to 2031, the residential care aide workforce will have nearly 1.2 million total job openings.** This figure includes 88,400 new jobs created by growth in demand plus 538,100 job openings caused by workers moving into other occupations and 561,100 job openings due to workers leaving the labor force altogether.[62] Projected job openings in residential care aide roles are nearly three times the sum of all projected job openings for the next top four occupations in residential care settings.

JOB GROWTH IN RESIDENTIAL CARE BY OCCUPATION, 2021 TO 2031



JOB OPENINGS IN RESIDENTIAL CARE BY OCCUPATION, 2021 TO 2031



CONCLUSION

As in home care, recruitment and retention in the residential care sector have been acutely challenging in recent years due to rising demand coupled with poor job quality for residential care aides. While the total number of residential care aide jobs recovered in 2022 after a temporary decline, job quality and retention issues persist; notably, residential care aide median hourly wages and median annual incomes have only increased slightly, while the number of residential care aides working part-time hours has increased. As a result of these challenges, total projected job openings for residential care aides have increased from previous estimates, due in part to a higher expected rate of transfers out of this occupation. Considering the prominent role of private payers and providers in determining compensation and other aspects of job quality for residential care aides, transforming these jobs continues to require significant investments through private as well as public channels.

Chart Source: U.S. Bureau of Labor Statistics (BLS), Employment Projections Program (EPP). 2022. *National Employment Matrix - Industry*. https://data.bls.gov/projections/nationalMatrixHome?ioType=i; analysis by PHI (June 2023). U.S. Bureau of Labor Statistics (BLS), Employment Projections Program (EPP). 2022. *National Employment Matrix - Industry*. https://data.bls.gov/projections/nationalMatrixHome?ioType=i; BLS EPP. 2021. *EP Data Tables, Table 1.10 Occupational Separations and Openings, Projected 2021–2031*. https://www.bls.gov/emp/tables.htm; analysis by PHI (June 2023).

NURSING ASSISTANTS IN NURSING HOMES

Nursing assistants provide 24-hour care and personal assistance to 1.2 million nursing home residents across the U.S.[63] While demand for nursing home care has declined in recent years, nursing homes continue to play a critical role in supporting individuals with complex needs. Low wages, heavy workloads, and long work hours—driven by chronic understaffing and greatly exacerbated by the ongoing COVID-19 pandemic—contribute to high rates of stress, injury, and burnout among nursing assistants in nursing homes.[64] For these reasons, the median turnover rate among nursing assistants in nursing homes is nearly 100 percent,[65] and employers struggle to fill vacant positions. To ensure quality care for nursing home residents, interventions aimed at improving job quality are needed to strengthen the nursing assistant workforce.

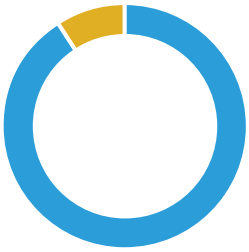
WHO ARE NURSING ASSISTANTS IN NURSING HOMES?

Nursing assistants are primarily women, people of color, and immigrants, and therefore face heightened risks of experiencing discrimination throughout their lives in areas including housing, education, employment, health care, and more.[66] Gender, racial, and other forms of equity are central concerns for this workforce.[67]

- **More than 90 percent of nursing assistants are women.**[68]
- **Nursing assistants have a median age of 38.** Twenty-one percent of nursing assistants are age 16 to 24, compared to 13 percent of the total U.S. labor force.
- **While people of color make up 40 percent of the total U.S. labor force,**[69] **they constitute 56 percent of all nursing assistants in nursing homes.** Thirty-five percent of nursing assistants are Black or African American.

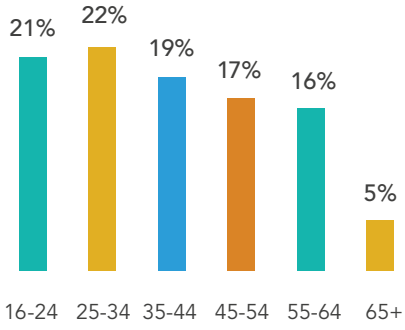
NURSING ASSISTANTS BY

SEX, 2021

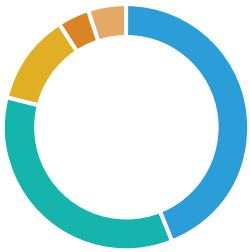


- Female 91%
- Male 9%

AGE, 2021



RACE AND ETHNICITY, 2021



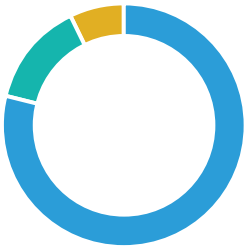
- White 44%
- Black or African American 35%
- Hispanic or Latino (Any Race) 12%
- Asian or Pacific Islander 4%
- Other 5%

Chart Source: Ruggles, Steven, Sarah Flood, Matthew Sobek, Danika Brockman, Grace Cooper, Stephanie Richards, and Megan Schouweiler. 2023. *IPUMS USA: Version 13.0. American Community Survey, 2021.* https://doi.org/10.18128/D010.V13.0; analysis by PHI (June 2023). "Hispanic or Latino" refers to people of any race who identify as Hispanic or Latino; these individuals are excluded from all other race/ethnicity categories.

- **Immigrants constitute 21 percent of the nursing assistant workforce, compared to 17 percent of the total U.S. labor force.**[70]
- **Thirty-six percent of nursing assistants have at least one child under the age of 18 living at home, and 14 percent have one or more children under the age of five living at home.**
- **Eighteen percent of nursing assistants provide unpaid family caregiving for one or more older adults,** which is similar to the 19 percent of workers who also fulfill this role in the U.S. labor force overall.[71]
- **Nearly half of nursing assistants have pursued education beyond high school.**

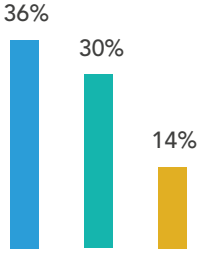
NURSING ASSISTANTS BY

CITIZENSHIP STATUS, 2021



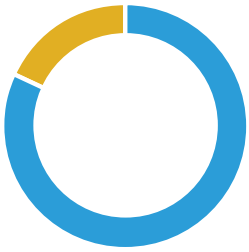
- U.S. Citizen by Birth 79%
- U.S. Citizen by Naturalization 14%
- Not a Citizen of the U.S. 7%

PARENTAL STATUS, 2021



- Any Child(ren) Under Age 18
- Child(ren) Age 5 to 17
- Child(ren) Under Age 5

UNPAID FAMILY CAREGIVING STATUS, 2021



- Provides Unpaid Family Caregiving for an Older Adult 18%
- Does Not Provide Unpaid Family Caregiving for an Older Adult 82%

EDUCATIONAL ATTAINMENT, 2021

- Less than High School 11%
- High School Graduate 43%
- Some College, No Degree 32%
- Associate's Degree or Higher 14%

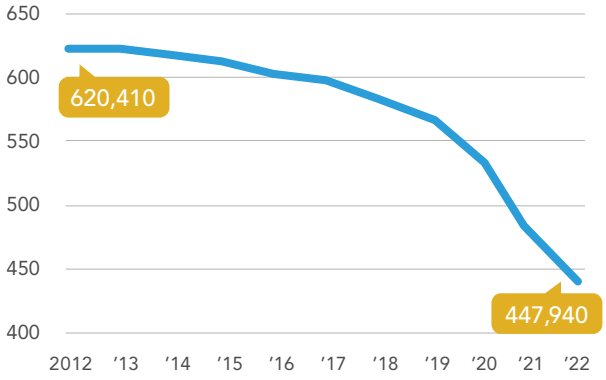
Chart Source: Ruggles, Steven, Sarah Flood, Matthew Sobek, Danika Brockman, Grace Cooper, Stephanie Richards, and Megan Schouweiler. 2023. *IPUMS USA: Version 13.0. American Community Survey, 2021*. https://doi.org/10.18128/D010.V13.0; analysis by PHI (June 2023). Flood, Sarah M., Liana C. Sayer, and Daniel Backman. *American Time Use Survey Data Extract Builder: Version 3.1. American Time Use Survey, 2011-2021*. https://doi.org/10.18128/D060.V3.1; analysis by PHI (June 2023). This estimate draws on a decade of pooled data from the American Time Use Survey.

THE ROLE OF NURSING ASSISTANTS IN NURSING HOMES

Nursing assistants support nursing home residents with daily tasks such as dressing, bathing, eating, and mobility. They also help residents participate in various social activities and events such as classes, performances, and religious services. Further, nursing assistants perform certain clinical tasks under the supervision of onsite licensed professionals. *(See Occupational Titles and Industry Classifications on page 28 for more details.)*

- **The number of nursing assistants in nursing homes has steadily declined over the past decade, from 620,410 in 2012 to 447,940 in 2022.** From 2021 to 2022 alone, the nursing assistant workforce lost 23,220 jobs. Five-year data indicate that the number of nursing home residents has also decreased by 10 percent from 2017 to 2022.[72]
- **Nursing assistants in nursing homes constitute nine percent of the total direct care workforce,** which also includes workers employed in home care, residential care, and other settings.
- **Among all nursing staff, nursing assistants spend the most time with residents, providing 62 percent of all nursing hours, at a median of two hours of direct care per resident per day.** Because of their frequent interactions with residents, nursing assistants are well-positioned to observe changes in resident condition and report these changes to licensed nursing staff.

NURSING ASSISTANT EMPLOYMENT IN NURSING HOMES, 2012 TO 2022



DIRECT CARE WORKER EMPLOYMENT BY INDUSTRY, 2022

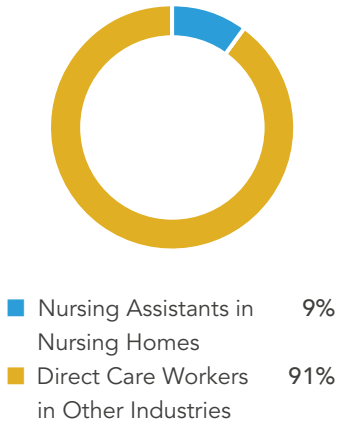
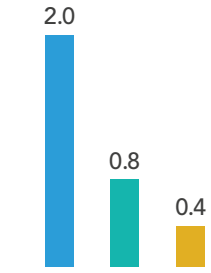


Chart Sources: U.S. Bureau of Labor Statistics (BLS), Division of Occupational Employment and Wage Statistics (OEWS). 2023. *May 2012 to May 2022 National Occupational Employment and Wage Estimates.* https://www.bls.gov/oes/current/oes_nat.htm; BLS OEWS. 2023. *May 2012 to May 2022 National Industry-Specific Occupational Employment and Wage Estimates.* https://www.bls.gov/oes/current/oessrci.htm; analysis by PHI (June 2023).

- **On average, nursing assistants support 12 residents during each shift,** while 10 percent of nursing assistants typically assist 18 or more residents.[73]
- **More than half of all nursing homes (56 percent) relied on nursing assistants from staffing agencies to fill staffing vacancies in 2022.** This figure indicates a continued reliance on contract staffing, which increased from 41 percent of all nursing homes in 2020 and peaked in 2021 at 62 percent.
- **Over one-third (34 percent) of nursing homes employ medication aides** who are nursing assistants that are trained and authorized to administer medications under the supervision of a licensed professional.[74]
- Nursing assistant jobs are predominantly government funded. Of the nursing home industry's $128 billion in total annual revenue, **payments from public programs (primarily Medicaid and Medicare) constitute 66 percent.**[75]

MEDIAN STAFF HOURS PER RESIDENT PER DAY BY OCCUPATION, 2022



NURSING HOMES WITH CONTRACTED NURSING ASSISTANT STAFF, 2022

NURSING HOME REVENUE BY SOURCE, 2021

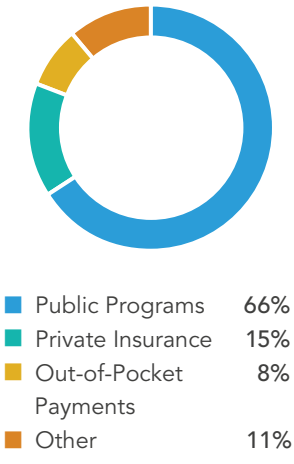


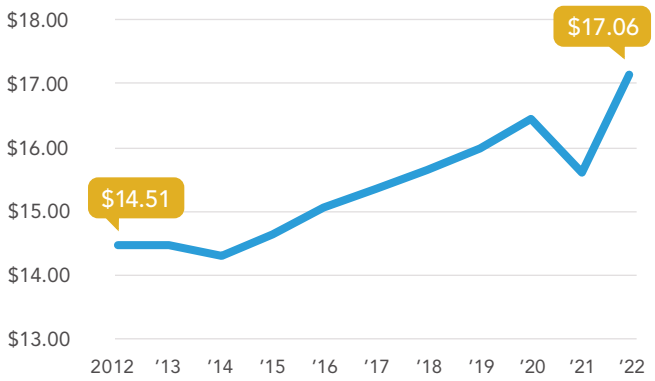
Chart Source: Centers for Medicare & Medicaid Services (CMS). 2023. *Payroll Based Journal Daily Nurse Staffing, Q1 through Q4 2022*. https://data.cms.gov/quality-of-care/payroll-based-journal-daily-nurse-staffing; analysis by PHI (June 2023). U.S. Census Bureau. 2022. *Service Annual Survey, Estimated Sources of Revenue for Employer Firms: 2013 through 2021*. https://www.census.gov/data/tables/2020/econ/services/sas-naics.html; analysis by PHI (June 2023). Other sources of revenue include other healthcare providers; contributions, gifts, and grants; investment and property income; property, auto, and casualty insurances; and all other non-classifiable sources of revenue.

CHALLENGES FOR NURSING ASSISTANTS IN NURSING HOMES

- **Nursing assistants' wages have risen slightly over the past 10 years, although with some variation:** inflation-adjusted median hourly wages increased from $14.51 in 2012 to $17.06 by 2022, but with notable wage decreases during that period as well. This overall trend means that nursing assistants' wages have only increased slightly faster than the costs of goods and services over the past decade.
- **More than one in four nursing assistants works part time,** defined as fewer than 35 hours per week.[76] That figure is up from 21 percent in the previous year.[77] Twenty-five percent work part time for "non-economic reasons," which include personal or family obligations and health issues, among other reasons. Three percent work part time for "economic reasons," which means they cannot find full-time work due to economic conditions at their workplaces or in the broader labor market.
- **Twelve percent of nursing assistants typically work more than 40 hours per week.**[78]
- Due to low wages and a prevalence of part-time hours, **nursing assistants earn a median annual income of $25,748.**[79]

NURSING ASSISTANT(S)

MEDIAN HOURLY WAGES, ADJUSTED FOR INFLATION, 2012 TO 2022



BY EMPLOYMENT STATUS, 2022

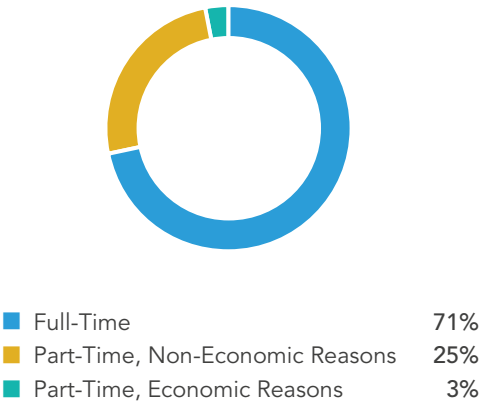
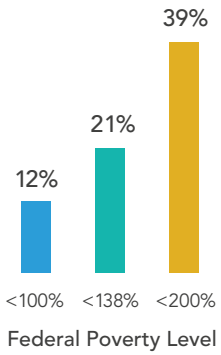


Chart Source: U.S. Bureau of Labor Statistics (BLS), Division of Occupational Employment Statistics (OEWS). 2023. *May 2012 to May 2022 National Industry-Specific Occupational Employment and Wage Estimates.* https://www.bls.gov/oes/current/oessrci.htm; analysis by PHI (June 2023). Flood, Sarah M., Miriam King, Renae Rodgers, Steven Ruggles, J. Robert Warren, and Michael Westberry. 2023. *Integrated Public Use Microdata Series, Current Population Survey, 2022: Version 9.0.* https://doi.org/10.18128/D030.V10.0; analysis by PHI (June 2023). The percentages shown in the employment status chart do not total 100 percent because they are rounded to the nearest whole percentage.

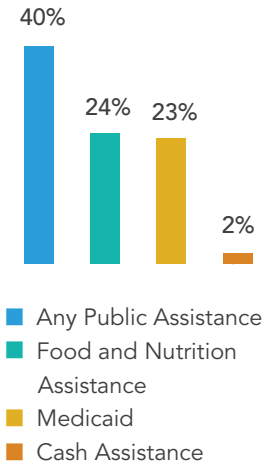
- Low incomes lead to high poverty rates among nursing assistants: **12 percent live in a household below the federal poverty level and 39 percent live in low-income households.**[80]
- Because poverty rates are high among nursing assistants, **40 percent rely on some form of public assistance.**
- **Thirty-two percent of nursing assistants are housing cost-burdened,** meaning that their housing costs—including rent or mortgage payments—exceed 30 percent of their household income.
- **Thirteen percent of nursing assistants in nursing homes lack health insurance.** Fifty-eight percent of nursing assistants have insurance through an employer or union (including insurance through their spouses), while 28 percent rely on public coverage, most commonly Medicaid.

NURSING ASSISTANTS

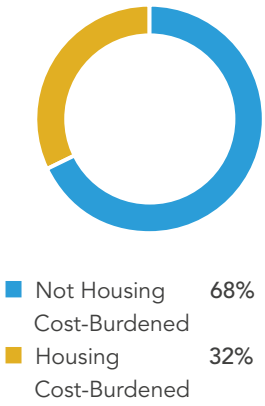
BY POVERTY LEVEL, 2021



ACCESSING PUBLIC ASSISTANCE, 2021



HOUSING COST-BURDENED, 2021



BY HEALTH INSURANCE STATUS, 2021

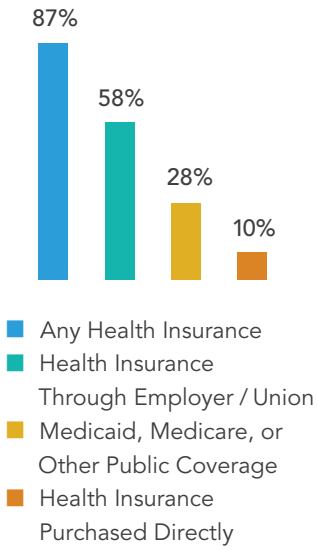


Chart Source: Ruggles, Steven, Sarah Flood, Matthew Sobek, Danika Brockman, Grace Cooper, Stephanie Richards, and Megan Schouweiler. 2023. *IPUMS USA: Version 13.0. American Community Survey, 2021*. https://doi.org/10.18128/D010.V13.0; analysis by PHI (June 2023). The percentages for specific forms of coverage in the health insurance chart do not total 87 percent because workers may have more than one source of coverage.

- **Nursing assistants are nearly eight times more likely to experience workplace injuries than the typical U.S. worker.** Because work-related illness is considered a "workplace injury," COVID-19 caused injury rates among nursing assistants to increase by more than 300 percent from 2019 (299 injuries per 10,000 workers) to 2020 (1,014 injuries per 10,000 workers), the most recent year of occupation-specific data available. Industry-level (but not occupation-specific) data do show a decrease in nursing home worker injuries and illnesses from 2020 to 2021, but overall injury and illness incidence rates in nursing homes remain some of the highest in any industry.

ANNUAL INJURY RATES PER 10,000 WORKERS BY CAUSE OF INJURY, 2020

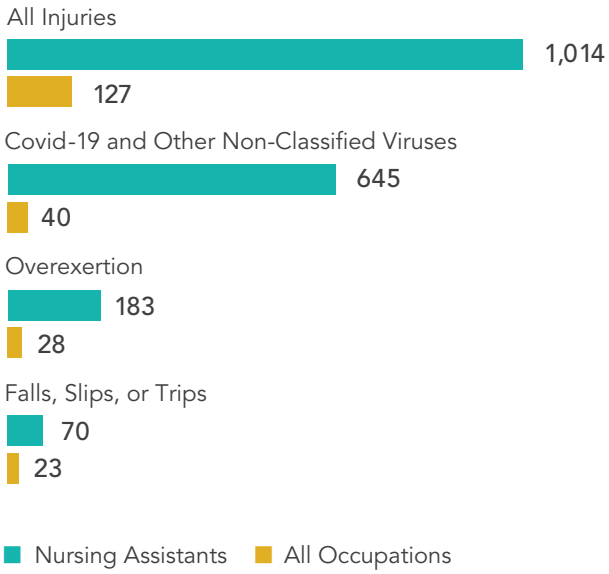


Chart Source: Work absences due to COVID-19 are included in a category of workplace injury called "Other diseases due to viruses, not elsewhere classified," according to the Occupational Injury and Illness Classification System, Version 2.01. A corresponding analysis of workplace injuries among home care workers and residential care aides has not been conducted for this report due to data limitations. U.S. Bureau of Labor Statistics (BLS), Injuries, Illnesses, and Fatalities (IIF). 2021. Occupational Injuries and Illnesses and Fatal Injuries Profiles. https://www.bls.gov/iif/; BLS IIF. 2021. Nonfatal Illnesses Due to Novel Viruses by Occupation. https://www.bls.gov/iif/how-covid-19-is-reflected-in-the-soii-data.htm; analysis by PHI (June 2022).

THE IMPACT OF COVID-19 ON NURSING HOMES

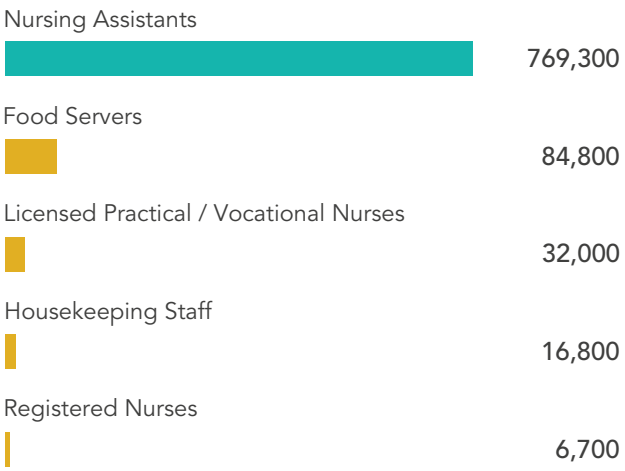
The COVID-19 pandemic devastated the nursing home sector, and the crisis is not over. While more nursing home staff (including nursing assistants) received vaccine booster doses in 2023 as compared to previous years, many staff and residents remain vulnerable to COVID-19, with deaths attributed to the disease continuing to climb.

From January 2020 to July 2023, 164,165 nursing home residents and 3,061 staff died from COVID-19. In the past year alone—from July 2022 through July 2023—over 11,000 resident deaths and nearly 700 staff deaths were attributed to COVID-19. Broad-based efforts are still needed to address the long-standing challenges in nursing homes that continue to amplify the negative consequences of the COVID-19 pandemic for this sector—and to help address the trauma experienced in recent years by those who live and work in nursing homes.

FUTURE DEMAND FOR NURSING ASSISTANTS IN NURSING HOMES

- **From 2021 to 2031, the nursing assistant workforce is projected to lose 17,200 jobs** due to decreasing demand for nursing home care overall.[85]
- **However, the projected number of total job openings for nursing assistants in nursing homes continues to increase. From 2021 to 2031, this workforce will have 769,300 total job openings.** This figure includes 442,400 job openings caused by workers moving into other occupations and 344,100 job openings due to workers exiting the labor force altogether.[86] Job openings for nursing assistants in nursing homes during this time period are projected to be over five times higher than job openings in the next four nursing home occupations combined.

JOB OPENINGS IN NURSING HOMES BY OCCUPATION, 2021 TO 2031



CONCLUSION

Although overall demand for nursing homes is declining, there is still a pressing need to recruit and retain enough nursing assistants to support individuals with complex needs in this care setting. The pandemic has both revealed and greatly exacerbated workforce challenges in nursing homes, as indicated, for example, by the increasing reliance on contract nursing assistants.[87] In response to these ongoing challenges, several states have taken steps to improve job quality and care quality by increasing Medicaid reimbursement to nursing homes with stipulations about nursing assistants' compensation.[88] Other states have set requirements for the percentage of nursing home revenue that must be invested in resident care, including wages and other job quality measures.[89] Additional states have set minimum staffing requirements to overcome widespread understaffing in nursing homes, a strategy that is currently being pursued at the federal level.[90] In order to support nursing assistants and nursing home residents now and into the future, such efforts must be significantly expanded and sustained.

Chart Sources: U.S. Bureau of Labor Statistics (BLS), Employment Projections Program (EPP). 2022. *National Employment Matrix - Industry*. https://data.bls.gov/projections/nationalMatrixHome?ioType=i; BLS EPP. 2021. *EP Data Tables, Table 1.10 Occupational Separations and Openings, Projected 2021–2031*. https://www.bls.gov/emp/tables.htm; analysis by PHI (June 2023).

OCCUPATIONAL TITLES AND INDUSTRY CLASSIFICATIONS

OCCUPATIONAL TITLES

The direct care worker occupational categories used in this report are defined by the Standard Occupational Classification (SOC) system developed by the Bureau of Labor Statistics (BLS) at the U.S. Department of Labor (DOL). Under this classification system, workers are classified based on their on-the-job responsibilities, skills, education, and training. Occupation definitions can be found at: http://www.bls.gov/SOC. In practice, state regulations, employer norms, and other factors determine the roles and responsibilities associated with occupational titles in different settings.

TITLE	OTHER TITLES	JOB DESCRIPTION
Personal Care Aides (SOC 31-1122)	Caregiver, Home Care Aide, Personal Care Assistant, Personal Care Attendant, Resident Care Assistant	In addition to assisting with activities of daily living (ADLs), personal care aides often help with housekeeping, chores, meal preparation, and medication management. They may also help individuals engage in employment and/or community life, and provide advice on nutrition, household maintenance, and other activities.
Home Health Aides (SOC 31-1121)	Certified Home Health Aide, Home Hospice Aide, Home Health Attendant	In addition to assisting with ADLs, home health aides may also perform clinical tasks such as wound care, blood pressure readings, and range-of-motion exercises. Their work is supervised remotely or intermittently onsite by a licensed professional.
Nursing Assistants (SOC 31-1131)	Certified Nursing Assistant, Certified Nursing Aide, Nursing Attendant, Nursing Aide, Nursing Care Attendant, Medication Aide	Nursing assistants assist individuals with ADLs and may also perform certain clinical tasks under the onsite supervision of a licensed professional.

A NOTE ON OTHER OCCUPATIONAL TITLES

Two other direct care occupations have distinct on-the-job responsibilities, but do not have their own federal occupation codes.

Independent providers are home care workers who are employed directly by older adults, people with disabilities, or their families through publicly funded consumer-direction programs or using private funds. Their roles may include a mix of personal care and health monitoring and maintenance tasks, depending on the needs and preferences of the individuals who employ them. Due to a 2017 methodological change, a proportion of independent providers hired through consumer-direction programs are now captured by the Bureau of Labor Statistics (BLS) Occupational Employment and Wage Statistics (OEWS) program.[91] However, the accuracy of these data varies by state and many independent providers are likely excluded. More broadly, these data do not include home care workers who are hired directly and paid out-of-pocket by consumers through the "gray market."[92]

Direct support professionals provide habilitation services, employment assistance, and other supports to people with intellectual and developmental disabilities.[93] They are included in BLS data and other public datasets (unless they are employed directly by consumers or their families in the "gray market"), but because they do not have their own federal occupation code, they are combined with other direct care workers and are not separately quantifiable.

INDUSTRY CLASSIFICATIONS

Long-term care industries are defined by the North American Industry Classification System (NAICS) developed by the Office of Management and Budget (OMB). Business establishments are coded based on their primary activity. Industry definitions can be found at: https://www.census.gov/eos/www/naics/.

TITLE	EXAMPLES	INDUSTRY DESCRIPTION
Home Care		
Home Health Care Services (NAICS 621610)	Home Health Care Agencies, Visiting Nurse Associations, In-Home Hospice Care Services	This industry comprises establishments that provide personal care, homemaking, and companionship services. These establishments also provide skilled nursing care and a range of other home-based medical services.
Services for the Elderly and Persons with Disabilities (NAICS 624120)	Non-Medical Home Care Providers, Homemaker Service Providers, Self-Help Organizations, Companion Service Providers, Adult Day Care Centers, Activity Centers for Older Adults and People with Disabilities	This industry comprises establishments that provide social assistance services to improve the quality of life for older adults, people with intellectual and developmental disabilities, and people with physical disabilities who live in their homes and communities. Services include non-medical personal care and homemaker services.
Residential Care		
Continuing Care Retirement Communities and Assisted Living Facilities for the Elderly (NAICS 623310)	Assisted Living Communities, Continuing Care Retirement Communities, Residential Care Homes, Personal Care Homes	This industry comprises establishments primarily engaged in providing residential and personal care services for older adults and people with disabilities. The care typically includes room, board, supervision, and assistance with daily tasks and activities.
Residential Intellectual and Developmental Disability Facilities (NAICS 623210)	Group Homes, Intermediate Care Facilities, Residential Care Homes, Homes for Individuals with Intellectual and Developmental Disabilities	This industry comprises establishments primarily engaged in providing residential care services for people with intellectual and developmental disabilities. These communities may provide some health care, though their focus is room, board, protective supervision, and counseling.
Nursing Homes		
Nursing Care Facilities (Skilled Nursing Homes) (NAICS 623110)	Skilled Nursing Facilities, Nursing Homes, Rest Homes with Nursing Care, Retirement Homes with Nursing Care, Group Homes for People with Disabilities with Nursing Care, Homes for the Aged with Nursing Care, Inpatient Hospice	This industry comprises establishments that are primarily engaged in providing 24-hour nursing, rehabilitative, and personal care services. These establishments have a permanent core staff of registered and licensed practical/vocational nurses who provide care along with nursing assistants and other staff.

DATA SOURCES AND METHODS

Hourly wage and employment data were sourced from the Bureau of Labor Statistics (BLS) Occupational Employment and Wage Statistics (OEWS) program and employment projections were sourced from the BLS Employment Projections Program (EPP). While nursing assistant wage data were drawn directly from the OEWS, home care worker and residential care aide wages were calculated as a weighted average of median hourly wages for each occupation in each industry. Median wages are preferable to mean wages in these calculations, since mean wages may be skewed by a small proportion of atypically high-paid workers. The Consumer Price Index for All Urban Consumers (Current Series) was used to adjust wages for inflation to 2022 dollars.

The U.S. Census Bureau's American Community Survey (ACS) and Current Population Survey (CPS) were used to calculate workforce demographics, parental status, full-time/part-time status, median annual earnings, poverty rate, use of public assistance, health insurance coverage, and access to affordable housing. The U.S. Census Bureau's American Time Use Survey (ATUS) pooled years of data from 2011-2021 were used to estimate the percentages of direct care workers and all U.S. workers that provide unpaid family caregiving for one or more older adults.

For nursing assistants in nursing homes specifically, Payroll-Based Journal data from the Centers for Medicare & Medicaid Services (CMS) were used to analyze staffing, including use of contract CNA staff, hours per resident day, medication aide employment, and residents per nursing assistant. To estimate the ratio of residents to nursing assistants, we divided the number of residents in each nursing home by the estimated number of full-time equivalent (FTE) nursing assistants. We estimated the number of FTE positions by dividing total daily nursing assistant hours by three (the typical number of shifts in a day) and eight (the number of hours in a full-time shift).

NOTES

1. U.S. Bureau of Labor Statistics (BLS), Division of Occupational Employment and Wage Statistics (OEWS). 2023. *May 2012 to May 2022 National Industry-Specific Occupational Employment and Wage Estimates.* https://www.bls.gov/oes/current/oessrci.htm; analysis by PHI (June 2023).

2. BLS OEWS, 2023.

3. U.S. Bureau of Labor Statistics (BLS), Employment Projections Program (EPP). 2022a. *National Employment Matrix - Industry.* https://data.bls.gov/projections/nationalMatrixHome?ioType=i; analysis by PHI (June 2023). U.S. Bureau of Labor Statistics (BLS), Employment Projections Program (EPP). 2022. EP Data Tables, Table 1.10 Occupational Separations and Openings, Projected 2021–2031. https://www.bls.gov/emp/tables.htm; analysis by PHI (June 2023).

4. BLS EPP, 2022.

5. BLS EPP, 2022b.

6. BLS EPP, 2022a.

7. BLS EPP, 2022a.

8. Binette, Joanne. 2021. *Where We Live, Where We Age: Trends in Home and Community Preferences.* Washington, D.C.: AARP Research. https://www.aarp.org/research/topics/community/info-2021/2021-home-community-preferences.html.

9. Tankersley, Jim. 2022. "An 'Ugly' Inflation Report Upended Hopes That Price Gains Would Ease." *New York Times*, June 10. https://www.nytimes.com/2022/06/10/business/economy/inflation-report-price-gains-biden.html

10. Musumeci, MaryBeth. 2020. *Key Questions About the New Increase in Federal Medicaid Matching Funds for COVID-19.* Washington, D.C.: Kaiser Family Foundation. https://www.kff.org/coronavirus-covid-19/issue-brief/key-questions-about-the-new-increase-in-federal-medicaid-matching-funds-for-covid-19/.

11. BLS OEWS, 2023.

12. Mutikani, Lucia. 2023. "U.S. job gains smallest in 2 ½ Years; Labor market still tight." *Reuters*, July 7. https://www.reuters.com/markets/us/slower-still-strong-us-job-growth-expected-june-2023-07-07/

13. Ruggles, Steven, Sarah Flood, Ronald Goeken, Megan Schouweiler, and Matthew Sobek. 2023. "American Community Survey, 2021." *IPUMS USA: Version 13.0*. https://doi.org/10.18128/D010.V13.0; analysis by PHI (June 2023).

14. Ruggles et al., 2023.

15. McCall, Stephen and Kezia Scales. 2022. *Direct Care Worker Disparities: Key Trends and Challenges*. Bronx, NY: PHI. https://www.phinational.org/resource/direct-care-worker-disparities-key-trends-and-challenges/.

16. To note, the U.S. Census Bureau has not published new population projections since 2017. U.S. Census Bureau. 2017. 2017 *National Population Projections Datasets, Projected Population by Single Year of Age, Sex, Race, and Hispanic Origin for the United States: 2016 to 2060.* https://www.census.gov/data/tables/2017/demo/popproj/2017-summary-tables.html; analysis by PHI (June 2023).

17. Campbell, Stephen, Angelina Del Rio Drake, Robert Espinoza, and Kezia Scales. 2021. *Caring for the Future: The Power and Potential of America's Direct Care Workforce.* Bronx, NY: PHI. https://phinational.org/caringforthefuture/.; Administration for Community Living. 2022. *2021 Profile of Older Americans. Washington, D.C.: Administration for Community Living, U.S. Department of Health and Human Services.* https://acl.gov/sites/default/files/Profile%20of%20OA/2021%20Profile%20of%20OA/2021ProfileOlderAmericans_508.pdf.

18. Campbell et al., 2021.

19. Alzheimer's Association. 2023. *2023 Alzheimer's Disease Facts and Figures.* Chicago, IL: Alzheimer's Association. https://www.alz.org/media/documents/alzheimers-facts-and-figures.pdf.

20. Rajan, Kumar, Jennifer Weuve, Lisa Barnes, Elizabeth, McAninch, Robert Wilson, and Denis Evans. 2021. "Population Estimate of People with Clinical AD and Mild Cognitive Impairment in the United States (2020-2060)." *Alzheimer's & Dementia: The Journal of the Alzheimer's Association*, 17(12):1966-75.

21. Harris-Kojetin, Lauren, Manisha Sengupta, Jessica Penn Lendon, Vincent Rome, Roberto Valverde, and Christine Caffrey. 2022. "Long-Term Care Providers and Services Users in the United States, 2017– 2018." *National Center for Health Statistics, Vital Health Stat* 3(43). https://stacks.cdc.gov/view/cdc/115346.

22. This number of home care consumers includes an estimated number of home health recipients, Medicaid state-plan personal care recipients, and enrollees in Medicaid waiver programs. It does not include the unquantifiable number of consumers who pay out-of-pocket for home care through home care agencies and on the gray market. Harris-Kojetin et al., 2022; O'Malley Watts, Molly, MaryBeth Musumeci, and Meghana Ammula. 2022. *Medicaid Home & Community-Based Services: People Served and Spending During COVID-19*. Washington, D.C.: Kaiser Family Foundation. https://www.kff.org/report-section/medicaid-home-community-based-services-people-served-and-spending-during-covid-19-appendix/; analysis by PHI (June 2022).

23. Binette, 2021.

24. Ferguson, Stephanie. 2023. "Understanding America's Labor Shortage." *U.S. Chamber of Commerce*, June 9. https://www.uschamber.com/workforce/understanding-americas-labor-shortage; Donlan, Andrew. 2023. "After 3-Year Dip, Home Care Turnover Soars To 77%." Home Health Care News, May 24s. https://homehealthcarenews.com/2023/05/after-dipping-for-three-years-home-care-turnover-rate-soared-to-77-in-2022/.

25. Carratala, Sofia. 2020. *Health Disparities by Race and Ethnicity.* Washington, D.C.: Center for American Progress (CAP). https://www.americanprogress.org/issues/race/reports/2020/05/07/484742/health-disparities-race-ethnicity/; Nowicki, Jacqueline. 2020. "Racial Disparities in Education and the Role of Government." *Government Accountability Office*, June 29. https://www.gao.gov/blog/racial-disparities-education-and-role-government; Nunn, Ryan, Jana Parsons, and Jay Shambaugh. 2019. *Race and Underemployment in the US Labor Market*. Washington, D.C.: Brookings Institution. https://www.brookings.edu/blog/up-front/2019/08/01/race-and-underemployment-in-the-u-s-labor-market/; Carratala, Sofia and Connor Maxwell. 2020. *Health Disparities by Race and Ethnicity.* Washington, D.C.: CAP. https://www.americanprogress.org/issues/race/reports/2020/05/07/484742/health-disparities-race-ethnicity/.

26. McCall and Scales, 2022.

27. The U.S. Census Bureau asks American Community Survey respondents about their current sex identity, and allows for "male" or "female" response. While sex and gender are different and neither sex nor gender are binary, this data source currently only asks about current sex with a binary response option. In this report we use "women" to refer to those who responded to the sex question with "female" and "men" to refer to those who responded to the sex question with "male."

28. Ruggles et al., 2023.

29. Ruggles et al., 2023.

30. Ruggles et al., 2023.

31. Flood, Sarah M., Liana C. Sayer and Daniel Backman. 2023b. American Time Use Survey Data Extract Builder: Version 3.1 "American Time Use Survey, 2011-2021." College Park, MD: University of Maryland and Minneapolis, MN: IPUMS, 2022. https://doi.org/10.18128/D060.V3.1; Analysis by PHI (June 2023).

32. Edemekong, Peter, Deb L. Bomgaars, Sukesh Sukumaran, and Caroline Schoo. "Activities of Daily Living." Last modified November 19, 2022. https://www.ncbi.nlm.nih.gov/books/NBK470404/.

33. North Carolina, Rhode Island, and Wyoming require some or all home care workers to complete training to become nursing assistants. Also, some employers might choose to hire certified nursing assistants to fill home health aide positions. PHI. "Personal Care Aide Training Requirements." Last modified August 10, 2020. https://phinational.org/advocacy/personal-care-aide-training-requirements/.

34. President's Committee for People with Intellectual Disabilities (PCPID). 2017. *America's Direct Support Workforce Crisis: Effects on People with Intellectual Disabilities, Families, Communities and the U.S. Economy.* Washington, D.C.: PCPID. https://acl.gov/sites/default/files/programs/2018-02/2017%20PCPID%20Full%20Report_0.PDF.

35. Edwards-Orr, Merle, Molly Morris, Casey DeLuca, Kathleen Ujvari, and Mark Sciegaj. 2020. *National Inventory of Self-Directed Long-Term Services and Supports Programs.* Washington, D.C.: AARP Public Policy Institute. https://www.longtermscorecard.org/~/media/Microsite/Files/SelfDirection%20Promising%20Practices%20and%20Emerging%20Trends_Sept%202020.pdf.

36. U.S. Bureau of Labor Statistics (BLS), Quarterly Census of Employment and Wages (QCEW). "QCEW News Release Notes." Last updated February 3, 2023. https://www.bls.gov/cew/about-data/news-release-notes.htm.

37. Campbell et al., 2021.

38. This reflects the most recent data for the home care industry. Updated Economic Census data are expected to be released in 2025. U.S. Census Bureau. 2021. *Economic Census of the United States, Health Care and Social Assistance: Sales, Value of Shipments, or Revenue by Type of Social Assistance for the U.S.: 2017.* https://data.census.gov/cedsci/table?q=ECNSOCIAL2017.EC1762SOCIAL&n=62412&tid=ECNSOCIAL2017.EC1762SOCIAL; U.S. Census Bureau. 2021. *Economic Census of the United States, Health Care and Social Assistance: Sales, Value of Shipments, or Revenue by Type of Payer for the U.S. and States: 2017.*

https://data.census.gov/cedsci/table?q=EC1762TYPEPAYER&n=6216%3A6231%3A6232%3A6233&tid=ECNTYPEPAYER2017.EC1762TYPEPAYER; analysis by PHI (June 2022).

39. U.S. Bureau of Labor Statistics (BLS). "Concepts and Definitions." Last updated January 11, 2023. https://www.bls.gov/cps/definitions.htm#fullpart-time.

40. Under the Fair Labor Standards Act (FLSA), workers must be paid overtime (at least one-and-a-half times their hourly wage) for any hours they work over 40 in a workweek for a single employer. U.S. Department of Labor (DOL) Wage and Hour Division (WHD). "Overtime Pay." Accessed July 8, 2020. https://www.dol.gov/agencies/whd/overtime; Ruggles et al., 2023.

41. Ruggles et al., 2023.

42. Federal poverty thresholds, which are updated each year, can be accessed here: https://www.census.gov/data/tables/time-series/demo/income-poverty/historical-poverty-thresholds.html.

43. BLS EPP, 2022a; 2022b.

44. Mozes, Alan. 2023. "Demand for in-home healthcare outpaces availability of workers." *HealthDay*, April 27. https://www.upi.com/Health_News/2023/04/27/home-healthcare-workers-shortage/5491682528257/.; Rowland, Christopher. 2022. "Seniors are stuck home alone as health aides flee for higher-paying jobs." *The Washington Post*, September 25. https://www.washingtonpost.com/business/2022/09/25/seniors-home-health-care/.

45. Harris-Kojetin et al., 2022; National Residential Information Systems Project (RISP). "Chart Gallery, Long-Term Supports and Services (LTSS) Recipients by Setting Type and Year, 2019." Accessed June 27, 2023. https://risp.umn.edu/viz. analysis by PHI (June 2023).

46. American Healthcare Association/National Center for Assisted Living. "REPORT: Nursing Homes Down 221,000 Jobs Since Start of Pandemic." Last updated November 10, 2021. https://www.ahcancal.org/News-and-Communications/Press-Releases/Pages/REPORT-Nursing-Homes-Down-221,000-Jobs-Since-Start-Of-Pandemic.aspx; BLS OEWS, 2023a; 2023b.

47. Carratala, 2020; Nowicki, 2020; Nunn et al., 2019; Carratala and Maxwell, 2020.

48. McCall and Scales, 2022.

49. The U.S. Census Bureau asks American Community Survey respondents about their current sex identity, and allows for "male" or "female" response. While sex and gender are different and neither sex nor gender are binary, this data source currently only asks about current sex with a binary response option. In this report we use "women" to refer to those who responded to the sex question with "female" and "men" to refer to those who responded to the sex question with "male."

50. Ruggles et al., 2023.

51. Ruggles et al., 2023.

52. Ruggles et al., 2023.

53. Flood et al., 2023b.

54. BLS OEWS, 2023a; 2023b.

55. Due to less precise coding in this data source, these data include residential mental health and substance abuse facilities. U.S. Census Bureau. 2022. *Service Annual Survey, Estimated Sources of Revenue for Employer Firms: 2013 through 2021*. https://www.census.gov/data/tables/2021/econ/services/sas-naics.html; analysis by PHI (July 2023).

56. U.S. Census Bureau SAS, 2022.

57. BLS CPS, 2023.

58. Flood, Sarah M., Miriam King, Renae Rodgers, Steven Ruggles, J. Robert Warren, and Michael Westberry. 2023. *IPUMS USA: Version 9.0. Current Population Survey, 2022.* https://doi.org/10.18128/D030.V10.0; analysis by PHI (June 2023).

59. Under the Fair Labor Standards Act (FLSA), workers must be paid overtime (at least one-and-a-half times their hourly wage) for any hours they work over 40 in a workweek for a single employer. DOL WHD, 2020; Ruggles et al., 2023.

60. Ruggles et al., 2023.

61. Federal poverty thresholds, which are updated each year, can be accessed here: https://www.census.gov/data/tables/time-series/demo/income-poverty/historical-poverty-thresholds.html.

62. BLS EPP 2022a; 2022b.

63. KFF. 2022. "Total Number of Residents in Certified Nursing Facilities." *KFF State Health Facts*. https://www.kff.org/other/state-indicator/number-of-nursing-facility-residents/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.

64. White, Elizabeth M., Terrie Fox Wetle, Ann Reddy, and Rosa R. Baier. 2021. "Front-line Nursing Home Staff Experiences During the COVID-19 Pandemic." *Journal of the American Medical Directors Association*, 22(1), 199-203. https://pubmed.ncbi.nlm.nih.gov/33321076/

65. Ghandi, Ashvin, Huizi Yu, and David Grabowski. 2021. "High Nursing Staff Turnover in Nursing Homes Offers Important Quality Information." *HealthAffairs* 40(3): 384–391. doi: 10.1377/hlthaff.2020.00957.

66. Carratala, 2020; Nowicki, 2020; Nunn, Parsons, and Shambaugh, 2019; Carratala and Maxwell, 2020.

67. McCall and Scales, 2022.

68. The U.S. Census Bureau asks American Community Survey respondents about their current sex identity, and allows for "male" or "female" response. While sex and gender are different and neither sex nor gender are binary, this data source currently only asks about current sex with a binary response option. In this report we use "women" to refer to those who responded to the sex question with "female" and "men" to refer to those who responded to the sex question with "male."

69. Ruggles et al., 2023.

70. Ruggles et al., 2023.

71. Flood et al., 2023b.

72. CMS, 2023.

73. CMS, 2023.

74. CMS, 2023.

75. U.S. Census Bureau SAS, 2022.

76. BLS, 2023.

77. Flood et al., 2023a.

78. Under the Fair Labor Standards Act (FLSA), workers must be paid overtime (at least one-and-a-half times their hourly wage) for any hours they work over 40 in a workweek for a single employer. DOL WHD, 2020; Ruggles et al., 2023.

79. Ruggles et al., 2023.

80. Federal poverty thresholds, which are updated each year, can be accessed here: https://www.census.gov/data/tables/time-series/demo/income-poverty/historical-poverty-thresholds.html.

81. U.S. Bureau of Labor Statistics (BLS), Injuries, Illnesses, and Fatalities. 2021. *Occupational Injuries and Illnesses and Fatal Injuries Profiles*. https://www.bls.gov/iif/; analysis by PHI (June 2022).

82. Nursing home industry injury and illness rates are only exceeded by those in veterinary services, spectator sports, bottled water manufacturing, ambulance services, and skiing facilities. Bureau of Labor Statistics, U.S. Department of Labor. 2023. "Incidence rates of nonfatal occupational injuries and illnesses by industry and case type, 2021." *Survey of Occupational Injuries and Illnesses*. https://www.bls.gov/web/osh/table-1-industry-rates-national.htm; analysis by PHI (July 2023).

83. The Centers for Medicare & Medicaid Services (CMS) began gathering data on COVID-19 in nursing homes in May 2020. Some nursing homes retroactively reported to January 2020 while others did not. Staff figures include all nursing home staff, including but not limited to nursing assistants. Centers for Medicare & Medicaid Services (CMS). "COVID-19 Nursing Home Data." Last updated June 2023. https://data.cms.gov/covid-19/covid-19-nursing-home-data. Analysis by PHI (June 2023).

84. National Academies of Science, Engineering, and Medicine (NASEM). 2022. *The National Imperative to Improve Nursing Home Quality: Honoring Our Commitment to Residents, Families, and Staff*. Washington, DC: NASEM. https://www.nationalacademies.org/our-work/the-quality-of-care-in-nursing-homes.

85. BLS EPP, 2022a.

86. BLS EPP, 2022b.

87. Porter, Kristie A., Denise A. Tyler, Angela Gasdaska, Micah Segelman, Galina Khatutsky, Marie Squillace, Judy Dey, and Iara Oliveira. 2022. *COVID-19 Pandemic Increased Nursing Homes' Reliance on Contract Staff to Address Staffing Shortages in 2020*. Washington, DC: Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. https://aspe.hhs.gov/sites/default/files/documents/f7c0751d7b3ae7337a3b5d5e3dcc2ae7/nh-reliance-contract-staff-brief.pdf

88. Medicaid and CHIP Payment and Access Commission (MACPAC). 2022. "Compendium: State Policies Related to Nursing Facility Staffing." Washington DC: MACPAC. https://www.macpac.gov/publication/state-policies-related-to-nursing-facility-staffing/.

89. Jaffe, Susan. 2021. "3 states limit nursing home profits in bid to improve care." *Kaiser Health News*, October 25. https://khn.org/news/article/3-states-limit-nursing-home-profits-in-bid-to-improve-care/.

90. The White House. 2022. "Fact Sheet: Protecting Seniors by Improving Safety and Quality of Care in the Nation's Nursing Homes." *Statements and Releases*, February 22. https://www.whitehouse.gov/briefing-room/statements-releases/2022/02/28/fact-sheet-protecting-seniors-and-people-with-disabilities-by-improving-safety-and-quality-of-care-in-the-nations-nursing-homes/.

91. BLS QCEW, 2021.

92. Campbell et al., 2021.

93. PCPID, 2017.

ABOUT PHI

PHI works to transform eldercare and disability services. We foster dignity, respect, and independence for all who receive care, and all who provide it. As the nation's leading authority on the direct care workforce, PHI promotes quality direct care jobs as the foundation for quality care.

Drawing on more than 30 years of experience working side-by-side with direct care workers and their clients in cities, suburbs, and small towns across America, PHI offers all the tools necessary to create quality jobs and provide quality care. PHI's trainers, researchers, and policy experts work together to:

- Learn what works and what doesn't in meeting the needs of direct care workers and their clients, in a variety of long-term care settings;
- Implement best practices through hands-on coaching, training, and consulting, to help long-term care providers deliver high-quality care;
- Support policymakers and advocates in crafting evidence-based policies to advance quality care.

For more information, visit PHI at **PHInational.org.**

PHI
QUALITY CARE
THROUGH
QUALITY JOBS

EXCLUSIVE DISCOUNTS

Unlock exclusive benefits with your PHA membership! Enjoy discounts on consulting, insurance, technology solutions, accreditation, workforce development, and much more. PHA partners with top providers to secure these perks, ensuring your agency thrives. Join us and leverage these advantages to boost your business and support your team.

Category	Business Partner	Services	PHA Member Exclusive	Contact Information
Insurance	Pennsylvania Home Care and Human Services Workers Compensation Trust/AVI Risk Services	A group trust for Workers' Compensation self-insurance developed specifically for home care and community-based organizations	The Workers' Compensation Trust is exclusive to PHA members. The Trust boasts Workers Compensation savings of up to 10% compared to fully insured plans.	**brochure** **website**
Insurance	My Benefit Advisor	Customized health insurance and business solutions	Offers members an extensive line of employee benefits, including individual and group medical insurance, dental and vision coverage, voluntary benefits and more!	Rob Higginbotham (724) 698-1363 **website**
Insurance **TB Testing**	Vitable	Vitable is an affordable, ACA-Compliant Health Benefit TB Testing program made specifically for home care organizations frustrated with expensive and complex health plans	Exclusive PHA pricing on TB QuantiFERON Tests from $55 – $80 at LabCorp and Quest locations. Additional $5 discount per test for Vitable health benefits customers.	Brian Cottone (267) 255-9140 brian@vitablehealth.com **website**
Consulting	MB Healthcare Consultants LLC	Home health and home care consulting services specializing in obtaining licensure, accreditation, and certification, as well as quality, compliance	10% off the hourly consulting rate, or package rate.	**website**

		and organizational improvement.		
Consulting	AZ Billing	Outsource your medical and non-medical billing, claims follow-up, accounts receivable, and KPI analytics to ensure that your cash flow is expertly managed.	Free RCM Health Audit and $500 off your first invoice.	**website**
Consulting	21st Century Health Care Consultants	Unlock the full potential of your home care business with comprehensive start up, licensing, accreditation, performance enhancement, and training solutions.	5% off all services exclusively for PHA membership.	**website**
Accreditation	Accreditation Commission for Health Care (ACHC)	Nationally recognized accreditation organization with CMS-deeming authority for home health, hospice and DME	PHA members receive a $500 discount on ACHC's accreditation fee, and a $50 discount on workshops or the purchase of ACHC's Accreditation Guide to Success workbooks.	**brochure** **website**
Accreditation	Community Health Accreditation Partner (CHAP)	Accrediting organization for home and community-based health care organizations with "deeming" authority granted by CMS.	50% discount on the application fee for initial or renewal certification or for initial palliative certification.	**website**
Training	My Learning Center	My Learning Center is a free learning management system developed by PHA for members. More than 80 courses are available in multiple languages, meeting many state regulatory requirements.	PHA members get exclusive access to employer reporting portal to track staff progress and download employee certificates.	**website**
Training	Decision Health	Elevate your coding skills with the Complete Home Health ICD-10-CM Diagnosis Coding Manual, the OASIS-C2 Forum Companion and study guides for the	Discounts on manuals, study guides and companion aides for certifications. Use discount code: PHA to access discounts.	**website**

		HCS-D, HCS-H, HSC-C and HSC-O certifications.		
General	T-Mobile	Phones, devices, and competitive talk/text/data plans to support your growing agency's needs.	9 smartphone devices for $25 per month per SIM (plus taxes and fees).	**brochure**
General	ColdTree	A full service advertising agency offering automotive advertising, direct mail marketing, radio & TV production, website development, and promotional materials.	Preferred pricing for PHA members on thousands of promotional products. % of proceeds from sales benefits the Pennsylvania Foundation for Home Care and Hospice.	**website**
General	Smart Homecare Technologies	Amazing CARA, is a transformative mobile native, voice interactive platform created to effortlessly and accurately, in real time, complete a home 'care givers daily documentation, boosting caregiver productivity and enhancing patient engagement.	All PHA members that might be interested in a Free 90 days trial of the AmazingCARA application would need to sign up prior to the end of the annual PHA conference in 2025.	partho.c@amazingcara.com
General	Alert GPS	AlertGPS provides safety technology for Home Healthcare workers, addressing risks in unpredictable settings. The ActiveHalo® device and app enable real-time monitoring and emergency response.	PHA members receive an exclusive 10% off any order, and 20% off orders of 100+ devices/apps. Use code PHA at checkout.	**website**

EXPERIENCE THE ACHC DIFFERENCE

OUR COMMITMENT TO QUALITY **EMPOWERS PROVIDERS** TO **ENHANCE PATIENT CARE**

ACHC has become synonymous with providing value, integrity, and the industry's best customer service. Our mission is simple: We aim to deliver the best possible accreditation experience. ACHC and Pennsylvania Homecare Association (PHA) are partnering to meet the specific needs of Home Health, Hospice, and Private Duty providers that seek accreditation services.

Our organizations are committed to guiding healthcare providers through the ACHC Accreditation process by offering PHA members a discount on educational resources and accreditation.

$500 OFF
ACCREDITATION

Discount will be applied upon final payment. Only one discount is applicable per company.

Get started by visiting **cc.achc.org**

$50 OFF
WORKSHOP

Attend an ACHC workshop and receive $50 off.

More info at **achcu.com**

$50 OFF
WORKBOOK

Purchase the *ACHC Accreditation Guide to Success* digital workbook and receive $50 off.

More info at **achcu.com**

PHA DISCOUNT CODE

PHA2217

$500 OFF ACCREDITATION
$50 OFF WORKSHOP OR WORKBOOK

$500 discount will be applied upon final payment. Only one accreditation discount is applicable per company. Applies to new and renewal accounts. $50 discount may be used more than once by any PHA member attending an ACHC Workshop or purchasing the *ACHC Accreditation Guide to Success* digital workbook, regardless of accreditation status.
USE THIS DISCOUNT CODE DURING CHECKOUT.

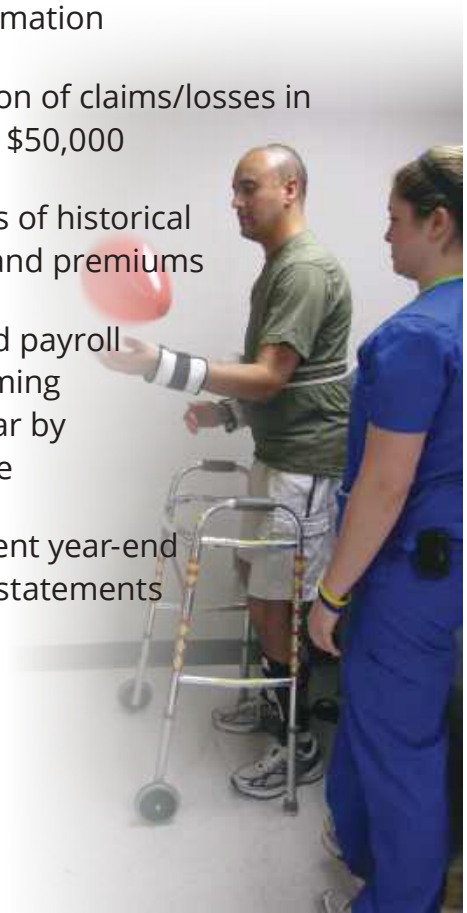
ACCREDITATION COMMISSION *for* HEALTH CARE

ISO 9001:2015 CERTIFIED. CMS APPROVED.

pahomecare.org | achc.org

Initial Application Requirements

- ❑ Acord application/underwriting submission including SIC Code and experience modification
- ❑ Five years of currently valued loss information
- ❑ Description of claims/losses in excess of $50,000
- ❑ Five years of historical payrolls and premiums
- ❑ Estimated payroll for upcoming policy year by class code
- ❑ Most recent year-end financial statements



AVI Risk Services
985 Old Eagle School Road
Suite 504
Wayne, Pennsylvania 19087
800.327.8181 • 610.687.3869

" Insurance and Risk Management Services that work for you."

AVI Risk Services

Your Workers' Compensation Claims & Risk Management Solution

PENNSYLVANIA
HOME CARE AND HUMAN SERVICES
WORKERS' COMPENSATION TRUST

Pennsylvania Home Care & Human Services Workers' Compensation Trust

About Us

AVI Risk Services is a full service individual and group Program Administrator for Self-Insured Workers' Compensation as well as offering Third-Party Administrative and Claims Management Services (TPA). Since its inception in 1991, AVI Risk Services has offered Self-Insurance, Large Deductible Programs, consulting, and brokerage services. AVI uniquely combines insurance and risk management strategies in the insurance marketplace to deliver innovative, cost-effective solutions in Workers' Compensation, Risk Management, and Safety & Loss Control. We currently administer and manage Self-Insurance Group Programs consisting of auto dealers, trucking, social services, food processors, and entertainment clients.

Pennsylvania Home Care & Human Services Workers' Compensation Trust

Pennsylvania Home Care & Human Services Workers' Compensation Trust (PAHC) was formed in 2008. The group includes employers in the home care and human services industry.

A Board of Trustees selected from the PAHC's membership provides oversight of the program. PAHC is approved and regulated by the Pennsylvania Department of Labor & Industry Bureau of Workers' Compensation.

PAHC is selective in their membership and only employers committed to safety and loss control are considered. Prospective members undergo a thorough underwriting process before an offer of membership is extended.

THE SUCCESS AND GROWTH OF PAHC IS THE RESULT OF SAFETY CONSCIOUS EMPLOYERS WORKING HAND IN HAND WITH AN EXPERIENCED PROGRAM ADMINISTRATOR AND AGGRESSIVE CLAIMS MANAGEMENT.

Group Program Benefits

AN INNOVATIVE APPROACH TO WORKERS' COMPENSATION INSURANCE FOR THE HOME CARE AND HUMAN SERVICES INDUSTRY

- Lower rates than traditional insurance or the State Fund (as much as 20%)
- Long term rate stability with potential return of contribution
- Self-Insured program owned by the members and managed by the Board of Trustees
- Approved and regulated by the PA Dept. of Labor & Industry Bureau of Workers' Compensation
- Experienced and dedicated claims and safety staff with expertise in the home care industry
- State certified, industry specific safety and loss control programs
- Excess insurance coverage provided by an "A" rated national insurance carrier
- Synergy of being in a group of similar employers that can spark ideas and facilitate solutions to industry related problems
- Endorsed by the Pennsylvania Homecare Association

TUBERCULOSIS SCREENING

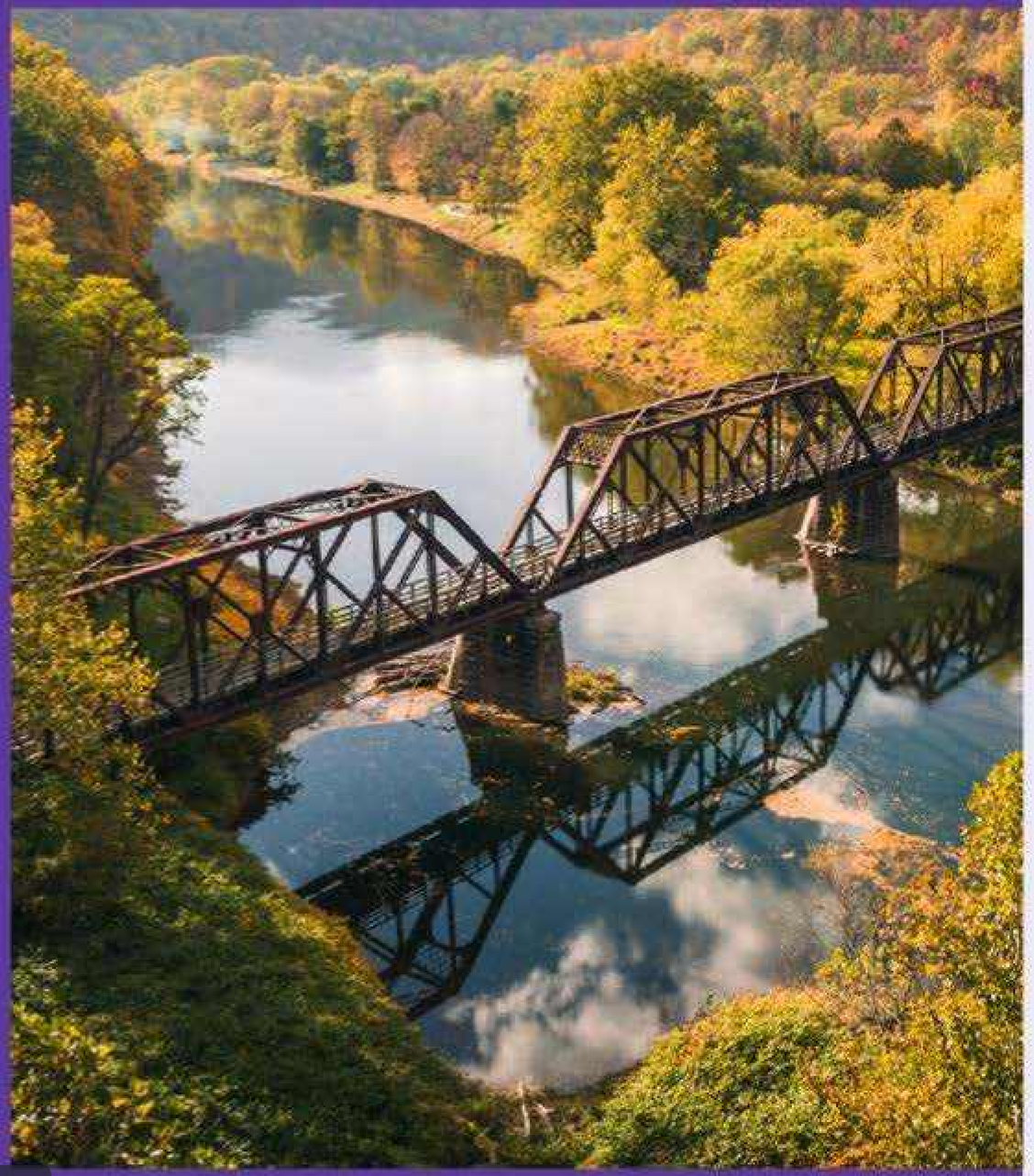
September 18, 2024

PHA

PENNSYLVANIA HOMECARE ASSOCIATION

Agenda

- **Initial Baseline**
  1. Risk Assessment
  2. Symptom Evaluation
  3. TB Education
  4. TB Testing
     - TB Skin Test
     - TB Blood Test
     - Test Results
     - Chest X Rays
- **Annual Requirements**



TUBERCULOSIS

Tuberculosis (TB) is A contagious infection caused by bacteria that mainly affects the lungs but can also affect any other organ including bone, brain and spine. TB is a disease that is spread through the air from one person to another.

On May 17, 2019 the Centers for Disease Control and Prevention (CDC) issued updated recommendations for TB testing of health care personnel.

These recommendations are summarized in this PowerPoint.

TB Initial Baseline

The following must be completed with results received PRIOR to direct patient contact:

1. Individual risk assessment

2. Individual symptom evaluation

3. Tuberculosis Education

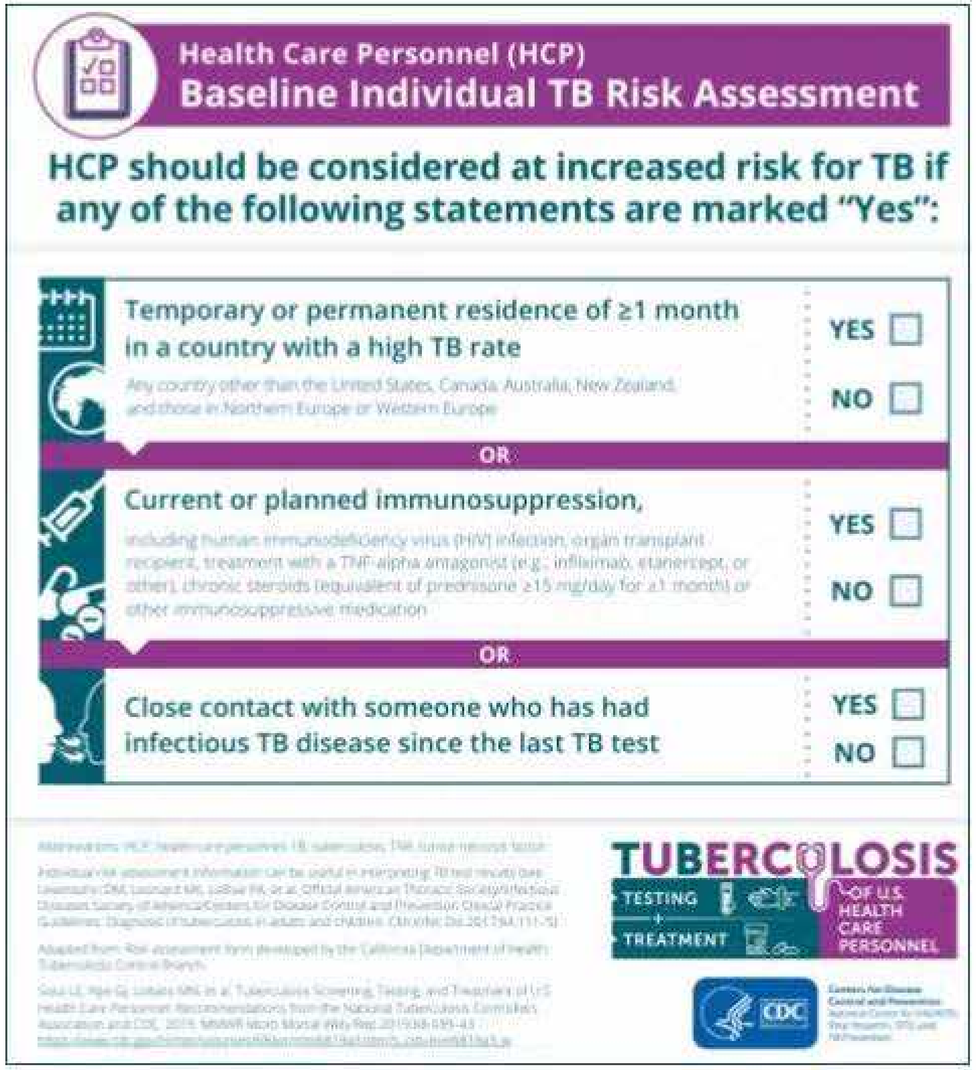
4. TB Testing:
   - TB Skin Test
     (abbreviated TST, also known as PPD for purified protein derivative)

     OR

   - TB Blood Test
     *(also known as interferon-gamma release assays or IGRAs, or BAMT, or **QuantiFERON**)*

PHA PENNSYLVANIA HOMECARE ASSOCIATION

Individual Risk Assessment



Health Care Personnel (HCP)

Baseline Individual TB Risk Assessment

HCP should be considered at increased risk for TB if any of the following statements are marked "Yes":

Temporary or permanent residence of ≥1 month in a country with a high TB rate

Any country other than the United States, Canada, Australia, New Zealand, and those in Northern Europe or Western Europe

YES ☐ NO ☐

OR

Current or planned immunosuppression,

including human immunodeficiency virus (HIV) infection, organ transplant recipient, treatment with a TNF-alpha antagonist (e.g., infliximab, etanercept, or other), chronic steroids (equivalent of prednisone ≥15 mg/day for ≥1 month) or other immunosuppressive medication

YES ☐ NO ☐

OR

Close contact with someone who has had infectious TB disease since the last TB test

YES ☐ NO ☐

TUBERCULOSIS TESTING + TREATMENT OF U.S. HEALTH CARE PERSONNEL

CDC

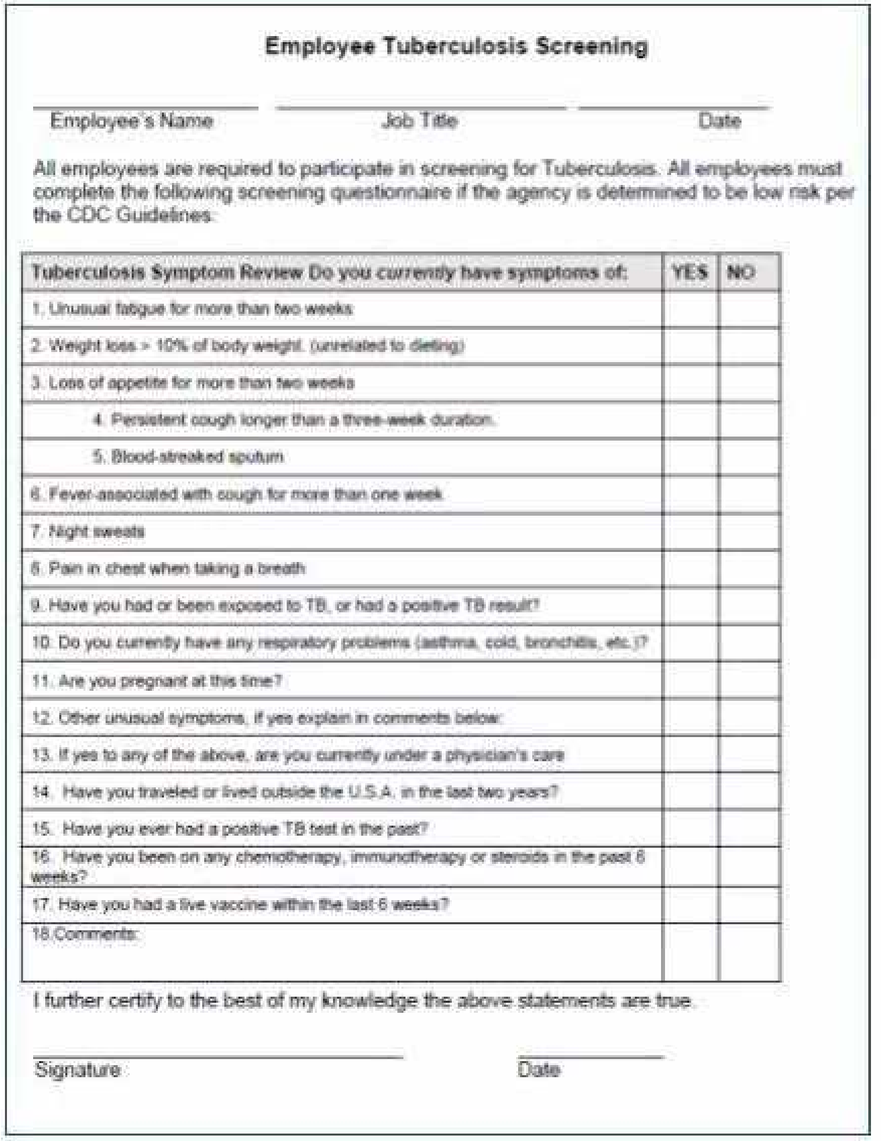
- Link to Printable Version:

[Health Care Personnel (HCP) Baseline Individual TB Risk Assessment (cdc.gov)]

PHA PENNSYLVANIA HOMECARE ASSOCIATION

Try Pitch

Individual Symptom Evaluation



Employee Tuberculosis Screening

Employee's Name _____ Job Title _____ Date _____

All employees are required to participate in screening for Tuberculosis. All employees must complete the following screening questionnaire if the agency is determined to be low risk per the CDC Guidelines.

Tuberculosis Symptom Review Do you *currently* have symptoms of:	YES	NO
1. Unusual fatigue for more than two weeks		
2. Weight loss > 10% of body weight. (unrelated to dieting)		
3. Loss of appetite for more than two weeks		
4. Persistent cough longer than a three-week duration.		
5. Blood-streaked sputum		
6. Fever-associated with cough for more than one week		
7. Night sweats		
8. Pain in chest when taking a breath		
9. Have you had or been exposed to TB, or had a positive TB result?		
10. Do you currently have any respiratory problems (asthma, cold, bronchitis, etc.)?		
11. Are you pregnant at this time?		
12. Other unusual symptoms, if yes explain in comments below:		
13. If yes to any of the above, are you currently under a physician's care		
14. Have you traveled or lived outside the U.S.A. in the last two years?		
15. Have you ever had a positive TB test in the past?		
16. Have you been on any chemotherapy, immunotherapy or steroids in the past 6 weeks?		
17. Have you had a live vaccine within the last 6 weeks?		
18.Comments:		

I further certify to the best of my knowledge the above statements are true.

Signature _____ Date _____

- Link to Printable PHA Evaluation

- Link to CDC symptom screening information:

Signs and Symptoms of Tuberculosis | Tuberculosis (TB) | CDC

Try Pitch

PHA PENNSYLVANIA HOMECARE ASSOCIATION

Tuberculosis Education

Keep Documentation that an applicant/employee completed training in Tuberculosis.

Optional educational material can be found at:

- Department of Health TB Training Video: https://www.youtube.com/watch?v=wA_fObLY6GE
- CDC TB Coursework for Health Care Workers: TB 101 - Main Menu | TB | CDC
- Department of Health TB resource library: TB Providers | Department of Health | Commonwealth of Pennsylvania

PHA PENNSYLVANIA HOMECARE ASSOCIATION

TB Skin Test (TST, PPD)

No Prior Testing

1. A 2 step TB Skin Test (TST), or PPD, may be administered by a Registered Nurse, License Practical Nurse, Certified Clinical Medical Assistant, Physicians Assistant, Physician, or CRNP with an active professional license. For purpose of this policy these will be known as "Certified Practitioner"
2. **An applicant or employee may not begin to work with patients until both steps of the PPD have been read by the Certified Practitioner and deemed negative.**
3. The TB skin test, or PPD, must be administered in the applicant or employee's forearm. For a 2-step screening, both the left arm and right arm should be utilized, one for each step of the screening.
4. All PPD steps must be read by a Certified Practitioner 48-72 hours following the date the PPD was administered. If this deadline is missed, the PPD step may not be considered to meet this protocol.
5. The second PPD step must be performed within 1 – 3 weeks of the date the 1st step of the PPD was read. If this deadline is missed, you must do an additional 2 steps within approved deadlines to meet this requirement.

PHA PENNSYLVANIA HOMECARE ASSOCIATION

TB Skin Test (TST, PPD)

With Prior Testing

If an applicant had a 2 step TST/PPD within the 12 months prior to hire, no further testing is required.

If an applicant had a 1 step TST/PPD within the 12 months prior to hire, a one step TST/PPD should be administered according to the policy on the previous slide.

PHA PENNSYLVANIA HOMECARE ASSOCIATION

TB Blood Test

No Prior Testing

- If an applicant has no previous TB testing, at the time of hire, the applicant may have a blood test performed to evaluate for Tuberculosis.
- QuantiFERON (QFT) is an interferon-γ release assay (IGRA) that aids in the evaluation of tuberculosis infections and is recommended by the CDC as an alternative to the tuberculin skin test (TST). This alternative offers more accurate and quicker results.
- For the test, a health care worker/Certified Practitioner will take some blood (less than a teaspoon) from your vein. The blood is then sent to a lab for testing.
- **An applicant or employee may not begin to work with patients until a negative result is received and on file.**

PHA PENNSYLVANIA HOMECARE ASSOCIATION

TB Blood Test

With Prior Testing

If an applicant had a documented negative blood test within the 12 months prior to hire, no further testing is required.

PHA PENNSYLVANIA HOMECARE ASSOCIATION

Test Results

A negative TB skin or blood test means the person's body did not react to the test, and that latent TB infection or TB disease is not likely.

A positive TB skin test or TB blood test only tells that a person has been infected with TB bacteria. It does not tell whether the person has latent TB infection (LTBI) or has progressed to TB disease. In cases where a person has a positive TB skin or blood test, additional testing will be required, such as a chest x-ray.

If a TB Skin Test/TB Blood Test AND chest x-ray are positive, the agency must contact the PA Department of Health for required exposure follow-up.

PHA PENNSYLVANIA HOMECARE ASSOCIATION

Chest X-Ray

- Evidence of a previous negative chest x-ray may be accepted if it was performed as a result of a history of positive/false positive TB skin test and/or TB blood test OR if a TB Skin Test or TB Blood Test was inconclusive.

- There are no time restrictions on chest x-rays, meaning you do not need to repeat chest x-rays there is potential exposure/symptoms at which time you should consulta physician.

- The chest x ray must indicate “no evidence of TB”.

- In this scenario, the employee may begin to work immediately with patients. However, the risk assessment and symptom evaluation must be documented and on file in addition to the x-ray results PRIOR to patient contact.

PHA PENNSYLVANIA HOMECARE ASSOCIATION

Annual (every 12 months) Individual Requirements

The Following Are Required Annually/Every 12 months:

1. TB Education
2. Individual Risk Assessment
3. Symptom Evaluation

- TB Skin Test/TB Blood Test is not required **unless** there is a known exposure to TB or if there is ongoing transmission within the health care facility

PHA PENNSYLVANIA HOMECARE ASSOCIATION

Questions?

PHA
PENNSYLVANIA
HOMECARE ASSOCIATION


PHA
PENNSYLVANIA
HOMECARE ASSOCIATION
Try Pitch

Agenda

- Problem We're Solving
- TB Testing
- Vitable Solution Tour
- Special Partner Pricing

Brian Cottone Jr.

VP of Sales

Vitable

Vitable was founded specifically for *Home Cares* frustrated with expensive and complex TB Testing and Health Benefits

Problem

Current State

- Current process typically involves 2-step TB Testing
- Caregivers are responsible for getting referral, paying for test, and bringing results back to you
- This causes delays with onboarding new caregivers which leads to bottleneck in filling cases
- Billable hours are slowed, affecting revenue growth

Future State

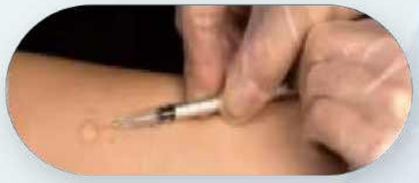
- 1-step TB Testing implemented
- Caregivers are provided referral and instructions on where to get tested with no cost to them
- Results are automatically delivered electronically directly to you
- Onboarding delays are cut in half, leading to more billable hours and increased cases filled

TB Testing

Accepted methods

QuantiFERON-GOLD

- Only 1 visit needed
- Electronic results delivered to you
- 3-5 day turnaround
- Not affected by BCG vaccine (false positive)
- Does not cause boosting



2-Step PPD

- 2 visits required for each step (4 total)
- High no-show rate
- False positives with BCG vaccine
- Manual placement, reading, and data entry
- Causes boosting that affects future testing

X-Ray

- 1 visit with limited options
- Early stage TB hard to detect
- Radiation exposure
- Outdated method

Simplified TB Testing

Accessible Locations

Access to over **1,000** Quest and LabCorp locations

Quest Diagnostics labcorp

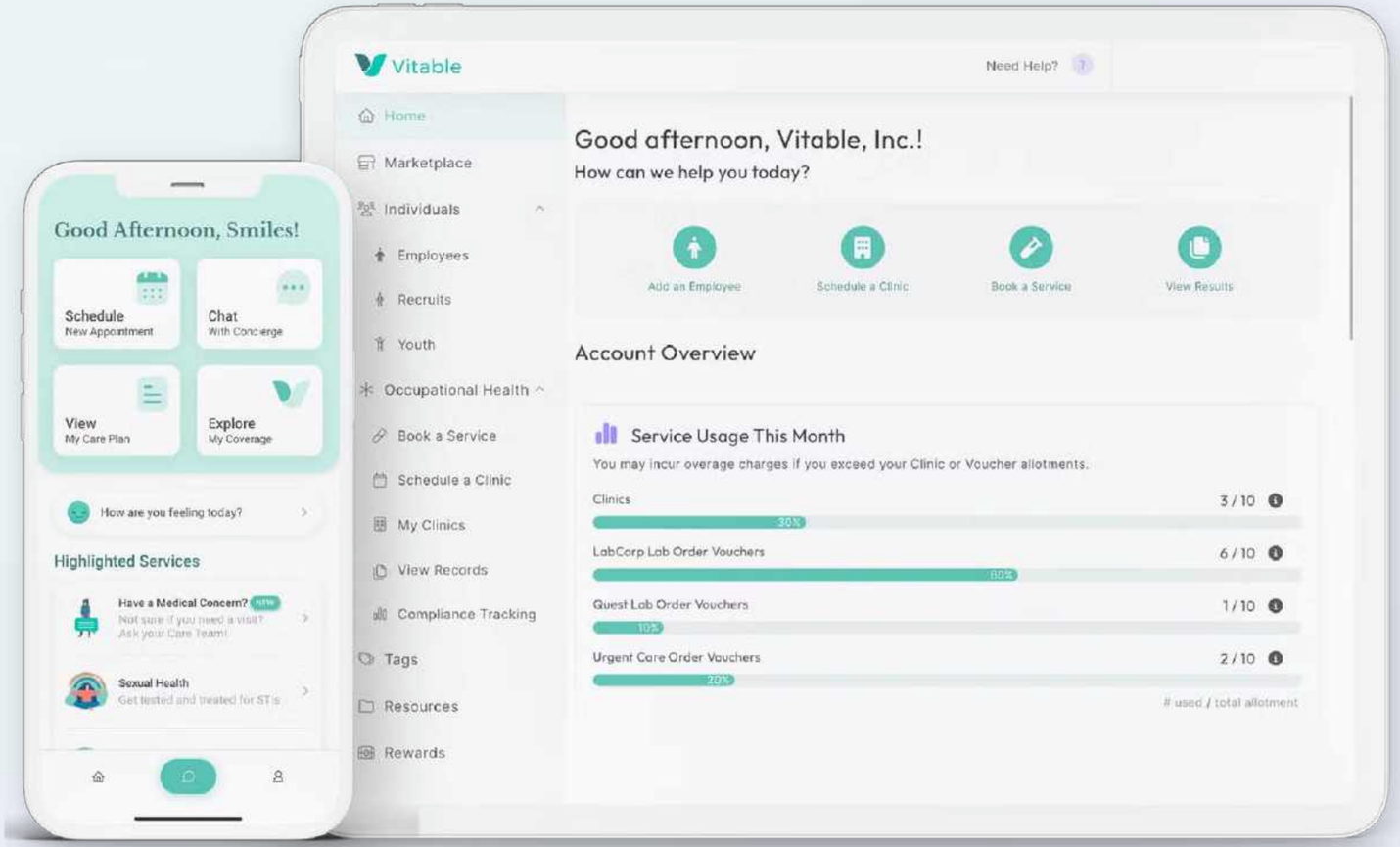
Get Results Faster

Automated lab order creation with a **3-5** business day results turnaround

Increase Billable Hours

1-step QuantiFERON-Gold TB Testing improves speed-to-hire and increase revenue

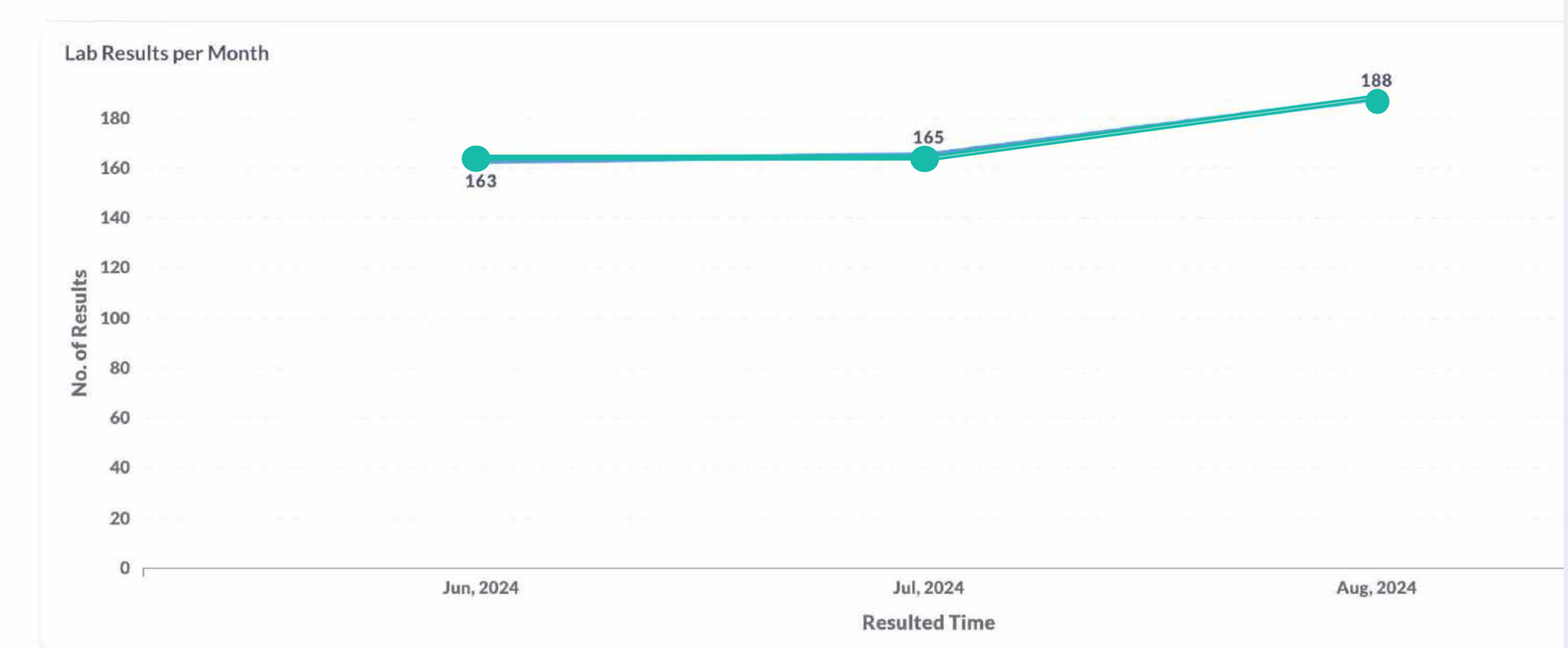
See it in Action



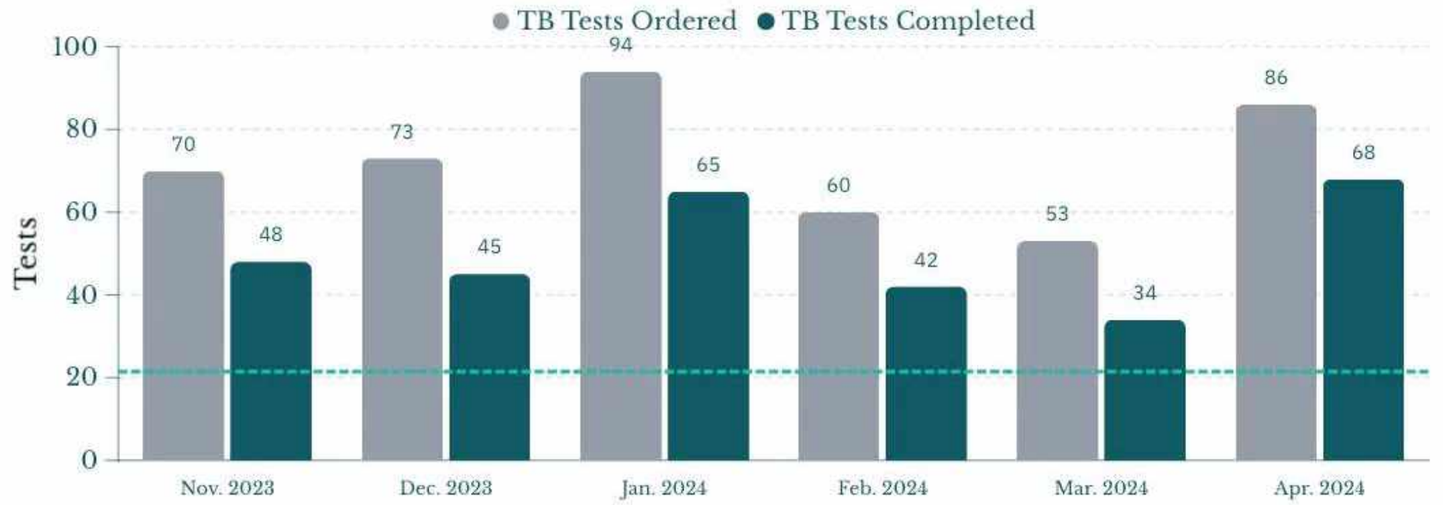
Service Usage Reporting

Conversion Rate Reporting

Result Trends



Utilization Reporting



Total Tests Ordered: 475

Tests Ordered Per Month Avg: 79.2

Tests Completed Per Quarter Avg: 161

Total Tests Completed: 322

Tests Completed Per Month Avg: 53.7

Number of Tests on Plan

Cost Comparison

Vitable

QuantiFERON-GOLD TB

Quest Diagnostics labcorp

Cost Per Test

$55 - $80

MedExpress

QuantiFERON-GOLD TB

Cost Per Test

$140

Ulta Lab Tests

QuantiFERON-GOLD TB

Cost Per Test

$145

Concentra

QuantiFERON-GOLD TB

Cost Per Test

$225

Exclusive Pricing for PHA PENNSYLVANIA HOMECARE ASSOCIATION

Vitable

Quest Diagnostics

Regular Price per test

~~$99~~

labcorp

Regular Price per test

~~$85~~

PHA Member Pricing

Quarterly TB Test Volume	Price Per Test	
	Quest Diagnostics	labcorp
20	$80	$65
21-49	$75	$60
50+	$70	$55

Platform Fee:	~~$999~~/QTR	*Waived*
Startup Cost:	~~$1,000~~	*Waived*

Includes

- Online Portal for ordering + results
- Unlimited admin users
- Dedicated customer success team
- Member support 7 days/week
- Personalized employee communication

Terms

- Quarterly billing
  - Annually billing: additional **5%** discount
- 12 month agreement
- $125 overage fee
  - Additional TB bundles can be purchased (min. 20)

In 2023, more than *1 of 4 Home Cares* were audited by the IRS for *non-compliance* with the ACA

Source: The Challenge of ACA Compliance, Trusaic

Home Cares are among *the most likely* to be audited by the IRS for non-compliance due to:

1. High number of hourly employees
2. High turnover rate
3. Low operating margins
4. Data collection errors

ACA Compliant Health Benefits

Our network of local Physicians, Nurse Practitioners, and other healthcare providers come to you virtually or onsite to assess, diagnose, and treat common health needs

ACA Compliance

Vitable Health Benefits keeps you ACA compliant from penalties as high as **$2,970** per employee

No Minimum Enrollment

Flat monthly rate based on Full Time Employees with no minimum number of employees required to enroll

Health Benefits for Caregivers

Simple and affordable, our health benefit plans are used by over 20,000 caregivers across 500+ Home Cares

Bonus *in partnership with* PHA PENNSYLVANIA HOMECARE ASSOCIATION

Meet with Vitable about our health benefit plan and
Get 10 ***Free TB tests*** when you sign up for *TB*

Sign up for ***Vitable Health Benefits*** for your caregivers and

Get additional 20 Free TB tests (30 Total)

+

Extra $5 discount per TB test

Try Pitch

Who we work with

Davetta Care

BOYS & GIRLS CLUBS OF AMERICA

ALL AMERICAN HOME CARE

Angels On Call
Home Care With An Angel's Touch℠

RED LION HOME CARE

Comfort Keepers®

America's Choice in Home Care®
Visiting Angels®
LIVING ASSISTANCE SERVICES

Zephoria Homecare

Paulino
HOME HEALTHCARE

Vitable

Brian Cottone Jr.

VP of Sales

(267) 255-9140

brian@vitablehealth.com

Pitch

Want to make a presentation like this one?

Start with a fully customizable template, create a beautiful deck in minutes, then easily share it with anyone.

Create a presentation (It's free)

Home Care Grant

About

The Pennsylvania Foundation for Home Care and Hospice has established the **Home Care Grant** to support home-based care agencies in providing temporary care to individuals who demonstrate a need for home and community-based services, but are not yet receiving, are waiting to be approved/renewed, or are not eligible for services through other payment programs, such as Medicaid. *Note that a consumer may receive certain OPTIONS benefits and still be eligible for grant funding.*

If selected as a grant recipient, agencies will be granted access to funds of up to $1,250 per client to be used as 50 hours of non-medical home care services at $25/hour *or* 10 medical home health visits at $125/visit.

All fund disbursements are at the sole discretion of the Pennsylvania Foundation for Homecare and Hospice.

Please note, agencies are limited to two (2) referrals per month and should reserve referrals for clients with the highest need level. A client is eligible for funding once per calendar year.

For more information and to download/print application materials visit www.pahomecare.org/foundation

Eligibility

- Individuals who temporarily or permanently reside in the Commonwealth of Pennsylvania
- Individuals who demonstrate a need for home-based care services, which includes home care, home health, and hospice services
- Individuals with monthly income less than $5,000 (single) or $10,000 (dual income, including spouse/partner, excluding any child income)*
- Individuals who are not currently receiving comparable home-based care services through the following programs:
  - Any Pennsylvania Medicaid Waiver Program (including managed care programs)
  - Veterans receiving home health care benefits through the Aide and Attendance Program
  - Any other similar program as determined by the Foundation

**Income limits and other terms and conditions are subject to change, at the sole discretion of The Foundation.*

PHA PENNSYLVANIA HOMECARE ASSOCIATION

How To

Record Your Own "*Mission Moment*"

Before You Record

Take a moment and gather a story. This is meant to be fun, sharing, and personal; relax!
We're all human with unique stories to share.

We're looking for a personal story of someone who touched your life or a real-life event that changed you. Please think of this as a narrative; a story (with real people and places) showcasing the power of helping people and what we do daily in personal care services.

Keep recordings under 1:30 minutes per clip. You can take as many takes as you'd like!

Recording With a Cell Phone

1. Place the phone at eye-level.
    - Make sure the phone is sturdy & stationary, prop it up on a few books or on top of a box that you can place on your desk. (*NO walking and talking!)
2. Please have the camera sideways or horizontally (We cannot use vertical video).
3. Please make sure your video camera settings are correct, please record 4K video.
    - iPhone: go to Settings > Camera > Record Video > (select 4K at 30 fps)
    - Android: While in video mode, swipe down from the top of the screen to open settings, change the resolution to 4K
4. Ideally, select a neutral background behind you.
    - For example, have a blank wall with a plant in the corner behind you.
    - Sit in front of something where YOU stand out in the foreground.
5. Have soft light in front of you, hitting your face.
    - Have a window with daylight in front of you OR position a desk lamp in front of you which will cast soft light onto your face.
    - Do not have bright light or an open window with daylight behind you.
6. ***IMPORTANT!**
    - When you hit record, count to three (ONE, TWO, THREE) and deep breathe before you start talking – then, share your name and your role as a caregiver. Highlight a specific benefit or experience with PHA.
    - Express gratitude and explain why PHA is important to you.
    - When you're finished, pause, and count to three (ONE, TWO THREE) before hitting the stop record button.
    - This will give us enough video for a fade in / out at the beginning and end.

Sending Your Video

Use the **QR Code** to the right to upload your video to our DropBox account
OR **email** your video to yourpartner@pahomecare.org

THANK YOU! You are the heart of our profession. Home is where the healing happens. It's where patients want to be, where they feel most comfortable, most secure, and most connected to their communities. We appreciate YOUR commitment to making this a reality for so many in our community! And we appreciate you sharing your voice.

Home Care Grant

About

The Pennsylvania Foundation for Home Care and Hospice has established the **Home Care Grant** to support home-based care agencies in providing temporary care to individuals who demonstrate a need for home and community-based services, but are not yet receiving, are waiting to be approved/renewed, or are not eligible for services through other payment programs, such as Medicaid. *Note that a consumer may receive certain OPTIONS benefits and still be eligible for grant funding.*

If selected as a grant recipient, agencies will be granted access to funds of up to $1,250 per client to be used as 50 hours of non-medical home care services at $25/hour *or* 10 medical home health visits at $125/visit.

All fund disbursements are at the sole discretion of the Pennsylvania Foundation for Homecare and Hospice.

Please note, agencies are limited to two (2) referrals per month and should reserve referrals for clients with the highest need level. A client is eligible for funding once per calendar year.

For more information and to download/print application materials visit www.pahomecare.org/foundation

Eligibility

- Individuals who temporarily or permanently reside in the Commonwealth of Pennsylvania
- Individuals who demonstrate a need for home-based care services, which includes home care, home health, and hospice services
- Individuals with monthly income less than $5,000 (single) or $10,000 (dual income, including spouse/partner, excluding any child income)*
- Individuals who are not currently receiving comparable home-based care services through the following programs:
  - Any Pennsylvania Medicaid Waiver Program (including managed care programs)
  - Veterans receiving home health care benefits through the Aide and Attendance Program
  - Any other similar program as determined by the Foundation

**Income limits and other terms and conditions are subject to change, at the sole discretion of The Foundation.*

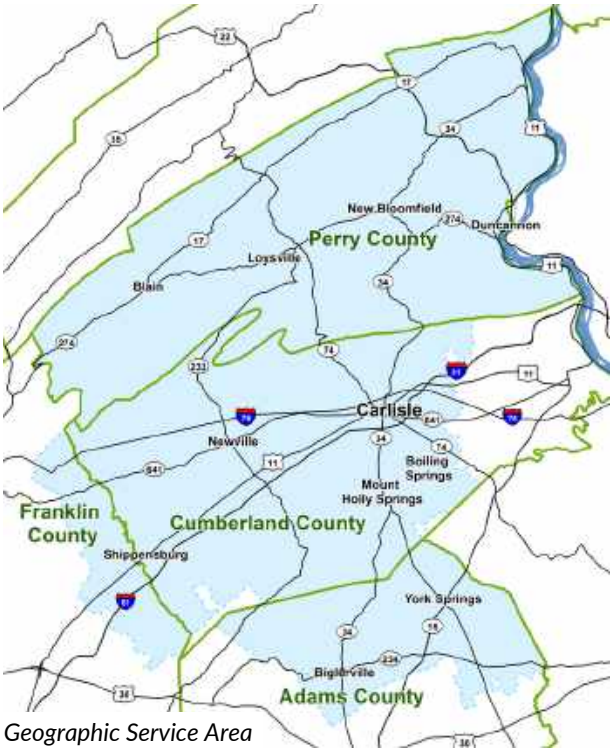
SOUTH CENTRAL PENNSYLVANIA HOME CARE GRANT

The Pennsylvania Foundation for Home Care and Hospice, through funding provided by the Partnership for Better Health, has established the **South Central Pennsylvania Home Care Grant** to support home-based care agencies in providing temporary care to individuals who demonstrate a need for home and community-based services, but are not yet receiving or eligible for services through other payment programs, such as Medicaid. *Note that a consumer may receive certain OPTIONS benefits and still be eligible for grant funding.*

If selected as a grant recipient, agencies are eligible for reimbursement of up to $2,500 per client, for up to 100 hours of non-medical home care services at $25/hour or 20 medical home health visits at $125/visit.

This grant is available to all home-based care providers that provide services to individuals in the eligible zip codes. There is no limit on the number of applications that can be submitted per agency. A client is eligible for funding once every calendar year.

All fund disbursements are at the sole discretion of the Pennsylvania Foundation for Homecare and Hospice. Funding for the South Central Pennsylvania Home Care Grant was provided by the Partnership for Better Health.



Geographic Service Area

Eligible Zip Codes:
17006;17020;17024;17037;17040;17045;17047;17053;17062;17068;17069;17071;17074;17090;17303;17304;17306;17307;17316;17324;17337;17372;17007;17013;17015;17065;17081;17240;17241;17257;17266

ELIGIBILITY

- **Individuals who temporarily or permanently reside in the Partnership for Better Health service area, which includes parts of Cumberland, Perry, Adams, and Franklin Counties.** ***Refer to the map and zip codes listed above.***
- Individuals who demonstrate a need for home-based care services, which includes home care, home health, and hospice services
- Individuals with monthly income less than $5,000 (single) or $10,000 (dual income, including spouse/partner, excluding any child income)*
- Individuals who are not currently receiving, are waiting to be approved/renewed, or are not eligible for comparable home-based care services through the following programs:
  - Any Pennsylvania Medicaid Waiver Program (including managed care programs)
  - Veterans receiving home health care benefits through the Aide and Attendance Program
  - Any other similar program as determined by the Foundation

**Income limits and other terms and conditions are subject to change, at the sole discretion of the Foundation.*

For more information and to download/print application materials visit www.pahomecare.org/foundation.

PENNSYLVANIA FOUNDATION FOR HOME CARE AND HOSPICE

PARTNERSHIP for Better Health

PENNSYLVANIA HOMECARE ASSOCIATION

Recruitment Checklist

Is your organization leveraging these strategies to attract new talent and enhance your workforce? Please refer to the following list for ideas on how to optimize your recruitment initiatives and maximize your candidate pipelines.

E-Recruitment

- ☐ Indeed
- ☐ SimplyHired
- ☐ Glassdoor
- ☐ myCNAjobs
- ☐ ZipRecruiter
- ☐ Monster
- ☐ Careerbuilder
- ☐ Google Jobs
- ☐ Professional Diversity Network
- ☐ Workplace Diversity
- ☐ snagajob
- ☐ get.it jobs
- ☐ nexxt jobs

Social Media

- ☐ LinkedIn
- ☐ Facebook
- ☐ Instagram
  - ☐ Threads
- ☐ X (Twitter)
- ☐ TikTok
- ☐ YouTube
- ☐ Reddit
- ☐ Snapchat
- ☐ Pinterest
- ☐ Tumblr
- ☐ Vimeo
- ☐ Nextdoor

Pennsylvania-based

- ☐ PHA Job Board
- ☐ PA CareerLink
- ☐ PA Workforce Development Boards
- ☐ Newspapers & radio
- ☐ Local TV
- ☐ Job Fairs
- ☐ PA Regional Refugee Social Service Providers
- ☐ Keystone Job Corps
- ☐ Geofencing Ads
- ☐ PA based associations: Social Work, Student Nurses, PA Nurses, Physical Therapy, more

Students & Learners

- ☐ Colleges & Universities (Handshake, College Central, Symplicity)
- ☐ Community Colleges
- ☐ High Schools (Vocational, public, private, charter)
- ☐ GED Programs
- ☐ Career Fairs
- ☐ Training programs: RN, LPN, CNA, HHA, MA, More
- ☐ BareFoot Student
- ☐ Host webinars or informational sessions about your roles, resume building & industry
- ☐ Alumni outreach

Grassroots

- ☐ Employee referral & discount programs
- ☐ Bulletin Boards (coffee shops, laundromats, grocery stores)
- ☐ Local newsletters & bulletins
- ☐ Faith & church communities
- ☐ Community engagement (advisory boards, chamber of commerce)
- ☐ Volunteering
- ☐ Libraries
- ☐ Recruitment Collateral (flyers, yard signs, brochures, car magnets)

Miscellaneous

- ☐ Company job board
- ☐ Applicant Tracking Systems
- ☐ Boomerangs - contact past employees
- ☐ Purchase licensure lists for direct mailers
- ☐ Evergreen requisitions
- ☐ Boolean searches
- ☐ Subscribe to job alerts widget
- ☐ Drafting/submitting op-eds
- ☐ Creating career pathways
- ☐ Testimonials & online reviews
- ☐ Leverage AI & Automation
- ☐ National Association Home Care & Hospice

Need help? Contact Becky Jacobs, PHA Workforce Development Director, at rjacobs@pahomecare.org.

Customizable Template Job Ad

Job Title: [Insert Job Title] - See page 3 for ideas

Include within the Job Posting

Location: [Insert Location] (Include if the job is in the community-based, county name, remote, hybrid, or on-site]

Employment Type: [Full-Time/Part-Time/Per Diem]

Shift: [Specific hours, days of the week, etc. Be as specific as possible with the requirements of your role]

Job Summary: [Elevator Pitch] We are seeking a [dynamic/experienced/skilled/etc.] [Job Title] to join our team. In this role, you will [briefly describe the main purpose of the job and how it contributes to the organization's goals]. The ideal candidate will have a passion for [related field/industry] and a drive to [main goal or mission related to the job].

Key Responsibilities:

- [Responsibility #1]
- [Responsibility #2]
- [Responsibility #3]
- [Add additional responsibilities as needed – no more than 10]

Qualifications:

- [Required qualification #1 (e.g., degree, certification, etc.)]
- [Required qualification #2 (e.g., experience, skills, etc.)]
- [Required qualification #3 (e.g., soft skills, technical skills, etc.)]
- [Preferred qualifications or experience (optional)]

What We Offer: [Benefits, perks, etc.]

- [Highlight key benefits like competitive salary, healthcare, retirement plans, professional development opportunities, etc.]
- [Mention any unique perks or workplace culture benefits (e.g., flexible work hours, remote work options, wellness programs, etc.)]

About Us:

[Provide a brief description of your company, its mission, values, and the work environment. Include a sentence about the industry you serve and any unique aspects that make your company stand out.]

Call to Action [optional]:

Ready to join our team? Apply now by [application instructions].

How to Apply [optional]:

Interested candidates should submit their [resume, etc.] to [contact email or application link]. Please include "[Job Title] Application" in the subject line. Applications will be accepted until [application deadline].

EEO Statement:

[Company Name] is an Equal Opportunity Employer. We celebrate diversity and are committed to creating an inclusive environment for all employees.

To learn more about crafting the perfect job ad, click here.

Job Titles for Organic Visibility

To enhance job titles for better organic visibility, it's essential to focus on both search engine optimization (SEO) and user engagement. Here are some key tips:

- **Use Relevant Keywords:** Incorporate industry-specific terms and keywords that potential candidates are likely to search for. For example, instead of just "Home Health Nurse" use "Home Health Registered Nurse (RN)" or "Private Duty Licensed Practical Nurse (LPN)."
- **Be Specific and Descriptive:** Clearly define the role in the job title.
- **Keep It Concise:** Aim for a job title that is clear and to the point. Long titles can be confusing and may not display well in search results.
- **Include Job Level:** Indicate the level of the position, such as "Junior," "Senior," or "Lead." This helps attract candidates with the appropriate experience.

- **Test and Optimize:** Regularly review and adjust job titles based on performance metrics. Use tools like Google Analytics to see which titles attract the most views and applications.
- **Avoid:** Use commonly understood terms rather than internal jargon or overly creative titles that might not be recognized by search engines or job seekers. Avoid using urgency words, enticements to apply, general click bait, symbols, or bonus information, as these can negatively impact organic search rankings.

Formula for success:

Title + Commonly Known Abbreviation + Industry or Department

This formula can be used in any order you see best. Just be sure to keep it consistent

Examples:

- Home Care Coordinator - Senior Services
- Home Health Registered Nurse (RN) - Pediatrics
- Hospice Care Manager - Palliative Services
- Direct Care Worker (DCW) - Home Care
- Home Health Aide (HHA)
- Home Health Physical Therapist (PT) - Rehabilitation
- Hospice Medical Social Worker (MSW)
- Home Health Occupational Therapist (OT) - Stroke Recovery
- Home Care Registered Nurse (RN) - Chronic Illness Management
- Caregiver - Home Care
- Home Health Licensed Practical Nurse (LPN) - Geriatrics

By following these guidelines, you can improve the visibility and attractiveness of your job titles, making it easier to attract qualified candidates.

PHA
PENNSYLVANIA
HOMECARE ASSOCIATION

Recruitment Strategies for Success

Presented by:
Becky Jacobs
Workforce Development Director

Job Titles for Organic Visibility

To optimize job titles for organic visibility, it's important to consider both search engine optimization (SEO) and user engagement. Here are some key tips:

- **Use Relevant Keywords:** Incorporate industry-specific terms and keywords that potential candidates are likely to search for. For example, instead of just "Home Health Nurse" use "Home Health Registered Nurse (RN)" or "Private Duty Licensed Practical Nurse (LPN)."
- **Be Specific and Descriptive:** Clearly define the role in the job title.
- **Keep It Concise:** Aim for a job title that is clear and to the point. Long titles can be confusing and may not display well in search results.
- **Include Job Level**: Indicate the level of the position, such as "Junior," "Senior," or "Lead." This helps attract candidates with the appropriate experience.
- **Test and Optimize:** Regularly review and adjust job titles based on performance metrics. Use tools like Google Analytics to see which titles attract the most views and applications.
- **Avoid:** Use commonly understood terms rather than internal jargon or overly creative titles that might not be recognized by search engines or job seekers. This includes urgency words, enticements to apply, general click bait, symbols, bonus information, etc. These can get flagged in organic search engines.

Example Job Titles

Formula for success: Title + Commonly Known Abbreviation + Industry or Department

- Home Care Coordinator - Senior Services
- Home Health Registered Nurse (RN) - Pediatrics
- Pediatric Home Health Licensed Practical Nurse (LPN)
- Hospice Care Manager - Palliative Services
- Direct Care Worker (DCW) - Home Care
- Home Health Aide (HHA)
- Home Health Physical Therapist (PT) - Rehabilitation
- Hospice Medical Social Worker (MSW)
- Home Care Director
- Home Health Occupational Therapist (OT) - Stroke Recovery
- Home Care Registered Nurse (RN) - Chronic Illness Management
- Personal Care Assistant (PCA) - Home Care
- Home Health Licensed Practical Nurse (LPN) - Geriatrics

This formula can be used in any order you see best. Just be sure to keep it consistent

Elevator Pitch: Join our dynamic team at [Company Name] as a [Job Title]! We are looking for a passionate and experienced individual to help us [briefly describe the main goal or impact of the role].

Company Overview: At [Company Name], we are dedicated to [mission/values]. We pride ourselves on [unique aspects of the company].

Job Description: No more then 10 bullet points

- [Responsibility 1]
- [Responsibility 2]
- [Responsibility 3]

Requirements:

- [Qualification 1]
- [Skill 1]
- [Experience 1]

Benefits and Perks:

- [Benefit 1]
- [Perk 1]
- [Unique Perk]

Call to Action: Ready to join us? Apply now by [application instructions].

Contact Information: For any questions, please contact [Name/Department] at [contact details].

Company Culture: We believe in [brief description of company culture].

Application Process: Our application process includes [brief description of steps].

Job Ad Recipe

INGREDIENTS

Organic Job Title	Clear and Concise
Elevator Pitch	Make Compelling
Job Description	10 or less bullet points
Requirements	Bullet points
Preferred Qualifications	Bullet points
Benefits & Perks	Bullet points
Call To Action	Attention grabbing
Contact Information	Name & email
Company Culture	Sell your mission

Indeed

Indeed stands as the premier job aggregator in the market. It serves as an all-encompassing platform for employers, offering extensive exposure to prospective candidates and streamlining the job posting process. Indeed equips employers with invaluable tools such as screener questions and skills assessments. It excels in sourcing candidates for entry-level and lower-tier roles. With its wide recognition and usage across diverse industries, Indeed has become an indispensable resource for employers aiming to fill a spectrum of positions.

01

Claim your Indeed Page: Allows companies to build their employer brand, increase visibility, and attract qualified applicants. Customize your Company Page to showcase your company culture, work environment, mission, values, and benefits.

02

Job Postings: Organic postings are free. They are placed based on keyword relevancy, then by chronological order. Sponsored postings are paid ads. Sponsored jobs are given “premium placement” in search results. and will yield more candidates.

03

Smart Sourcing: AI-powered tool that matches quality candidates to your job, streamlining the hiring process. It offers instant candidate recommendations, customizable contact templates,

04

Virtual interviewing: allows seamless, hassle-free interviewing. It offers flexible interview options, reminders, tips for success, and features for effective interviewing, such as customizable welcome messages and resume previews

SIMPLYHIRED

SimplyHired is a valuable platform for employers, offering a wide reach by aggregating job listings from various sources. It allows free job postings and provides alerts when candidates apply, ensuring prompt responses. Employers can access an extensive resume database and only pay when they decide to proceed with a candidate. For increased visibility, job sponsorship is available.

The integration with Indeed enhances SimplyHired's offerings. This platform is particularly beneficial for high-volume recruitment, enabling employers to reach a large pool of potential candidates efficiently. SimplyHired is a strategic tool for attracting top talent.

Glassdoor

Glassdoor is another prominent job aggregator and employer branding site. It is recognized and used across diverse industries, Glassdoor has become an essential platform for employers looking to strengthen their brand and attract top talent..

Reviews

It offers unique tools like employee reviews and interview feedback, making it particularly useful for understanding company culture and work conditions from the employees' and past applicants' perspectives.

Job Ads

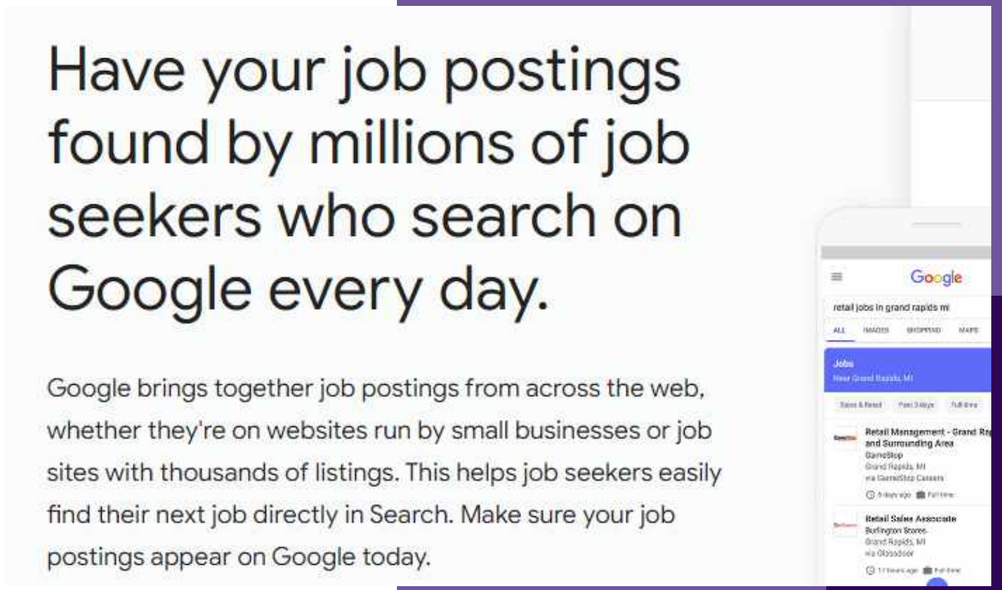
Any paid job posted on Indeed also gets posted on Glassdoor, increasing the reach of job postings.

Claim your page

Claiming your Glassdoor page allows control over your brand story, highlights your culture and benefits, and enables response to reviews.

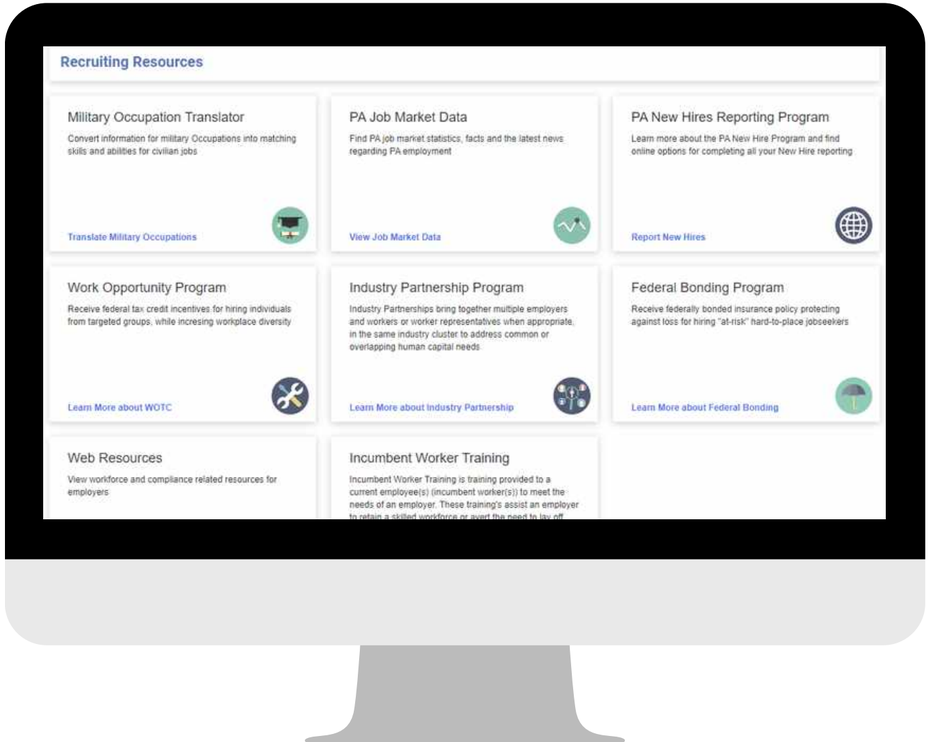
Google Jobs Network

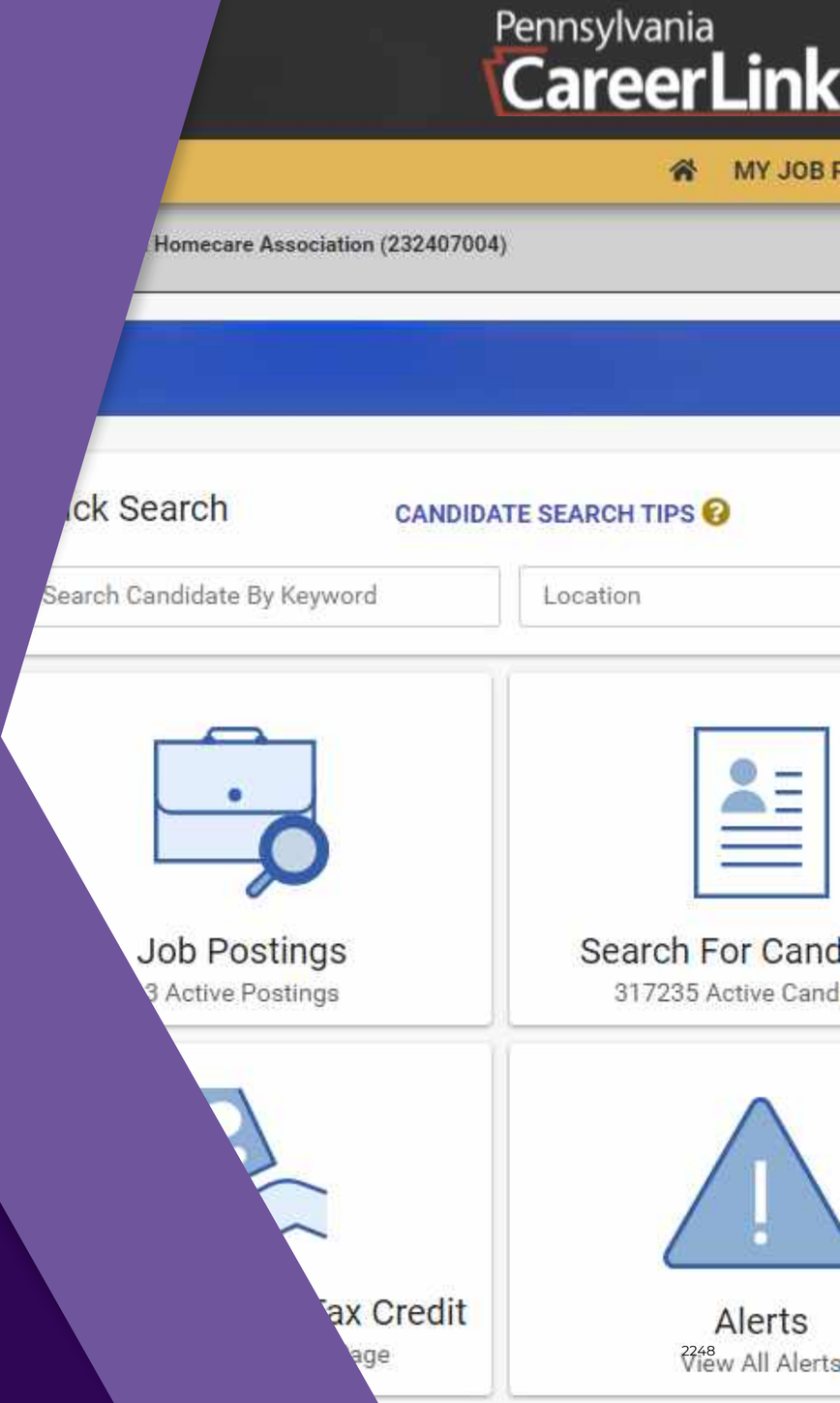
Google Job Networks is a powerful tool for employers. It aggregates job listings from across the web, including company websites and job boards. This broad reach helps employers attract a diverse pool of candidates. Employers can post jobs directly or through third-party job sites1. Google also offers structured data for job postings, enhancing visibility in search results



PA CAREERLINK

The PA CareerLink is a free service that aids employers with job posting, candidate search, and management. It offers recruitment assistance, including job posting creation, pre-screening, and candidate referrals. The platform supports diversity through the Work Opportunity Tax Credit program and provides training for current employees. It also fosters industry partnerships to bring together employers and workers in the same industry.





Body

myCNAjobs is a comprehensive platform for employers in the caregiving industry. It offers a suite of hiring, engagement, and training tools to facilitate high-volume recruitment1. Employers can advertise jobs, make hiring decisions, and connect with potential candidates. It's top rated in Senior Care ROI, providing trusted recruitment solutions. It's an effective resource for companies seeking to hire Certified Nursing Assistants (CNAs), Home Health Aides (HHAs), and caregivers.

MONSTER & CAREERBUILDER

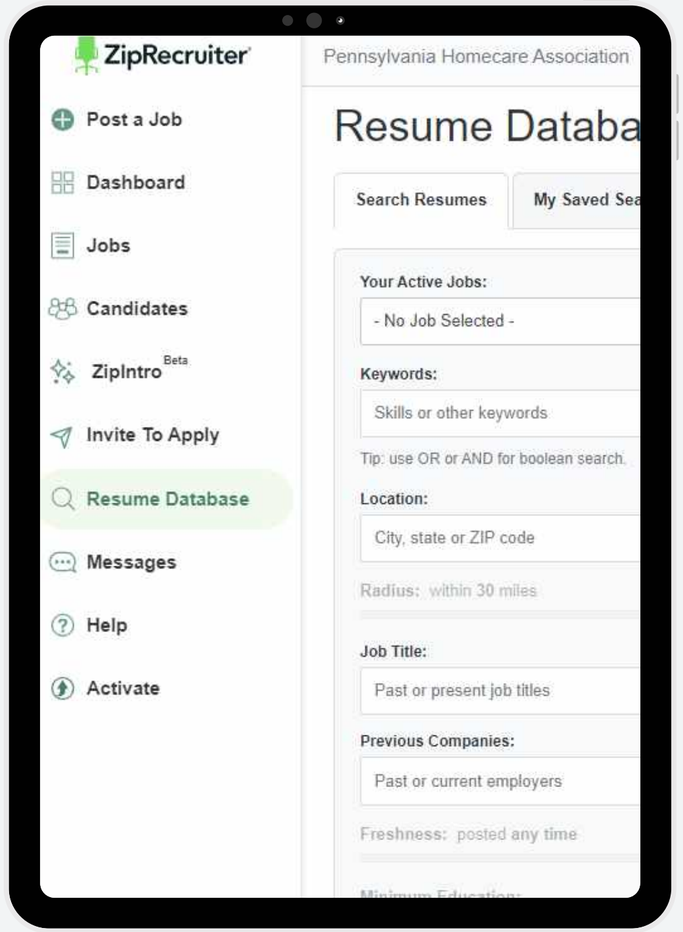
- **Paid Services:** Both offer different pricing plans to fit the needs of different businesses.
- **Job Postings:** Recruiters can post jobs on the sites, mobile app, and extensive network of job boards and partner sites.
- **Resume Searches:** Both allow recruiters to search through resumes to find potential candidates.
- **Applicant Tracking:** Both offer some applicant tracking functions.
- **Proactive Messaging:** Recruiters have the ability to proactively message qualified candidates.
- **Collaboration:** Both allow multiple team members to collaborate.

Contact **Samuel Harris** for inclusive trial pricing!
Sam.Harris@ziprecruiter.com | p: 480.401.3981

ZIPRECRUITER

ZipRecruiter is a **paid** online job posting platform. It allows employers to post job listings to over 100 job sites with one click.

The platform uses advanced AI-driven applicant matching technology to find candidates based on skills and experience. It also provides tools for screening and managing applicants, and tracking the success of job postings.



Evergreen Requisitions

Evergreen Requisitions are always open job postings for high volume, high turnover positions.

Benefits:

- Continuous Talent Pool: Ensures a steady pipeline of pre-screened candidates.
- Reduced Time-to-Fill: Speeds up the hiring process.
- Efficient Management: Groups jobs together for easier management.
- Reporting: Helps with tracking and analysis of high volume jobs.

Evergreen Requisitions are an efficient tool for quick staffing solutions.

The **PHA Job Board** is a niche platform designed specifically to recruit professionals in the home-based care sector.

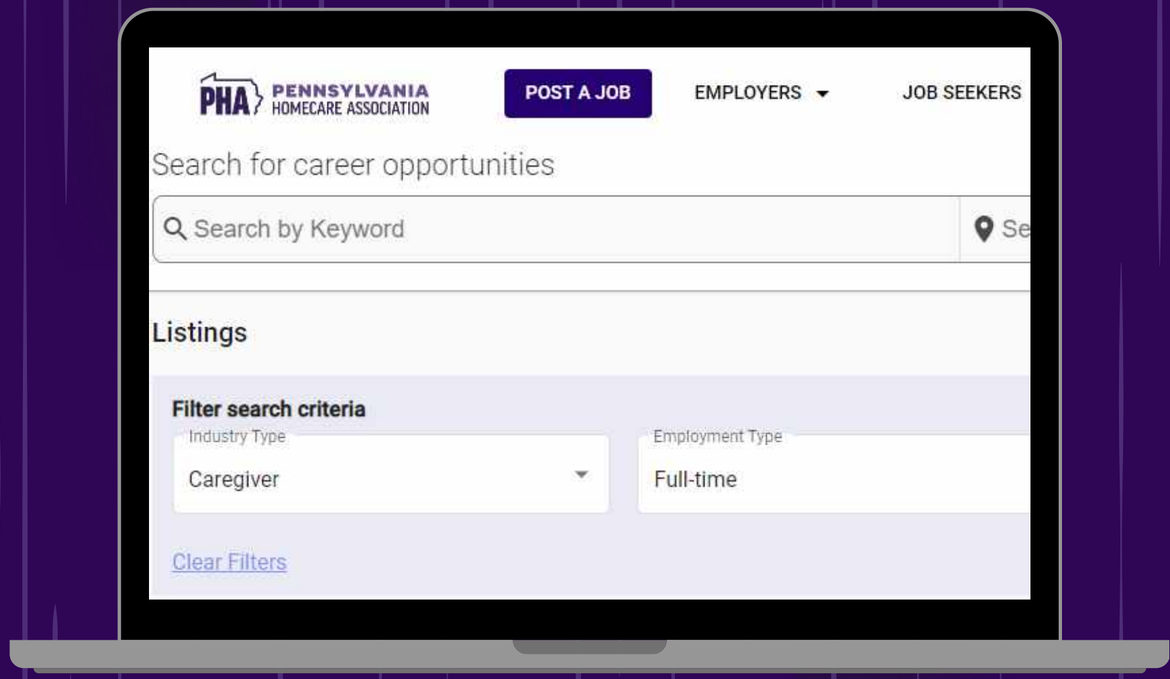
PHA will provide several free job advertisements as part of membership

PHA will promote:	Standard Price	Featured Price ($50/Ad)
Social Media Posts (organic and paid)	X	X
College websites: Handshake, College Central, Simplcity, & more	X	X
CareerLink	X	X
Indeed		X
SimplyHired		X
Published to Google Jobs Network		X
Highlighted on job board		X
Pinned to the top of job board		X
Distribution to CNA database (80K)		X
Distribution to RN & LPN Schools		X
Distribution to PT, OT, & SLP Schools		X
Distribution to CNA Programs		X
Distribution various candidate databases based on job title/requirements		X
Get.It Jobs *(feeds to multiple sites including LinkedIn)*		X

Use code **FEATURED50** for 50% off 1 featured listing

Expires:9/12/24

PHA Job Board



DIVERSITY JOB BOARDS

Workplace Diversity

- Offers job posting
- Candidate search
- Career fairs and events
- Job alerts
- $200-$295/job

They will also distribute job postings to:

- HispanicDiversity.com
- VeteransConnect.com
- LGBTconnect.com
- DisabilityConnect.com
- OutandEqual.com
- AllDiversity.com
- WomensJobCenter.com
- BlackJobCenter.com

Professional Diversity Network

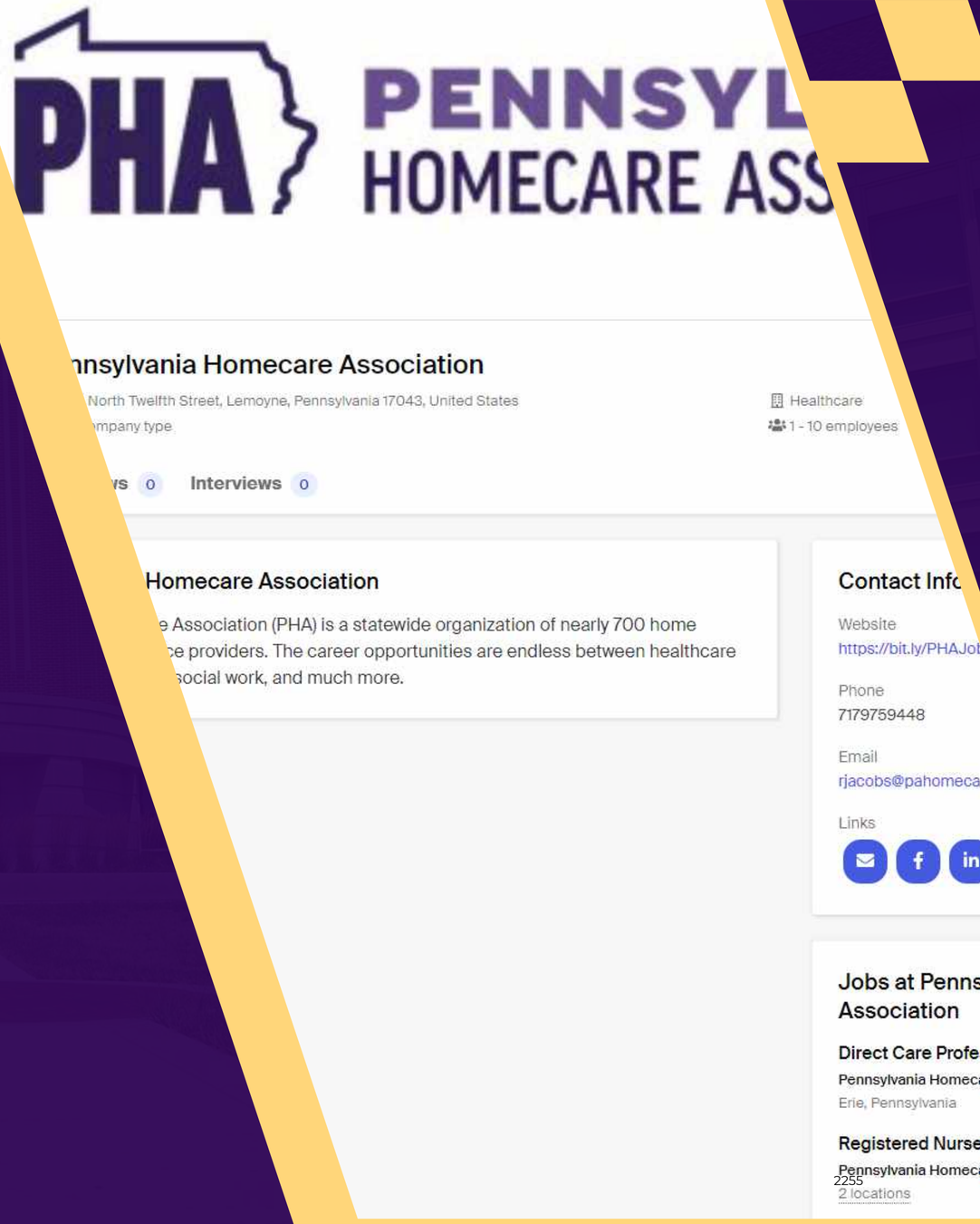
- 350k + monthly new members
- Millions of monthly emailed job alerts
- 30 national career recruitment events
- $495-$795/per job

They will also distribute job postings to:

- iHispano
- Military 2 Career
- Asian Career Network
- Black Career Network
- Women's Career Network
- Out Professional Network
- Pro Able

HANDSHAKE

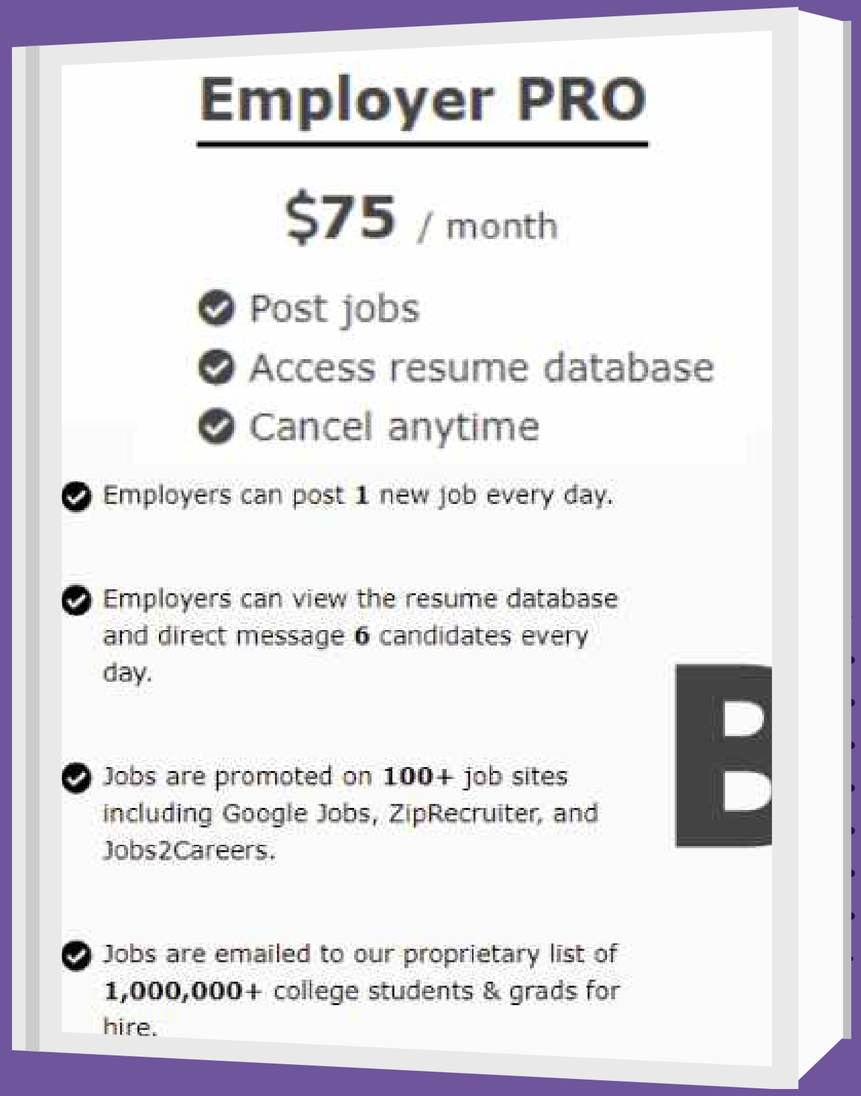
Handshake is a robust college recruitment platform tailored for employers seeking early-career talent. It's trusted by over 900K employers, including those in the healthcare sector. Handshake provides tools for brand promotion, sourcing talent, and scaling recruitment within the healthcare industry. It connects employers with 15M+ students and recent graduates from 90% of top US institutions, many of whom are pursuing healthcare-related careers. Employers can post jobs, collect resumes, identify potential candidates, and communicate with them directly. Handshake also provides a platform for hosting virtual and in-person job fairs and events, allowing employers to engage with potential candidates in a dynamic setting, thereby enhancing their recruitment process.



BAREFOOT STUDENT

Barefoot Student is an online community platform that connects university students and recent graduates with employers. It serves as a job board for student hiring, providing a comprehensive database of highly qualified students, graduates, and interns. This platform is particularly beneficial for small businesses seeking a one-stop job posting site. It's a valuable HR solution that simplifies the hiring process, making it easier to find and recruit talented interns and entry-level employees.

Free and Paid Job Advertisements

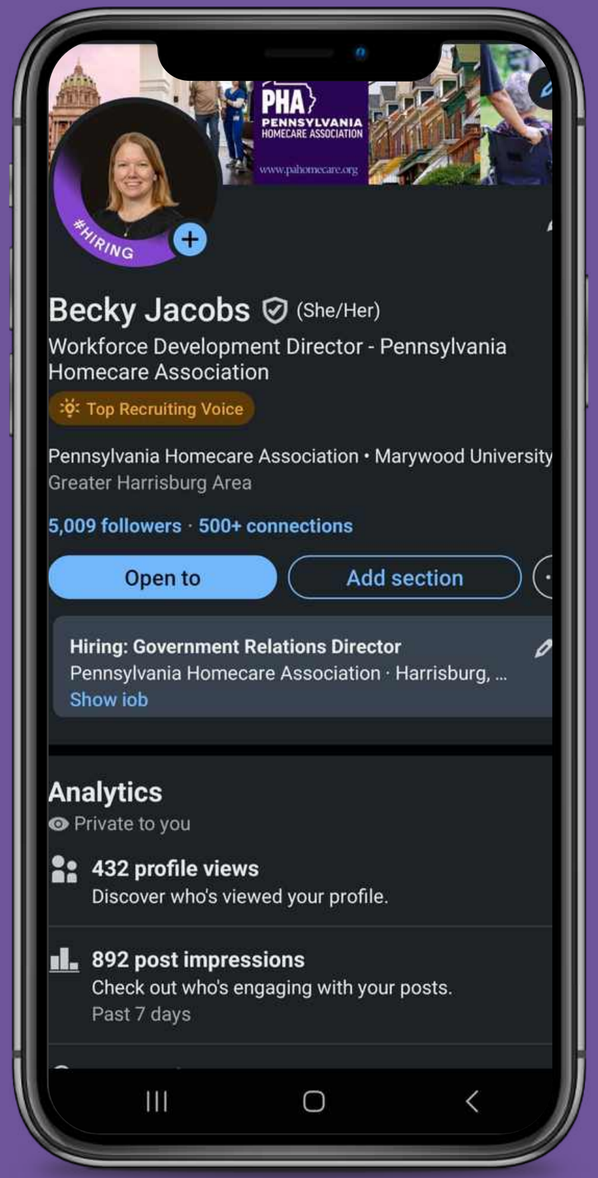


Vocational & High Schools

Creating career pathways from high schools and vocational schools involves a strategic approach that connects education with real-world work roles.

- **Job Fairs:** Attend job fairs to gain awareness for your company and meet students.
- **Post Jobs at Schools**: Some schools also have online platforms where employers can post job openings directly. Others allow flyers posted in a certain location within the school.
- **Internships/Shadow Experiences**: These can provide students with new skills, work experience, and professional contacts
- **Work with Career & Guidance Counselors:** Counselors can provide guidance to students about their professional goals. They can help students understand their options, evaluate challenging professional decisions, and provide resources for securing a great job.. Recruiters can work with these counselors to understand the skills and interests of students, which can help in targeting the right candidates.

LinkedIn



To increase your reach on LinkedIn for <u>free</u>, you can:

- **Optimize Your Profile:** Complete your profile to 100% to receive more reach. This includes having a professional photo, compelling headline, detailed work history, and a well-crafted summary.
- **Engage with Others:** Comment on relevant posts and join LinkedIn groups to network with your ideal candidates.
- **Create Quality Content**: Regularly post valuable content that resonates with your audience.
- **Leverage Your Network:** Encourage your team to engage with your posts. Their interactions can increase your visibility and reach.
- **Use Keywords:** Incorporate industry-related keywords in your profile to improve its visibility in search results.
- **Contribute to Collaborative Articles:** Share your unique perspectives, personal examples, and professional opinions on these articles.
- **Hiring frame:** Tool that recruiters can add to their profile picture to signal that they're hiring
- **Company Page**: dedicated profile for businesses to connect with the LinkedIn community, showcasing their brand, products, services, and career opportunities. Keep it fresh and post updates

Keep in Mind:

- **Don't Send Generic Connection Requests:** Always personalize your connection requests.
- **Don't Spam Connect:** Always visit a person's profile before sending a connection request. This allows you to customize your invitation.
- **Don't Neglect Your Profile:** An incomplete or outdated profile can be a turn-off for potential connections. Make sure your profile is up-to-date and fully filled out.
- **Don't Be Inactive:** Regularly post updates, engage with your connections, and contribute to discussions.

LinkedIn Recruiter

Paid Service

Sourcing Candidates

Filter by candidate requirements like job titles, locations, and skills, with 40+ advanced filters.

LinkedIn Recruiter uses AI to match job requirements with candidate profiles, optimizing search results based on skills, experience, and job interest.

Prioritize Candidate Reach-outs

Instantly identify candidates who want to hear from you using the “Open to work” filter

Increase the likelihood of an InMail response by up to 20% when reaching out to candidates found through these filters

In-Mail

Write highly personalized InMails with one click using AI-assisted messaging.

Save time with customizable InMail templates and bulk-messaging capabilities.

Schedule and send automated follow-ups to stay top of mind.

Boolean Search

Operator	Description	Example
AND	Narrows search to include only results with all required keywords.	"registered nurse" AND "home health
OR	Expands search to include results with any of the defined keywords or phrases.	"caregiver" OR "home health aide" OR "personal care assistant"
NOT	Limits search by excluding defined keywords or phrases from results.	"Certified Nursing Assistant" NOT "medical assistant"
Quotation Marks	Returns results with the exact phrase in the specified order.	"home health RN" *This search will return results that include the exact phrase 'home health RN'*
Parentheses	Gives priority to the keywords within over other elements.	(LPN OR "Licensed Practical Nurse") AND "home health" *This search will return results that include either 'LPN' or 'Licensed Practical Nurse', and also include 'home health'*

Grassroots Recruitment

Grassroots recruitment is a strategy that leverages relationships with local communities and businesses to attract potential candidates. It involves using recruiting collateral in candidate-frequented locations and technology like mobile recruiting. It's also involved employees in recruitment efforts, promoting your organization passively.

Examples:

Rip-Tab Signs
(Coffee shops, Laundry mats, more)

Recruitment Collateral
(Brochures, Flyers, Yard Signs, More)

Local & College Job Fairs

Employee Referral Programs

Community Engagement & Volunteering

Church Communities
(Newsletters, Bulletin Boards, More)

The key to successful grassroots recruiting is building strong relationships within the community

Social Media Recruitment

Facebook, Instagram, LinkedIn, X (Twitter), YouTube TikTok, & More

Organic and Paid Content

Do's:

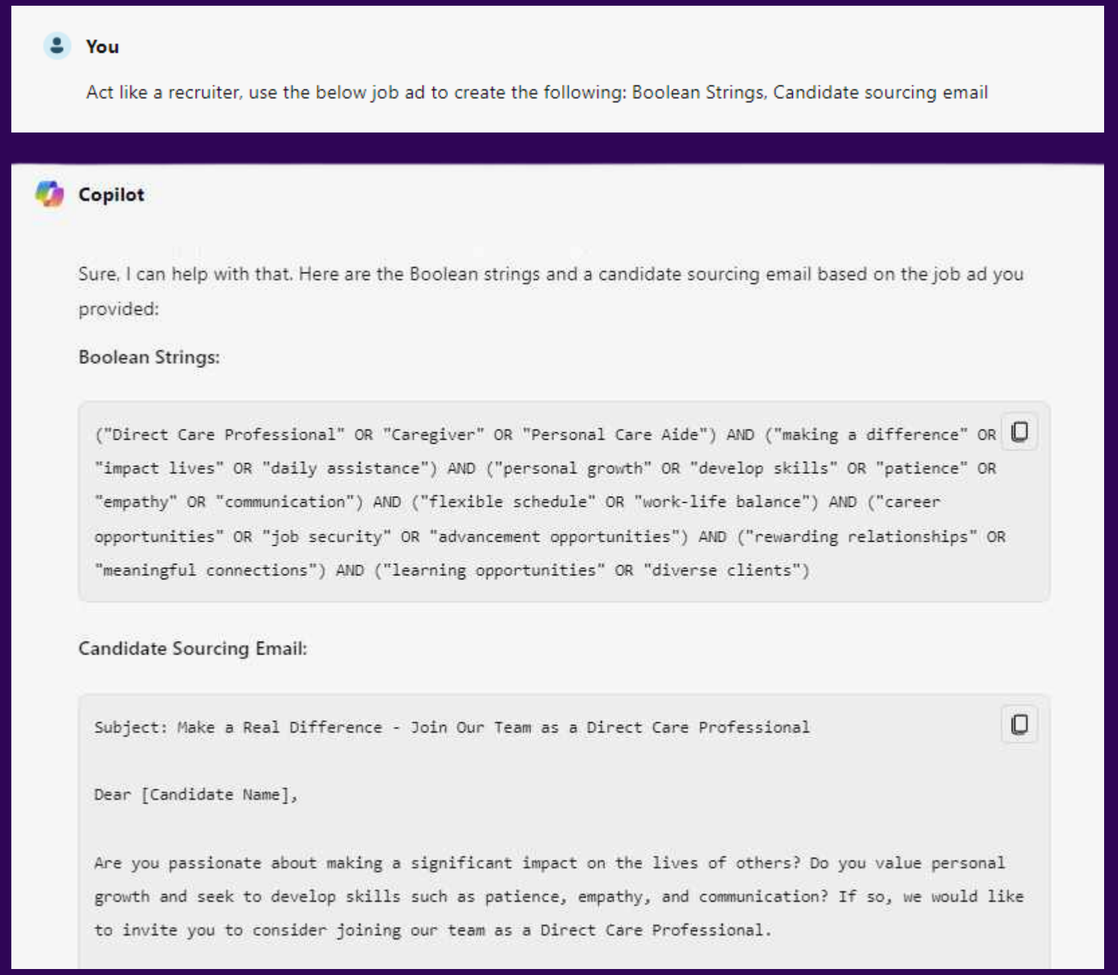
- **Use Different Platforms:** Each social media platform has a unique audience. Select the right channel to connect with target candidates
- **Create a Compelling Recruiter Profile:** Your profile should be impressive and professional. Include information about your tenure at the company and background in the recruiting industry
- **Participate in Groups**: Become active in relevant groups on social media sites like Facebook and LinkedIn.
- **Engage with Candidates:** Respond promptly to inquiries and feedback.
- **Use Advanced Tools:** Some platforms have tools for searching specific certifications or training.

Don'ts:

- **Limit Yourself to One Platform:** Don't restrict yourself to one platform. Different platforms can reach different audiences
- **Ignore Your Online Presence:** Don't neglect your online presence. Your profile should be professional and engaging
- **Be Inactive in Groups:** Don't just join groups, participate actively
- Ignore Candidate Inquiries: Don't ignore inquiries or feedback from candidates
- **Ignore Advanced Tools:** Don't overlook the advanced tools offered by some platforms

Utilizing AI & Automation in Recruitment

- **Scheduling Interviews:** Tools like Microsoft Bookings, Calendly, and Google Calendar can automate the scheduling of interviews. Candidates can self-schedule their preferred interview times, reducing the need for time-consuming email exchanges.
- **Optimize Job Descriptions:** AI can analyze language and keywords to improve search engine optimization (SEO) for job ads. This increases the chances of job postings appearing in relevant searches
- **Remove Biases:** AI helps in removing biases from job ads, promoting diversity and inclusivity in hiring practices.
- **Generate Ad Creatives:** AI can quickly generate a variety of ad creatives, saving time and resources in the design process.
- **Boolean Search Strings:** AI can significantly enhance the effectiveness of Boolean searches in job recruitment. It can help recruiters refine their Boolean queries, making them more accurate and encompassing.
- **Draft Email Generation:** AI can quickly generate draft emails, eliminating those dreaded moments of staring at a blank screen. With AI, you'll find yourself with a draft within seconds, allowing you to focus your energy on perfecting your message rather than starting from scratch. Remember to add personalization & your voice to these messages.



PHA Business Partners

Polsinelli Online Solutions for Home Care (POSH) provides an online, affordable, one-of-a-kind experience for home-based care employers of all sizes. POSH subscribers have access to a comprehensive set of customizable up-to-date forms, tools and resources at the federal, state, and local levels. This invaluable service helps home care business owners throughout the business cycle from pre-hire through termination stay in compliance with the everchanging complexities of the industry's regulatory and legal landscape.

We are offering a **$500 discount** using the code PA2024 for anyone who would like to become a subscriber. Mention this lunch & learn when emailing. Email us at onlinesolutions@polsinelli.com if have any questions or would like a demo. Here is a link to our website: https://online.polsinelli.com/

Nevvon is a global healthcare education company that offers an advanced e-training platform designed to simplify mandatory annual education for caregivers. Our user-friendly app allows caregivers to complete training at their own pace and on their own schedule. We provide over 200 hours of training content, including modules on compliance, home health aide certification, and value-based care. Our platform helps agencies ensure caregivers meet state-specific training requirements and maintain regulatory compliance, ultimately enhancing the quality of care provided.

Caribou is a rewards and engagement application built to elevate care agencies to world-class employer status. With programs designed to make caregivers feel seen and valued, Caribou fuels excellence across your entire organization, improving retention, recruitment, and staff performance, all while improving overall operational efficiency. Agencies using Caribou have seen on average, 400%+ ROI within 12-months, 10% increase in staff capacity within 3-months, and 50% increase in mobile EVV rates.

PHA Business Partners

CareConnect is an AI-powered workforce optimization platform that delivers a fresh, connected experience for home care agencies and drives value from recruiting to engagement and retention. CareConnect's ShiftMatch.AI provides agencies with top tools to streamline workflows, increase referrals, reduce cost penalties, and improve caregiver engagement - all in one place.

Looking to transform your agency? Visit www.careconnectmobile.com to learn more or schedule a discussion.

Boost your recruitment efforts with ColdTree Creative, Inc. As a full-service advertising agency, ColdTree specializes in promotional products, marketing, print design, direct mail, media purchasing & production, web development, digital marketing and more. They help clients across the East Coast increase sales and profits. With their expert team, ColdTree can elevate your recruitment strategy and grow your business!

Paycor helps leaders develop their people and build winning teams. Their human capital management (HCM) software gets you out of the weeds, our focus on talent development helps you build a great place to work and our tailored industry solutions give you a competitive advantage.

PHA Business Partners

Ava is an enterprise AI platform helping healthcare providers streamline administrative busywork so that they can get back to care. In an industry where employee engagement and retention are crucial yet increasingly challenging to maintain, Ava provides an effective AI-driven solution that's beneficial for clients, caregivers, and providers. Integrating seamlessly with Electronic Health Records (EHRs), Ava offers an engaging experience for caregivers and clinicians while providing administrators with a robust suite of tools for business intelligence, employee management, and gamified incentives.
For more information, visit joinava.com.

Burdened with critical open positions or rising recruitment costs? Whether you need to fill a one-off or offload your entire recruitment division, ARG can help. Our team of on and offshore home care recruitment specialists deliver top home care talent from entry-level branch staff to C-Suite at a fraction of the cost.

Get top home care talent fast and cut recruitment costs. Find out if a partnership with Advantage Recruiting Group makes sense today. Visit www.advantagerecruitinggroup.com to learn more or schedule a time to connect https://calendly.com/mbetsch-arg.

Preferred Benefits Consultants are a national benefit consultants that have worked with hundreds of Homecare agencies throughout the country.

We offer benefit solutions tailored specifically for your company. We will assess risks that need to be accounted for while designing a plan at an affordable price.

Our variety of services and benefits are tailored to meet the needs of each employer and their employees.

PHA Business Partners

Post Lunch & Learn Handouts

PENNSYLVANIA HOMECARE ASSOCIATION

Recruitment Checklist

Is your organization leveraging these strategies to attract new talent and enhance your workforce? Please refer to the following list for ideas on how to optimize your recruitment initiatives and maximize your candidate pipelines.

E-Recruitment

- ☐ Indeed
- ☐ SimplyHired
- ☐ Glassdoor
- ☐ myCNAjobs
- ☐ ZipRecruiter
- ☐ Monster
- ☐ Careerbuilder
- ☐ Google Jobs
- ☐ Professional Diversity Network
- ☐ Workplace Diversity
- ☐ snagajob
- ☐ get.it jobs
- ☐ nexxt jobs

Social Media

- ☐ LinkedIn
- ☐ Facebook
- ☐ Instagram
  - ☐ Threads
- ☐ X (Twitter)
- ☐ TikTok
- ☐ YouTube
- ☐ Reddit
- ☐ Snapchat
- ☐ Pinterest
- ☐ Tumblr
- ☐ Vimeo
- ☐ Nextdoor

Pennsylvania-based

- ☐ PHA Job Board
- ☐ PA CareerLink
- ☐ PA Workforce Development Boards
- ☐ Newspapers & radio
- ☐ Local TV
- ☐ Job Fairs
- ☐ PA Regional Refugee Social Service Providers
- ☐ Keystone Job Corps
- ☐ Geofencing Ads
- ☐ PA based associations: Social Work, Student Nurses, PA Nurses, Physical Therapy, more

Students & Learners

- ☐ Colleges & Universities (Handshake, College Central, Symplicity)
- ☐ Community Colleges
- ☐ High Schools (Vocational, public, private, charter)
- ☐ GED Programs
- ☐ Career Fairs
- ☐ Training programs: RN, LPN, CNA, HHA, MA, More
- ☐ BareFoot Student
- ☐ Host webinars or informational sessions about your roles, resume building & industry
- ☐ Alumni outreach

Grassroots

- ☐ Employee referral & discount programs
- ☐ Bulletin Boards (coffee shops, laundromats, grocery stores)
- ☐ Local newsletters & bulletins
- ☐ Faith & church communities
- ☐ Community engagement (advisory boards, chamber of commerce)
- ☐ Volunteering
- ☐ Libraries
- ☐ Recruitment Collateral (flyers, yard signs, brochures, car magnets)

Miscellaneous

- ☐ Company job board
- ☐ Applicant Tracking Systems
- ☐ Boomerangs - contact past employees
- ☐ Purchase licensure lists for direct mailers
- ☐ Evergreen requisitions
- ☐ Boolean searches
- ☐ Subscribe to job alerts widget
- ☐ Drafting/submitting op-eds
- ☐ Creating career pathways
- ☐ Testimonials & online reviews
- ☐ Leverage AI & Automation
- ☐ National Association Home Care & Hospice

Need help? Contact Becky Jacobs, PHA Workforce Development Director, at rjacobs@pahomecare.org.

In the digital file, hover over the text to reveal hidden hyperlinks

Hover over the logo to reveal hidden hyperlinks

Get those creative juices flowing!

THANK YOU

Becky Jacobs
Workforce Development Director

rjacobs@pahomecare.org

717-975-9448 x21

www.pahomecare.org